DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Parts 5, 13, 19, 170, 173, 186, 194, 195, 196, 197, 200, 201, 211, 212, 213, 231, 240, 250, 251 and 252

[Notice No. 329]

Implementing the Distilled Spirits Tax Revision Act of 1979 (Public Law 96-39)

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF).

ACTION: Proposed rulemaking cross-reference to temporary regulations.

SUMMARY: In the Rules and Regulations portion of this **Federal Register**, the Bureau of Alcohol, Tobacco and Firearms is issuing temporary regulations regarding the implementation of the Distilled Spirits Tax Revision Act of 1979, Subtitle A of Title VIII of the Trade Agreements Act of 1979 (Pub. L. 96-39). The temporary regulations also serve as a notice of proposed rulemaking for final regulations.

DATES: The effective date of the temporary regulations is January 1, 1980. Written comments must be delivered or mailed by September 11, 1980.

ADDRESS: Send comments to Director, Bureau of Alcohol, Tobacco and Firearms, P.O. Box 385, Washington, DC 20044, (Attn: Chief, Regulations and Procedures Division).

Disclosure of Comments: Any person may inspect the written comments or suggestions during normal business hours at the ATF Reading Room, Office of Public Affairs, Room 4408, Federal Building, 12th and Pennsylvania Avenue, NW., Washington, DC 20226.

FOR FURTHER INFORMATION CONTACT: Edward J. Sheehan, E. J. Ference, John V. Jarowski, Regulations and Procedures Division, Bureau of Alcohol, Tobacco and Firearms, Washington, DC 20226, Telephone: 202-566-7626.

SUPPLEMENTARY INFORMATION:

Public Participation: Interested persons may submit written comments and suggestions regarding the temporary regulations. All communications received within the comment period will be considered before final regulations are issued. Any person who desires an opportunity to comment orally at a public hearing on the temporary regulations should submit a written request to the Director within the comment period. However, the Director reserves the right to determine whether a public hearing should be held.

The temporary regulations in this Part of this issue of the **Federal Register** revised, rescind, and add new regulations in 27 CFR Parts 5, 13, 19, 170, 173, 186, 194, 195, 196, 197, 200, 201, 211, 212, 213, 231, 240, 250, 251 and 252. For the text of the temporary regulations, see [T.D. ATF-62] published in this Part of this issue of the **Federal Register**.

Signed: November 14, 1979.

J. R. Dickerson,

Director.

Approved: November 30, 1979.

Richard J. Davis,

Assistant Secretary (Enforcement and Operations).

[FR Doc. 79-37531 Filed 12-3-79; 4:07 pm]

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DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Parts 5, 13, 19, 170, 173, 186, 194, 195, 196, 197, 200, 201, 211, 212, 213, 231, 240, 250, 251 and 252

[T.D. ATF-62]

Implementing the Distilled Spirits Tax Revision Act of 1979 (Public Law 96-39)

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF).
ACTION: Temporary Rule (Treasury decision).

SUMMARY: This temporary rule implements the Distilled Spirits Tax Revision Act of 1979, Subtitle A of Title VIII of the Trade Agreements Act of 1979 (Public Law 96-39). In addition, detailed rules for transition to the new distilled spirits excise tax system are provided. The Bureau of Alcohol, Tobacco and Firearms will issue final regulatons only after careful consideration of the comments received on these temporary regulations.

EFFECTIVE DATE: Effective date of temporary regulations: January 1, 1980.

FOR FURTHER INFORMATION CONTACT: Edward J. Sheehan, E. J. Ference, John V. Jarowski, Regulations and Procedures Division, Bureau of Alcohol, Tobacco and Firearms, Washington, DC 20226, Telephone 202/566-7626.

SUPPLEMENTAL INFORMATION: This document contains temporary regulations implementing the Distilled Spirits Tax Revision Act of 1979 (Public Law 96-39). The temporary regulations provided by this document will remain in effect until superseded by final regulations on this subject. A notice of proposed rulemaking with respect to final regulations appears elsewhere in this issue of the Federal Register.

Legislative Background

As a result of the Tokyo Round of multilateral trade negotiations, the United States agreed to eliminate the wine gallon method for imposing the distilled spirits tax. Accordingly, the Administration proposed and the Congress passed a legislative package for eliminating the wine gallon method of taxing distilled spirits, which is cited as the Distilled Spirits Tax Revision Act of 1979, Subtitle A of Title VIII of the Trade Agreements Act of 1979 (Public Law 96-39).

Public Law 96-39 amended or repealed other provisions of 26 U.S.C. Chapter 51 in the interest of tax parity for all distilled spirits products, both domestic and imported. The new law also modernizes and simplifies the distilled spirits tax system by providing for the all-in-bond method of tax administration.

The following paragraphs provide a discussion of the major points of (1) existing law and (2) the changes effected by Pub. L. 96-39.

Existing Law (Prior to January 1, 1980)

1. *Wine gallon and proof gallon methods of taxing distilled spirits.*

Under present law, an excise tax is imposed on all distilled spirits produced in or imported into the United States. Depending on the proof of spirits, the tax is determined at $10.50 on each proof or wine gallon (or proportionate part thereof).

One of two methods is used to compute the tax. Under the first of these methods, the proof-gallon method, the distilled spirits tax is based both upon the volume of spirits and the alcohol content when the tax is determined. The proof gallon method applies to spirits at or above 100° proof at the time of tax determination.

The second method is the wine-gallon method, which is based solely upon the volume of liquid, measured in U.S. gallons (wine gallons), and applies to spirits that are below 100° proof at the time the tax is determined.

Generally, domestic producers withdraw bulk spirits from bond for bottling when they are above 100° proof, and subsequently reduce the spirits to the proof at which they are bottled (for example, 80° or 86° proof) by the addition of water and other ingredients. Because these domestic spirits are usually at or above 100° proof when the tax is determined, the tax is computed on the basis of proof gallons. Some foreign produced spirits are imported in bulk at or above 100° proof; these spirits are also taxed on a proof gallon basis when removed from bond. However, most foreign produced spirits are bottled in the country of origin and imported below 100° proof. Such spirits are taxed at $10.50 on each wine gallon when removed from bond, resulting in a higher effective rate of tax on bottled imported spirits than on spirits taxed on a proof gallon basis.

2. *Rectification.*

In addition to the $10.50 per gallon distilled spirits tax, a commodity tax is imposed on rectified distilled spirits or wines at a rate of $.30 per proof gallon (or proportionate part thereof).

Rectified distilled spirits or wines are those which have been blended, purified, refined, processed or otherwise changed from their original state. This tax is subject to numerous complicated statutory exceptions. It applies only to spirits rectified in the United States and does not apply to imported products (either bottled or in bulk) which have been rectified abroad but have not been further rectified in the United States. Similar rectification taxes are imposed on cordials, liqueurs and similar compounds of distilled spirits which contain more than 2.5 percent, by volume, of wine which has an alcohol content of more than 14 percent ($1.92 per wine gallon) and on some mixed or blended rums or fruit brandies which have been aged in wood for less than two years ($.30 per proof gallon). In addition, rectifiers must pay a special occupational tax before engaging in the business.

3. *Government supervision of distilled spirits operations.*

Under existing law, the Director has strict control of distilled spirits, including those for beverage and industrial purposes, from the beginning of the production process to the point where the spirits are removed from bond. This control has been maintained through a rigid system of separate premises, permits, inspections, investigations and on-site supervision. However, in recent years the Bureau has recognized the need for modernizing this system of control.

The production and processing of distilled spirits involves a number of seprate operations. Under present law only some operations are conducted on the bonded premises portion of the distilled spirits plant, which is the part of the plant where distilled spirits may be held before tax determination. Operations on bonded premises include fermentation, distillation, storage and aging distilled spirits in bulk, denaturation, and bottling in bond. Subsequent operations including processing, rectifying, bottling, and storage of bottled spirits are conducted on nonbonded premises. Existing law also limits the permissible activities that may be performed within the bonded premises of a plant to the extent of requiring separate bonded facilities, for production, denaturation, bottling in bond, export storage, and warehousing.

In addition to segregation of facilities, present law requires the physical presence of an ATF officer before certain operations on bonded premises may be performed. Currently, distilled spirits may be produced only in a closed distilling system, with the spirits required to be kept under Government lock or seal until the production gauge is made and the spirits have been entered for deposit, denatured, tax-determined, or removed for a legitimate tax-exempt

or tax-free purpose, such as use for exportation, testing or experimental purposes. Rooms and buildings in which undenatured distilled spirits are stored may not be unlocked or remain open except when an ATF officer is on the plant premises. Gauges for spirits produced, transferred, tax-determined, or removed tax-free, must be either made or supervised by an ATF officer.

4. *Tax payment provisions.*

With the physical separation required under existing law between bonded premises and the premises where tax-determined or taxpaid spirits are rectified or bottled, tax determination for domestically bottled spirits occurs in almost all cases when they are removed from bond for bottling or rectification at the same plant. Although the tax is determined when spirits are removed from bond, payment may be deferred. As a result of this deferral procedure, existing law has established a system of crediting the proprietor with the amount of tax on spirits lost during rectifying and bottling operations.

Under existing regulations, distilled spirits products for beverage use, which have been bottled and cased, may be stored by a proprietor on nonbonded premises of a distilled spirits plant (designated as "control premises") as part of the proprietor's controlled stock. A rather complex procedure to account for the distilled spirits tax liability on controlled stock assures payment of the tax at the appropriate time. The effect of this procedure is to require the tax to be paid upon shipment from the control premises, or, if the spirits are kept in controlled stock inventory, payment of the tax can be delayed on the average for not more than six months.

Present law also includes a complicated system of requirements to insure that the distilled spirits tax liability of the plant proprietor (or importer) is adequately secured from the time these taxes are imposed until they are finally paid. This security is provided through a series of liens and surety bonds, at some points with overlapping coverage.

For example, the taxes are a first lien on the spirits from the time they are created. The taxes on distilled spirits produced are also a first lien on the distillery premises (including land, buildings and equipment).

Collection of the tax is further secured by a series of surety bonds to cover different operations or combinations of operations within a distilled spirits plant. For example, separate bonds are available for distilling, warehousing, and rectification operations. In addition, other bonds may be used for combined operations at a distilled spirits plant (such as at a plant with an adjacent bonded wine cellar) and to cover operations at more than one distilled spirits plant located in a single geographical area. Finally, a withdrawal bond is required in order to defer payment of the tax between the time the tax is determined and the actual payment of the tax. Each of these bonds is subject to differing maximum and minimum amounts.

Both the distilled spirits tax and the rectification tax are collected on the basis of returns under regulations prescribed by the Secretary of the Treasury. These regulations provide semi-monthly return periods which run from the 1st day through the 15th day of the month and from the 16th day through the last day of the month. Where tax becomes payable during one return period, the liability must be reported and the tax paid by the end of the following return period. For example, if the distilled spirits tax becomes payable on January 10 (during the January 1–15 return period) the liability must be reported and the tax paid by January 31, the last day of the succeeding return period which runs from January 16 through January 31.

Changes Due to Public Law 96–39 (Effective January 1, 1980)

1. *In general.*

The provisions of Public Law 96–39 significantly change the existing methods for the taxation of distilled spirits and the control of distilled spirits production. These revisions will result in a more uniform system of taxation by eliminating the tax differential between spirits of less than 100° proof and spirits which are 100° proof or higher at the time of tax determination. In addition, the bonded premises of a distilled spirits plant have been redefined to encompass all operations of a plant, from original production of the spirits through bottling, and the mechanism for Government supervision and control of distilled spirits operations is substantially simplified. Finally, the timing of distilled spirits excise tax payments has been amended, in order to address disparity under present law between the time the tax is required to be paid by the domestic bottler and the time the tax amount is collected by the bottler from distributors upon payment for the goods.

2. *Repeal of wine gallon method of taxing distilled spirits.*

The wine-gallon method for determining the excise tax on distilled spirtis is repealed. Consequently, the basis for determination of the distilled spirits tax will be the proof-gallon method. Under this method, the tax will be computed on the basis of alcohol content (including that which is derived from wine, alcoholic flavorings, etc.), of distilled spirits or distilled spirits products when withdrawn from bond. The uniform determination of tax on this basis eliminates the differential under present law between distilled spirits which are 100° proof or higher and distilled spirits which are below 100° proof at the time of tax determination.

3. *Repeal of rectification taxes.*

The new law repeals rectification taxes on rectified distilled spirits and wines, as well as the rectification taxes on cordials and liqueurs which contain wine, and on certain blended rums and fruit brandies. The repeal of these rectification taxes and related administrative rules will eliminate the disparity in tax treatment which exists between domestically rectified distilled spirits products and similar products of foreign origin. The present rectifier's occupational tax is also repealed.

4. *All-in-bond system.*

Adoption of the all-in-bond system results in the taxation of both domestic and imported products on the basis of the alcohol content of the finished product, including that part of the alcohol content derived from wine or other alcoholic ingredients added to a distilled spirits product. The bonded premises of a distilled spirits plant will be expanded to include all distilled spirits operations. This new system will simplify the operations of a distilled spirits plant by eliminating the distinction between bonded and non-bonded operations and premises. Also eliminated are claim procedures which presently must be followed for relief from tax on operational losses.

The provisions relating to distilled spirits bottled in bond, the 20-year statutory force-out rule for spirits in storage, and the lien provisions applicable to the bonded premises of a distilled spirits plant producing distilled spirits are also eliminated.

The repeal of the existing bottling in bond provisions eliminates the distinct status of "bottled in bond" products for tax purposes since all spirits will now literally be bottled in bond. However, "bottled-in-bond" whiskey has achieved recognition as a specific type of whiskey. "Bottled-in-bond" as a distinctive product designation will continue under the labeling regulations of the Federal Alcohol Administration Act with specific standards so that "bottled-in-bond" as a domestic labeling term will continue to have the same meaning as before.

The requirement for a distinctive strip stamp for "bottled-in-bond" spirits was eliminated from law. The existing strip

stamp for these spirits for domestic consumption is green, while a red stamp is used on other domestic products. Although for tax purposes it will no longer be necessary to have a distinctive strip stamp for these goods, the green stamp has gained considerable consumer recognition as a distinctive mark of the "bottled-in-bond" spirits. In view of this fact, and consistent with the retention of "bottled-in-bond" as a domestic labeling designation, the use of a green strip stamp as a distinctive feature will be continued.

5. *Establishment and operation of distilled spirits plants.*

Under the all-in-bond system, the business and operations of a distiller, warehouseman, or processor (a new term, which includes but is not limited to, a rectifier, a bottler and a denaturer) of distilled spirits may be conducted only on the bonded premises of a distilled spirits plant by a person qualified to carry on these operations. The purpose of this provision is to clarify that persons may not engage in these operations except at a qualified distilled spirits plant or as otherwise provided by law. (This latter phrase recognizes that activities, such as those of apothecaries, customs bonded warehouses, manufacturers of nonbeverage products, and users of specially denatured alcohol may continue to be carried on outside a distilled spirits plant.) The law also precludes the establishment of a distilled spirits plant for the processing and storage in bulk of taxpaid distilled spirits.

The establishment of a distilled spirits plant will be restricted to persons who intend to conduct operations as either a distiller, or a warehouseman, or both. Any person so qualified may also, upon application and after approval, process distilled spirits. No operation other than those set forth in the application may be conducted at a plant unless further registration has been submitted and approved. In addition, the Secretary of the Treasury has the authority to prescribe, for each type of operation, minimum capacity and level of activity requirements for distilled spirits plants. This provision is designed to prevent the establishment of token distilled spirits plants which would jeopardize revenue collections and cause excessive administrative and supervisory costs.

Each person not qualified by a basic permit under the Federal Alcohol Administration Act is required to obtain an operating permit under the internal revenue code. The operating permit must be obtained prior to beginning operations. However, the term processor is not covered under the Federal Alcohol Administration Act and regulations. This new term encompasses (but is not limited to) all of the activities performed by rectifiers and bottlers. If the rectifier or bottler proposes to denature or to manufacture articles on bonded premises, he will have to qualify as a processor.

The all-in-bond system also substantially simplifies the qualification and use of distilled spirits plant premises by eliminating the requirement that separate facilities for the various distilled spirits operations be maintained within a plant. Since the tax under the all-in-bond system will be determined when spirits are removed from the plant, there is no longer any need for the delineation and physical separation requirements. Under the all-in-bond system, these operations will be accounted for within recordkeeping accounts (i.e., production, storage, or processing). Commercial records will replace prescribed Government forms in many instances. Tanks, rooms or buildings may be used for multiple purposes, with the accountability of the spirits being maintained by appropriate records. However, operations on the bonded premises of a distilled spirits plant will be restricted to those with respect to distilled spirits, denatured distilled spirits or articles.

While wines may no longer be either rectified or bottled at a distilled spirits plant, they may be received on the premises for use in the manufacture of a distilled spirits product. The transfer of wine in bond between a bonded wine cellar and a distilled spirits plant or between distilled spirits plants is now authorized. Wine received at a distilled spirits plant may be used in the manufacture of a distilled spirits product but may not be removed for consumption or sale as wine. The liability for wine tax will continue until the wine is used in a distilled spirits product or until the proprietor is relieved from liability for the tax. To the extent that they do not involve the addition of distilled spirits (other than wine spirits as authorized under 26 U.S.C. 5373(a)), operations involving the rectification or bottling of wines formerly permitted on the premises of a distilled spirits plant will be required to be conducted at a bonded wine cellar or taxpaid wine bottling house, as appropriate.

Under existing law, no proprietor of a bonded wine cellar or taxpaid wine bottling house engaged in producing, receiving, storing or using any standard wine, may produce, receive, store or use any wine other than standard wine, except to the extent authorized by law. With the establishment of the all-in-bond system for distilled spirits plants, and the termination of the use of the bottling premises of a distilled spirits plant for the rectification or bottling of wines, a taxpaid wine bottling house may bottle other than standard wines, and a bonded wine cellar may rectify and bottle other wine products.

In addition, Pub. L. 96–39 does not authorize the in bond transfer of bottled distilled spirits. Only bulk distilled spirits may be transferred in bond. Consistent with this restriction, the return of distilled spirits to the bonded premises of a distilled spirits plant with abatement, credit or refund of tax will be authorized only for destruction, denaturation, redistillation, reconditioning, or rebottling.

6. *Simplification of bonding requirements.*

Another significant change made with the adoption of the all-in-bond system involves the treatment of surety bonds to secure unpaid liabilities for the distilled spirits tax. While the present requirements for surety bonds are continued, the bond system is simplified to reflect the expansion of bonded premises under the all-in-bond system.

The bonding requirements have been completely revised, and the provisions relating to liens on distillery property and the furnishing of indemnity bonds as methods of securing tax payment were repealed. A bond is required in order to engage in distilled spirits operations and a withdrawal bond is required for removal of spirits from bonded premises before the tax has been paid. A proprietor is allowed to provide one bond to cover all operations and a separate withdrawal bond for removal of spirits from bonded premises before the tax has been paid. In addition, the operations bond may cover the operations at a bonded wine cellar adjacent to the distilled spirits plant and operated by the same person, and also operations at two or more distilled spirits plants (and adjacent bonded wine cellars), where these plants are located in the same geographical area, and are operated by the same person.

Withdrawal bonds may cover withdrawals from one or more bonded premises where the operations on these multiple premises could be covered under the same operations bond. A new category of bond, called a unit bond, covers both operations and withdrawals of one or more distilled spirits plants which could be covered by the same operations bond.

7. *Controls and supervision.*

The new law repealed the requirement that bonded warehouses must be kept under Government lock

and that certain activities on the bonded premises could be conducted only when an ATF officer is on the premises. The Secretary now has discretionary authority to assign ATF officers and require Government locks at plants where necessary, or to eliminate the supervision where it is unnecessary.

In addition, the requirement for a closed distilling system is eliminated. Discretionary authority is retained to prescribe controls over the distilling system as necessary to adequately protect the revenue. The controls may be exercised over the entire distilling system, regardless of whether the spirits are in a potable or readily recoverable state.

8. *Extension of time for payment of tax on distilled spirits bottled in the United States.*

An additional semimonthly period is provided for the payment of the distilled spirits tax on spirits withdrawn from bonded premises. The additional deferral will be phased in over three years at 5 additional days for 1980, 10 additional days for 1981, and an entire semimonthly period for 1982 and subsequent years. For example, for distilled spirits tax that becomes payable during the January 1–15 tax return period, the first semimonthly return period in 1980, the taxpayer will have until February 5 to pay the tax. After this provision is fully phased-in during 1982, the taxpayer will have until February 15 to pay the tax for the January 1–15 period.

9. *Transitional rules.*

Transitional rules are provided to facilitate an orderly changeover to the all-in-bond system on January 1, 1980, so that taxable distilled spirits products will neither escape tax nor be subjected to double taxation.

The change, under the all-in-bond system, of nonbonded premises to bonded premises means that, if any tax which is due and payable on January 1, 1980, on controlled stock is to be credited or refunded, the spirits in controlled stock must be converted from tax-determined to nontax-determined spirits.

Under the transitional rules, the tax on all distilled spirits in controlled stock will become immediately due. The proprietor may elect, to the extent applicable, to extinguish this liability either by paying the tax or by converting any part of the controlled stock to bonded stock. Converting the spirits to bonded stock will allow the proprietor credit for the taxes previously paid or determined on the spirits or wine contained in the controlled stock. The election to convert controlled stock is intended to permit proprietors to pay the taxes already determined under the old system if it is more advantageous to them. Bulk wine in distilled spirits plants may also be converted to bonded stock with credit or refund of taxes paid.

Distilled spirits may be returned to bond for certain purposes with a credit or refund of tax. Under the transitional rules, distilled spirits to which alcoholic ingredients other than distilled spirits have been added and which have been withdrawn from a distilled spirits plant before January 1, 1980, may be returned only to the plant from which withdrawn, so that the amount of tax paid on the products can be determined from records at that plant.

All proprietors are required to have filed and have approval of new bonds effective January 1, 1980, if they are to continue operating after that date. Proprietors must also file new applications for registration and (except where all operations are conducted pursuant to basic permits) new applications for operating permits before January 1, 1980. However, operations may be continued under the former registration and operating permit pending final action on the new applications. In addition, no plants which were qualified as of May 1, 1979, will be denied new qualification by reason of the new conditions placed on qualification.

Advance Notice of Proposed Rulemaking

ATF published an advance notice of proposed rulemaking in the **Federal Register** on July 18, 1979 [44 FR 41833]. The advance notice highlighted major areas of the distilled spirits plant and wine regulations affected by the Distilled Spirits Tax Revision Act of 1979 and solicited comments from consumers and industry to assist the Bureau in drafting these temporary regulations. The advance notice invited general suggestions and recommendations relating to the then proposed law with specific emphasis on the following areas: (1) Qualification; (2) Records and Reports; (3) Bonds; (4) Transition; and (5) Elimination of Standard Wine Premises.

Discussion of Comments

1. *General.*

Twenty written comments were received in response to the advance notice of proposed rulemaking. Fifteen of these comments were from members of the distilled spirits industry or their trade associations. The remaining comments were from wine interests (2), importers/wholesalers (2), and a consumer group.

In general, commenters favored the all-in-bond system in concept and submitted proposals and suggestions for its implementation. In some areas, however, commenters believed either that the law had failed to provide for certain operations or that the implementing regulations might pose too great an administrative burden on the industry. In contrast, the one consumer comment opposed any liberalization of the regulations governing the industry.

With regard to specific issues, commenters who addressed a point generally agreed in principle as to the best course of action. The following paragraphs summarize the comments on the major issues that were addressed.

2. *Qualifying documents.*

As to qualification of distilled spirits plants, all commenters who responded favored reduction and simplification of the qualifying documents. Plats and plans, corporate documents and reporting of changes in the application data were areas where simplification was suggested.

The temporary regulations simplify the requirements as to plans, listing of equipment, and reporting of changes in construction and equipment. Required corporate information has not been significantly reduced at this time.

3. *Records and reports.*

Commenters favored reduction and/or elimination of required Government forms for internal plant transactions. Required periodic reports were viewed as subject to reduction in number and simplification. One commenter pointed to the time and study which would be required for some industry members to replace all Government transaction forms with their own commercial records, and suggested that supplies of obsoleted Government forms continue to be made available to proprietors who want to use them through the end of 1980.

The temporary regulations have eliminated some forms, modified others and left some essentially unchanged. Further reductions are anticipated in the final rule. Alternate records and forms provisions under the temporary regulations allow proprietors to substitute commercial records for required forms on notice to the regional regulatory administrator so long as the substitute records contain all information which would have been included on the form and certain conditions are met. Proprietors who desire to use obsolete forms, appropriately modified to conform to the new system, may do so where a new form has not been prescribed by regulations.

4. *Bonds.*

Commenters addressing bonding

requirements unanimously opposed any increase in the maximum penal sums. Experience factors were cited as support for the contention that current amounts are adequate. The temporary regulations leave the bond amounts generally the same as before. However, the Bureau will study further the sufficiency of bond penal sums in light of the new tax system.

5. *Conversion of controlled stock.*

With respect to treatment of the tax liability on controlled stock on hand at the close of business December 31, 1979, commenters suggested converting all remaining controlled stock to bond, taking credit at $10.50 for each proof gallon in the controlled stock inventory. Without considering any other adjustments, this would offset the outstanding tax liability reported on the final Form 4077. While simple, the method suggested by the commenters would result in excessive credit or refund of taxes to those proprietors who hold in controlled stock inventory products containing wine and alcoholic flavorings, which would be credited at the distilled spirits rate. Proprietors who had no products containing wines or alcoholic flavorings in their inventory, on similarly converting all controlled stock, would exactly satisfy their outstanding tax liability. Subpart X of 27 CFR Part 19 provides regulations to allow conversion of controlled stock and bulk wine as simply as possible, consistent with the legal requirement that credit or refund may be given only for those taxes actually paid or determined.

The question in the advance notice relative to "standard conversion rates" was not understood by most commenters. Commenters were concerned that a standard rate would be inequitable by failing to allow for differences between plants and variations in the formulation of products.

As provided in the regulations, standard conversion rates are to be established on a plant-by-plant basis and will apply only where alcoholic ingredients are consistently used in the same proportion in preparing batches of a product. Standard rates are an alternative method for computing the taxes actually paid or determined on products in the controlled stock inventory. If standard rates would give a false computation of taxes actually paid or determined, i.e., where ingredients are used in varying proportions from one batch to another, average rates may be used.

6. *Separation of stock.*

Commenters who addressed the separation of taxpaid goods, which are allowed to remain on bonded premises through December 31, 1980, favored achieving separation by means of tagging, separate pallets, and other methods short of designating specific rooms or buildings on bonded premises where such goods may be stored. The law calls for physical separation of taxpaid goods remaining on bonded premises. Subpart X of 27 CFR Part 19 provides that this separation can be maintained by separate tanks, rooms, buildings, by partitions or by other means acceptable to the regional regulatory administrator.

7. *Nonstandard wines and alternate operations.*

In connection with the elimination of standard wine premises from the regulations, commenters suggested that particular requirements for maintaining segregation of standard from nonstandard wines not be spelled out in the regulations. The regulations allow proprietors flexibility in determining how separation will be maintained.

With respect to alternation of premises between distilled spirits plants and bonded wine cellars, commenters suggested that separation of alternated areas be maintained by the boundaries of bottling lines, tanks and so on, which are being alternated. The temporary regulations provide for this method.

8. *Other issues.*

Many commenters addressed issues which were not included in the advance notice, but which nonetheless are appropriate to the implementation of the all-in-bond system. Some provided detailed recommendations for change directed at specific sections of regulations. These suggestions have been considered in drafting the temporary regulations to the extent possible, given the short time available for study. The following paragraphs discuss some of the major concerns brought out in the comments.

A few commenters suggested that imported cased goods should be permitted entry into ATF bond in the same manner as bulk imported spirits. Others urged that we allow cased goods specifically designated for export to be transferred in bond or returned to bond at other plants to allow for movement of the goods closer to the point of shipment. The law does not provide for transfer in bond of bottled distilled spirits and allows returns to bond only for certain enumerated purposes. Thus, these suggestions would require enabling legislation.

Movement of wines and taxpaid spirits across bonded premises was another point raised by commenters. Concern was expressed that required separation of taxpaid stocks during 1980 and the prohibition against taxpaid spirits on bonded premises thereafter could result in additional plant space requirements or cause delays in shipping. While taxpaid spirits and wines may not be stored or allowed to remain on bonded premises, except as provided in regulations for 1980, conveyance of such spirits and wines across bonded premises is provided for in 27 CFR 19.97.

The provisions for taxpayment of unexplained shortages of bottled distilled spirits were addressed by most commenters in light of the present procedures for treatment of casualty losses on plant premises. Such losses are reported to ATF officers and the proprietor may file a claim for the tax if the loss exceeds 10 proof gallons. Under the temporary regulations, reports may be required at the discretion of the regional regulatory administrator, but are not required as a general rule. However, records of all losses are required, including explanations for bottled distilled spirits lost. Unexplained shortages of bottled distilled spirits are to be taxpaid on discovery.

Several commenters recommended simplification of the requirements for samples withdrawn for research, development and testing. The temporary regulations simplify these requirements.

Regarding proof and fill tolerances, several commenters recommended broadening the determination of compliance to include more than just a single run or batch. Some suggested raising the permissible drop in proof to 0.5 degrees in the case of cordials. The temporary regulations make no change in the current standard for proof. With respect to fill, an overall objective of 100 percent fill for all bottled products is prescribed in lieu of the former standard, "substantially as much overfill as underfill for each lot of spirits bottled."

The temporary regulations incorporate many of the commenters' suggestions. Others may be implemented in the final regulations after further study. The Bureau will consider all comments on the temporary regulations before final regulations are issued.

Major Changes to the Regulations

1. *General.*

The following paragraphs enumerate some of the principal differences between existing regulations and the provisions of this temporary rule. Matters which were treated in discussion of the comments are not repeated here. In the interest of making this preamble more useful as an

overview, no attempt is made to discuss every change from existing regulations.

2. *Recodification of Parts 186 and 201.*

Although the regulations in this document represent temporary rules, Part 186, Gauging Manual, and Part 201, Distilled Spirits Plants, are being recodified in furtherance of a program instituted in 1975 with redesignation of ATF regulations from Title 26 of the Code of Federal Regulations (CFR) to Title 27 CFR.

3. *Strip stamps and alternative devices.*

ATF Notice No. 312 proposed amendment of regulations in several parts of Title 27 CFR concerning the use of strip stamps and devices other than strip stamps on containers of spirits. After careful consideration of all comments on the notice, regulations are included in the temporary rules to provide for the use of alternative devices by domestic distilled spirits plants. In addition, the stamp regulations are amended to delete the serial numbering of strip stamps and eliminate blue and white strip stamps. Red strip stamps will be used in lieu of blue and white stamps.

4. *Denaturation of spirits.*

Title 27 CFR 201.120 currently provides that spirits may be denatured by a proprietor authorized to produce spirits. Section 201.120 further provides that a subsidiary corporation may denature spirits based on the production qualification of a parent corporation and vece versa. Section 201.120 has been revoked. The temporary regulations provide for denaturation of spirits by any proprietor of a distilled spirits plant qualified to process.

5. *Manufacture of articles.*

The temporary regulations provide for the manufacture of articles by qualified proprietors. Under existing regulations, articles such as proprietary solvents and special industrial solvents may not be manufactured on distilled spirits plant premises. This prohibition necessitated the establishment of specially denatured alcohol users premises adjacent to distilled spirits plants to permit proprietors to manufacture industrial solvents. The temporary regulations eliminate the necessity for this dual qualification.

6. *Statement of security.*

The temporary regulations require proprietors to submit a statement of plant security to the regional regulatory administrator for approval. The statement will generally outline security measures employed at the distilled spirits plant and will include a description of locks to be utilized by proprietors in lieu of Government locks. Regional regulatory administrators will notify proprietors when the initial statement of security is due.

7. *ATF supervision.*

Existing regulations provide for the direct or general supervision of numerous distilled spirits plant operations by ATF officers. Direct supervision requires the presence of an ATF officer on the plant premises or the premises of an adjacent bonded wine cellar. The temporary regulations provide that the regional regulatory administrator may require supervision of plant operations when considered necessary for protection of the revenue.Three types of supervision are defined in the temporary regulations. "General supervision" which does not require the presence of an ATF officer on the plant premises. "Direct supervision" is provided when an ATF officer is on the plant premises. "Immediate supervision" requires that an operation be conducted in the immediate presence of an ATF officer. This system will provide regional regulatory administrators flexibility in providing ATF supervision on a plant-by-plant basis.

8. *Mingling, blending and mixing of spirits.*

Existing regulations prescribe detailed eligibility requirements for the mingling, blending, and mixing of spirits. Rigid age spreads and additional eligibility requirements currently restrict operational flexibility by limiting the manipulation of spirits on bonded premises. The temporary regulations prescribe the extent to which spirits may be mingled or blended during storage operations. Additionally, operational flexibility is broadened by increasing the extent of manipulation of spirits permitted for processing operations on bonded premises.

9. *Elimination of operational applications.*

Numerous sections currently in Part 201 require the submission of letterhead applications to ATF officers assigned to the distilled spirits plant or to the regional regulatory administrator. The majority of these applications cover transactions or operations which have minimal impact on the security of the revenue. Therefore, the temporary regulations replace many letterhead applications with notices and/or requirements for recording the transaction or operation in required daily records. Letterhead applications are kept to a minimum to allow operational flexibility for distilled spirits plant operations.

10. *Bottling record.*

Existing regulations prescribe preparation of ATF Form 2637 to document bottling operations on bottling premises with a separate Form 2637 required for each tank of spirits bottled. ATF Form 1515 is prescribed for the bottling of spirits on bonded premises. Form 1515 may be prepared to cover the contents of multiple tanks of spirits. The temporary regulations do not prescribe a standard form to cover the bottling of spirits. The bottling record which is prescribed permits accounting for the bottling of spirits on the basis of lots of spirits, which may encompass multiple tanks. To ensure proper accounting for spirits, the temporary regulations require a gauge for each tank of spirits to be bottled, with resultant losses or gains recorded for each tank.

11. *Bottling-in-bond.*

A labeling standard for bottled in bond spirits is provided in 27 CFR 5.42 as amended in this temporary rule. The standard is essentially the same as was previously included in Part 201, except that no standard for spirits to be exported is provided because Part 5 does not apply to exports. Green strip stamps will be used on spirits labeled as bottled in bond, but overprinting is optional.

12. *Form 27–B Supplemental.*

Proprietors are currently required to file each formula and process utilized in rectification of spirits with the Director for approval on Form 27–B Supplemental. The formula enables a proper determination with respect to tax classification and labeling of the finished product. With the elimination of rectification tax, the primary significance of formulation will concern labeling of the finished product. Therefore, the requirement for Form 27–B Supplemental is moved to Part 5 to ensure proper labeling. In addition the form has been redesignated as ATF Form 5110.38. Proprietors holding current approved formulas on Form 27–B Supplemental need not resubmit them merely to reflect the change in the form number or change in the regulatory provisions.

13. *Physical inventories.*

Existing regulations prescribe bulk physical inventories of spirits in production facilities and in storage facilities each month. Inventories of controlled stock are conducted on a semiannual or an annual basis. The temporary regulations provide for quarterly inventories of bulk spirits in production, storage and processing. Semiannual inventories are prescribed for bottled spirits in processing, with the current provision for such inventories on an annual basis when approved by the regional regulatory administrator.

14. *Record accounts.*

The records maintained pursuant to the temporary regulations will be

arranged into operational accounts to coincide with the tri-operational concept of bonded premises. Operational accounts will be maintained for production, storage and processing. Daily records for each account will note receipts, movement between accounts and dispositions of spirits, denatured spirits, articles and wines.

15. *Modified forms and substitute records.*

The temporary regulations provide for the modification of prescribed forms and utilization of substitute records in lieu of prescribed forms on notice to the regional regulatory administrator. Certain forms are excluded to ensure uniformity, e.g., claims, tax returns and operational reports.

Generally, however, the temporary rules permit proprietors to utilize commercial records in lieu of prescribed forms if the commercial records contain all mandatory data.

16. *Forms.*

Numerous forms are eliminated or revised due to changes in the temporary regulations. These changes are detailed in ATF Industry Circular 79–12.

17. *Reporting Puerto Rican and Virgin Islands spirits tax-determined.*

Proprietors who remove products containing Puerto Rican or Virgin Islands spirits on determination of tax are required to report monthly (on ATF Form 5110.28, Monthly Report of Processing Operations) the total taxes determined attributable to such spirits. Under the existing system, these spirits are tax-determined on Form 179, and ATF personnel at the regional level prepare comparable reports based on copies of Forms 179 received. Due to the elimination of Form 179, a substitute procedure is necessary to obtain data for settlement of tax accounts between the United States and the treasuries of Puerto Rico and the Virgin Islands.

18. *Tax determination/tax payment.*

The system of withdrawal on determination and payment of tax under the temporary regulations differs greatly from existing regulations. Under the temporary regulations, a record of tax determination (e.g., invoice or shipping document) is required to document the basis for computing tax. If taxes on spirits are to be prepaid, Form 5110.32 shall be executed before the spirits are withdrawn from bond. If tax is to be deferred, the proprietor shall summarize all records of tax determination on a daily summary record. Tax for the return period will be paid by filing Form 5110.35 with remittance.

19. *Exportation with benefit of drawback.*

The change in the method of tax determination required addition of new §§ 252.195a and 252.195b to cover export drawback claims for spirits tax-determined before January 1, 1980 and after January 1, 1980, respectively.

20. *Manufacturing bonded warehouses.*

The provisions in 26 U.S.C. Chapter 51 relating to manufacturing bonded warehouses have been repealed. Manufacturing bonded warehouses are also provided for under 19 U.S.C. and Title 19 of the Code of Federal Regulations. Because such facilities are operated under Customs supervision, the parallel provisions under 26 U.S.C. were superfluous.

21. *Changes relating to Puerto Rican and Virgin Islands spirits (Parts 170 and 250).*

Subparts F and G of 27 CFR Part 170 are revoked. Similar provisions have been incorporated in Parts 19 and 250, as applicable. Repeal of the wine gallon method of tax determination eliminates the need for a gauge of the spirits prior to their use in the manufacture of distilled spirits products or articles. The tax will now be computed on the alcoholic content of the finished product when it is ready for shipment to the United States. The extension of the tax deferral period and the requirement for a new bond effective January 1, 1980, both of which were previously discussed, apply to Puerto Rican manufacturers who defer taxes.

22. *Rectification taxes and formulas (Puerto Rico and Virgin Islands).*

All references to rectification tax are eliminated from Part 250. Segregation of spirits to be rectified from spirits to be bottled without rectification is no longer required. The formula requirements for Puerto Rican and Virgin Islands liquors and articles are revised to conform with requirements for similar products made in the United States.

23. *Changes specific to bonded wine cellars and taxpaid wine bottling houses.*

A number of sections in 27 CFR Parts 231 and 240 have been amended to provide for alternation of premises with distilled spirits plant premises, and to allow, by approved formula, for production of other than standard wine on bonded wine cellar premises. Another major revision in 27 CFR Part 240 provides for the transfer of wine in bond between a bonded wine cellar and a distilled spirits plant.

24. *Conforming changes.*

Minor conforming and editorial changes have been made to other regulations in Title 27 (aside from recodified Parts 13 and 19 and changes in wine regulations). The principal reasons for these changes are as follows: (1) the all-in-bond system; (2) repeal of rectification taxes; (3) the recodifications; (4) changes in references; and (5) obsolescence of certain regulations.

Proposed Revisions

1. *General.*

The Bureau has identified several additional operational matters which may merit further liberalization or clarification. Due to time constraints associated with the drafting of this document, a decision has been made to propose further regulatory revision in these areas and obtain public and industry input prior to implementation of the revisions in final regulations. The following paragraphs provide a summary of the proposed revisions.

2. *Elimination of forms.*

The Bureau proposes to eliminate some distilled spirits plant operational forms in the final rule. Commercial records would be prescribed in lieu of the forms. Public comments are invited to assist the Bureau in determining which forms may be eliminated.

3. *Monthly reports.*

The monthly operational reports submitted by proprietors are used to compile industry-wide statistics. Other governmental agencies and industry groups, as well as the Bureau, make use of these statistics. The Bureau proposes to reduce the required filings of operational reports to a quarterly basis.

4. *Alternative devices.*

The temporary regulations authorize domestic bottlers to use alternative devices in lieu of strip stamps on bottled distilled spirits. The Bureau proposes to extend this option to foreign, Puerto Rican and Virgin Islands bottlers.

5. *Proof tolerance for cordials.*

Some commenters on the Advance Notice of Proposed Rulemaking for these temporary regulations proposed raising the permissible drop in proof during bottling to 0.5 degrees in the case of cordials. The Bureau will consider implementing this proposal for products which contain solids in excess of 600 mg per 100 ml. Other products would remain subject to the current limit of 0.3 degrees of proof.

6. *Elimination of labeling designation for gin and vodka as bottled-in-bond.*

The temporary regulations incorporate in 27 CFR 5.42 the same standards for bottled-in-bond spirits which were previously in 27 CFR Part 201. The intent was to preserve the existing meaning of the term "bottled-in-bond" despite the repeal of tax provisions under 26 U.S.C. 5233. Since it appears that the labeling designation for bottled in bond gin or vodka is not used today, the Bureau proposes to delete this label designation.

Statement of Administrative Action

1. *On-premises supervision.*

With repeal of the present statutory obligation to assign ATF officers to distilled spirits plants, the Bureau anticipates the gradual removal of ATF officers from such plants to be accomplished on a plant-by-plant basis. This will provide the Government with an opportunity to evaluate the degree of control needed at each plant, and will provide proprietors the opportunity to adjust to their new responsibilities. However, the removal of ATF officers assigned at distilled spirits plants will necessitate an expanded inspection-audit program to ensure the protection of the revenue. Unless otherwise notified, proprietors may assume that the level of supervision in effect on December 31, 1979, will be continued on and after January 1, 1980.

2. *Manufacturers of nonbeverage products.*

Some manufacturers of alcoholic flavorings may wish to establish distilled spirits plants in order to receive spirits in bond and transfer finished flavorings in bond to distilled spirits plants. In considering such applications, where the exclusive purpose is to manufacture flavorings as intermediate distilled spirits products, the Bureau may waive the minimum storage capacity requirements for warehousing set forth in 27 CFR 19.134.

Drafting Information

The authors of this document are numberous headquarters and field personnel of the Bureau of Alcohol, Tobacco and Firearms, assigned or detailed to the Research and Regulations Branch (Regulatory Enforcement). Other personnel of the Bureau and the Treasury Department participated in the preparation of this document, both in matters of substance and style.

Waiver of Procedural Requirements of Treasury Directive

Expeditious adoption of the provisions contained in this document is necessary in order to provide immediate guidelines for use by the distilled spirits and wine industries in implementing the Distilled Spirits Tax Revision Act of 1979. For this reason, Richard J. Davis, Assistant Secretary (Enforcement and Operations) of the Treasury, has determined that the provisions of paragraph 10 of the Treasury Department directive implementing Executive Order 12044 must be waived.

Effective Date

There is a need for immediate guidance with respect to the provisions contained in this Treasury decision. For this reason, it is found impracticable to issue it with notice and public procedure under subsection (b) of section 553 of Title 5 of the United States Code or subject to the effective date limitation of subsection (d) of that section. Accordingly, this Treasury decision becomes effective on January 1, 1980.

Authority and Issuance

These regulations are issued under the authority contained in 26 U.S.C. 7805 (68A Stat. 917, as amended) and in 27 U.S.C. 205 (49 Stat. 981, as amended).

Accordingly, Title 27 Code of Federal Regulations is amended as follows:

Section A. Part 5 is amended as follows:

PART 5—LABELING AND ADVERTISING OF DISTILLED SPIRITS

Paragraph 1. The table of contents is amended to reflect the addition of Subpart Ca—Formulas, immediately following Subpart C—Standards of Identity for Distilled Spirits, and the table of contents is also amended to delete § 5.49, Bottles per shipping case. As amended, the table of contents reads as follows:

* * * * *

Subpart Ca—Formulas

Sec.
5.25 Application.
5.26 Formula requirements.
5.27 Formulas for processing operations.
5.28 Adoption of predecessor's formulas.

* * * * *

Subpart E—Standards of Fill for Bottled Distilled Spirits

* * * * *

5.49 [Deleted]

* * * * *

§ 5.2 [Amended]

Paragraph 2. Section 5.2 is amended to delete the phrase "27 CFR Part 201—Distilled Spirits Plants." and to insert immediately after "27 CFR Part 7—Labeling and Advertising of Malt Beverages." the phrase "27 CFR Part 19—Distilled Spirits Plants."

Paragraph 3. Section 5.11 is amended, in alphabetical order, by revising the definition of "Distilled spirits" and by adding the definitions "Area Supervisor" and "Season". As amended, § 5.11 reads as follows:

§ 5.11 Meaning of terms.

* * * * *

Area supervisor. The supervisory officer of the Bureau of Alcohol, Tobacco and Firearms area office.

* * * * *

Distilled spirits. Ethyl alcohol, hydrated oxide of ethyl, spirits of wine, whisky, rum, brandy, gin, and other distilled spirits, including all dilutions and mixtures thereof, for nonindustrial use.

* * * * *

Season. The period from January 1 through June 30 is the spring season and the period from July 1 through December 31 is the fall season.

* * * * *

Paragraph 4. Section 5.22 is amended by changing the last sentence in paragraph (b)(1)(iii) to read as follows:

§ 5.22 The standards of identity.

* * * * *

(b) * * *

(1) * * *

(iii) * * * "Straight whisky" includes mixtures of straight whiskies of the same type produced by the same proprietor at the same distillery all of which are not less than four years old.

* * * * *

Paragraph 5. Subpart Ca—Formulas, is added immediately following the regulations in Subpart C—Standards of Identity for Distilled Spirits. As added, Subpart Ca reads as follows:

Subpart Ca—Formulas

§ 5.25 Application.

The requirements of this subpart shall apply to:

(a) Proprietors of distilled spirits plants qualified as processors under 27 CFR Part 19;

(b) Persons in Puerto Rico who manufacture distilled spirits products for shipment to the United States. Formulas need only be filed for those products which will be shipped to the United States; and

(c) Persons who ship into the United States, Virgin Islands distilled spirits products.

§ 5.26 Formula requirements.

(a) *General.* An approved formula is required to blend, mix, purify, refine, compound, or treat spirits in a manner which results in a change of character, composition, class or type of the spirits. Form 5110.38 (27–B Supplemental) shall be filed with the Director in accordance with the instructions on the form and shall designate all ingredients and, if required, the process used. Any approved formula on Form 27–B Supplemental or Form 5110.38 shall remain in effect until revoked, superseded, or voluntarily surrendered.

Any existing qualifying statements as to the rate of tax or the limited use of drawback flavors appearing on a Form 27–B Supplemental are obsolete.

(b) *Change in formula.* Any change in an approved formula shall require the filing of a new Form 5110.38. After a change in a formula is approved, the original formula shall be surrendered to the Director.

§ 5.27 Formulas for processing operations.

Formulas are required for processing operations which change the character, composition, class or type of spirits as follows:

(a) The compounding of spirits through the mixing of any coloring, flavoring, wine, or other material with distilled spirits;

(b) Any filtering or stabilizing process which results in a product which does not possess the taste, aroma, and characteristics generally attributed to that class or type of distilled spirits; and, in the case of straight whisky, results in the removal of more than 15 percent of the fixed acids, volatile acids, esters, soluble solids, or higher alcohols, or more than 25 percent of the soluble color;

(c) The mingling of spirits (including merchandise returned to bond) produced by different distillers, or at different distilleries, or which differ in class or type of materials from which produced;

(d) The mingling of spirits stored in charred cooperage with spirits stored in plain or reused cooperage, or the mixing of spirits that have been treated with wood chips with spirits not so processed, or the mixing of spirits that have been subjected to any treatment which changes their character with spirits not so treated, unless it is determined that the composition of the spirits is the same, notwithstanding the storage in different kinds of cooperage or the treatment of a portion of the spirits;

(e) The use (except as authorized for production or storage operations as provided by 27 CFR Part 19) of any physical or chemical process or any apparatus which accelerates the maturing of the spirits;

(f) The steeping or soaking of fruits, berries, aromatic herbs, roots, seeds, etc., in spirits or wines;

(g) The artificial carbonating of spirits;

(h) The blending in Puerto Rico of spirits with any liquors manufactured outside of Puerto Rico;

(i) The production of gin by—(1) Redistillation over juniper berries and other natural aromatics, or the extracted oils of such, of spirits distilled at or above 190 degrees of proof, free from impurities, including spirits of such a nature recovered by redistillation of imperfect gin spirits; and

(2) Mixing gin produced by redistillation with other spirits;

(j) The treatment of gin by—(1) The addition or abstraction of any substance or material other than pure water after redistillation in a manner that would change its class and type designation; and

(2) The addition of any substance or material other than juniper berries or other natural aromatics, or the extracted oils of such, or pure water to the spirits, before or during redistillation, in a manner that would change its class and type designation;

(k) The production of vodka by—(1) The treatment of neutral spirits with not less than one ounce of activated carbon per 100 wine gallons of spirits;

(2) Redistillation of pure spirits so as to be without distinctive character, aroma, taste, or color;

(3) Mixing with other spirits or with any other substance or material except pure water, after production; and

(4) Adding any substance or material which imparts to the product any distinctive character, aroma, taste, or color before or during production.

§ 5.28 Adoption of predecessor's formulas.

The adoption by a successor of approved Forms 5110.38 (27–B Supplemental) shall be in the form of an application filed with the Director. The application shall list the formulas for adoption by—

(a) formula number,

(b) name of product, and

(c) date of approval.

The application shall clearly show that the predecessor has authorized the use of his previously approved formulas by the successor.

Paragraph 6. Section 5.31 is amended by revising paragraph (b) to read as follows:

§ 5.31 General.

* * * * *

(b) *Alteration of labels.* It shall be unlawful for any person to alter, mutilate, destroy, obliterate, or remove any mark, brand, or label on distilled spirits held for sale in interstate or foreign commerce or after shipment therein, except—

(1) As authorized by Federal law;

(2) That the area supervisor may, on written application, permit additional labeling or relabeling of bottled distilled spirits with labels covered by certificates of label approval which comply with the requirements of this part and with State law;

(3) That there may be added to the bottle, after removal from customs custody, or prior to or after removal from bonded premises, without application for permission to relabel, a label identifying the wholesale or retail distributor thereof or identifying the purchaser or consumer, and containing no references whatever to the characteristics of the product.

Paragraph 7. Section 5.36 is amended by revising paragraph (a)(2) to read as follows:

§ 5.36 Name and address.

(a) *"Bottled by".*

* * * * *

(2) Where distilled spirits are bottled by or for the distiller thereof, there may be stated, in lieu of the phrase "bottled by", "packed by", or "filled by", followed by the bottler's name (or trade name) and address, the phrase "distilled by", followed by the name, or the trade name under which the particular spirits were distilled, or (except in the case of distilled spirits labeled as bottled in bond) any trade name shown on the distiller's permit (covering the premises where the particular spirits were distilled), and the address (or addresses) of the distiller.

* * * * *

Paragraph 8. Section 5.40 is amended by revising the first sentence of paragraph (a) to read as follows:

§ 5.40 Statements of age and percentage.

(a) *Statements of age and percentage for whisky.* In the case of domestic or foreign whisky, whether or not mixed or blended, all of which is 4 years old or more, statements of age and percentage are optional. * * *

Paragraph 9. Section 5.42(b) (1), (3) and (4) are amended to read as follows:

§ 5.42 Prohibited practices.

* * * * *

(b) *Miscellaneous.* (1) Labels shall not be of such design as to resemble or simulate a stamp of the U.S. Government or any State or foreign government. Labels, other than stamps authorized or required by this or any other government, shall not state or indicate that the distilled spirits are distilled, blended, made, bottled, or sold under, or in accordance with, any municipal, State, Federal, or foreign authorization, law, or regulations, unless such statement is required or specifically authorized by Federal, State, municipal, or foreign law or regulations. The statements authorized by this part to appear on labels for domestic distilled spirits are "Distilled (produced, barreled, warehoused, blended, or bottled, or any combination thereof, as

the case may be) under United States (U.S.) Government supervision", or in the case of distilled spirits labeled as bottled in bond, "Bottled in bond under United States (U.S.) Government supervision". If the municipal, State, or Federal Government permit number is stated on a label, it shall not be accompanied by any additional statement relating thereto.

* * * * *

(3) The words "bond", "bonded", "bottled in bond", "aged in bond", or phrases containing these or synonymous terms, shall not be used on any label or as part of the brand name of domestic distilled spirits unless the distilled spirits are—

(i) Composed of the same kind of spirits produced from the same class of materials;

(ii) Produced in the same distilling season by the same distiller at the same distillery;

(iii) Stored for at least four years in wooden containers wherein the spirits have been in contact with the wood surface except for gin and vodka which must be stored for at least four years in wooden containers coated or lined with paraffin or other substance which will preclude contact of the spirits with the wood surface;

(iv) Unaltered from their original condition or character by the addition or subtraction of any substance other than by filtration, chill proofing, or other physical treatments (which do not involve the addition of any substance which will remain incorporated in the finished product or result in a change in class or type);

(v) Reduced in proof by the addition of pure water only to 100 degrees of proof; and

(vi) Bottled at 100 degrees of proof.

In addition to the requirements of § 5.36(a) (1) or (2), the label shall bear the real name of the distillery or the trade name under which the distillery produced and warehoused the spirits, and the plant (or registered distillery) number in which produced; and the plant number in which bottled. The label may also bear the name or trade name of the bottler.

(4) The words "bond", "bonded", "bottled in bond", "aged in bond", or phrases containing these or synonymous terms, shall not be used on any label or as part of the brand name of imported distilled spirits unless the distilled spirits meet in all respects the requirements applicable to distilled spirits bottled for domestic consumption, so labeled, and unless the laws and regulations of the country in which such distilled spirits are produced authorize the bottling of distilled spirits in bond and require or specifically authorize such distilled spirits to be so labeled. All spirits labeled as "bonded", "bottled in bond", or "aged in bond" pursuant to the provisions of this subparagraph shall bear in direct conjunction with such statement and in script, type, or printing substantially as conspicuous as that used on such statement, the name of the country under whose laws and regulations such distilled spirits were so bottled.

* * * * *

Paragraph 10. Section 5.46 is amended by revising paragraph (b) to read as follows:

§ 5.46 Standard liquor bottles.

* * * * *

(b) *Headspace.* A liquor bottle of a capacity of 200 milliliters or more shall be held to be so filled as to mislead the purchaser if it has a headspace in excess of 8 percent of the total capacity of the bottle after closure.

Paragraph 11. Section 5.47a deletes paragraph (e) and redesignates paragraph (f) as (e). As amended, paragraph (e) of § 5.47a reads as follows:

§ 5.47a Metric standards of fill.

* * * * *

(e) *Distilled spirits bottled before January 1, 1980.* Distilled spirits bottled domestically before January 1, 1980, may be marketed after December 31, 1979, if such distilled spirits were bottled in accordance with § 5.47. (See § 5.53 for similar provisions relating to distilled spirits imported in original containers.)

§ 5.49 [Deleted]

Paragraph 12. Section 5.49 is deleted because a requirement to pack a set number of bottles in a shipping case has been found to be unnecessary.

PART 186 [REVISED AND REDESIGNATED]

Section B. Part 186 is revised and renumbered as Part 13 as follows:

Preamble 1. The regulations in this part supersede 27 CFR Part 186 in its entirety.

2. These regulations do not affect any act done or any liability or right accruing, or accrued, or any suit or proceeding had or commenced before the effective date of these regulations.

3. The regulations in this part are effective on January 1, 1980.

PART 13—GAUGING MANUAL

Subpart A—Scope of Regulations

Sec.

13.1 Gauging of distilled spirits.

Subpart B—Definitions

13.11 Meaning of terms.

Subpart C—Gauging Instruments

Sec.

13.21 General requirements.
13.22 Hydrometers and thermometers.
13.23 Use of precision hydrometers and thermometers.
13.24 Specific gravity hydrometers.
13.25 Use of precision specific gravity hydrometers.

Subpart D—Gauging Procedures

13.31 Determination of proof.
13.32 Determination of proof obscuration.

Determination of Quantity

13.36 General requirements.

Determination of Quantity by Weight

13.41 Bulk spirits.
13.42 Denatured spirits.
13.43 Packaged spirits.
13.44 Entry or filling gauge for packages.
13.45 Withdrawal gauge for packages.

Determination of Quantity by Volume

13.51 Procedure for measurement of bulk spirits.
13.52 Procedure for measurement of cased spirits.

Subpart E—Prescribed Tables

13.61 Table 1, showing the true percent of proof spirit for any indication of the hydrometer at temperatures between 0 and 100 degrees Fahrenheit.
13.62 Table 2, showing wine gallons and proof gallons by weight.
13.63 Table 3, for determining the number of proof gallons from the weigth and proof of spirituous liquor.
13.64 Table 4, showing the fractional part of a gallon per pound at each percent and each tenth percent of proof of spirituous liquor.
13.65 Table 5, showing the weight per wine gallon (at 60 degrees Fahrenheit) and proof gallon at each percent of proof of spirituous liquor.
13.66 Table 6, showing respective volumes of alcohol and water and the specific gravity in both air and vacuum of spirituous liquor.
13.67 Table 7, for correction of volume of spirituous liquors to 60 degrees Fahrenheit.

Authority: Sec. 7805, 68A Stat. 917, as amended; 26 U.S.C. 7805, unless otherwise noted.

Subpart A—Scope of Regulations

§ 13.1 Gauging of distilled spirits.

This part, the "Gauging Manual", relates to the gauging of distilled spirits. By "gauging" is meant the determination of the proof and the quantity of distilled spirits. Tables 1–7, together with their instructions, are provided as a part hereof and should be used, wherever applicable, in making the necessary computations from gauge data. Table 1 provides a method of correcting hydrometer indications at temperatures between 0 and 100 degrees Fahrenheit to true proof. If distilled spirits contain dissolved solids, temperature-correction

of the hydrometer reading by the use of this table would result in apparent proof rather than true proof. Tables 2 and 3 show the gallonage of spirituous liquor according to weight and proof, Table 4 shows the gallons per pound at each one-tenth proof from 1 to 200 proof, Table 5 shows the weight per wine gallon and proof gallon at each proof, Table 6 shows the volumes of alcohol and water, and the specific gravity (air and vacuum) of spirituous liquor at each proof, and Table 7 provides a means of ascertaining the volume (at 60 degrees Fahrenheit) of spirits at various temperatures ranging from 18 degrees through 100 degrees Fahrenheit. The procedures prescribed in, or authorized under the provisions of, this part shall, except as may be otherwise authorized in this chapter, be followed in making any determination of quantity or proof of distilled spirits required by or under the authority of regulations in this chapter.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C 5204))

Subpart B—Definitions

§ 13.11 Meaning of terms.

When used in this part, where not otherwise distinctly expressed or manifestly incompatible with the intent thereof, terms shall have the meanings ascribed in this section. Words in the plural form shall include the singular, and vice versa, and words importing the masculine gender shall include the feminine. The terms "includes" and "including" do not exclude things not enumerated which are in the same general class.

ATF officer. An officer or employee of the Bureau of Alcohol, Tobacco and Firearms (ATF) authorized to perform any function relating to the administration or enforcement of this part.

Bulk conveyance. Any tank car, tank truck, tank ship, tank barge, or other similar container approved by the Director, authorized for the conveyance of spirits (including denatured spirits) in bulk.

CFR. The Code of Federal Regulations.

Container. Any receptacle, vessel, or form of package, bottle, tank, or pipeline used, or capable of use, for holding, storing, transferring or conveying distilled spirits.

Denatured spirits or denatured alcohol. Spirits to which denaturants have been added pursuant to formulas prescribed in Part 212 of this chapter.

Director. The Director, Bureau of Alcohol, Tobacco and Firearms, the Department of the Treasury, Washington, DC.

Gallon or wine gallon. The liquid measure equivalent to the volume of 231 cubic inches.

I.R.C. The Internal Revenue Code of 1954, as amended.

Package. Any cask, barrel, drum, or similar container approved under the provisions of this chapter.

Proof. The ethyl alcohol content of a liquid at 60 degrees Fahrenheit, stated as twice the percent of ethyl alcohol by volume.

Proof gallon. A United States gallon of proof spirits, or the alcoholic equivalent thereof.

Proof spirits. That liquid which contains one-half its volume of ethyl alcohol of a specific gravity of seven thousand nine hundred and thirty-nine ten-thousandths (0.7939) in vacuum at 60 degrees Fahrenheit referred to water at 60 degrees Fahrenheit as unity.

Regional regulatory administrator. The principal ATF regional official responsible for administering regulations in this part.

Spirits, spirituous liquor, or distilled spirits. That substance known as ethyl alcohol, ethanol, or spirits of wine in any form, including all dilutions and mixtures thereof, from whatever source or by whatever process produced, but not denatured spirits unless specifically stated.

This chapter. Title 27, Code of Federal Regulations, Chapter I (27 CFR Chapter I).

U.S.C. The United States Code.

Subpart C—Gauging Instruments

§ 13.21 General requirements.

ATF officers shall use only hydrometers and thermometers furnished by the Government. However, where this part requires the use of a specific gravity hydrometer, ATF officers shall use precision grade specific gravity hydrometers conforming to the provisions of § 13.24, furnished by the proprietor. However, the Director may authorize ATF officers to use other instruments approved by the Director as being equally satisfactory for determination of specific gravity and for gauging. From time to time ATF officers shall verify the accuracy of hydrometers and thermometers used by proprietors. The proof of distilled spirits shall be determined by the use of gauging instruments as prescribed in this part.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5204))

§ 13.22 Hydrometers and thermometers.

The hydrometers furnished to ATF officers are graduated to read the proof of aqueous alcoholic solutions at 60 degrees Fahrenheit; thus, they read, 0 for water, 100 for proof spirits, and 200 for absolute alcohol. Because of temperature-density relationships and the selection of 60 degrees Fahrenheit for reporting proof, the hydrometer readings will be less than the true percent of proof at temperatures below 60 degrees Fahrenheit and greater than the true percent of proof at temperatures above 60 degrees Fahrenheit. Hence, corrections are necessary for hydrometer readings at temperatures other than 60 degrees Fahrenheit. Precision hydrometers shall be used for gauging spirits. Hydrometers and thermometers shall be used and the true percent of proof shall be determined in accordance with § 13.31. Hydrometers are designated by letter according to range of proof and are provided in ranges and subdivisions of stems as follows:

Precision	Range	Subdivision
F	0 to 20	0.2°
G	20 to 40	.2°
H	40 to 60	.2°
I	60 to 80	.2°
K	75 to 95	.2°
L	90 to 110	.2°
M	105 to 125	.2°
N	125 to 145	.2°
P	145 to 165	.2°
Q	165 to 185	.2°
R	185 to 206	.2°

Thermometers are designated by type according to range of degrees Fahrenheit and are provided in ranges and subdivisions of degrees as follows:

Type	Range	Subdivision
Pencil type	10° to 100°	1°
V-back	10° to 100°	1°
Glass shell (earlier model)	40° to 100°	½°
Glass shell (later model)	40° to 100°	¼°

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5204))

§ 13.23 Use of precision hydrometers and thermometers.

Care should be exercised to obtain accurate hydrometer and thermometer readings. In order to accomplish this result, the following precautions should be observed. Bulk spirits should be thoroughly agitated so that the test samples will be representative of the entire quantity. The hydrometers should be kept clean and free of any oily substance. Immediately before readings are taken, the glass cylinder containing the thermometer should be rinsed several times with the spirits which are to be gauged so as to bring both the cylinder and the thermometer to the temperature of the spirits (if time

permits, it is desirable to bring both the spirits and the instruments to room temperature). If the outer surface of the cylinder becomes wet, it should be wiped dry to avoid the cooling effect of rapid evaporation. During the readings the cylinder should be protected from drafts or other conditions which might affect its temperature or that of the spirits which it contains. The hands should not be placed on the cylinder in such a manner as to warm the liquid contained therein. The hydrometer should be inserted in the liquid and the hydrometer bulb raised and lowered from top to bottom 5 or 6 times to obtain an even temperature distribution over its surface, and, while the hydrometer bulb remains in the liquid, the stem should be dried and the hydrometer allowed to come to rest without wetting more than a few tenths degrees of the exposed stem. Special care should be taken to ascertain the exact point at which the level of the surface liquid intersects the scale of proof in the stem of the hydrometer. The hydrometer and thermometer should be immediately read, as nearly simultaneously as possible. In reading the hydrometer, a sighting should be made slightly below the plane of the surface of the liquid and the line of sight should then be raised slowly, being kept perpendicular to the hydrometer stem, until the appearance of the surface changes from an ellipse to a straight line. The point where this line intersects the hydrometer scale is the correct reading of the hydrometer. When the correct readings of the hydrometer and the thermometer have been determined, the true percent of proof shall be ascertained from Table 1. Another sample of the spirits should then be taken and be tested in the same manner so as to verify the proof originally ascertained. Hydrometer readings should be made to the nearest 0.05 degree and thermometer readings should be made to the nearest 0.1 degree, and instrument correction factors, if any, should be applied. It is necessary to interpolate in Table 1 for fractional hydrometer and thermometer readings.

Example. A hydrometer reads 192.85° at 72.10° F. The correction factors for the hydrometer and thermometer, respectively are minus 0.03° and plus 0.05°. The corrected reading, then, is 192.82° at 72.15° F.

	Degrees
From Table 1:	
193.0° at 72.0° F	190.2
192.0° at 72.0° F	189.1
Difference	1.1
192.0° at 72.0° F	189.1
192.0° at 73.0° F	188.9
Difference	0.2

The hydrometer difference (1.1°) multiplied by the fractional degree of the hydrometer reading (0.82°)=0.902.

The temperature difference (0.2°) multiplied by the fractional degree of the temperature reading (0.15°)=0.03°.

Proof at 60° F.=189.1+0.902−0.03=189.972°=190.0°.

As shown, the final proof is rounded to the nearest tenth of a degree of proof. In such cases, if the hundredths decimal is less than five, it will be dropped; if it is five or over, a unit will be added.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5204))

§ 13.24 Specific gravity hydrometers.

The specific gravity hydrometers furnished by proprietors to ATF officers shall conform to the specifications of the American Society for Testing Materials or the National Bureau of Standards for such instruments. Such specific gravity hydrometers shall be of a precision grade, standardization temperature 60°/60° F., and provided in the following ranges and subdivisions:

Range:	Subdivision
1.0000 to 1.0500	0.0005
1.0500 to 1.1000	0.0005
1.1000 to 1.1500	0.0005
1.1500 to 1.2000	0.0005
1.2000 to 1.2500	0.0005

No instrument shall be in error by more than 0.0005° specific gravity. A certificate of accuracy prepared by the instrument manufacturer for the instrument shall be furnished to the ATF officer.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5204))

§ 13.25 Use of precision specific gravity hydrometers.

The provisions of § 13.23 respecting the care, handling, and use of precision instruments shall be followed with respect to the care, handling, and use of precision grade specific gravity hydrometers. Specific gravity hydrometers shall be read to the nearest subdivision. Because of temperature density relationships and the selection of the standardization temperature of 60°/60° F., the specific gravity readings will be greater at temperatures below 60 degrees Fahrenheit and less at temperatures above 60 degrees Fahrenheit. Hence, correction of the specific gravity readings will be made for temperatures other than 60 degrees Fahrenheit. Such correction may be ascertained by dividing the specific gravity hydrometer reading by the applicable correction factor in Table 7.

Example: The specific gravity hydrometer reading is 1.1525, the thermometer reading is 68 degrees Fahrenheit, and the true proof of the spirits is 115 degrees. The correct specific gravity reading will be ascertained as follows:

(a) From Table 7, the correction factor for 115° proof at 68° F. is 0.996.

(b) 1.1525 divided by 0.996=1.1571, the corrected specific gravity.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5204))

Subpart D—Gauging Procedures

§ 13.31 Determination of proof.

The proof of spirits shall be determined to the nearest tenth degree which shall be the proof used in determining the proof gallons. The proof of spirits shall be determined by the use of a hydrometer and thermometer in accordance with the provisions of § 13.23 except that (a) if such spirits contain solids in excess of 400 milligrams but not in excess of 600 milligrams per 100 milliliters at gauge proof, there shall be added to the proof so determined the obscuration determined as prescribed in § 13.32, or

(b) If such spirits contain solids in excess of 600 milligrams per 100 milliliters at gauge proof, the proof shall be determined on the basis of true proof determined as follows:

(1) By the use of a hydrometer and a thermometer after the spirits have been distilled in a small laboratory still and restored to the original volume and temperature by the addition of pure water to the distillate; or

(2) By a recognized laboratory method which is equal or superior in accuracy to the distillation method.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended, 1362, as amended (26 U.S.C. 5204, 5211))

§ 13.32 Determination of proof obscuration.

Solids or other substances in solution in beverage spirits have an effect on the specific gravity of the spirits and, depanding on the density or specific gravity of the substances, obscure the true proof of the liquid. Experience has shown that 0.1 gram (100 milligrams) of solids per 100 milliliters will obscure the true proof by 0.4 of 1 degree of proof. The amount of solids in the spirits may be determined

(a) By evaporating the water and alcohol from a carefully measured 25 milliliter sample of the spirits, drying the residue at 100 degrees centigrade for 30 minutes and then weighing the residue precisely. The number of grams of solids thus determined, multiplied by 4, will give the amount of solids in 100 milliliters of the spirits, and that figure, multiplied by 4, will give the obscuration. For example, if a blended whisky contains 0.25 gram of solids per 100 milliliters, the obscuration is 4 times 0.25, which is one degree of proof. This value, added to the temperature

corrected hydrometer reading, will give the true proof; or

(b) By determining the apparent proof and temperature of the sample of spirits and then by distilling a carefully measured sample in a small laboratory still, and collecting a quantity of the distillate, 1 or 2 milliliters less than the original sample. The distillate is adjusted to the original temperature and restored to the original volume by addition of distilled water. The proof of the restored distillate is then determined by use of a precision hydrometer and thermometer in accordance with the provisions of § 13.23 to the nearest 0.1 degree of proof. The difference between the proof so determined and the apparent proof of the undistilled sample is the obscuration; or

(c) By determination of the specific gravity of the undistilled sample, distillation and restoration of the samples as provided in paragraph (b) of this section and determination of the specific gravity of the restored distillate by means of a pycnometer. The specific gravities so obtained will be converted to degrees of proof by interpolation of Table 6 to the nearest 0.1 degree of proof. The difference in proof so obtained is the obscuration.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5204))

Determination of Quantity

§ 13.36 General requirements.

The quantity determination of distilled spirits that are withdrawn from bond in bulk upon tax determination or payment shall be by weight. The quantity of other distilled spirits or denatured spirits may be determined by weight or by volume. When the quantity of distilled spirits or denatured distilled spirits is determined by volume, such determination may be by meter as provided in 27 CFR Part 19, or when approved by the Director, another device. The Director may also authorize the determination of quantity of distilled spirits or denatured distilled spirits by a statistical control method.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5204))

Determination of Quantity By Weight

§ 13.41 Bulk spirits.

When spirits (including denatured spirits) are to be gauged by weight in bulk quantities, the weight shall be determined by means of weighing tanks, mounted on accurate scales. Before each use, the scales shall be balanced at zero load; thereupon the spirits shall be run into the weighing tank and proofed as prescribed in § 13.31. However, if the spirits are to be reduced in proof, the spirits shall be so reduced before final determination of the proof. The scales shall then be brought to a balanced condition and the weight of the spirits determined by reading the beam to the nearest graduation mark. From the weight and the proof thus ascertained, the quantity of the spirits in proof gallons shall be determined by reference to Table 4. However, in the case of spirits which contain solids in excess of 400 milligrams per 100 milliliters, the quantity in proof gallons shall be determined by first ascertaining the wine gallons per pound of the spirits and multiplying the wine gallons per pound by the weight, in pounds, of the spirits being gauged and by the true proof (determined as prescribed in § 13.31) and dividing the result by 100. The wine gallons per pound of spirits containing solids in excess of 400 milligrams per 100 milliliters shall be ascertained by:

(a) Use of a precision hydrometer and thermometer, in accordance with the provisions of § 13.23, to determine the apparent proof of the spirits (if specific gravity at the temperature of the spirits is not more than 1.0) and reference to Table 4 for the wine gallons per pound, or

(b) Use of a specific gravity hydrometer, in accordance with the provisions of § 13.25, to determine the specific gravity of the spirits (if the specific gravity at the temperature of the spirits is more than 1.0) and dividing that specific gravity (corrected to 60 degrees Fahrenheit) into the factor 0.120074 (the wine gallons per pound for water at 60 degrees Fahrenheit). When withdrawing a portion of the contents of a weighing tank, the difference between the quantity (ascertained by proofing and weighing) in the tank immediately before the removal of the spirits and the quantity (ascertained by proofing and weighing) in the tank immediately after the removal of the spirits shall be the quantity considered to be withdrawn.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5204))

§ 13.42 Denatured spirits.

The quantity, in gallons, of any lot or package of specially denatured spirits may be determined by weighing it and then dividing its weight by the weight per gallon of the formula concerned, as given in the appropriate tables in Subpart H of 27 CFR Part 212. In the case of completely denatured spirits, the gallonage of any lot or package may be ascertained by determining its weight and apparent proof (hydrometer indication, corrected to 60 degrees Fahrenheit) and then multiplying the weight of the wine gallons per pound factor shown in Table 4 for the (apparent) proof.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5204))

§ 13.43 Packaged spirits.

When the quantity of spirits (including denatured spirits when gauged by weight) in packages, such as barrels, drums, and similar portable containers, is to be determined by gauge of the individual packages, such quantity shall, except as provided in paragraph (b) of this section, be determined by weighing each package on an accurate weighing beam or platform scale having a beam or dial showing weight in pounds and half pounds, where packages having a capacity in excess of 10 wine gallons are to be gauged, or in pounds and ounces, or pounds and hundredths of a pound, where packages designed to hold 10 wine gallons or less are to be gauged. In either case the tare must be determined and subtracted from the gross weight to obtain the net weight. From the proof and weight ascertained, the quantity of the spirits in proof gallons shall be determined by reference to Table 2, 3, or 4. However, if the spirits contain solids in excess of 400 milligrams per 100 milliliters, the proof gallons shall be determined as prescribed for such spirits in § 13.41. Notwithstanding the provisions of this section or of § 13.44, (a) gross weights and tares of packages being filled need not be taken in any case where the gauge of the spirits is not derived from such weights under the gauging procedure being utilized, and (b) meters, other devices, or other methods may be used for determining the quantity of spirits in individual packages, when such meter is used as provided in 27 CFR Part 19, or, when such other device or method has been approved by the Director.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended, 1362, as amended (26 U.S.C. 5204, 5211))

§ 13.44 Entry or filling gauge for packages.

(a) *General.* The spirits in the tank from which the packages are to be filled shall be thoroughly agitated before taking the proof. The proof determined (as prescribed in § 13.31) after such agitation shall be regarded as the proof of the spirits run into all packages filled from the tank. No package which contains or has on its interior or exterior any substance which will prevent the correct ascertainment of tare shall be used. An average tare (rounded to the nearest half pound) may be ascertained and used for metal packages of the same kind and capacity produced by the same manufacturer which are to be filled with

spirits for industrial use, or with denatured spirits, by weighing not less than 20 percent of any lot of such packages. The quantity of spirits in packages which have been filled from tanks may be determined in wine gallons (if desired) and proof gallons, from the proofs and net weights of the packages, by use of Table 2, 3, or 4, whichever is applicable. However, if the spirits contain solids in excess of 400 milligrams per 100 milliliters, the wine gallon and proof gallon contents shall be determined as prescribed for such spirits in § 13.41.

(b) *Weighing packages of more than 10 wine gallons.* The weight of packages having a capacity in excess of 10 wine gallons shall be determined and recorded in pounds and half pounds.

(c) *Weighing containers of 10 wine gallons or less.* The weight for packages and other containers of a capacity of 10 wine gallons or less shall be determined in pounds and ounces, or pounds and hundredths of a pound, and shall be recorded in pounds and hundredths of a pound. The equivalent pounds and hundredths of pounds and the corresponding wine gallons and proof gallons shall be expressed as shown in the following table for the respective weights in pounds and ounces and proofs shown therein or, as applicable, computed in accordance with rules in this section.

Weight of contents

Size [1]	Pounds	Ozs.	Weight [2]	Contents [3]	Proof gallons
190 Proof Spirits					
1	6	13	6.81	1	1.9
2	13	10	13.63	2	3.8
5	34	00	34.00	5	9.5
10	68	00	68.00	10	19.0
192 Proof Spirits					
1	6	13	6.81	1	1.9
2	13	9	13.56	2	3.8
5	33	13	33.81	5	9.6
10	67	10	67.63	10	19.2
200 Proof Spirits					
1	6	10	6.63	1	2.0
2	13	4	13.25	2	4.0
5	33	1	33.06	5	10.0
10	66	2	66.12	10	20.0

[1] Of container, wine gallons.
[2] In pounds and hundredths of a pound.
[3] In wine gallons.

(d) *Packages of other proofs or sizes.* Where packages of proofs or sizes not shown above are to be filled, the following rule may be used for ascertaining the weight of the spirits to be placed in the package: Divide the number of gallons representing the quantity of spirits to be placed in the container by the fractional part of a gallon equivalent to 1 pound, to obtain the weight of the spirits in pounds and fractions of a pound to two decimal places. Reduce the decimal fraction of a pound to ounces by multiplying by 16, calling any fraction of an ounce a whole ounce. The pounds and ounces thus obtained will determine the point to which the spirits must be weighed to produce the results desired. If the weight must be marked on the package in pounds and decimal fractions of a pound, it will be necessary to convert the ounces to hundredths of a pound. The fraction of a gallon equivalent to 1 pound at any given proof shall be ascertained by reference to Table 4. However, if the spirits contain solids in excess of 400 milligrams per 100 milliliters, the fraction of a gallon equivalent to 1 pound shall be determined as prescribed for such spirits in § 13.41.

Example. It is desired to fill a 1-gallon can with precisely 1 wine gallon of 194 proof spirits:

1.00 divided by 0.14866=6.73 pounds.
0.73 multiplied by 16=11.68 ounces, rounded to 12 ounces.
Weight of spirits—6 pounds, 12 ounces.
Weight, if required, to be marked on can—6.75 pounds.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended, 1362, as amended (26 U.S.C. 5204, 5211))

§ 13.45 Withdrawal gauge for packages.

(a) *Wooden packages.* When wooden packages are to be individually gauged for withdrawal, actual tare of a package shall be determined. The actual tare of the packages shall be determined by weighing it after its contents (including rinse water, if any) have been temporarily removed to a separate container or vessel. Where the contents of packages have been temporarily removed for determination of tare, the proof, if any rinse water is added to the spirits, shall be determined after a thorough mixing of the rinse water and the spirits and before return of the spirits to the rinsed packages, and the gross weight shall be determined after the spirits and any added rinse water have been returned to the packages.

(b) *Metal packages.* When metal packages are to be individually gauged for withdrawal, the tare established at the time of filling shall be used unless it appears that there has been a change in tare or the established tare is incorrect, in which case a new tare will be established. From the proofs and the net weights of the packages, the wine gallon (if desired) and the proof gallon contents shall be determined by the use of Table 2. However, if the spirits contain solids in excess of 400 milligrams per 100 milliliters, the wine gallon and proof gallon contents shall be determined as prescribed for such spirits in § 13.41. If either the weight or the proof is beyond the limitations of Table 2, either Table 3 or Table 4 may be used.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5204))

Determination of Quantity By Volume

§ 13.51 Procedures for measurement of bulk spirits.

Where the quantity of spirits (including denatured spirits) in bulk is to be determined by volume as authorized by this chapter, the measurement shall be made in tanks, by meters as provided in 27 CFR Part 19, or by other devices or methods authorized by the Director, or as otherwise provided in this chapter, or such measurement may be made in tank cars or tank trucks if calibration charts for such conveyances are provided and such charts have been accurately prepared, and certified as accurate, by engineers or other persons qualified to calibrate such conveyances. Volumetric measurements in tanks shall be made only in accurately calibrated tanks equipped with suitable measuring devices, whereby the actual contents can be correctly ascertained. If the temperature of spirits (including denatured spirits) is other than the standard of 60 degrees Fahrenheit, gallonage determined by volumetric measurements shall be corrected to the standard temperature by means of Table 7. In the case of denatured spirits, the temperature-correction factor for the proof of the spirits used in denaturation will give sufficiently accurate results, except that the temperature-correction factor used for specially denatured spirits, Formula No. 18, should be that given in Table 7 for 100 proof spirits. When the quantity of spirits, in wine gallons, has been determined by volumetric measurement, the number of proof gallons shall be obtained by multiplying the wine gallons by the proof of the spirits.

Example.

Gauge glass reading inches	88
Wine gallons per inch	48.96
Temperature °F	72
Proof of spirits	86.8
Temperature correction factor (Table 7)	.995

48.96 W.G. × 88=4306.48 wine gallons.
4306.48 W.G. × 0.995=4286.94 wine gallons.
4286.94 W.G. × 0.868=3721.06392=3721.1 proof gallons.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5204))

§ 13.52 Procedure for measurement of cased spirits.

Where the quantity of spirits in a case is to be determined by volume, such determination shall be made by ascertaining the contents of one bottle in the case and multiplying that figure by the number of bottles in the case. For

cases containing bottles filled according to the metric system of measure, the quantity determined shall be converted to wine gallons, as provided in § 19.742 of this chapter. The wine gallons of spirits thus determined for one case may then be multiplied by the number of cases containing spirits at the same proof when determining the quantity of spirits for more than one case. The proof gallons of spirits in cases shall be determined by multiplying the wine gallons by the proof (divided by 100).

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5204))

Subpart E—Prescribed Tables

§ 13.61 Table 1, showing the true percent of proof spirit for any indication of the hydrometer at temperatures between zero and 100 degrees Fahrenheit.

This table shows the true percent of proof of distilled spirits for indications of the hydrometer likely to occur in practice at temperatures between zero and 100 degrees Fahrenheit and shall be used in determining the proof of spirits. The left-hand column contains the reading of the hydrometer and on the same horizontal line, in the body of the table, in the "Temperature" column corresponding to the reading of the thermometer is the corrected reading or "true percent of proof." The table is computed for tenths of a percent.

Example.

Temperature, °F	75
Hydrometer reading	193
True percent of proof	189.5

Where fractional readings are ascertained, the proper interpolations will be made (see § 13.23). If the distilled spirits contain dissolved solids, temperature-correction of the hydrometer reading by the use of this table would result in apparent proof rather than true proof.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5204))

§ 13.62 Table 2, showing wine gallons and proof gallons by weight.

The wine and proof gallon content by weight and proof of packages of distilled spirits usually found in actual practice will be ascertained from this table. The left-hand column contains the weights. The true percent of proof is shown on the heading of each page in a range from 90 degrees to 200 degrees. Under the true percent of proof and on the same horizontal line with the weight will be found the wine gallons (at 60 degrees Fahrenheit) and the proof gallons respectively. Where either the weight or the proof of a quantity of spirits is beyond the limitations of this table, the number of proof gallons may be ascertained by reference to Table 3. This table may also be used to ascertain the wine gallons (at 60 degrees Fahrenheit) and proof gallons of spirituous liquor containing dissolved solids where the weight, apparent proof (hydrometer indication corrected to 60 degrees Fahrenheit), and obscuration factor have been determined.

Example.

334 lbs. of distilled spirits.
Apparent proof—105.0°.
Obscuration—0.8°.
True Proof 105.0° + 0.8° = 105.8° = 106°.
334 lbs. at 105.0° apparent proof = 43.2 wine gallons.
43.2 wine gallons × 1.06 = 45.8 proof gallons.

In addition this table may be used to obtain the wine gallons, at the prevailing temperature, of most liquids within the range of the table, from the weight of the liquid and the uncorrected reading of the hydrometer stem. An application of this would be in determining the capacity of a package.

Example. It is desired to determine, or to check, the rated capacity of a package having a net weight of 395 pounds when completely filled with spirits having an uncorrected hydrometer reading of 113.0°. The full capacity of the package, 51.5 wine gallons, would be found by referring to the table at 395 pounds and 113° proof (hydrometer reading).

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended, 1362, as amended (26 U.S.C. 5204, 5211))

§ 13.63 Table 3, for determining the number of proof gallons from the weight and proof of spirituous liquor.

When the weight or proof of a quantity of distilled spirits is not found in Table 2, the proof gallons may be ascertained from Table 3. The wine gallons (at 60 degrees Fahrenheit) may be ascertained by dividing the proof gallons by the proof.

Example. A tank car of spirits of 190 degrees of proof weighed 60,378 pounds net. We find—

	Proof gallons
60,000 pounds equal to	16,778.4
300 pounds equal to	83.9
70 pounds equal to	19.6
8 pounds equal to	2.2
	16,884.1

That is, the total weight of 60,378 pounds of spirits at 190 proof is equal to 16,884.1 proof gallons. The equivalent gallonage for 70 pounds is found from the column 700 pounds by moving the decimal point one place to the left; that for 8 pounds from the column 800 pounds by moving the decimal point two places to the left.

Example. A package of spirits at 86 proof weighed 321½ pounds net. We find—

	Proof gallons
300 pounds equal to	32.7
20 pounds equal to	2.2
1 pound equal to	.1
½ pound equal to	.1
	35.1

That is, 321½ pounds of spirits at 86 proof is equal to 35.1 proof gallons. The equivalent gallonage for 20 pounds is found from the column 200 pounds by moving the decimal point one place to the left; that for 1 pound from the column 100 pounds by moving the decimal point two places to the left; that for the ½ pound from the column 500 pounds by moving the decimal point three places to the left. Fractional gallons beyond the first decimal ascertained through use of this table will be dropped if less than 0.05 or will be added as 0.1 if 0.05 or more.

The wine gallons (at 60 degrees Fahrenheit) may be determined by dividing the proof gallons by the proof. For example: 35.1 divided by 0.86 equals 40.8 wine gallons.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5204))

§ 13.64 Table 4, showing the fractional part of a gallon per pound at each percent and each tenth percent of proof of spirituous liquor.

This table provides a method for use in ascertaining the wine gallon (at 60 degrees Fahrenheit) and/or proof gallon contents of containers of spirits by multiplying the net weight of the spirits by the fractional part of a gallon per pound shown in the table for spirits of the same proof. Fractional gallons beyond the first decimal will be dropped if less than 0.05 or will be added as 0.1 if 0.05 or more.

Example. It is desired to ascertain the wine gallons and proof gallons of a tank of 190 proof spirits weighing 81,000 pounds.

81,000 × 0.14718 = 11,921.58 = 11,921.6 wine gallons.
81,000 × 0.27964 = 22,650.84 = 22,650.8 proof gallons.

This table may also be used for ascertaining the quantity of water required to reduce to a given proof. To do this, divide the proof gallons of spirits to be reduced by the fractional part of a proof gallon per pound of spirits at the proof to which the spirits are to be reduced, and subtract from the quotient the net weight of the spirits before reduction. The remainder will be the pounds of water needed to reduce the spirits to the desired proof.

Example. It is desired to ascertain the quantity of water needed to reduced 1,000 pounds of 200 proof spirits, 302.58 proof gallons, to 190 proof:

302.58 divided by 0.27964 equals 1,082.03 pounds, weight of spirits after reduction.
1,082.03 minus 1,000 equals 82.03 pounds, weight of water required to reduce to desired proof.

The slight variation between this table and Tables 2, 3, and 5 on some calculations is due to the dropping or adding of fractions beyond the first decimal in those tables. This table may also be used to determine the wine gallons (at 60 degrees Fahrenheit) of distilled spirits containing dissolved solids from the total weight of the liquid and its apparent proof (hydrometer indication, corrected to 60 degrees Fahrenheit). The proof gallons may then be found by multiplying the wine gallons by the true proof.

Example.
5,350 pounds of blended whisky containing added solids

Temperature of °F	75.0°
Hydrometer reading	92.0°
Apparent proof	85.5°
Obscuration	0.5°
True proof	86.0°

5,350.0 lbs. × 0.12676 (W.G. per pound factor for apparent proof of 85.5°) = 678.2 wine gallons.

678.2 W.G. × 0.86 = 583.3 proof gallons.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended 1362, as amended (26 U.S.C. 5204, 5211))

§ 13.65 Table 5, showing the weight per wine gallon (at 60 degrees Fahrenheit) and proof gallon at each percent of proof of spirituous liquor.

This table may be used to ascertain the weight of any given number of wine gallons (at 60 degrees Fahrenheit) or proof gallons of spirits by multiplying the pounds per gallon by the given number of gallons of the spirits. The table should be especially useful where it is desired to weigh a precise quantity of spirits.

Example. It is desired to ascertain the weight of 100 wine gallons of 190 proof spirits:

6.79434 × 100 equals 679.43 pounds, net weight of 100 wine gallons of 190 proof spirits.

Example. It is desired to ascertain the weight of 100 proof gallons of 190 proof spirits.

3.57597 × 100 equals 357.60 pounds, net weight of 100 proof gallons of 190 proof spirits.

The slight variation between this table and Tables 2 and 3 on some calulations is due to dropping or adding of fractions beyond the first decimal on those tables. This table also shows the weight per wine gallon (at the prevailing temperature) corresponding to each uncorrected reading of a proof hydrometer.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5204))

§ 13.66 Table 6, showing respective volumes of alcohol and water and the specific gravity in both air and vacuum of spirituous liquor.

This table provides an alternate method for use in ascertaining the quantity of water needed to reduce the strength of distilled spirits by a definite amount. To do this, divide the alcohol in the given strength by the alcohol in the required strength, multiply the quotient by the water in the required strength, and subtract the water in the given strength from the product. The remainder is the number of gallons of water to be added to 100 gallons of spirits of the given strength to produce a spirit of a required strength.

Example. It is desired to reduce spirits of 191 proof to 188 proof. We find that 191 proof spirits contains 95.5 parts alcohol and 5.59 parts water, and 188 proof spirits contains 94.0 parts alcohol and 7.36 parts water.

95.5 (the strength of 100 wine gallons of spirits at 191 proof) divided by 94.0 (the strenght of 100 wine gallons of spirits at 188 proof) equals 1.01.

7.36 (the water in 188 proof) multiplied by 1.01 equals 7.43.

7.43 less 5.59 (the water in 191 proof spirits) equal 1.84 gallons of water to be added to each 100 wine gallons of 191 proof spirits to be reduced.

This rule is applicable for reducing to any proof; but when it is desired to reduce to 100 proof, it is sufficient to point off two decimals in the given proof, multiply by 53.73, and deduct the water in the given strength. Thus, to reduce 112 proof spirits to 100 proof:

1.12 × 53.73–47.75 equals 12.42 gallons of water to be added to each 100 wine gallons of spirits to be reduced.

This table may also be used to obtain the proof gallonage of spirituous liquor according to weight and percent of proof.

Example.
It is desired to determine the number of gallons in 400 pounds of spirits of 141 percent of proof. Multiply the weight of one gallon of water in air by the specific gravity in air of the spirits—8.32823 by 0.88862—the product (7.40063) divided into 400 gives 54.049 wine gallons, which rounded to the nearest hundredth is 54.05 and multiplied by 1.41 gives 76.2 proof gallons. In rounding off where the decimal is less than five, it will be dropped; if it is five or over a unit will be added.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5204))

§ 13.67 Table 7, for correction of volume of spirituous liquors to 60 degrees Fahrenheit

This table is prescribed for use in correcting spirits to volume at 60 degrees Fahrenheit. To do this, multiply the wine gallons of spirits which it is desired to correct to volume at 60 degrees Fahrenheit by the factor shown in the table at the percent of proof and temperature of the spirits. The product will be the corrected gallonage at 60 degrees Fahrenheit. This table is also prescribed for use in ascertaining the true capacity of containers where the wine gallon contents at 60 degrees Fahrenheit have been determined by weight in accordance with Tables 2, 3, 4, or 5. This is accomplished by dividing the wine gallons at 60 degrees Fahrenheit by the factor shown in the table at the percent of proof and temperature of the spirits. The quotient will be the true capacity of the container.

Example. It is desired to ascertain the volume at 60 degrees Fahrenheit of 1,000 wine gallons of 190 proof spirits at 76 degrees Fahrenheit.

1,000 × 0.991 equals 991 wine gallons, the corrected gallonage at 60 degrees Fahrenheit.

Example. It is desired to ascertain the capacity of a container of 190 proof spirits at 76 degrees Fahrenheit, shown by Table 2 to contain 55.1 wine gallons at 60 degrees Fahrenheit:

55.1 divided by 0.991 equals 55.6 wine gallons, the true capacity of the container when filled with spirits of 60 degrees temperature.

It will be noted that the table is prepared in multiples of 5 percent of proof and 2 degrees temperature. Where the spirits to be corrected are of an odd temperature, one-half of the difference, if any, between the factors for the next higher and lower temperature, should be added to the factor for the next higher temperature.

Example. It is desired to correct spirits of 180 proof at 51 degrees temperature:

1.006 (50°) − 1.005 (52°) = 0.001 divided by 2 = 0.0005

0.0005 + 1.005 = 1.0055 correction factor at 51° F.

Example. It is desired to correct spirits of 180 proof at 53 degrees temperature:

1.005 (52°) − 1.003 (54°) = 0.002 divided by 2 = 0.001

0.001 + 1.003 = 1.004 correction factor at 53° F.

Where the percent of proof is other than a multiple of five, the difference, if any, between the factors for the next higher and lower proofs should be divided by five and multiplied by the degrees of proof beyond the next lower proof, and the fractional product so obtained should be added to the factor for the next lower proof (if the temperature is above 60 degrees Fahrenheit, the fractional product so obtained must be subtracted from the factor for next lower proof), or if it is also necessary to correct the factor because of odd temperature, to the temperature corrected factor for the next lower proof.

Example. It is desired to ascertain the correction factor for spirits of 112 proof at 47 degrees temperature:

1.006 (46°) − 1.005 (48°) = 0.001 divided by 2 = 0.0005

0.0005 + 1.005 = 1.0055 corrected factor at 47° F.

1.007 (115 proof) − 1.006 (110 proof) = 0.001

0.001 divided by 5 = 0.0002 (for each percent of proof) × 2 (for 112 proof) = 0.0004

0.0004 + 1.0055 (corrected factor at 47° F.) = 1.0059 correction factor to be used for 112 proof at 47° F.

Example. It is desired to ascertain the correction factor for spirits of 97 proof at 93 degrees temperature:

0.986 (92°) − 0.985 (94°) = 0.001 divided by 2 = 0.0005

0.0005 + 0.985 = 0.9855 corrected factor at 93° F.

0.986 (95 proof) − 0.985 (100 proof) = 0.001

0.001 divided by 5=0.0002 (for each percent of proof)×2 (for 97 proof)=0.0004
0.9855 (corrected factor at 93° F.)−0.0004=0.9851 correction factor to be used for 97 proof at 93° F.

(Sec. 201, Pub. L. 85-859, 72 Stat. 1358, as amended (26 U.S.C. 5204))

PART 201 [REVISED AND REDESIGNATED]

Section C. Part 201 is revised and renumbered as Part 19 as follows:

Preamble 1. The regulations in this part supersede 27 CFR Part 201 in its entirety.

2. These regulations do not affect any act done or any liability or right accruing, or accrued, or any suit or proceeding had or commenced before the effective date of these regulations.

3. The regulations in this part are effective on January 1, 1980.

PART 19—DISTILLED SPIRITS PLANTS

Subpart A—Scope

Sec.
19.1 General.
19.2 Territorial extent.
19.3 Related regulations.

Subpart B—Definitions

19.11 Meaning of terms.

Subpart C—Taxes

Spirits

19.21 Tax.
19.22 Attachment of tax.
19.23 Lien.
19.24 Persons liable for tax.
19.25 Time for tax determination.

Occupational Taxes

19.26 Liquor dealer's special (occupational) tax.
19.27 Still manufacturer's special tax.

Assessments

19.31 Production not accounted for.
19.32 Assessment of tax on spirits or wines in bond which are lost, destroyed or removed without authorization.

Wine

19.36 Tax.

Claims

19.41 Claims on spirits, articles, or wines lost or destroyed in bond.
19.42 Claims on spirits returned to bonded premises.
19.43 Claims relating to spirits lost after tax determination.
19.44 Execution of claims and supporting documents.
19.45 Claims for credit of tax.
19.46 Adjustments for credited tax.

Subpart D—Administrative and Miscellaneous Provisions

Authorities of the Director

19.61 Forms prescribed.
19.62 Alternate methods or procedures; and emergency variations from requirements.
19.63 Pilot operations.
19.64 Experimental distilled spirits plant.
Sec.
19.65 Application to establish experimental plants.
19.66 Spirits produced in industrial processes.
19.67 Other businesses.
19.68 Recovery and reuse of denatured spirits in manufacturing processes.
19.69 Disaster exemptions.
19.70 Exemptions to meet the requirements of National defense.
19.71 Discontinuance of storage facilities.
19.72 Experimental or research operations by scientific institutions and colleges of learning.

Authorities of the Regional Regulatory Administrator

19.73 Other businesses.
19.75 Assignment of officers and hours of operation.
19.76 Allowance of remission, abatement, credit, or refund of tax.
19.77 Installation of meters, tanks and other apparatus.
19.78 Approval of qualifying documents.

Authorities of ATF Officers

19.80 Right of entry and examination.
19.81 Authority to break up ground or walls.
19.82 Detention of containers.
19.83 Samples for the United States.
19.84 Gauging and measuring equipment.

Entry and Examination of Premises

19.85 Premises to be kept accessible.
19.86 Furnishing facilities and assistance.

Gauging of Spirits or Wines

19.91 General.
19.92 Quantity determination of spirits in bond.

Sealing of Conveyances Used for Transporting Spirits

19.96 Sealing of conveyances.

Conveyance of Spirits or Wines on Plant Premises

19.97 Taxpaid spirits or wines on bonded premises.
19.98 Conveyance of untaxpaid spirits or wines within a distilled spirits plant.
19.99 Spirits in customs custody.

Penalties of Perjury

19.100 Execution under penalties of perjury.

Subpart E—Supervision of Operations

19.111 General.
19.112 Supervision of operations.
19.113 Schedule of operations.
19.114 Breaking government locks or seals.
19.115 Submission of forms and reports.

Subpart F—Location and Use

19.131 Restrictions as to location.
19.132 Continuity of premises.
19.133 Use of distilled spirits plant premises.
19.134 Bonded warehouses not on premises qualified for production of spirits.

Subpart G—Qualification of distilled Spirits Plants

19.151 General requirements for registration.
19.152 Data for application for registration.
Sec.
19.153 Notice of registration.
19.154 Maintenance of registration file.
19.155 Powers of attorney.
19.156 Operating permits.
19.157 Data for application for operating permits.
19.158 Exceptions to operating permit requirements.
19.159 Issuance of operating permits.
19.160 Duration of permits.
19.161 Denial of permit.
19.162 Correction of permits.
19.163 Suspension or revocation.
19.164 Rules of practice in permit proceedings.
19.165 Trade names.
19.166 Major equipment.
19.167 Organizational documents.
19.168 Description of plant.
19.169 Registry of stills.
19.170 Statement of production procedure.
19.171 Plans.

Changes After Original Qualification

19.180 Application for amended registration.
19.181 Automatic termination of permits.
19.182 Change in name of proprietor.
19.183 Change of trade name.
19.184 Changes in stockholders.
19.185 Changes in officers.
19.186 Change in proprietorship.
19.187 Adoption of plans and formulas.
19.188 Continuing partnerships.
19.189 Change in location.
19.190 Changes in premises.
19.191 Change in operations.
19.192 Change in production procedure.
19.193 Changes in construction and use of buildings and equipment.

Operations by Alternating Proprietors

19.201 Procedure for alternating proprietors.

Alternate Operations

19.202 Alternate use of premises and equipment for customs purposes.
19.203 Alternation of distilled spirits plant and bonded wine cellar premises.
19.204 Alternation of distilled spirits plant and taxpaid wine bottling house premises.

Permanent Discountinuance of Business

19.211 Notice of permanent discontinuance.

Subpart H—Bonds and Consents of Surety

19.231 General.
19.232 Additional condition of operations bond.
19.233 Corporate surety.
19.234 Filing of powers of attorney.
19.235 Execution of powers of attorney.
19.236 Deposit of securities in lieu of corporate surety.
19.237 Consents of surety.
19.238 Authority to approve bonds and consents of surety.
19.239 Disapproval of bonds or consents of surety.
19.240 Appeal to Director.
19.241 Operations bond—distilled spirits plant and adjacent bonded wine cellar.
19.242 Area operations bond.
19.243 Withdrawal bond.
19.244 Unit bond.
19.245 Bonds and penal sums of bonds.
19.246 Strengthening bonds.

Sec.

New or Superseding Bonds

19.247 General.
19.248 New or superseding bond.

Termination of Bonds

19.249 Termination of bonds.
19.250 Application of surety for relief from bond.
19.251 Relief of surety from bond.
19.252 Release of pledged securities.

Subpart I—Construction, Equipment and Security

19.271 Construction of buildings.
19.272 Equipment.
19.273 Tanks.
19.274 Pipelines.
19.275 Continuous distilling system.
19.276 Package and case scales.
19.277 Measuring devices and proofing instruments.
19.278 Identification of structures, areas, apparatus, and equipment.
19.279 Government office.
19.280 Signs.
19.281 Security.

Subpart J—Production

19.311 Notice by proprietor.
19.312 Receipt of materials.
19.313 Use of materials in production of spirits.
19.314 Removal of fermenting material.
19.315 Removal or destruction of distilling material.
19.316 Distillation procedure.
19.317 Treatment during production.
19.318 Addition of caramel to rum or commercial brandy and addition of oak chips to spirits.
19.319 Production gauge.
19.320 Identification of spirits.
19.321 Entry.
19.322 Receipts for redistillation.
19.323 Redistillation.
19.324 Losses in production.
19.325 Distillates containing extraneous substances.

Chemical Byproducts

19.326 Spirits content of chemicals produced.
19.327 Disposition of chemicals.
19.328 Wash water.

Inventories

19.329 Inventories.

Subpart K—Storage

19.341 General.
19.342 Receipt and storage of bulk spirits and wines.
19.343 Addition of oak chips to spirits and addition of caramel to brandy and rum.

Filling and Changing Packages

19.344 Filling of packages from tanks.
19.345 Change of packages.

Mingling or Blending of Spirits

19.346 Mingling or blending of spirits for further storage.
19.347 Packages dumped for mingling or blending.
19.348 Determining age of mingled or blended spirits or date of fill for imported spirits.
19.349 Mingled or blended spirits or wines held in tanks.
19.350 Transfer, withdrawal or movement between accounts.

Inventories

19.353 Inventories.

Subpart L—Processing Operations Other Than Denaturation and Manufacture of Articles

19.371 General.

Receipt of Spirits and Wines

19.376 Receipt of spirits and wines for processing.
19.377 Receipt of Puerto Rican and Virgin Islands spirits.
19.378 Tank record of alcoholic flavoring materials.
19.379 Containers bearing evidence of theft or unusual loss.

Use of Alcoholic Ingredients

19.381 Record of use.
19.382 Manufacture of nonbeverage or intermediate products.
19.383 Production of gin or vodka in processing.

Bottling, Packaging and Removal of Products

19.391 Removals from processing.
19.392 Bottling tanks.
19.393 Bottling tank gauge.
19.394 Bottling record.
19.395 Labels to agree with contents of tanks and containers.
19.396 Liquor bottles.
19.397 Filling of bottles.
19.398 Completion of bottling.
19.399 Strip stamps or alternative devices.
19.400 Cases.
19.401 Remnants.
19.402 Filling packages.
19.403 Removals in bulk.
19.404 Rebottling.
19.405 Restamping, reaffixing alternative devices and relabeling.
19.406 Bottled in bond spirits.
19.407 Labels for export spirits.
19.408 Spirits removed for shipment to Puerto Rico.
19.409 Spirits not originally intended for export.

Alcohol

19.410 General.
19.411 Stamps, labels, marks and brands.

Records

19.416 Daily summary record of spirits bottled or packaged.

Inventories

19.421 Inventories of wines and bulk spirits (except packages).
19.422 Inventories of bottled and packaged spirits.

Subpart M—Denaturing Operations and Manufacture of Articles

19.451 General.

Denaturation

19.452 Formulas.
19.453 Testing of denaturants.
19.454 Gauge for denaturation.
19.455 Dissolving of denaturants.
19.456 Adding denaturants.
19.457 Restoration and redenaturation of recovered denatured spirits and recovered articles.
19.458 Mixing of denatured spirits.
19.459 Conversion of specially denatured alcohol.
19.460 Receipt and storage of denatured spirits.
19.461 Filling of packages from tanks.
19.462 Containers for denatured spirits.

Inventories

19.463 Inventories.

Articles

19.471 Manufacture of articles.

Subpart N—Importation

Spirits Imported Into the United States

19.481 Importation of spirits.
19.482 Transfers and withdrawals of imported spirits.
19.483 Markings for containers of imported spirits.
19.484 Exceptions to specifications for package marking requirements.
19.485 Recording gauge.

Deposit, Storage, Transfer and Withdrawal of Puerto Rican and Virgin Islands Spirits

19.486 Transaction forms and records.
19.487 Marks on containers.
19.488 Additional tax on nonbeverage spirits.

Miscellaneous Provisions

19.489 Abatement, remission, credit or refund.

Subpart O—Transfers and Withdrawals

General

19.501 Authority to withdraw.
19.502 Examination of containers.
19.503 Withdrawal of spirits on original gauge.
19.504 Determination of tare.

Transfer Between Bonded Premises

19.505 Authorized transfers.
19.506 Application to receive spirits in bond.
19.507 Termination of application.
19.508 Consignor premises.
19.509 Reconsignment in transit.
19.510 Consignee premises.

Removal of Spirits to Production

19.511 Removal of spirits for redistillation.

Withdrawal on Determination and Payment of Tax

19.512 Determination and payment of tax.
19.513 Bond account.
19.514 Proprietor's statement.
19.515 Gauge for tax determination.
19.517 Imported spirits.
19.518 Daily summary record of tax determinations.
19.519 Methods of taxpayment.
19.520 Employer identification number.
19.521 Application for employer identification number.
19.522 Taxes to be collected by returns.
19.523 Time for filing returns.

Sec.
19.524 Manner of filing returns.
19.525 Removal of spirits on tax determination.

Withdrawal of Spirits Without Payment of Tax

19.531 Authorized withdrawals without payment of tax.
19.532 Withdrawals of spirits for use in wine production.
19.533 Withdrawal of spirits without payment of tax for experimental or research use.

Withdrawal of Spirits Free of Tax

19.536 Authorized withdrawals free of tax.
19.537 Withdrawal of spirits free of tax.
19.538 Permits for withdrawal of spirits by the United States.
19.539 Disposition of excess spirits.
19.540 Removal of denatured spirits and articles.
19.541 Reconsignment in transit.

Withdrawals Authorized by Puerto Rico

19.546 Withdrawals authorized by Puerto Rico.

Subpart P—Losses and Shortages

19.561 Allowable losses.
19.562 Losses of spirits from packages.
19.563 Losses in bond.
19.564 Shortages of bottled distilled spirits.
19.565 Losses after tax determination.
19.566 Losses of wine in bond.

Subpart Q—Containers and Marks and Brands

Containers

19.581 General.
19.582 Containers of 1 gallon (3.785 liters) or less.
19.583 Cases.
19.584 Containers holding from 1 gallon to 10 gallons.
19.585 Encased containers.
19.586 Packages.
19.587 Bulk conveyances.
19.588 Tanks.
19.589 Pipelines.
19.590 Construction of bulk conveyances.
19.591 Restrictions on disposition of bulk spirits.

Marks and Brands

19.592 General.
19.593 Package identification numbers.
19.594 Numbering of packages and cases.
19.595 Specifications for marks and brands.
19.596 Marks on packages of spirits filled on bonded premises.
19.597 Kind of spirits.
19.598 Authorized abbreviations to identify spirits.
19.599 Change of packages.
19.600 Packages of blended brandy or rum.
19.601 Marks on approved containers of specially denatured spirits.
19.602 Marks on containers of completely denatured alcohol.
19.603 Marks on tanks.
19.604 Caution label.
19.605 Additional marks on portable containers.
19.606 Marks on bulk conveyances.
19.607 Marks on cases.
19.608 Cases of bottled alcohol.
19.609 Additional marks for cases.
19.610 Obliteration of marks, brands, stamps, and labels.
19.611 Relabeling and restamping off bonded premises.
19.612 Authorized abbreviations to identify required marks.
19.613 Identification marks on devices other than strip stamps.

Subpart R—Liquor Bottle and Label Requirements

19.631 Scope of Subpart.

Liquor Bottle Requirements

19.632 Bottles authorized.
19.633 Indicia for bottles.
19.634 Distincitive liquor bottles.
19.635 Receipt and storage of liquor bottles.
19.636 Bottles to be used for display purposes.
19.637 Bottles for testing purposes.
19.638 Bottles not constituting approved containers.
19.639 Disposition of stocks of liquor bottles.
19.640 Use and resale of liquor bottles.

Bottle Label Requirements

19.641 Certificate of label approval or exemption.
19.642 Statements required on labels under an exemption from label approval.
19.643 Brand name, class and type, alcohol content, and State of distillation.
19.644 Net contents.
19.645 Name and address of bottler.
19.646 Age of whisky containing no neutral spirits.
19.647 Age of whisky containing neutral spirits.
19.648 Age of brandy.
19.649 Presence of neutral spirits and coloring, flavoring, and blending materials.
19.650 Country of origin.

Subpart S—Stamps

Strip Stamps and Alternative Devices

19.661 General.
19.662 Strip stamp format.
19.663 Alternative devices.
19.664 Procurement of strip stamps.
19.665 Affixing stamps or alternative devices.
19.666 Strip stamp and alternative device accounting.
19.667 Restamping of spirits.

Distilled Spirits Stamps

19.668 General.
19.669 Procurement of distilled spirits stamps.
19.670 Affixing of distilled spirits stamps.
19.671 Restamping packages, conveyances, or other containers.
19.672 Distilled spirits stamp accounting.

Imitation Stamps

19.673 Imitation of prescribed stamps prohibited.

Subpart T—Voluntary Destruction

19.681 General.
19.682 Voluntary destruction procedures.
19.683 Record of destruction.

Subpart U—Return of Spirits to Bonded Premises

19.701 Return of taxpaid spirits to bonded premises.
19.702 Receipt and disposition of returned taxpaid spirits.
19.703 Return of recovered denatured spirits and recovered articles.
19.704 Articles and spirits residues received for redistillation.
19.705 Return of recovered tax-free spirits, and spirits and denatured spirits withdrawn free of tax.
19.706 Return of spirits withdrawn without payment of tax.
19.707 Abandoned spirits.

Subpart V—Spirits Withdrawn for Research, Development, or Testing

19.721 General.
19.722 Taxable withdrawals.
19.723 Labels.
19.724 Withdrawals for testing or laboratory analysis.
19.725 Withdrawals for research, development or testing.

Subpart W—Records and Reports

General

19.741 Records.
19.742 Conversion between metric and U.S. units.
19.743 Maintenance and preservation of records.
19.744 Variations from prescribed forms or records.
19.745 Symbols for proof of distillation.
19.746 Photographic copies of records.

Daily Records

19.751 General.
19.752 Details of daily records.

Production Account

19.756 Daily production records.

Storage Account

19.760 Daily storage records.
19.761 Storage summary records.

Processing Account

19.766 Processing.
19.767 Daily records of bottling operations.
19.768 Production of gin or vodka.
19.769 Records of finished products.
19.770 Records of denaturation operations.
19.771 Records for manufacture of articles.

Other Records

19.776 Records of spirits withdrawn for research, development, testing, or laboratory analysis.
19.777 Daily record of strip stamps and alternative devices.
19.778 Daily records of distilled spirits stamps.
19.779 Record of liquor bottles.
19.780 Daily record of wholesale liquor dealer and taxpaid storeroom operations.

Procedures Which Affect All Acccount Categories

19.781 Inventories.
19.782 Submission of transaction forms, records and reports.

Sec.

19.786 Reports.

Subpart X—Transitional Rules for the All-In-Bond Method of Distilled Spirits Plant Operation

19.901 Scope of subpart.
19.902 Filing of final returns.
19.903 Liability for payment of tax.
19.904 Physical inventory.
19.905 Rectification and wine taxes.
19.906 Election to convert controlled stock and bulk wine.
19.907 Tax on converted products.
19.908 Nondrawback alcoholic flavoring ingredients.
19.909 Taxpayment from Customs bond.
19.910 Disposition of on-hand bulk spirits.
19.911 Spirits in export storage.
19.912 Final operational loss claim.
19.913 Continuation of business under new bond.
19.914 Qualification of distilled spirits plants in existence on December 31, 1979.
19.915 Establishment of finished products records.
19.916 Taxpaid stock on bonded premises.
19.917 Records of taxpaid stock remaining on bonded premises during 1980.
19.918 Filing of tax return, ATF Form 5110.35.
19.919 Return of products containing taxpaid wine.
19.920 Curtailment and extension of distilled spirits plant and bonded wine cellar premises.
19.921 Continuation of alternate methods or procedures.
19.922 Supervision.
19.923 Removal of seals from the distilling system and other equipment.
19.924 Approval of locks.
19.925 Pilot operations.
19.926 New sign.

Authority: Sec. 7805, 68A Stat. 917; 26 U.S.C. 7805, unless otherwise noted.

Subpart A—Scope

§ 19.1 General.

The regulations in this part relate to the location, construction, equipment, arrangement, qualification, and operation (including activities incident thereto) of distilled spirits plants.

§ 19.2 Territorial extent.

This part applies to the several States of the United States and the District of Columbia.

§ 19.3 Related regulations.

Regulations relating to this part are listed below:

27 CFR Part 1—Basic Permit Requirements Under the Federal Alcohol Administration Act.
27 CFR Part 2—Nonindustrial Use of Distilled Spirits and Wine.
27 CFR Part 3—Bulk Sales and Bottling of Distilled Spirits.
27 CFR Part 4—Labeling and Advertising of Wine.
27 CFR Part 5—Labeling and Advertising of Distilled Spirits.
27 CFR Part 13—Gauging Manual.
27 CFR Part 170—Miscellaneous Regulations Relating to Liquor.
27 CFR Part 173—Returns of Substances, Articles, or Containers.
27 CFR Part 194—Liquor Dealers.
27 CFR Part 196—Stills.
27 CFR Part 197—Drawback on Distilled Spirits Used in Manufacturing Nonbeverage Products.
27 CFR Part 200—Rules of Practice in Permit Proceedings.
27 CFR Part 211—Distribution and Use of Denatured Alcohol and Rum.
27 CFR Part 212—Formulas for Denatured Alcohol and Rum.
27 CFR Part 213—Distribution and Use of Tax-Free Alcohol.
27 CFR Part 231—Taxpaid Wine Bottling Houses.
27 CFR Part 240—Wine.
27 CFR Part 250—Liquors and Articles from Puerto Rico and the Virgin Islands.
27 CFR Part 251—Importation of Distilled Spirits, Wines, and Beer.
27 CFR Part 252—Exportation of Liquors.
31 CFR Part 225—Acceptance of Bonds, Notes, or Other Obligations Issued or Guaranteed by the United States as Security in Lieu of Surety or Sureties on Penal Bonds.

Subpart B—Definitions

§ 19.11 Meaning of terms.

When used in this part and in forms prescribed under this part, where not otherwise distinctly expressed or manifestly incompatible with the intent thereof, terms shall have the meaning ascribed in this section. Words in the plural form include the singular, and vice versa, and words indicating the masculine gender include the feminine. The terms "includes" and "including" do not exclude other things not enumerated which are in the same general class.

Alcoholic flavoring materials. The term "alcoholic flavoring materials" means those nonbeverage products on which drawback has been or will be claimed under 26 U.S.C. 5131–5134 or flavors imported free of tax which are unfit for beverage purposes. The term does not include flavorings or flavoring extracts manufactured on the bonded premises of a distilled spirits plant as an intermediate product.

Application for registration. The application required under 26 U.S.C. 5171(c).

Area supervisor. The supervisory officer of the Bureau of Alcohol, Tobacco and Firearms area office.

Article. A product, containing denatured spirits, which was manufactured under 27 CFR Part 211 or this part.

ATF bond. For purposes of this part, ATF bond means the internal revenue bond as prescribed in 26 U.S.C. Chapter 51.

ATF officer. An officer or employee of the Bureau of Alcohol, Tobacco and Firearms (ATF) authorized to perform any function relating to the administration or enforcement of this part.

Basic permit. The document authorizing the person named therein to engage in a designated business or activity under the Federal Alcohol Administration Act.

Bonded premises. The premises of a distilled spirits plant, or part thereof, as described in the application for registration, on which distilled spirits operations defined in 26 U.S.C. 5002 are authorized to be conducted.

Bottler. A proprietor of a distilled spirits plant qualified under this part as a processor who bottles distilled spirits.

Bulk container. Any approved container having a capacity in excess of one wine gallon.

Bulk conveyance. A tank car, tank truck, tank ship, tank barge, or a compartment of any such conveyance, or any other container approved by the Director for the conveyance of comparable quantities of spirits, including denatured spirits, and wines.

Bulk distilled spirits. The term "bulk distilled spirits" means distilled spirits in a container having a capacity in excess of one gallon.

Business day. Any day, other than a Saturday, Sunday, or a legal holiday. (The term legal holiday includes all holidays in the District of Columbia and statewide holidays in the particular State in which the claim, report, or return, as the case may be, is required to be filed, or the act is required to be performed.)

Carrier. Any person, company, corporation, or organization, including a proprietor, owner, consignor, consignee, or bailee, who transports distilled spirits (including denatured spirits) or wine in any manner for himself or others.

CFR. The Code of Federal Regulations.

Completions. The spirits products bottled and cased or otherwise packaged or placed in approved containers for removal from the bonded premises.

Container. A receptacle, vessel, or form of bottle, can, package, tank or pipeline (where specifically included) used or capable of being used to contain, store, transfer, convey, remove, or withdraw spirits (including denatured spirits).

Denaturant or denaturing material. Any material authorized under 27 CFR Part 212 for addition to spirits in the production of denatured spirits.

Denatured spirits. Spirits to which denaturants have been added as provided in 27 CFR Part 212.

Director. The Director, Bureau of Alcohol, Tobacco and Firearms, the Department of the Treasury, Washington, D.C.

Director of the service center. A director of an internal revenue service center.

Distilled spirits operations. Any authorized distilling, warehousing, or processing operations conducted on the bonded premises of a plant qualified under this part.

Distillery. A distilled spirits plant, as described in the application for registration, authorized for the production of spirits.

Distilling material. Any fermented or other alcoholic substance capable of, or intended for use in, the original distillation or other original processing of spirits.

District director. A district director of internal revenue.

Executed under penalties of perjury. Signed with the prescribed declaration under the penalties of perjury as provided on or with respect to the return, claim, form, or other document or, where no form of declaration is prescribed, with the declaration: "I declare under the penalties of perjury that this. * * * (insert type of document, such as, statement, report, claim, certificate), including the documents submitted in support thereof, has been examined by me and, to the best of my knowledge and belief, is true, correct, and complete."

Export or exportation. A severance of goods from the mass of things belonging to the United States with the intention of uniting them to the mass of things belonging to some foreign country and shall include shipments to any possession of the United States. For the purposes of this part, shipments to the Commonwealth of Puerto Rico, to the territories of the Virgin Islands, American Samoa, and Guam, and to the Panama Canal Zone shall also be treated as exportations.

Fermenting material. Any material which is to be subjected to a process of fermentation to produce distilling material.

Fiduciary. A guardian, trustee, executor, administrator, receiver, conservator, or any person acting in any fiduciary capacity for any person.

Gallon or wine gallon. The liquid measure equivalent to the volume of 231 cubic inches.

In bond. When used with respect to spirits (including denatured spirits), articles, or wine refers to spirits, articles, or wine possessed under bond to secure the payment of the taxes imposed by 26 U.S.C. Chapter 51, and on which such taxes have not been determined. The term includes such spirits, articles, or wine on the bonded premises of a distilled spirits plant, such spirits or wines in transit between bonded premises (including, in the case of wine, bonded wine cellar premises). Additionally, the term refers to spirits in transit from customs custody to bonded premises, and spirits withdrawn without payment of tax under 26 U.S.C. 5214, and with respect to which relief from liability has not occurred under the provisions of 26 U.S.C. 5005(e)(2).

Intermediate product. Any product manufactured pursuant to an approved formula under 27 CFR Part 5, not intended for sale as such but for use in the manufacture of a distilled spirits product.

I.R.C. The Internal Revenue Code of 1954, as amended.

Kind. As applied to spirits, except as provided in § 19.597, kind shall mean class and type as prescribed in 27 CFR Part 5. As applied to wines, kind shall mean the classes and types of wines as prescribed in 27 CFR Part 4.

Liquor bottle. A bottle made of glass or earthenware, or of other suitable material approved by the Director, designed or intended for use as a container for distilled spirits for sale for beverage purposes.

Liter. A metric unit of capacity equal to 1,000 cubic centimeters of alcoholic beverage, and equivalent to 33.814 fluid ounces. A liter is divided into 1,000 milliliters. Milliliter or milliliters may be abbreviated as "ml".

Lot identification. The lot identification described in § 19.593.

Mash, wort, wash. Any fermented material capable of, or intended for, use as a distilling material.

Nonindustrial use. As applied to spirits, shall have the meaning ascribed in 27 CFR Part 2.

Operating permit. The document issued pursuant to 26 U.S.C. 5171(d), authorizing the person named therein to engage in the business or operation described therein.

Package. A cask or barrel or similar wooden container, or a drum or similar metal container.

Package identification number. The package identification number described in § 19.593.

Person. An individual, trust, estate, partnership, association, company, or corporation.

Plant or distilled spirits plant. An establishment qualified under this part for distilling, warehousing, processing or any combination thereof.

Plant number. The number assigned to a distilled spirits plant by the regional regulatory administrator.

Processor. Except as otherwise provided under 26 U.S.C. 5002(a)(6), any person qualified under this part who manufactures, mixes, or otherwise processes distilled spirits (including denatured spirits), or manufactures any article.

Proof. The ethyl alcohol content of a liquid at 60 degrees Fahrenheit, stated as twice the percent of ethyl alcohol by volume.

Proof of distillation. The composite proof of the spirits at the time the production gauge is made, or, if the spirits had been reduced in proof prior to the production gauge, the proof of the spirits prior to such reduction, unless the spirits are subsequently redistilled at a higher proof than the proof prior to reduction.

Proof gallon. A gallon of liquid at 60 degrees Fahrenheit which contains 50 percent by volume of ethyl alcohol having a specific gravity of 0.7939 at 60 degrees Fahrenheit referred to water at 60 degrees Fahrenheit as unity, or the alcoholic equivalent thereof.

Proprietor. The person qualified under this part to operate the distilled spirits plant.

Reconditioning. The dumping of distilled spirits products in bond after their original bottling or packaging, for purposes other than destruction, denaturation, redistillation, or rebottling. The term may include the filtration, clarification, stabilization, or reformulation of a product.

Recovered article. An article containing specially denatured spirits salvaged without all of its original ingredients, or an article containing completely denatured alcohol salvaged without all of the denaturants for completely denatured alcohol, under 27 CFR Part 211.

Region. A Bureau of Alcohol, Tobacco and Firearms region.

Regional regulatory administrator. The principal regional official responsible for administering regulations in this part.

Secretary. The Secretary of the Treasury or his delegate.

Spirits or distilled spirits. That substance known as ethyl alcohol, ethanol, or spirits of wine in any form (including all dilutions and mixtures thereof, from whatever source or by whatever process produced), but not denatured spirits unless specifically stated.

Spirits residues. Residues, containing distilled spirits, of a manufacturing process related to the production of an article under 27 CFR Part 211.

Tax-determined or determined. When used with respect to the tax on any distilled spirits to be withdrawn from bond on determination of tax, shall mean that the taxable quantity of spirits has been established.

Taxpaid. When used with respect to distilled spirits shall mean that all applicable taxes imposed by law in respect of such spirits have been determined or paid as provided by law.

This chapter. Title 27, Code of Federal Regulations, Chapter I (27 CFR Chapter I).

Transfer in bond. The removal of spirits (including denatured spirits) and wines from one bonded premises to another bonded premises.

Unfinished spirits. Spirits in the production system prior to production gauge.

U.S.C. The United States Code.

Warehouseman. A proprietor of a distilled spirits plant qualified under this part to store bulk distilled spirits.

Wine spirits. The term "wine spirits" means spirits authorized for use in wine production by 26 U.S.C. 5373.

Subpart C—Taxes

Spirits

§ 19.21 Tax.

A tax is imposed by 26 U.S.C. 5001 on all spirits produced in or imported into the United States at the rate prescribed in such section on each proof gallon and a proportionate tax at a like rate on all fractional parts of a proof gallon. Wines containing more than 24 percent of alcohol by volume are taxed as spirits. All products of distillation, by whatever name known, which contain spirits, on which the tax imposed by law has not been paid, and any alcoholic ingredient added to such products, are considered and taxed as spirits.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1314, as amended (26 U.S.C. 5001))

§ 19.22 Attachment of tax.

Under the provisions of the 26 U.S.C. 5001(b), the tax attaches to spirits as soon as the substance comes into existence as such, whether it be subsequently separated as pure or impure spirits, or be immediately, or at any subsequent time, transferred into any other substance, either in the process of original production, or by any subsequent process.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1314, as amended (26 U.S.C. 5001))

§ 19.23 Lien.

Under 26 U.S.C. 5004, the tax becomes a first lien on the spirits from the time the spirits come into existence as such. The conditions under which the first lien shall be terminated are described in 26 U.S.C. 5004.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1317, as amended (26 U.S.C. 5004))

§ 19.24 Persons liable for tax.

(a) *Distilling.* 26 U.S.C. 5005 provides that the distiller of spirits is liable for the tax and that each proprietor or possessor of, and person in any manner interested in the use of, any still, distilling apparatus, or distillery, shall be jointly and severally liable for the tax on distilled spirits produced. However, a person, not an officer or director of a corporate proprietor, owning or having the right of control of not more than 10 percent of any class of stock of that proprietor, is not liable by reason of the stock ownership or control. Persons transferring spirits in bond so liable for the tax are relieved of liability if (1) the proprietors of transferring and receiving premises are independent of each other and neither has a proprietary interest, directly or indirectly, in the business of the other, and (2) no person so liable for the tax on the spirits transferred retains any interest in the spirits.

(b) *Storage on bonded premises.* 26 U.S.C. 5005(c) provides that each person operating bonded premises shall be liable for the tax on all spirits while the spirits are stored on the premises, and on all spirits which are in transit to the premises from the time of removal from the transferor's bonded premises, pursuant to an approved application. Liability for the tax continues until the spirits are transferred or withdrawn from bonded premises as authorized by law, or until the liability for tax is relieved under the provisions of 26 U.S.C. 5008(a). Claims for relief from liability for spirits lost are provided for in § 19.41. Voluntary destruction of spirits in bond is provided for in Subpart T of this part.

(c) *Withdrawals without payment of tax.* Under 26 U.S.C. 5005(e), any person who withdraws spirits from the bonded premises of a plant without payment of tax, as provided in 26 U.S.C. 5214, shall be liable for the tax on the spirits from the time of withdrawal. The person shall be relieved of any liability at the time the spirits are exported, deposited in a foreign-trade zone, used in production of wine, deposited in a customs bonded warehouse, laden as supplies upon or used in the maintenance or repair of certain vessels or aircraft, or used for certain research, development or testing, as provided by law.

(d) *Withdrawals free of tax.* Persons liable for tax under paragraph (a) of this section, are relieved of the liability on spirits withdrawn from bonded premises free of tax under this part, at the time the spirits are withdrawn.

(e) *Withdrawal from customs custody without payment of tax.* 26 U.S.C. 5232(a) provides that when imported distilled spirits in bulk containers are withdrawn from customs custody and transferred to the bonded premises of a distilled spirits plant without payment of the tax imposed on imported distilled spirits by 26 U.S.C. 5001, the person operating the bonded premises of the distilled spirits plant to which spirits are transferred shall become liable for the tax on the spirits upon their release from customs custody, and the importer shall there upon be relieved of liability for the tax.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1318, as amended (26 U.S.C. 5005); Sec. 3, Pub. L. 90–630, 82 Stat. 1328, as amended (26 U.S.C. 5232); Sec. 3, Pub. L. 91–659, 84 Stat. 1965, as amended (26 U.S.C. 5066))

§ 19.25 Time for tax determination.

The tax on spirits in bond shall be determined when the spirits are withdrawn from bond. The tax on spirits withdrawn from the bonded premises of a distilled spirits plant shall be determined upon completion of the gauge for determination of tax and before withdrawal from bonded premises.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1320, as amended (26 U.S.C. 5006))

Occupational Taxes

§ 19.26 Liquor dealer's special (occupational) tax.

A proprietor shall be subject to or exempt from a liquor dealer's occupational tax as provided in 27 CFR Part 194.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1340, as amended (26 U.S.C. 5111, 5113))

§ 19.27 Still manufacturer's special tax.

Special occupational tax as a still manufacturer and a commodity tax for each still or condenser manufactured is imposed by 26 U.S.C. 5101 on certain persons who manufacture stills or condensers to be used in distilling. Provisions for occupational and commodity taxes imposed on manufacturers of stills or condensers are contained in 27 CFR Part 196.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1339 (26 U.S.C. 5101))

Assessments

§ 19.31 Production not accounted for.

Where the regional regulatory administrator finds that a distiller has not accounted for all spirits produced by him, assessment shall be made for the tax on the difference between the

quantity reported and the quantity found to have been actually produced.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1320, as amended (26 U.S.C. 5006))

§ 19.32 Assessment of tax on spirits or wines in bond which are lost, destroyed or removed without authorization.

When spirits (including denatured spirits) or wines in bond are lost or destroyed (except spirits or wines on which the tax is not collectible by reason of the provisions of 26 U.S.C. 5008 (a) or (d) or 26 U.S.C. 5370, as applicable) and the proprietor or other person liable for the tax on the spirits or wines fails to file a claim for remission as provided in § 19.41(a) or when the claim is denied, the tax shall be assessed. In any case where spirits or wines in bond are removed from bonded premises other than as authorized by law, the tax shall be assessed. In the case of losses under circumstances described in 26 U.S.C. 5006(b) with respect to packages of spirits deposited in storage in bond or spirits filled on bonded premises into packages after entry and deposit, the tax shall be assessed if the tax is not paid upon the demand of the regional regulatory administrator.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1320, as amended, 1323, as amended, 1381, as amended (26 U.S.C. 5006, 5008, 5370))

Wine

§ 19.36 Tax.

(a) *Imposition of tax.* A tax is imposed by 26 U.S.C. 5041 on wines (including imitation, substandard, or artificial wine, and compounds sold as wine) produced in or imported into the United States. Proprietors of distilled spirits plants may become liable for wine taxes under 26 U.S.C. 5362(b)(3) in connection with wine transferred in bond to a distilled spirits plant.

(b) *Liability for tax.* Except as otherwise provided by law, the liability for tax on wine transferred in bond from a bonded wine cellar to a distilled spirits plant, or transferred in bond between distilled spirits plants, shall continue until the wine is used in a distilled spirits product.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1331, as amended, 1380, as amended, (26 U.S.C. 5041, 5362))

Claims

§ 19.41 Claims on spirits, articles, or wines lost or destroyed in bond.

(a) *Claims for remission.* All claims for remission of tax required by this part, relating to the destruction or loss of spirits (including denatured spirits), articles, or wines in bond, shall be filed with the regional regulatory administrator and shall set forth the following:

(1) Identification (including serial numbers if any) and location of the container or containers from which the spirits (including denatured spirits), articles, or wines were lost, or removed for destruction;

(2) Quantity of spirits (including denatured spirits), articles, or wines lost or destroyed from each container, and the total quantity of spirits or wines covered by the claim;

(3) Total amount of tax for which the claim is filed;

(4) Name, number, and address of the plant from which withdrawn without payment of tax or removed for transfer in bond (if claim involves spirits so withdrawn or removed or if claim involves wines transferred in bond) and date and purpose of such withdrawal or removal, except that in the case of imported spirits lost or destroyed while being transferred from customs custody to ATF bond as provided in § 19.481, the name of the customs warehouse, if any, and port of entry will be given instead of the plant name, number, and address;

(5) Date of the loss or destruction (or, if not known, date of discovery), the cause or nature thereof, and all the facts relative thereto;

(6) Name of the carrier, where a loss in transit is involved;

(7) The name and address of the consignee, in the case of spirits withdrawn without payment of tax which are lost before being used for research, development or testing;

(8) If lost by theft, facts establishing that the loss did not occur as the result of any negligence, connivance, collusion or fraud on the part of the proprietor of the plant, owner, consignor, consignee, bailee, or carrier, or the employees or agents of any of them;

(9) In the case of a loss by theft, whether the claimant is indemnified or recompensed for the spirits or wines lost and if so, the amount and nature of indemnity or recompense and the actual value of the spirits or wines, less the tax.

(b) *Claims for abatement, credit or refund.* Claims for abatement of an assessment, or for credit or refund of tax which has been paid or determined, for spirits (including denatured spirits), articles, or wines lost or destroyed in bond shall be filed with the regional regulatory administrator. The claims shall set forth the information required under paragraph (a) of this section and, in addition, shall set forth (1) the date of assessment or payment (or of tax determination, if the tax has not been assessed or paid) of the tax for which abatement, credit or refund is claimed, and (2) the name, plant number, and the address of the plant where the tax was determined, paid, or assessed (or name, address and capacity of any other person who paid or was assessed the tax, if the tax was not paid by or assessed against a proprietor).

(c) *Supporting document.* (1) Claims under paragraphs (a) and (b) of this section shall be supported (whenever possible) by affidavits of persons having personal knowledge of the loss or destruction. For claims on spirits (including denatured spirits), articles, or wines lost while being transferred by carrier, the claim shall be supported by a copy of the bill of lading.

(2) For claims pertaining to losses of spirits withdrawn without payment of tax and lost prior to being used for research, development or testing, the claim shall be supported by a copy of the proprietor's approved application or schedule prescribed in Subpart V of this part.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1323, as amended, 1381 as amended (26 U.S.C. 5008, 5370))

§ 19.42 Claims on spirits returned to bonded premises.

Claims for credit or refund of tax on spirits which have been withdrawn from bonded premises on payment or determination of tax and which are returned under 26 U.S.C. 5215 shall be filed with the regional regulatory administrator and shall set forth the following:

(a) Quantity of spirits so returned;

(b) Amount of tax for which the claim is filed;

(c) Name, address, and plant number of the plant to which the spirits were returned and the date of the return;

(d) The purpose for which returned; and

(e) The serial number of ATF F 5110.17 recording the gauge of spirits returned to bonded premises. If the spirits contain Puerto Rican or Virgin Islands spirits, the claim shall show: (1) The precise quantity (in proof gallons) of the finished product derived from Puerto Rican or Virgin Islands spirits; and (2) The amount of tax and the applicable rate of tax imposed by 26 U.S.C. 7652, determined at the time of withdrawal from bond on the Puerto Rican or Virgin Islands spirits contained in the product. Claims for credit or refund of tax shall be filed by the proprietor of the plant to which the spirits were returned within six months of the date of the return. If the claim is allowed, refund (without interest) will be made or credit (without interest) will be allowed.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1323, as amended (26 U.S.C. 5008); Sec. 807, Pub. L. 96–39, 93 Stat. 285 (26 U.S.C. 5215))

§ 19.43 Claims relating to spirits lost after tax determination.

Claims for abatement, credit, or refund of tax under this part, relating to losses of spirits occurring on bonded premises after tax determination but prior to physical removal from such premises, shall be prepared and filed as provided in, and contain the information called for under § 19.41(b) and be supported by documents as provided under § 19.41(c).

(Sec. 201, Pub. L. 85–859, 72 Stat. 1323, as amended (26 U.S.C. 5008))

§ 19.44 Execution of claims and supporting documents.

All claims filed under this part for abatement or refund shall be filed on Form 843. All claims filed under this part for credit or remission of tax shall be filed on Form 2635. Claims for abatement, remission, credit, or refund shall (a) show the name, address, and capacity of the claimant, (b) be signed by the claimant or his duly authorized agent, and (c) be executed under the penalties of perjury as provided in § 19.100. Forms, supporting statements, and any other documents required by this part to be submitted with a claim shall be attached to the claim and shall be deemed to be a part thereof. The regional regulatory administrator may require the submission of additional evidence in support of any claim filed under this part when deemed necessary for proper action on the claim.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1323, as amended (26 U.S.C. 5008))

§ 19.45 Claims for credit of tax.

Claims for credit of tax, as provided in this part, may be filed after determination of the tax whether or not the tax has been paid. The claimant may not anticipate allowance of a credit or make an adjusting entry in a tax return pending action on the claim.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1323, as amended (26 U.S.C. 5008))

§ 19.46 Adjustments for credited tax.

When notification of allowance of credit is received from the regional regulatory administrator, including notification of credit for tax on spirits exported with benefit of drawback as provided in 27 CFR Part 252, the claimant shall make an adjusting entry and explanatory statement (specifically identifying the notification of allowance of credit) in the next distilled spirits tax return (or returns) to the extent necessary to exhaust the credit.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1323, as amended, 1336, as amended (26 U.S.C. 5008, 5062))

Subpart D—Administrative and Miscellaneous Provisions

Authorities of the Director

§ 19.61 Forms prescribed.

The Director is authorized to prescribe all forms required by this part. All of the information called for in each form shall be furnished, as indicated by the headings on the form and the instructions thereon or issued in respect thereto, and as required by this part.

(Sec. 807, Pub. L. 96–39, 93 Stat. 284 (26 U.S.C. 5207))

§ 19.62 Alternate methods or procedures; and emergency variations from requirements.

(a) *Alternate methods or procedures.* The proprietor, on specific approval by the Director as provided in this paragraph, may use an alternate method or procedure in lieu of a method or procedure specifically prescribed in this part. The Director may approve an alternate method or procedure, subject to stated conditions, when he finds that—

(1) Good cause has been shown for the use of the alternate method or procedure;

(2) The alternate method or procedure is within the purpose of, and consistent with the effect intended by, the specifically prescribed method or procedure, and affords equivalent security to the revenue; and

(3) The alternate method or procedure will not be contrary to any provision of law, and will not result in an increase in cost to the Government or hinder the effective administration of this part.

No alternate method or procedure relating to the giving of any bond or to the assessment, payment, or collection of tax, shall be authorized under this paragraph. Where the proprietor desires to employ an alternate method or procedure, he shall submit a written application to do so to the regional regulatory administrator, for transmittal to the Director. The application shall specifically describe the proposed alternate method or procedure, and shall set forth the reasons therefor. Alternate methods or procedures shall not be employed until the application has been approved by the Director. The proprietor shall, during the period of authorization of an alternate method or procedure, comply with the terms of the approved application. Authorization for any alternate method or procedure may be withdrawn whenever in the judgment of the Director the revenue is jeopardized or the effective administration of this part is hindered by the continuation of such authorization. As used in this paragraph, alternate methods or procedures shall include alternate construction or equipment.

(b) *Emergency variations from requirements.* The Director may approve construction, equipment, and methods of operation other than as specified in this part, where he finds that an emergency exists and the proposed variations from the specified requirements are necessary, and the proposed variations—

(1) Will afford the security and protection to the revenue intended by the prescribed specifications;

(2) Will not hinder the effective administration of this part; and

(3) Will not be contrary to any provisions of law.

Variations from requirements granted under this paragraph are conditioned on compliance with the procedures, conditions, and limitations with respect thereto set forth in the approval of the application. Failure to comply in good faith with such procedures, conditions, and limitations shall automatically terminate the authority for such variations and the proprietor thereupon shall fully comply with the prescribed requirements of regulations from which the variations were authorized. Authority for any variation may be withdrawn whenever in the judgment of the Director the revenue is jeopardized or the effective administration of this part is hindered by the continuation of such variation. Where the proprietor desires to employ such variation, he shall submit a written application to do so to the regional regulatory administrator for transmittal to the Director. The application shall describe the proposed variations and set forth the reasons therefor. Variations shall not be employed until the application has been approved.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1353, as amended, 1395, as amended (26 U.S.C. 5178, 5552))

§ 19.63 Pilot operations.

The Director may waive any regulatory provisions of 26 U.S.C. Chapter 51, and of the regulations in this part, for temporary pilot or experimental operations for the purpose of facilitating the development and testing of improved methods of governmental supervision (necessary for the protection of the revenue) over plants. For this purpose, the Director may, with the approval of the proprietor thereof, designate any plant for such operations. The provision of law and regulations

waived and the period of time during which such waiver shall continue shall be stated in writing by the Director. The provisions of this section shall not be construed as authority to waive the filing of any bond or the payment of any tax provided for in 26 U.S.C. Chapter 51.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1395, as amended (26 U.S.C. 5554))

§ 19.64 Experimental distilled spirits plant.

The Director may authorize the establishment and operation of experimental plants for specific and limited periods of time solely for experimentation in, or development of—

(a) Sources of materials from which spirits may be produced;

(b) Processes by which spirits may be produced or refined; or

(c) Industrial uses of spirits.

The Director may waive any provision of 26 U.S.C. Chapter 51 (other than 26 U.S.C. 5312) and of this part (other than this section and § 19.65) to the extent he deems necessary to effectuate the purposes of 26 U.S.C. 5312(b), except that he may not waive the payment of any tax on spirits removed from such plant.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1375, as amended (26 U.S.C. 5312))

§ 19.65 Application to establish experimental plants.

Any person desiring to establish an experimental plant shall make written application to the Director, through the regional regulatory administrator, and obtain the Director's approval of the proposed establishment. The applicant shall file with such application a bond in such form and penal sum as required by the Director. The application shall state the nature, extent, and purpose of the operations to be conducted and describe the operations and equipment, the location of the plant (including the proximity to other premises or operations subject to the provisions of 26 U.S.C. Chapter 51) and the security measures to be provided. The Director may require the submission of additional information as he deems necessary. The regional regulatory administrator shall not permit operations until he has found that the plant conforms to the specifications set forth in the application, as approved, and the applicant has complied with provisions of 26 U.S.C. Chapter 51, and this part not specifically waived by the Director.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1375, as amended (26 U.S.C. 5312))

§ 19.66 Spirits produced in industrial processes.

Distillers are persons producing spirits in industrial processes (including spirits produced as a byproduct in connection with chemical or other processes). They are required to qualify under the provisions of 26 U.S.C. Chapter 51 and this part. Where nonpotable chemical mixtures containing spirits are produced (a) for transfer to the bonded premises of a distilled spirits plant for completion of distilling, or (b) as a by-product (which would require expensive and complex equipment for the recovery of spirits therefrom) (1) which is destroyed on the premises where produced, or (2) which contains the minimum quantity of spirits practicable with the procedure employed and will not be subjected to further operations to purify or remove the spirits and which the Director finds is as nonpotable as completely denatured alcohol and the recovery of spirits therefrom would be at least as difficult as the recovery of spirits from completely denatured alcohol, the Director may waive any provision of 26 U.S.C. Chapter 51, or this part, with respect to the production of such mixture, including any provision relating to qualification. Where the producer of such nonpotable mixtures desires to secure a waiver of any of such provisions he shall file an application therefor with the Director through the regional regulatory administrator. The application shall be submitted and shall set out the name and address of the producer, the chemical composition and source of the nonpotable mixture, and the approximate percentages of the chemicals and of the spirits in the mixture, the method of operation proposed, and, if applicable, the bonded premises whereat the mixture will be distilled, and such other information as the Director may require. If the Director finds that the waiver of the requirements, or any of them, will not jeopardize the revenue and will not unduly hinder supervision of the operations, he may approve the application under such terms and conditions as he deems advisable, and subject to the furnishing of any bond which he deems necessary.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

§ 19.67 Other businesses.

The director may authorize the carrying on of other businesses (not specifically prohibited by 26 U.S.C. 5601(a)(6)) on premises of plants as he finds will not jeopardize the revenue, hinder effective administration of this part, or be contrary to law. The authorization will designate the premises (i.e., bonded or general) on which such other business is authorized to be conducted.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1353, as amended (26 U.S.C. 5178))

§ 19.68 Recovery and reuse of denatured spirits in manufacturing processes.

The following persons are not, by reasons of the activities listed below, subject to the provisions of this part but they shall comply with the provisions of 27 CFR Part 211 relating to the use and recovery of spirits or denatured spirits:

(a) Manufacturers who use denatured spirits, or articles or substances containing denatured spirits in a process wherein any part or all of the spirits, including denatured spirits, are recovered.

(b) Manufacturers who use denatured spirits in the production of chemicals which do not contain spirits but which are used on the permit premises in the manufacture of other chemicals resulting in spirits as a by-product.

(c) Manufacturers who use chemicals or substances which do not contain spirits or denatured spirits (but which were manufactured with specially denatured spirits) in a process resulting in spirits as a by-product.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1372, as amended (26 U.S.C. 5273))

§ 19.69 Disaster exemptions.

The Director may, whenever he finds that it is necessary or desirable, by reason of disaster, temporarily exempt the proprietor of any plant from any provision of the internal revenue laws and this part relating to spirits, except those requiring the payment of tax on spirits, to the extent he may deem necessary or desirable.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1397, as amended (26 U.S.C. 5562))

§ 19.70 Exemptions to meet the requirements of national defense.

The Director may temporarily exempt proprietors from any provision of the internal revenue laws or this part relating to spirits except those requiring payment of tax thereon whenever in his judgment it is expedient to do so to meet the requirements of the National defense.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1397, as amended (26 U.S.C. 5561))

§ 19.71 Discontinuance of storage facilities.

When the Director finds that any facilities for the storage of spirits on bonded premises are unsafe or unfit for use, or the spirits contained therein are subject to great loss or wastage, he may

require the discontinuance of the use of such facilities and require the spirits contained therein to be transferred to such other storage facilities as he may designate. Such transfer shall be made at such time and under such supervision as the Director may require and the expense of the transfer shall be paid by the owner or the warehouseman of the spirits. Whenever the owner of such spirits or the warehouseman fails to make such transfer within the time prescribed or to pay the just and proper expense of such transfer, as ascertained and determined by the Director, such spirits may be seized and sold in the same manner as goods sold on distraint for taxes, and the proceeds of such sale shall be applied to the payment of the taxes due thereon and the cost and expense of such sale and removal, and the balance shall be paid over to the owner of such spirits.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1369, as amended (26 U.S.C. 5236))

§ 19.72 Experimental or research operations by scientific institutions and colleges of learning.

(a) *General.* The Director may authorize any scientific university, college of learning, or institution of scientific research to produce, receive, blend, treat, test, and store spirits, without payment of tax, for experimental or research use but not for consumption (other than organoleptic tests) or sale, in quantities as may be reasonably necessary for such purposes. The Director may waive any provision of 26 U.S.C. Chapter 51 (other than 26 U.S.C. 5312), or this part (other than this section) to the extent necessary to effectuate the purposes of 26 U.S.C. 5312(a), except he may not waive the payment of any tax on distilled spirits removed from any university, college, or institution.

(b) *Qualification.* Any university, college, or institution desiring to conduct any of the experimental or research operations listed in the preceding paragraphs shall make written application, to the Director, through the regional regulatory administrator, and obtain the Director's approval of the proposed operations. The applicant shall file with the application a bond in a form and penal sum as required by the Director. The application shall state the nature, extent, and purpose of the operations to be conducted and describe the operations and equipment, the location at which operations will be conducted (including identification of the building or buildings, or the portions thereof to be used), and the security measures to be provided. The Director may require any additional information. Operations shall not be commenced until authorized by the Director.

(c) *Records.* Reports concerning the operations need not be submitted unless required by the Director, but records of the quantities of spirits produced, received, and used each day shall be made and retained for inspection by ATF officers.

(d) *Discontinuance of operations.* When operations authorized by the Director are discontinued, all remaining spirits shall be disposed of by destruction. Notice of the proposed destruction shall be given to the regional regulatory administrator at least 5 days in advance of the destruction. When these spirits have been destroyed notice of the discontinuance of operations shall be given to the regional regulatory administrator.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1375, as amended (26 U.S.C. 5312))

Authorities of the Regional Regulatory Administrator

§ 19.73 Other businesses.

Application to conduct at a distilled spirits plant a type of business other than that of a distiller, warehouseman, or processor may be approved by the regional regulatory administrator if the Director has, as provided in § 19.67, authorized the carrying on of a business of the type proposed, unless the regional regulatory administrator finds that there are particular conditions in respect of the applicant's plant that would cause the carrying on of such business to be a danger to the revenue or a hindrance to the effective administration of this part.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1353, as amended (26 U.S.C. 5178))

§ 19.75 Assignment of officers and hours of operation.

The regional regulatory administrator may assign such number of ATF officers to plants as necessary to maintain supervision of operations conducted on such premises. When operations at a plant are to be conducted under the direct supervision of an ATF officer, such operations shall not be conducted on Sunday unless specifically authorized by the regional regulatory administrator in each instance on the showing of an emergency. All operations requiring direct supervision shall be conducted during an 8-hour period between 7 a.m. and 5 p.m. unless, pursuant to the proprietor's application the regional regulatory administrator authorizes the performance and supervision of operations during other hours. The regional regulatory administrator, in administering this provision, shall not restrict such operation or function to a greater extent than did the provisions of internal revenue law and regulations on June 30, 1959.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1395, as amended (26 U.S.C. 5553); Sec. 806, Pub. L. 96–39 93 Stat. 279 (26 U.S.C. 5202))

§ 19.76 Allowance of remission, abatement, credit, or refund of tax.

The regional regulatory administrator is authorized to allow claims for remission, abatement, credit, and refund of tax, filed under the provisions of this part.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1323, as amended (26 U.S.C. 5008))

§ 19.77 Installation of meters, tanks, and other apparatus.

The regional regulatory administrator is authorized to require the proprietor to install meters, tanks, pipes, or any other apparatus which the regional regulatory administrator deems advisable for the purpose of protecting the revenue. Any proprietor refusing or neglecting to install such apparatus when so required shall not be permitted to conduct business.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1395, as amended (26 U.S.C. 5552))

§ 19.78 Approval of qualifying documents.

The regional regulatory administrator is authorized to approve, except as otherwise provided in this part, all qualifying documents required by this part.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1349, as amended, 1394, as amended (26 U.S.C. 5172, 5551); Sec. 805, Pub. L. 96–39, 93 Stat. 275, 276 (26 U.S.C. 5171, 5173))

Authorities of ATF Officers

§ 19.80 Right of entry and examination.

Any ATF officer may at all times, as well by night as by day, enter any distilled spirits plant, or any other premises where distilled spirits operations are carried on, or structure or place used in connection therewith for storage or other purposes; to make examination of the materials, equipment, and facilities thereon; and make such gauges and inventories as he deems necessary. Whenever any ATF officer, having demanded admittance, and having declared his name and office, is not admitted into such premises by the proprietor or other person having charge thereof, he may at all times, use such force as is necessary for him to gain entry to such premises.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1357, as amended (26 U.S.C. 5203))

§ 19.81 Authority to break up ground or walls.

Any ATF officer, and any person acting in his aid, may break up the ground on any part of a distilled spirits plant, or any other premises where distilled spirits operations are carried on, or any ground adjoining or near to such plant or premises, or any wall or partition thereof, or belonging thereto, or other place, to search for any pipe, cock, private conveyance, or utensil; and, upon finding any such pipe or conveyance leading therefrom or thereto, to break up any ground, house, wall, or other place through or into which such pipe or other conveyance leads, and to break or cut away such pipe or other conveyance and turn any cock, or to examine whether such pipe or other conveyance conveys or conceals any spirits, mash, wort, or beer, or other liquor, from the sight or view of the officer, so as to prevent or hinder him from taking a true account thereof.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1357, as amended (26 U.S.C. 5203))

§ 19.82 Detention of containers.

Any ATF officer may detain any container containing, or supposed to contain, spirits when he has reason to believe that the tax imposed by law on such spirits has not been paid or determined as required by law or this part, or that such container is being removed in violation of law or this part, and every such container may be held by him at a safe place until it shall be determined whether the property so detained is liable by law to be proceeded against for forfeiture; but such summary detention shall not continue in any case longer than 72 hours without process of law or intervention of the regional regulatory administrator, unless the person in possession of the container immediately prior to its detention, in consideration of the container being kept on his premises during detention, executes a waiver of the 72-hours limitation on detention of the container.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1375, (26 U.S.C. 5311))

§ 19.83 Samples for the United States.

Any ATF officer is authorized to take samples of spirits (including denatured spirits), articles, wines, or any other materials which may be added to such products for analysis, or testing, other determinations to ascertain whether there is compliance with the provisions of law and regulations.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1323, as amended, 1357, as amended (26 U.S.C. 5201, 5203))

§ 19.84 Gauging and measuring equipment.

All gauging and measuring equipment and means required by 27 CFR Part 13 and this part to be furnished by the proprietor for the purpose of ascertaining the quantity, alcoholic content, specific gravity, and producing capacity of any materials denaturants mash, wort, or beer, or the quantity and alcoholic content of spirits (including denatured spirits) or wines, shall be maintained by the proprietor in accurate and readily usable condition. Any ATF officer may disapprove the use of any equipment or means if he finds it would be insufficiently accurate and the proprietor shall promptly provide acurate equipment or means in lieu of the disapproved facilities.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1320, as amended, 1358, as amended (26 U.S.C. 5006, 5204))

Entry and Examination of Premises

§ 19.85 Premises to be kept accessible.

The proprietor shall furnish the regional regulatory administrator as many keys to such of the proprietor's locks as the regional regulatory administrator may require for ATF officers to gain access to the premises and any structures thereon, and such premises shall always be kept accessible to any ATF officer having such keys.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1357, as amended (26 U.S.C. 5203))

§ 19.86 Furnishing facilities and assistance.

On the demand of any ATF officer or agent, the proprietor shall furnish the necessary facilities and assistance to enable the officer or agent to gauge the spirits in any container or to examine any apparatus, equipment, containers, or materials on the distilled spirits plant premises. The proprietor shall also, on demand of an ATF officer or agent, open all doors, and open for examination all containers on the plant premises. The proprietor shall, on request of an ATF officer, furnish the exact locations (including the number of containers at each location) of all packages and similar portable approved containers within a given lot, and the exact location of each case stored on bonded premises.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1357, as amended (26 U.S.C. 5203))

Gauging of Spirits or Wines

§ 19.91 General.

Gauges shall be made by the proprietor unless the regional regulatory administrator requires that such gauges be made by or made in the presence of an ATF officer. Gauges of spirits (including denatured spirits) or wine shall be made by determining the proof and quantity pursuant to 27 CFR Part 13. However, the gauge for wine that is to be transferred to a bonded wine cellar shall be recorded by kind and percentage of alcohol. When spirits (including denatured spirits) or wines are to be volumetrically measured, the measurement shall be in a tank or bulk conveyance for which a calibration chart is provided, or by a meter or by other methods approved by the Director. Such calibration charts must have been prepared and certified as accurate by persons qualified to calibrate such conveyances.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended; 1396, as amended (26 U.S.C. 5204, 5559); Sec. 806, Pub. L. 96–39, 93 Stat. 279 (26 U.S.C. 5202))

§ 19.92 Quantity determination of spirits in bond.

Where bulk spirits in bond are gauged for determination of tax, or are gauged in packages, the quantity shall be determined by weight and proof pursuant to the provisions of 27 CFR Part 13. In all other instances where spirits are gauged in bond, or are gauged for transfer in bond or for withdrawal from bond free of tax or without payment of tax, unless a determination by weight (or by another method approved by the regional regulatory administrator) is required by this part, the quantity may be determined by volume.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1396, as amended (26 U.S.C. 5559))

Sealing of Conveyances Used for Transporting Spirits

§ 19.96 Sealing of conveyances.

(a) *Construction for sealing.* If a conveyance is required by this part to be sealed, the conveyance shall be constructed in such manner that all openings, including valves (if any) on bulk conveyances, may be closed and secured.

(b) *Approval of certain sealing devices.* (1) All seals, locks, or other devices that are to be used on conveyances in which spirits are: (i) Transferred in bond, (ii) withdrawn free of tax, or (iii) withdrawn without payment of tax, shall be approved by the Director prior to use.

(2) Seals, locks or other devices that are used on conveyances to transport: (i) Taxpaid spirits, or (ii) denatured spirits transferred in bond or withdrawn free of tax, need not be approved.

(c) *Furnishing and affixing seals.* (1) Seals, locks, or other devices for use on conveyances shall be furnished and affixed by the proprietor.

(2) The regional regulatory administrator may, if he deems necessary, require conveyances in which spirits are: (i) Transferred in bond, (ii) withdrawn free of tax, or (iii) withdrawn without payment of tax, to be secured by seals, locks, or other devices approved and furnished by the Bureau and affixed by an ATF officer.

(3) Seals, locks, or other devices shall be affixed: (i) As soon as the conveyances is loaded for shipment, and (ii) in such a manner that access to the contents of the conveyance cannot be gained without showing evidence of tampering.

(d) *Numbers and marks on proprietor's seals.* Seals, locks, or other devices that are furnished by the proprietor for use on conveyances shall be serially numbered.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended (26 U.S.C. 5206))

Conveyance of Spirits or Wines on Plant Premises

§ 19.97 Taxpaid spirits or wines on bonded premises.

Spirits or wines on which the tax has been paid or determined may be conveyed within a plant across bonded premises, but such spirits or wines shall not be stored or allowed to remain on the bonded premises and shall be kept separate and apart from spirits or wines on which the tax has not been paid or determined. However, bulk spirits in the process of prompt removal from bonded premises on payment or determination of the tax shall be allowed to remain on the bonded premises until the close of the business day following the day on which the tax was paid or determined, and spirits returned to bonded premises in accordance with the provisions of 26 U.S.C. 5215 shall be allowed to remain on the bonded premises.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended, 1404, as amended, (26 U.S.C. 5201, 5612))

§ 19.98 Conveyance of untaxpaid spirits or wines within a distilled spirits plant.

Untaxpaid spirits or wines may be conveyed between different portions of the bonded premises of the same distilled spirits plant, across any other premises of such plant; or (by uninterrupted transportation) over any public thoroughfare; or (by uninterrupted transportation) over a private roadway if the owner, or lessee, of the roadway agrees, in writing, to allow ATF officers access to the roadway to perform their necessary duties. The conveyance of spirits as authorized in this section is subject to the following conditions:

(a) The spirits or wines are not stored or allowed to remain on any premises of such plant other than bonded premises,

(b) The spirits or wines are kept completely separate and apart from spirits on which the tax has been paid or determined,

(c) A description of the means and route of the conveyance and of the portions of the distilled spirits plant between which spirits or wines will be conveyed, and a copy of any agreement furnished by the owner, or lessee, of a private roadway have been submitted to and approved by the regional regulatory administrator, and

(d) Consent of surety on the operations or unit bond has been furnished by the proprietor, on Form 1533, extending the terms of the bond to cover conveyance of the spirits or wines.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended, 1398, as amended, (26 U.S.C. 5201, 5601))

§ 19.99 Spirits in customs custody.

Spirits in customs custody may be conveyed, when necessary, across distilled spirits plant premises if (a) the spirits are not stored or allowed to remain on the premises of the distilled spirits plant, (b) the spirits are kept separate and apart from other spirits on the premises and are moved expeditiously, (c) a description of the means and route of conveyance of the spirits across the plant premises has been submitted to and approved by the regional regulatory administrator, and (d) consent of surety on the operations or unit bond has been furnished by the proprietor, on Form 1533, extending the terms of the bond to cover the conveyance of the spirits.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended, (26 U.S.C. 5201))

Penalties of Perjury

§ 19.100 Execution under penalties of perjury.

When a return, form, or other document called for under this part is required by this part or in the instructions on or with the return, form, or other document to be executed under penalties of perjury, it shall be so executed, as defined in Subpart B of this part, and shall be signed by the proprietor, or other duly authorized person.

(Act of August 16, 1954, Pub. L. 591—Chapter 736, 68A Stat. 749 (26 U.S.C. 6065))

Subpart E—Supervision of Operations

§ 19.111 General.

The regional regulatory administrator may require supervision of a distilled spirits plant by ATF officers to the extent necessary to protect the revenue and to ensure compliance with provisions of 26 U.S.C. Chapter 51.

(Sec. 806, Pub. L. 96–39, 93 Stat. 279, (26 U.S.C. 5202))

§ 19.112 Supervision of operations.

(a) *Types of supervision.* (1) Supervision of distilled spirits plant operations by an ATF officer may include, but is not limited to—

(i) General supervision, when an ATF officer may be on the plant premises; or

(ii) Direct supervision, when an ATF officer is on the plant premises; or

(iii) Immediate supervision, when an operation is required to be conducted in the immediate presence of an ATF officer.

(2) The regional regulatory administrator may require a proprietor to delay any operation so that it may be conducted under the direct or immediate supervision of an ATF officer.

(b) *Gauging.* The regional regulatory administrator may require any gauge made pursuant to this part to be made or supervised by an ATF officer.

(c) *Sealing of conveyances.* The regional regulatory administrator may require conveyances in which spirits are transferred in bond or removed (except on tax determination) to be secured with Government locks, seals, or other devices affixed by ATF officers.

(d) *Locking and sealing.* When a proprietor is required by the provisions of this part to affix locks and/or seals to buildings, rooms, tanks, or other items of equipment, the regional regulatory administrator may require the affixing of Government locks and/or seals in addition to, or in lieu of the proprietor's locks and/or seals.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

§ 19.113 Schedule of operations.

When the regional regulatory administrator requires supervision of operations at a distilled spirits plant by ATF officers, the proprietor shall furnish the ATF officer or the area supervisor with a written schedule of operations at least one business day in advance of the operations to be conducted. The schedule of operations shall list all operations related to production, storage

or processing which are required to be supervised by ATF officers. The schedule shall also indicate specific hours of plant operation.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201); Sec. 806, Pub. L. 96–39, 73 Stat. 279 (26 U.S.C. 5202))

§ 19.114 Breaking Government locks or seals.

Except as provided in § 19.923, government locks or seals shall not be removed from a distilling system or other equipment without the authorization of an ATF officer or the regional regulatory administrator, except where persons or property is in imminent danger from a disaster or other emergency. When a disaster or other emergency occurs, and it is impractical to first obtain authorization from an ATF officer, Government seals or locks may be removed, by the proprietor, or by police or firefighters. When such action is taken, the proprietor shall see that security measures are taken to prevent illegal removal of spirits and, as soon as practical, shall notify the area supervisor of the action taken and then submit within 5 days a written report, executed under the penalties of perjury, describing the emergency and the action.

(Sec. 806, Pub. L. 96–39, 93 Stat. 279, (26 U.S.C. 5202))

§ 19.115 Submission of forms and reports.

The regional regulatory administrator may require the proprietor to submit copies of prescribed transaction forms, records, and reports to an ATF officer.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended, 1396, as amended (26 U.S.C. 5201, 5555))

Subpart F—Location and Use

§ 19.131 Restrictions as to location.

Distilled spirits plants shall not be located in any dwelling house, or in any shed, yard, or enclosure connected with any dwelling house, or on board any vessel or boat, or on premises where beer or wine is produced, or liquors of any description are retailed, or (except as provided in § 19.133) on premises where any other business is conducted.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1353, as amended (26 U.S.C. 5178))

§ 19.132 Continuity of premises.

The continuity of the distilled spirits plant shall be unbroken except for separations by public waterways, thoroughfares, or carrier rights-of-way. However, where there are other separations of the plant premises and all parts of the plant premises are in the same general location, the regional regulatory administrator may approve the registration of the distilled spirits plant if he finds no jeopardy to the revenue.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1353, as amended (26 U.S.C. 5178))

§ 19.133 Use of distilled spirits plant premises.

(a) *General.* No business or operation shall be conducted on the premises of a distilled spirits plant other than those authorized to be carried on or conducted by the notice of registration.

(b) *Bonded premises.* Bonded premises shall be used exclusively for the purpose of production, warehousing and processing operations, except that the use of bonded premises for other businesses may be authorized as provided in Subpart D. Spirits in packages, cases, or other portable containers on bonded premises shall be stored in a room or building.

(c) *General premises.* General premises are any portion of the distilled spirits plant described in the notice of registration other than bonded premises. General premises may not be used for any of the operations required to be conducted on bonded premises. Business offices and service facilities may be included as a part of general premises. General premises may be utilized for the conduct of other business as may be authorized under the provisions of Subpart D.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1353 as amended (26 U.S.C. 5178))

§ 19.134 Bonded warehouses not on premises qualified for production of spirits.

A bonded warehouse, other than one established on the bonded premises of a distilled spirits plant qualified for production of spirits, or contiguous to a distillery operated by the warehouseman, may be established if the need therefor is clearly shown and the prospective needs of the warehouseman will be for the bonded storage of not less than 250,000 wine gallons of bulk distilled spirits. However, where commercial bonded warehouses are not available in an area and it is impractical to have a warehouse of 250,000 wine gallon capacity, the regional regulatory administrator may approve the establishment of a warehouse without regard to the minimum storage requirements. The application for registration to establish a warehouse shall be accompanied by a separate written application setting forth the necessity for the establishment of the warehouse, the approximate quantity of bulk distilled spirits that will be received, stored, and withdrawn annually, the probable number of depositors of spirits, and the approximate number of persons to be served from the warehouse, together with any other data or documents indicating the prospective volume of business or need for establishment. The regional regulatory administrator may approve the application for registration if the proposed location of the warehouse will not be a jeopardy to the revenue and there is satisfactory evidence of the need for establishing a warehouse. The regional regulatory administrator may also limit the type of operation to be conducted at a bonded warehouse established with less than the minimum storage requirements. The proprietor of a warehouse established for a limited type of operation shall not, in any manner, expand or change his operation to include any other type of operations until pursuant to written application to make such change, he has obtained the approval of the regional regulatory administrator.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1353, as amended (26 U.S.C. 5178); Sec. 805a, Pub. L. 96–39, 93 Stat. 275 (26 U.S.C. 5171))

Subpart G—Qualification of Distilled Spirits Plants

§ 19.151 General requirements for registration.

(a) *Operations.* Except as otherwise provided by law, operations as a distiller, warehouseman, or processor may be conducted only on the bonded premises of a distilled spirits plant by a person qualified to carry out such operations under this subpart.

(b) *Establishment.* A distilled spirits plant may be established only by a person who intends to conduct at such plant operations as a distiller, as a warehouseman, or as both.

(c) *Registration.* Each person shall, before commencing operations at a distilled spirits plant, make application for and receive notice of registration of his plant with respect to such operations as provided in this part. Application for registration shall be made on Form 5110.41 to the regional regulatory administrator. Each application shall be executed under penalties of perjury, and all written statements, affidavits, and other documents submitted in support of the application or incorporated by reference shall be deemed to be a part thereof. The regional regulatory administrator may, in any instance where the outstanding notice of registration is inadequate or incorrect in any respect, require by registered or certified mail the filing of an application on Form 5110.41 to amend the notice of

registration, specifying the respects in which amendment is required. Within 60 days after the receipt of such notice, the proprietor shall file such application.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1349, as amended (26 U.S.C. 5172); Sec. 805(a), Pub. L. 96–39, 93 Stat. 275 (26 U.S.C. 5171))

§ 19.152 Data for application for registration.

Application on Form 5110.41 shall be prepared in accordance with the instructions on the form, and shall include the following information:

(a) Serial number and statement of purpose for which filed.

(b) Name and principal business address of the applicant, and the location of the distilled spirits plant if different from the business address.

(c) Statement of the type of business organization and of the persons interested in the business, supported by the items of information listed in § 19.167.

(d) Statement of the operations to be conducted.

(e) In respect of the plant to which the Form 5110.41 relates, a list of applicant's operating and basic permits, and of the operations, withdrawal, or unit bonds (including those filed with the application) with the name of the surety or sureties for each bond.

(f) List of the offices, the incumbents of which are authorized by the articles of incorporation or the board of directors to act on behalf of the proprietor or to sign the proprietor's name.

(g) Plans (see § 19.171).

(h) Description of the plant (see § 19.168).

(i) List of major equipment (see § 19.166).

(j) Statement of maximum proof gallons that will be produced in the distillery during a period of 15 days, stored on bonded premises, and in transit to the bonded premises. (Not required if the operations or unit bond is in the maximum sum.)

(k) As applicable, the following:

(1) With respect to the operations of a distiller:

(i) Statement of daily producing capacity in proof gallons.

(ii) Statement of production procedure (see § 19.170).

(2) With respect to the operations of a warehouseman:

(i) Description of the system of storage.

(ii) Statement of bulk storage capacity in wine gallons.

(3) With respect to the operations of a processor:

(i) Statement whether bottling operations will be conducted.

(ii) Statement whether denaturing operations will be conducted.

(iii) Statement whether articles will be manufactured.

(iv) Statement whether gin and/or vodka will be produced by other than original and continuous distillation.

(v) Description of the system of storage of spirits bottled and cased or otherwise packaged or placed in approved containers for removal from bonded premises.

(4) If any other business is to be conducted on the distilled spirits plant premises, as provided by Subpart D of this part, a description of the business, a list of the buildings and/or equipment to be used, and a statement as to the relationship, if any, of the business to distilled spirits operations at the plant.

If any of the information required by paragraph (c) or paragraph (g) of this section is on file with the regional regulatory administrator, that information, if accurate and complete, may by incorporation by reference, be made part of the application. The applicant shall, when required by the regional regulatory administrator, furnish as a part of the application for registration, additional information as may be necessary to determine whether the application for registration should be approved.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1349, as amended (26 U.S.C. 5172); Sec. 805(a), Pub. L. 96–39, 93 Stat. 275 (26 U.S.C. 5171))

§ 19.153 Notice of registration.

The application for registration, when approved, shall constitute the notice of registration of the distilled spirits plant. A distilled spirits plant shall not be registered or reregistered under this subpart until the applicant has complied with all requirements of law and regulations relating to the qualification of the business or operations in which the applicant intends to engage. A plant shall not be operated unless the proprietor has a valid notice of registration covering the businesses and operations to be conducted at such plant. In any instance where a bond is required to be given or a permit is required to be obtained with respect to a business or operation before notice of registration of the plant may be received with respect thereto, the notice of registration shall not be valid with respect to such business or operation in the event that such bond or permit is no longer in effect. An application for reregistration shall be filed and notice of registration again obtained before thereafter engaging in such business or operation at such plant. Reregistration is not required when a new bond or a strengthening bond is filed pursuant to § 19.246 or 19.247.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1349, as amended (26 U.S.C. 5172); Sec. 805a, Pub. L. 96–39, 93 Stat. 275 (26 U.S.C. 5171))

§ 19.154 Maintenance of registration file.

The proprietor shall maintain the registration file in looseleaf form in complete and current condition, readily available at the plant for inspection by ATF officers.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1349, as amended (26 U.S.C. 5172))

§ 19.155 Powers of attorney.

The proprietor shall execute and file with the regional regulatory administrator a Form 1534, in accordance with the instructions on the form, for each person authorized to sign or to act on behalf of the proprietor. (Not required for persons whose authority is furnished in the application for registration.)

(Sec. 201, Pub. L. 85–859, 72 Stat. 1349, as amended (26 U.S.C. 5172))

§ 19.156 Operating permits.

Except as provided in § 19.158, each person required to file an application for registration under § 19.151 shall make application for and obtain an operating permit before commencing any of the following operations:

(a) Distilling for industrial use.

(b) Warehousing of spirits for industrial use.

(c) Denaturing spirits.

(d) Warehousing of spirits (without bottling) for nonindustrial use.

(e) Bottling or packaging of spirits for industrial use.

(f) Manufacturing articles.

(g) Any other distilling, warehousing, or processing operation not required to be covered by a basic permit under the Federal Alcohol Administration Act (49 Stat. 978, 27 U.S.C. 203, 204). Application for such operating permit shall be made on Form 5110.25 to the regional regulatory administrator.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1370, as amended (26 U.S.C. 5271); Sec. 805(a), Pub. L. 96–39, 93 Stat. 275 (26 U.S.C. 5171))

§ 19.157 Data for application for operating permits.

Each application on Form 5110.25 shall be executed under the penalties of perjury, and all written statements, affidavits, and other documents submitted in support of the application shall be deemed to be a part thereof. Applications on Form 5110.25 shall be prepared in accordance with the instructions on the form, and shall include the following information:

(a) Name and principal business address of the applicant.

(b) Plant address, if different from the business address.

(c) Description of the operation to be conducted for which an operating permit must be obtained.

(d) Statement of type of business organization and of the persons interested in the business, supported by the items of information listed in § 19.167.

(e) Trade names (see § 19.165).

(f) On specific request of the regional regulatory administrator, furnish a statement as to whether the applicant or any of the persons whose names and addresses are required to be furnished under the provisions of § 19.167(a)(4) and (c) has ever—(1) been convicted of a felony or misdemeanor- under Federal or State law, (2) been arrested or charged with any violation of State or Federal law (convictions or arrests or charges for traffic violations need not be reported as to subparagraphs (1) and (2) of this paragraph, if these violations are not felonies), or (3) applied for, held, or been connected with a permit, issued under Federal law to manufacture, distribute, sell, or use spirits or products containing spirits, whether or not for beverage use, or held any financial interest in any business covered by any such permit, and, if so, give the number and classification of the permit, the period of operation, and state in detail whether the permit was ever suspended, revoked, annulled, or otherwise terminated.

Where any of the information required by paragraph (d) of this section is on file with the regional regulatory administrator, the applicant may, by incorporation or by reference, state that the information is made a part of the application for an operating permit. The applicant shall, when required by the regional regulatory administrator, furnish as a part of his application for an operating permit additional information as may be necessary for the regional regulatory administrator to determine whether the applicant is entitled to the permit.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1370, as amended (26 U.S.C. 5271); Sec. 805(a), Pub. L. 96–39, 93 Stat. 275 (26 U.S.C. 5171))

§ 19.158 Exceptions to operating permit requirements.

The provisions of § 19.156 shall not apply to any agency of a State or political subdivision thereof, or to any officer or employee of any such agency acting for the agency.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1370, as amended (26 U.S.C. 5271); Sec. 805(a), Pub. L. 96–39, 93 Stat. 275 (26 U.S.C. 5171))

§ 19.159 Issuance of operating permits.

Only one operating permit will be issued for a plant. The operating permit shall designate the operations permitted. All of the provisions of this part relating to the performance of the operations covered by the permit shall be included in the provisions and conditions of the permit. Operating permits shall be kept posted available for inspection at the distilled spirits plant.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1370, as amended (26 U.S.C. 5271); Sec. 805(a), Pub. L. 96–39, 93 Stat. 275 (26 U.S.C. 5171))

§ 19.160 Duration of permits.

Operating permits are continuing, unless automatically terminated by the terms thereof, suspended or revoked as provided in § 19.163, or voluntarily surrendered. The provisions of § 19.181 shall be a part of the terms and conditions of all operating permits issued under this part.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1370, as amended (26 U.S.C. 5271))

§ 19.161 Denial of permit.

If, on examination of an application for an operating permit (or on the basis of inquiry or investigation), the regional regulatory administrator has reason to believe that—

(a) The applicant (including, in the case of a corporation, any officer, director, or prinicipal stockholder, and, in the case of a partnership, a partner) is, by reason of his business experience, financial standing, or trade connections, not likely to maintain operations in compliance with 26 U.S.C. Chapter 51, or regulations issued thereunder; or

(b) The applicant has failed to disclose any material information required, or has made any false statement, as to any material fact, in connection with the application; or

(c) The premises on which the applicant proposes to conduct the operations are not adequate to protect the revenue; the regional regulatory administrator may institute proceedings for the denial of the application in accordance with the procedures set forth in 27 CFR Part 200.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1370, as amended (26 U.S.C. 5271))

§ 19.162 Correction of permits.

Where an error in an operating permit is discovered, the proprietor shall, on demand of the regional regulatory administrator, immediately return the permit for correcton.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1370, as amended (26 U.S.C. 5271))

§ 19.163 Suspension or revocation.

Whenever the regional regulatory administrator has reason to believe that any person holding an operating permit—

(a) Has not in good faith complied with the provisions of 26 U.S.C. Chapter 51, or regulations issued thereunder; or

(b) Has violated conditions of the permit; or

(c) Has made any false statement as to any material fact in the application therefor; or

(d) Has failed to disclose any material information required to be furnished; or

(e) Has violated or conspired to violate any law of the United States relating to intoxicating liquor or has been convicted of any offense under Title 26, U.S.C. punishable as a felony or of any conspiracy to commit such offense; or

(f) Has not engaged in any of the operations authorized by the permit for a period of more than 2 years;

the regional regulatory administrator may institute proceedings for the revocation or suspension of the permit in accordance with the procedures set forth in 27 CFR Part 200.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1370, as amended (26 U.S.C. 5271))

§ 19.164 Rules of practice in permit proceedings.

The regulations in 27 CFR Part 200 are made applicable to the procedure and practice in connection with the disapproval of any application for an operating permit required by this subpart, and in connection with the suspension and revocation of such permit.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1370, as amended (26 U.S.C. 5271))

§ 19.165 Trade names.

Where a trade name is to be used in connection with the operations of a plant for which an operating permit is required, the proprietor shall list that trade name on Form 5110.25 (showing the operations in which the trade name will be used), and the offices where the name is registered, supported by copies of any certificate or other document filed or issued in respect to the trade name. Where any distilling, warehousing, or processing operation is required to be covered by a basic permit under the Federal Alcohol Administration Act (49 Stat. 978; 27 U.S.C. 203, 204), regulations issued under such Act govern the approval and use of trade names for those operations. Operations shall not be conducted under a trade name until the proprietor is in possession of an operating or basic permit covering the use of such name.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1370, as amended (26 U.S.C. 5271))

§ 19.166 Major equipment.

The following items of major equipment, if on the plant premises, shall be described in the application for registration:

(a) Tanks (serial number and capacity) used in the production, storage, and processing of distilled spirits, wine, denatured spirits and articles;

(b) Bottling lines (list separately by serial number or other designation); and

(c) Stills (serial number, kind, capacity and intended use). The capacity shall be stated as the estimated maximum proof gallons of spirits capable of being produced every 24 hours, or (for column stills) may be represented by a statement of the diameter of the base and number of plates.

A statement of certification of accurate calibration shall be included in the description of tanks that are to be used for gauging distilled spirits or wine for any purpose.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1349, as amended, 1352, as amended (26 U.S.C. 5172, 5179))

§ 19.167 Organizational documents.

The supporting information required by paragraph (c) of § 19.152, and paragraph (d) of § 19.157, includes, as applicable, copies of—

(a) *Corporate documents.* (1) Articles of incorporation and any amendments thereto.

(2) Corporate charter or a certificate of corporate existence or incorporation.

(3) Certificate authorizing the corporation to operate in the State where the plant is located (if other than that in which incorporated).

(4) List of directors and officers, showing their names and addresses.

(5) Bylaws.

(6) Certified extracts or digests of minutes of meetings of board of directors, authorizing certain individuals to sign for the corporation.

(7) Statement showing the number of shares of each class of stock or other evidence of ownership, authorized and outstanding, and the voting rights of the respective owners or holders.

(b) *Articles of partnership.* True copy of the articles of partnership or association, if any, or certificate of partnership or association where required to be filed by any State, county, or municipality.

(c) *Statement of interest.* (1) Names and addresses of the 10 persons having the largest ownership or other interest in each of the classes of stock in the corporation, or other legal entity, and the nature and amount of the stockholding or other interest of each, whether the interest appears in the name of the interested party or in the name of another for him. If a corporation is wholly owned or controlled by another corporation, those persons of the parent corporation who meet the above standards are considered to be the persons interested in the business of the subsidiary, and the names thereof need be furnished only upon request of the regional regulatory administrator.

(2) In the case of an individual owner or partnership, the name and address of each person interested in the plant, whether the interest appears in the name of the interested party or in the name of another for that person.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1349, as amended, 1370, as amended (26 U.S.C. 5172, 5271))

§ 19.168 Description of plant.

The application for registration shall include a description of each tract of land comprising the distilled spirits plant. The description shall be by courses and distances, in feet and inches (or hundredths of feet), with the particularity required in conveyances of real estate. Each building and outside tank shall be described (location, size, construction, arrangement, and means of protection and security), referring to each by its designated number or letter. If a plant consists of a room or floor of a building, a description of the building in which the room or floor is situated and its location shall be given.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1349, as amended (26 U.S.C 5172))

§ 19.169 Registry of stills.

The provisions of 27 CFR Part 196 are applicable to stills located on plant premises. The listing of stills in the application for registration, and the approval of the application for registration, shall constitute registration of stills as required by 27 CFR 196.45.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1349, as amended, 1355, as amended (26 U.S.C 5172, 5179))

§ 19.170 Statement of production procedure.

The statement of production procedure in the application for registration shall set forth a step-by-step description of the procedure employed to produce spirits, commencing with the treating, mashing, or fermenting of the raw materials or substances and continuing through each step of the distilling, redistilling, purifying and refining procedure to the production gauge. The kind and approximate quantity of each material or substance used in producing, purifying, or refining each type of spirits shall be shown.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1349, as amended (26 U.S.C 5172))

§ 19.171 Plans.

(a) *General.* Each person filing an application for registration shall submit, in duplicate, a plan showing the boundaries of the distilled spirits plant. If the distilled spirits plant has any buildings of more than one floor and the floors differ in the descriptions required by (d) of this section, an additional plan shall be prepared for each floor.

(b) *Preparation.* Each plan shall be drawn to scale on paper having outside measurements of not less than 8½×11 inches and shall show the cardinal points of the compass. Each plan sheet shall have a distinctive title and be numbered in consecutive order with the first plan sheet #1. Any revised plan sheet shall have the same number as the sheet superseded, but given a new date.

(c) *Certificate of accuracy.* The plans shall bear a certificate of accuracy on each sheet, signed by the proprietor, substantially as follows:

(Name of Proprietor)

(Distilled spirits plant No.)

(Address)

Accuracy certified by:

(Name and capacity—for the proprietor)

Sheet No. ——, Date————

(d) *Plan details.* The plan shall show the boundaries of the bonded premises and any other premises to be included as a part of the distilled spirits plant and shall agree with the boundary descriptions given in the application for registration. The plan shall also show:

(1) Buildings and other enclosed areas, including the means of ingress and egress, on the distilled spirits plant premises used for the production, storage and processing of spirits (including denatured spirits), articles or wines;

(2) All driveways, public thoroughfares, and railroad rights-of-way on or leading to the distilled spirits plant premises;

(3) The relative location of any contiguous premises on which spirits, wine or beer are manufactured, stored or sold, and any pipelines or other connections between a contiguous premises and the distilled spirits plant (public utility pipelines and similar connections excepted);

(4) The entire building and the land on which located if the distilled spirits plant is less than an entire building; and

(5) Tanks and bottling equipment if alternated to bonded wine cellar

premises, taxpaid wine bottling housed premises or customs custody. A separate diagram shall be submitted to show the location of tanks and bottling equipment after alternation to other premises.

(e) *Revised plans.* Proprietors shall submit revised plans as provided in §§ 19.189 and 19.190 to cover changes in location or premises. Submission of revised plan sheets for changes in construction and use of buildings and equipment may be delayed, unless the regional regulatory administrator requires immediate amendment as provided in § 19.193.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1349, as amended (26 U.S.C. 5172))

Changes After Original Qualification

§ 19.180 Application for amended registration.

Where there is a change with respect to the information shown in the notice of registration, the proprietor shall submit, within 10 days of such change (except as otherwise provided in this subpart and § 19.193), an application on Form 5110.41 for amended registration. Such application shall set forth, on sheets appropriately numbered or otherwise identified, the information necessary to make the notice of registration accurate and current. Where the change affects only pages or parts of pages of the notice of registration, such complete pages shall be submitted as will enable the replacement of the pages affected and maintenance of the file as provided in § 19.154.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1349, as amended (26 U.S.C. 5172); Sec. 805(a), Pub. L. 96–39, 93 Stat. 275 (26 U.S.C. 5171))

§ 19.181 Automatic termination of permits.

(a) *Permits not transferrable.* Operating permits issued under this part shall not be transferred. In the event of the lease, sale, or other transfer of such a permit, or of the operations authorized thereby, the permit shall thereupon automatically terminate.

(b) *Corporations.* In the case of a corporation holding an operating permit under this part, if actual or legal control of the permittee corporation changes, directly or indirectly, whether by reason of change in stock ownership or control (in the permittee corporation or in any other corporation), by operation of law, or in any other manner, the permittee shall, within 10 days of such change, give written notice thereof, executed under the penalties of perjury, to the regional regulatory administrator; such permit may remain in effect with respect to the operation covered thereby until the expiration of 30 days after such change, whereupon such permit shall automatically terminate. However, if within such 30-day period an application for a new permit covering such operation is made, then the outstanding operating permit may remain in effect with respect to the continuation of the operation covered thereby until final action is taken on such application. When such final action is taken, such outstanding operating permit shall thereupon automatically terminate.

(c) *Basic permits.* The termination of basic permits is governed by the provisions of 27 CFR Part 1.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1370, as amended (26 U.S.C. 5271))

§ 19.182 Change in name of proprietor.

Where there is to be a change in the individual, firm, or corporate name, the proprietor shall file application to amend the registration and to amend the operating and/or basic permit; a new bond or consent of surety will not be required. Operations may not be conducted under the new name prior to approval of the amended registration and issuance of the amended permit.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1349, as amended, 1370, as amended (26 U.S.C. 5172, 5271))

§ 19.183 Change of trade name.

If there is to be a change in, or addition of, a trade name, the proprietor shall file application to amend the operating and/or basic permit; a new bond or consent of surety will not be required. Operations may not be conducted under the new trade name prior to issuance of the amended permit.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1370, as amended (26 U.S.C. 5271))

§ 19.184 Changes in stockholders.

Changes in the list of stockholders furnished under the provisions of § 19.167(c)(1) may, in lieu of submission within 10 days of the change under the provisions of § 19.180 be submitted annually by the proprietor on May 1, except where the sale or transfer of capital stock results in a change in the control or management of the business.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1349, as amended, 1370, as amended (26 U.S.C. 5172, 5271))

§ 19.185 Changes in officers.

Where there is any change in the list of officers furnished under the provisions of § 19.167(a)(4), the proprietor shall submit, within 10 days of any such change, an application on Form 5110.41 for amended registration, supported by a new list of officers and a statement of the changes reflected in such list. If the operations of a distilled spirits plant are conducted pursuant to an operating permit, but not a basic permit, the regional regulatory administrator may extend to 30 days the time within which applications for amended registration to cover such changes in officers shall be filed. Where the proprietor has shown to the satisfaction of the regional regulatory administrator that certain corporate officers listed on the original application have no responsibilities in connection with the operations covered by the registration, the regional regulatory administrator may waive the requirements for submitting applications for amended registration to cover changes in such corporate officers.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1349, as amended (26 U.S.C. 5172); Sec. 805(a), Pub. L. 96–39, 93 Stat. 275 (26 U.S.C. 5171))

§ 19.186 Change in proprietorship.

(a) *General.* If there is a change in the proprietorship of a plant qualified under this part, the outgoing proprietor shall comply with the requirements of § 19.211, and the successor shall, before commencing operations, apply for and obtain the required permits, file the required bonds, and file application for and receive notice of registration of the plant in the same manner as a person qualifying as the proprietor of a new plant, except that the successor may, in the manner provided in § 19.187, adopt the plans and approved Forms 5110.38 and 1479–A of the predecessor. Spirits may be transferred from an outgoing proprietor of a plant to a successor in the manner provided in § 19.201.

(b) *Fiduciary.* If the successor to the proprietorship of a plant is an administrator, executor, receiver, trustee, assignee or other fiduciary, he shall comply with the provisions of paragraph (a) of this section except that he may, in lieu of filing a new bond, furnish consent of surety extending the terms of the predecessor's bond, and he may also incorporate by reference in the application for registration on Form 5110.41 any pertinent information contained in the predecessor's notice of registration. The fiduciary shall furnish a certified copy of the order of the court or other pertinent document showing qualification as such fiduciary. The effective dates of the qualifying documents filed by the fiduciary shall be the effective date of the court order, or the date specified therein for him to assume control. If the fiduciary was not appointed by a court, the date of assuming control shall coincide with the effective date of the qualifying documents filed by the fiduciary.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1349, as amended (26 U.S.C. 5172))

§ 19.187 Adoption of plans and formulas.

(a) *Plans.* The adoption by a successor of the plans of his predecessor shall be in the form of a certificate to be made a part of the application for registration, in which shall be set forth the identity of the plant and of the predecessor. The required certificate shall set forth a description (by sheet number and title) of each plan sheet adopted, and a certification that the adopted plans accurately depict the premises.

(b) *Forms 5110.38.* The adoption by a successor of approved Forms 5110.38 (27–B Supplemental) shall be in the form of an application, filed with the Director. The application shall list the formulas for adoption by (1) formula number, (2) name of product, and (3) date of approval. The application shall clearly show that the predecessor has authorized the use of its previously approved formulas by the successor.

(c) *Forms 1479–A.* The adoption by a successor of approved Forms 1479–A shall be in accordance with 27 CFR 211.62.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1349, as amended (26 U.S.C. 5172))

§ 19.188 Continuing partnerships.

If under the laws of the particular State, the partnership is not terminated on death or insolvency of a partner, but continues until the winding up of the partnership affairs is completed, and the surviving partner has the exclusive right to the control and possession of the partnership assets for the purpose of liquidation and settlement, such surviving partner may continue to operate the plant under the prior qualification of the partnership, provided a consent of surety is filed, wherein the surety and the surviving partner agree to remain liable on the operations or unit bond. If such surviving partner acquires the business on completion of the settlement of the partnership, he shall qualify in his own name from the date of acquisition, as provided in § 19.186(a). The rule set forth in this section shall also apply where there is more than one surviving partner.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1349, as amended (26 U.S.C. 5172))

§ 19.189 Change in location.

Where there is a change in the location of the plant, the proprietor shall file applications to amend the registration of the plant and the operating and/or basic permit, new plans, and either a new bond or a consent of surety on Form 1533. Operation of the plant may not be commenced at the new location prior to approval of the amended registration and issuance of the amended permit.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1349, as amended, 1370, as amended (26 U.S.C. 5172, 5271); Sec. 805(c), Pub. L. 96–39, 93 Stat. 276 (26 U.S.C. 5173))

§ 19.190 Changes in premises.

Except as provided in §§ 19.202, 19.203 and 19.204, where bonded premises, or any other premises included as a part of the plant are to be extended or curtailed, the proprietor shall file (a) an application for registration, Form 5110.41, to cover such extension or curtailment, and (b) amended plans. Premises and equipment to be included by extension or to be excluded by curtailment shall not, prior to approval by the regional regulatory administrator of the required documents, be used for other than previously approved purposes.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1349, as amended (26 U.S.C. 5172))

§ 19.191 Change in operations.

If the proprietor proposes to conduct a new business or operation involving spirits, he shall file applications to amend the registration of the plant and the operating and/or basic permit. If the proprietor desires to engage, on the plant premises, in a business, other than operations as a distiller, warehouseman, or processor, he shall submit application to amend the registration of the plant to include the information required under § 19.152(k)(4). The additional operation or business may not be carried on prior to approval of the amended registration and (if required) issuance of the amended permit.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1349, as amended, 1370, as amended (26 U.S.C. 5172, 5271); Sec. 805(a), Pub. L. 96–39, 93 Stat. 275 (26 U.S.C. 5171))

§ 19.192 Change in production procedure.

If the proprietor desires to produce a new product or make a change in a production procedure which would affect the designation, or substantially affect the character of his product, the proprietor shall file an application to amend the registration of the plant to include the amended or new statement of production procedure. The new or changed procedure may not be used prior to approval of the amended registration.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1349, as amended (26 U.S.C. 5172))

§ 19.193 Changes in construction and use of buildings and equipment.

Where a material change is to be made (a) in the buildings or equipment of a plant (other than a change covered by §§ 19.190, 19.202, 19.203, or 19.204), (b) in the use of any portion of a plant, or (c) with respect to plant equipment, which affects the accuracy of the notice of registration (including the plans), the proprietor shall, before making such change, submit a letterhead notice, to the regional regulatory administrator through the area supervisor. The letterhead notice shall describe the proposed change specifically and in detail. When the change has been completed, the proprietor shall file an amended notice of registration, Form 5110.41 to reflect the change covered by the letterhead notice. Such change may be reflected in the next required amendment of the plans unless the regional regulatory administrator requires immediate amendment. The proprietor may make emergency repairs without prior notification, but where such emergency repairs are made, the proprietor shall promptly notify the area supervisor and file with him a report.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1349, as amended (26 U.S.C. 5172))

Operations by Alternating Proprietors

§ 19.201 Procedure for alternating proprietors.

(a) *General.* A plant, or any part thereof which is suitable for qualification as a separate plant, may be operated alternately by proprietors who have filed and received approval of the necessary bonds and applications for registration, and have otherwise qualified under the provisions of this subpart. Where operations by alternating proprietors are limited to parts of the plant, the notice of registration shall describe the areas, rooms or buildings or combination thereof, which will be alternated, and shall be accompanied by special plans designating the parts of the plant which are to be alternated. A special plan shall be submitted for each arrangement, other than that reflected by the basic plan, under which the premises will be operated. Once such qualifying documents have been approved, and initial operations have been conducted thereunder, the plant, or parts thereof, may be alternated by the proprietor filing notices on Form 5110.34 with the regional regulatory administrator. Any transfer of spirits (including denatured spirits), and wines shall be indicated on Form 5110.34 filed by each proprietor. Bottled spirits in containers of 1 gallon or less shall not be transferred and shall

be removed from premises affected by the notices prior to the effective date and hours shown in the notices.

(b) *Production.* Distilling materials and unfinished spirits in any bonded areas, rooms or buildings to be alternated shall be processed to completion by the outgoing proprietor unless transferred to the incoming proprietor. All finished spirits shall be marked and removed by the outgoing proprietor in the name in which produced, before production gauge is made of any spirits by the incoming proprietor.

(c) *Warehousing.* Spirits and wines in any bonded areas, rooms, or buildings to be alternated shall be transferred to the incoming proprietor on Form 5110.27. The outgoing proprietor shall execute a consent of surety on Form 1533 to continue in effect the operations or unit bond whenever operation of the areas, rooms, or buildings is to be resumed by him following suspension of operations by an alternate proprietor.

(d) *Processing.* Spirits (including denatured spirits), wines and articles in any rooms, areas, or buildings to be alternated shall be processed to completion and removed from the affected areas, rooms, or buildings by the outgoing proprietor prior to the effective date and hours given in the notice unless transferred or retained in locked tanks as provided in this paragraph. Spirits (including denatured spirits) and wines may be transferred to the incoming proprietor. In this case, the outgoing proprietor shall execute Form 5110.27 transferring the spirits (including denatured spirits) and wines to the incoming proprietor. Further, the outgoing proprietor shall execute a consent of surety on Form 1533 to continue in effect the operations or unit bond whenever operation of the affected areas, rooms, or buildings is to be resumed by him following suspension of operations by the alternate proprietor. Denatured spirits and articles may be retained in tanks locked by approved locks, the keys to which are in the custody of the outgoing proprietor. In this case, the outgoing proprietor shall execute a consent of surety on Form 1533 to continue liability on the operations or unit bond for the tax on such denatured spirits or articles retained in such tanks, notwithstanding the change in proprietorship.

(e) *Records.* Each proprietor shall maintain separate records and submit separate reports. All transfers of distilling materials, unfinished spirits, spirits (including denatured spirits), and wines shall be reflected in the records of each proprietor.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1349, as amended, 1370, as amended (26 U.S.C. 5172, 5271))

Alternate Operations

§ 19.202 Alternate use of premises and equipment for customs purposes.

(a) *General.* The premises of a distilled spirits plant may, as provided in this section, be alternately curtailed and extended to permit the facilities of the distilled spirits plant to be used temporarily by customs officers, under applicable customs law and regulations, for the purpose of gauging or processing distilled spirits. The use of the excluded portion of the premises for customs purposes is subject to the approval of the district director of customs. When it is necessary to convey spirits in customs custody across the premises of a distilled spirits plant, the proprietor shall comply with the provisions of § 19.99. When a portion of the distilled spirits plant premises is first to be excluded as provided in this section, the proprietor shall file with the regional regulatory administrator (1) an application for registration, Form 5110.41, to cover alternate curtailment and extension of premises, (2) a special plan delineating the premises as they will exist, both during extension and curtailment, and (3) a special diagram, in duplicate, clearly depicting all buildings, rooms, areas, equipment and spirits lines (identified individually by letter or number) which are to be subject to alternation, in their relative operating sequence. Once such qualifying documents have been approved by the regional regulatory administrator, the designated premises and equipment may be alternately curtailed or extended pursuant to notice on Form 5110.34. Portions of the premises to be excluded by curtailment or included by extension shall not be used for purposes other than as set forth in the current notice. The proprietor shall remove all spirits from the premises or equipment affected by the notice prior to the effective date and hours of the notice. However, on release by customs, spirits being transferred to bonded premises under 26 U.S.C. 5232, may remain on the premises to be reincluded in bonded premises.

(b) *Separation of premises.* The portion of the premises which is to be excluded from the distilled spirits plant premises as provided in this section shall be separated from the remaining portion of the distilled spirits plant premises in a manner satisfactory to the regional regulatory administrator.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1349, as amended, 1358, as amended (26 U.S.C. 5172, 5178))

§ 19.203 Alternation of distilled spirits plant and bonded wine cellar premises.

(a) *General.* A proprietor of a distilled spirits plant operating a contiguous bonded wine cellar desiring to alternate the use of each premises by extension and curtailment shall file necessary qualifying documents with the regional regulatory administrator.

(b) *Qualifying documents.* The proprietor shall file with the regional regulatory administrator:

(1) Form 5110.41 and Form 698 to cover the proposed alternation of premises;

(2) Plans, in duplicate, showing the distilled spirits plant premises and bonded wine cellar premises after alternation. The plan should include diagrams of equipment on the alternated premises so that the area designated for each premises can be determined; and

(3) Evidence of existing bond, consent of surety, or a new bond to cover the proposed alternation of premises.

(c) *Proprietor's responsibility.* After approval of qualifying documents for the alternation of premises, and after initial operations have been conducted thereunder, the proprietor shall execute Form 5110.34, Notice of Change in Status of Plant, each time the premises are alternated. Prior to the effective hour of the date shown on the Form 5110.34, the proprietor shall remove all spirits (including denatured spirits), articles, and wines from the distilled spirits plant premises alternated to bonded wine cellar premises. Any wine on bonded wine cellar premises shall be removed prior to alternation to distilled spirits plant premises unless wine is being simultaneously transferred in bond to the distilled spirits plant.

(d) *Separation of premises.* Separation of distilled spirits plant premises from bonded wine cellar premises after alternation shall be in a manner which satisfies the regional regulatory administrator that the revenue will not be jeopardized.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1349, as amended, 1353, as amended (26 U.S.C. 5172, 5178))

§ 19.204 Alternation of distilled spirits plant and taxpaid wine bottling house premises.

(a) *General.* A proprietor of a distilled spirits plant operating a contiguous taxpaid wine bottling house desiring to alternate the use of each premises by extension and curtailment shall file necessary qualifying documents with the regional regulatory administrator.

(b) *Qualifying documents.* The proprietor shall file with the regional regulatory administrator:

(1) Form 5110.41 and Form 2975 to cover the proposed alternation of premises;

(2) Plans, in duplicate, showing the distilled spirits plant premises and taxpaid wine bottling house premises after alternation. The plan should include diagrams of equipment on the alternated premises so that the area designated for each premises can be determined; and

(3) Evidence of existing bond, consent of surety, or a new bond to cover the proposed alternation of premises.

(c) *Proprietor's responsibility.* After approval of qualifying documents for the alternation of premises, and after initial operations have been conducted thereunder, the proprietor shall execute Form 5110.34, Notice of Change in Status of Plant, each time the premises are alternated. Prior to the effective hour of the date shown on the Form 5110.34, the proprietor shall remove all spirits (including denatured spirits), articles, and wines from the distilled spirits plant premises alternated to taxpaid wine bottling house premises. Any wine on taxpaid wine bottling house premises shall be removed prior to alternation to distilled spirits plant premises.

(d) *Separation of premises.* Separation of distilled spirits plant premises from taxpaid wine bottling house premises after alternation shall be in a manner which satisfies the regional regulatory administrator that the revenue will not be jeopardized.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1349, as amended, 1353, as amended (26 U.S.C. 5172, 5178))

Permanent Discontinuance of Business

§ 19.211 Notice of permanent discontinuance.

When the proprietor permanently discontinues any or all of the operations listed in the notice of registration, he shall, after completion of the operations, file a Form 5110.41 to cover such discontinuance. Form 5110.41 shall be accompanied (a) by all permits issued to the proprietor under this subpart covering the discontinued operations, any by his request that such permits be canceled; (b) by the proprietor's written statement disclosing, as applicable, whether (1) all spirits (including denatured spirits), articles, wines, indicia bottles, strip stamps, and other pertinent items have been lawfully disposed of, (2) any spirits (including denatured spirits), wines, indicia bottles, or strip stamps are in transit to the premises, (3) all approved applications for transfer of spirits (including denatured spirits) to the premises have been secured and returned to the regional regulatory administrator for cancellation; and (c) by pertinent reports covering the discontinued operations (each report shall be marked "Final Report").

(Sec. 201, Pub. L. 85–859, 72 Stat. 1349, as amended, 1370, as amended (26 U.S.C. 5172, 5271))

Subpart H—Bonds and Consents of Surety

§ 19.231 General.

Every person intending to establish a distilled spirits plant shall file an operations or unit bond as prescribed in this subpart, covering distilled spirits operations at such plant, with the regional regulatory administrator, at the time of filing the original application for registration of the plant, and at such other times as are required by this part. Such bond shall be conditioned that he shall faithfully comply with all provisions of law and regulations relating to activities covered by such bond, will pay all taxes imposed by 26 U.S.C. Chapter 51, and shall pay all penalties incurred or fines imposed for violation of any such provisions. The regional regulatory administrator may require, in connection with any operations or unit bond, a statement, executed under the penalties of perjury, as to whether the principal or any person owning, controlling, or actively participating in the management of the business of the principal has been convicted of or has compromised any offense set forth in § 19.239(a) or has been convicted of any offense set forth in § 19.239(b). In the event the above statement contains an affirmative answer, the applicant shall submit a statement describing in detail the circumstances surrounding such conviction or compromise. No person shall commence or continue distilled spirits operations at such plant unless he has a valid operations or unit bond (and consent of surety, if necessary), as required in respect of such operations by this part.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1394, as amended, (26 U.S.C. 5551); Sec. 805(c), Pub. L. 96–39, 93 Stat. 276 (26 U.S.C. 5173))

§ 19.232 Additional condition of operations bond.

In addition to the requirements of § 19.231, the operations bond shall be conditioned on payment of the tax now or hereafter in force, except as provided by law, including taxes on all unexplained shortages of bottled distilled spirits.

(Sec. 805(c), Pub. L. 96–39, 93 Stat. 276 (26 U.S.C. 5173))

§ 19.233 Corporate surety.

Surety bonds required by this part may be given only with corporate sureties holding certificates of authority from, and subject to the limitations prescribed by, the Secretary as set forth in the current revision of Treasury Department Circular 570.

(Ch. 390, Pub. L. 80–280, 61 Stat. 648 (6 U.S.C. 6, 7))

§ 19.234 Filing of powers of attorney.

Each bond, and each consent to changes in the terms of a bond, shall be accompanied by a power of attorney authorizing the agent or officer who executed the bond or consent to so act on behalf of the surety. The regional regulatory administrator who is authorized to approve the bond may require additional evidence of the authority of the agent or officer to execute the bond or consent.

(Ch. 390, Pub. L. 80–280, 61 Stat. 648 (6 U.S.C. 6, 7))

§ 19.235 Execution of powers of attorney.

The power of attorney shall be prepared on a form provided by the surety company and executed under the corporate seal of the company. If the power of attorney submitted is other than a manually signed original, it shall be accompanied by certification of its validity.

(Ch. 390, Pub. L. 80–280, 61 Stat. 648 (6 U.S.C. 6, 7))

§ 19.236 Deposit of securities in lieu of corporate surety.

In lieu of corporate surety, the principal may pledge and deposit, as surety for his bond, securities which are transferable and are guaranteed as to both interest and principal by the United States, in accordance with the provisions of 31 CFR Part 225.

(Ch. 390, Pub. L. 80–280, 61 Stat. 650 (6 U.S.C. 15))

§ 19.237 Consents of surety.

Consents of surety to changes in the terms of bonds shall be executed on Form 1533 by the principal and by the surety with the same formality and proof of authority as is required for the execution of bonds.

(Sec. 805(c) Pub. L. 96–39, 93 Stat. 276 (26 U.S.C. 5173))

§ 19.238 Authority to approve bonds and consents of surety.

Regional regulatory administrators are authorized to approve all bonds and consents of surety required by this part.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1394, as amended (26 U.S.C. 5551))

§ 19.239 Disapproval of bonds or consents of surety.

The regional regulatory administrator may disapprove any bond or consent of surety submitted in respect to the operations of a distiller, warehouseman, or processor, if the principal or any person owning, controlling, or actively participating in the management of the business of the principal shall have been previously convicted, in a court of competent jurisdiction of—

(a) Any fraudulent noncompliance with any provision of any law of the United States, if such provision related to internal revenue or customs taxation of spirits, wines, or beer, or if such an offense shall have been compromised with the person on payment of penalties or otherwise, or

(b) Any felony under a law of any State or the District of Columbia, or the United States, prohibiting the manufacture, sale, importation, or transportation of spirits, wine, beer, or other intoxicating liquor.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1394, as amended (26 U.S.C. 5551))

§ 19.240 Appeal to Director.

Where a bond or consent of surety is disapproved by the regional regulatory administrator, the person giving the bond may appeal from such disapproval to the Director, who will hear such appeal. The decision of the Director shall be final.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1394, as amended (26 U.S.C. 5551))

§ 19.241 Operations bond—distilled spirits plant and adjacent bonded wine cellar.

(a) *General.* No wine cellar under the provisions of 27 CFR Part 240 shall be treated as being adjacent to a distilled spirits plant unless—

(1) such distilled spirits plant is qualified under Subpart G for the production of distilled spirits; and

(2) such wine cellar and distilled spirits plant are operated by the same person (or in the case of a corporation, by such corporation and its controlled subsidiaries). For the purpose of this section a controlled subsidiary is a corporation where more than 50 percent of the voting shares are owned by the parent corporation.

(b) *Bond in lieu of wine cellar bond.* In the case of an adjacent bonded wine cellar, a bond furnished under this subpart which covers operations at such bonded wine cellar shall be in lieu of any bond which would otherwise be required under 26 U.S.C. 5354 with respect to such wine cellar (other than supplemental bonds required under the second sentence of 26 U.S.C. 5354) and the operations bond listed in § 19.245(a)(1).

(c) *Liability.* Bonds given under this section shall contain the terms and conditions of the bonds in lieu of which they are given. The total amount of such operations bond shall be available for the satisfaction of any liability incurred under the terms or conditions of such bond.

(Sec. 805(c), Pub. L. 96–39, 93 Stat. 276 (26 U.S.C. 5173))

§ 19.242 Area operations bond.

Any person (or, in the case of a corporation, a corporation and its controlled subsidiaries) operating more than one plant in a region may give an area operations bond covering the operation of any two or more of such plants, and any bonded wine cellars which are adjacent to such plants and which otherwise could be covered by an operations bond. For the purpose of this section, a controlled subsidiary is a corporation where more than 50 percent of the voting shares are owned by the parent corporation. Bonds given under this section shall be in lieu of the bonds which would be required under § 19.245(a) and shall contain the terms and conditions of such bonds. If the area operations bond covers the operations of more than one corporation, each corporation shall be shown as principal, and the bond shall be signed for each corporation. The total amount of the area operations bond shall be available for the satisfaction of any liability incurred under the terms or conditions of such bond.

(Sec. 805(c), Pub. L. 96–39, 93 Stat. 276 (26 U.S.C. 5173))

§ 19.243 Withdrawal bond.

Any person (or, in the case of a corporation, a corporation and its controlled subsidiaries) operating one or more distilled spirits plants within a region and who intends to withdraw spirits from bond on determination, but before payment, of the tax shall, before making any such withdrawal, furnish a withdrawal bond to secure payment of the tax on all spirits so withdrawn. Such bond shall be in addition to the operations bond, and if the distilled spirits are withdrawn under the withdrawal bond, the operations bond shall no longer cover liability for payment of the tax on the spirits withdrawn. For the purpose of this section, a controlled subsidiary is a corporation where more than 50 percent of the voting shares are owned by the parent corporation.

The bond, if it covers more than one plant, shall show as to each plant covered by the bond the part of the total sum which represents the penal sum (computed in accordance with § 19.245) for each such plant. If the penal sum of the bond covering a plant, or the penal sum allocated to any plant (where the bond covers more than one plant), is in an amount less than the maximum prescribed in § 19.245, withdrawals from such plant shall not exceed the quantity permissible, as reflected by the penal sum in the bond for such plant. Such withdrawal bond shall be conditioned that the total amount of the bond shall be available for satisfaction of any liability incurred under the terms and conditions of such bond.

(Sec. 805(c), Pub. L. 96–39, 93 Stat. 276 (26 U.S.C. 5173))

§ 19.244 Unit bond.

Any person (or, in the case of a corporation, a corporation and its controlled subsidiaries) who would otherwise be required to give bonds for both operations at one or more distilled spirits plants (and any adjacent bonded wine cellars) and withdrawals from one or more distilled spirits plants within a region may, in lieu of furnishing separate bonds for operations and withdrawals, furnish a unit bond containing the terms and conditions of the bonds in lieu of which it is given. For the purpose of this section, a controlled subsidiary is a corporation where more than 50 percent of the voting shares are owned by the parent corporation. The unit bond shall show as to each plant covered by the bond the part of the total sum which represents the penal sum (computed in accordance with § 19.245) for operations at and withdrawals from each plant. If the penal sum of the bond covering a plant, or the penal sum allocated to any plant (if the bond covers more than one plant), is in an amount less than the maximum prescribed in § 19.245, operations at and/or withdrawals from such plant shall not exceed the quantity permissible as reflected by the penal sum in the bond for such plant. The unit bond shall be conditioned that the total amount of the bond shall be available for satisfaction of any liability incurred uder the terms and conditions of such bond.

(Sec. 805(c), Pub. L. 96–39, 93 Stat. 276 (26 U.S.C. 5173))

§ 19.245 Bonds and penal sums of bonds.

The bonds, and the penal sums thereof, required by this subpart, are as follows:

Penal Sum

Type of bond	Basis	Minimum	Maximum
(a) Operations bond:			
(1) One plant bond:			
(i) Distiller	The amount of tax on spirits produced during a period of 15 days.	$5,000	$100,000
(ii) Warehouseman	The amount of tax on spirits and wines deposited in, stored on, and in transit to bonded premises.	5,000	200,000
(iii) Distiller and warehouseman	The amount of tax on spirits produced during a period of 15 days, and the amount of tax on spirits and wines deposited in, stored on, and in transit to bonded premises.	10,000	200,000
(iv) Distiller and processor	The amount of tax on spirits produced during a period of 15 days, and the amount of tax on spirits (including denatured spirits), articles, and wines deposited in, stored on, and in transit to bonded premises.	10,000	200,000
(v) Warehouseman and processor	The amount of tax on spirits (including denatured spirits), articles, and wines deposited in, stored on, and in transit to bonded premises.	10,000	250,000
(vi) Distiller, warehouseman, and processor.	The amount of tax on spirits produced during a period of 15 days, and the amount of tax on spirits (including denatured spirits), articles, and wines deposited in, stored on, and in transit to bonded premises.	15,000	250,000
(2) Adjacent bonded wine cellars:			
(i) Distiller and bonded wine cellar	The sum of amount of tax calculated in (a)(1)(i) and with respect to bonded wine cellar operations, the amount of tax on wines and wine spirits possessed and in transit.	6,000	150,000
(ii) Distiller, warehouseman and bonded wine cellar..	The sum of amount of tax calculated in (a)(1)(iii) and with respect to bonded wine cellar operations, the amount of tax on wines and wine spirits possessed and in transit.	11,000	250,000
(iii) Distiller, processor and bonded wine cellar.	The sum of amount of tax calculated in (a)(1)(iv) and with respect to bonded wine cellar operations, the amount of tax on wines and wine spirits possessed and in transit.	11,000	250,000
(iv) Distiller, warehouseman, processor and bonded wine cellar..	The sum of amount of tax calculated in (a)(1)(vi) and with respect to bonded wine cellar operations, the amount of tax on wines and wine spirits possessed and in transit.	16,000	300,000
(b) Area operations bond:	The penal sum shall be calculated in accordance with the following table:		

Total penal sums as determined under (a)	Requirements for penal sum of area operations bond.
Not over $300,000	100 percent.
Over $300,000 but not over $600,000	$300,000 plus 70 percent of excess over $300,000.
Over $600,000 but not over $1,000,000	$510,000 plus 50 percent of excess over $600,000.
Over $1,000,000 but not over $2,000,000	$710,000 plus 35 percent of excess over $1,000,000.
Over $2,000,000	$1,060,000 plus 25 percent of excess over $2,000,000.

(c) Withdrawal bond:			
(1) One plant qualified for distilled spirits operations.	The amount of tax which, at any one time, is chargeable against such bond but has not been paid.	$1,000	$1,000,000
(2) Two or more plants in a region qualified for distilled spirits operations.	Sum of the penal sums for each plant calculated in (c)(1) of this section.	[1]	[2]
(d) Unit bond:			
(1) Both operations at a distilled spirits plant (and any adjacent bonded wine cellar) and withdrawals from the bonded premises of the same distilled spirits plant.	Total penal sums of (a) and (c)(1) of this section.	6,000	1,300,000
(2) Both operations at two or more distilled spirits plants (and any adjacent bonded wine cellar) within the same region and withdrawals from the bonded premises of the same distilled spirits plants.	Total penal sums of (b) and (c)(2) of this section in lieu of which given.	[3]	[4]

[1] Sum of the minimum penal sums required for each plant covered by the bond.
[2] Sum of the maximum penal sums required for each plant covered by the bond (The maximum penal sums for one plant is $1,000,000).
[3] Sum of the minimum penal sums for operations and withdrawal bonds required for each plant covered by the bond.
[4] Sum of the maximum penal sums for area operations bonds and withdrawal bonds required for the plants covered by the unit bond.

(Sec. 805(c), Pub. L. 96-39, 93 Stat. 276 (26 U.S.C. 5173))

§ 19.246 Strengthening bonds.

In all cases when the penal sum of any bond becomes insufficient, the principal shall either give a strengthening bond with the same surety to attain a sufficient penal sum, or give a new bond to cover the entire liability. Strengthening bonds will not be approved where any notation is made thereon which is intended, or which may be construed, as a release of any former bond, or as limiting the amount of any bond to less than its full penal sum. Strengthening bonds shall show the current date of execution and the effective date.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1394, as amended (26 U.S.C. 5551); Sec. 805(c), Pub. L. 96–39, 93 Stat. 276 (26 U.S.C. 5173))

New or Superseding Bonds

§ 19.247 General.

New bonds shall be required in case of insolvency or removal of any surety, and may, at the discretion of the regional regulatory administrator, be required in any other contingency affecting the validity or impairing the efficiency of such bond. Executors, administrators, assignees, receivers, trustees, or other persons acting in a fiduciary capacity, continuing or liquidating the business of the principal, shall execute and file a new bond or obtain the consent of the surety or sureties on the existing bond or bonds. When, under the provisions of § 19.250, the surety on any bond given under this subpart has filed an application to be relieved of liability under said bond and the principal desires or intends to continue the business or operations to which such bond relates, he shall file a valid superseding bond to be effective on or before the date specified in the surety's notice. New or superseding bonds shall show the current date of execution and the effective date.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1353, as amended, 1394, as amended (26 U.S.C. 5175, 5176, 5551); Sec. 805(c), Pub. L. 96–39, 93 Stat. 276 (26 U.S.C. 5173))

§ 19.248 New or superseding bond.

(a) *Operations bond.* When a new or superseding operations bond is not given as required in § 19.247, the principal shall immediately discontinue the business or distilled spirits operations to which such bond relates.

(b) *Withdrawal bond.* When a new or superseding withdrawal bond is not given as required by § 19.247, the principal may not withdraw any distilled spirits from bonded premises (other than distilled spirits withdrawn under 26 U.S.C. 5214 or 7510) except on prior payment of tax.

(c) *Unit bond.* When a new or superseding unit bond is not given as required by § 19.247, the principal shall immediately discontinue the business or distilled spirits operations to which such bond relates and may not withdraw any distilled spirits from bonded premises (other than distilled spirits withdrawn under 26 U.S.C. 5214 or 7510) except on prior payment of tax.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1353, as amended (26 U.S.C. 5175, 5176); Sec. 805(c), Pub. L. 96–39, 93 Stat. 276 (26 U.S.C. 5173))

Termination of Bonds

§ 19.249 Termination of bonds.

Operations, withdrawal, or unit bonds may be terminated as to liability for future withdrawals and/or to future production or deposits (a) pursuant to application of the surety as provided in § 19.250, (b) on approval of a superseding bond, (c) on notification by the principal that he has discontinued withdrawals under the bond if such bond was filed solely as a withdrawal bond, or (d) on notification by the principal that he has discontinued business.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1353, as amended (26 U.S.C. 5175, 5176); Sec. 805(c), Pub. L. 96–39, 93 Stat. 276 (26 U.S.C. 5173))

§ 19.250 Application of surety for relief from bond.

A surety on any operations, withdrawal, or unit bond may at any time in writing notify the principal and the regional regulatory administrator in whose office the bond is on file that he desires, after a date named, to be relieved of liability under said bond. Such date shall not be not less than 10 days after the date the notice is received by the regional regulatory administrator in the case of a withdrawal bond, and not less than 90 days after the date the notice is received in the case of an operations or unit bond. The surety shall also file with the regional regulatory administrator an acknowledgement or other proof of service on the principal. If such notice is not thereafter in writing withdrawn, the rights of the principal as supported by said bond shall be terminated on the date named in the notice, and the surety shall be relieved from liability to the extent set forth in § 19.251.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1353, as amended (26 U.S.C. 5175, 5176); Sec. 805(c), Pub. L. 96–39, 93 Stat. 276 (26 U.S.C. 5173))

§ 19.251 Relief of surety from bond.

(a) *General.* The surety on an operations, withdrawal, or unit bond who has filed application for relief from liability as provided in § 19.250 shall be relieved from liability under such bond as set forth in this section.

(b) *Operations or unit bonds.* Where a new or superseding bond is filed, the surety shall be relieved of future liability with respect to production and deposits wholly subsequent to the effective date of the new or superseding bond. Notwithstanding such relief, the surety shall remain liable for the tax on all distilled spirits or wines produced, or for other liabilities incurred, during the term of the bond. Where a new or superseding bond is not filed the surety shall, in addition to the continuing liabilities above specified, remain liable under the bond for all spirits or wines on hand or in transit to the bonded premises or bonded wine cellar, as the case may be, on the date named in the notice until all such spirits or wines have been lawfully disposed of, or a new bond has been filed by the principal covering the same.

(c) *Withdrawal or unit bonds.* The surety shall be relieved from liability for withdrawals made wholly subsequent to the date specified in the notice, or the effective date of a new bond, if one is given.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1353, as amended (26 U.S.C. 5176); Sec. 805(c), Pub. L. 96–39, 93 Stat. 276 (26 U.S.C. 5173))

§ 19.252 Release of pledged securities.

Securities of the United States pledged and deposited as provided in § 19.236 shall be released only in accordance with the provisions of 31 CFR Part 225. Such securities will not be released by the regional regulatory administrator until liability under the bond for which they were pledged has been terminated. When the regional regulatory administrator is satisfied that they may be released, he shall fix the date or dates on which a part or all of such securities may be released. At any time prior to the release of such securities, the regional regulatory administrator may extend the date of release for such additional length of time as he deems necessary.

(Ch. 390, Pub. L. 80–280, 61 Stat. 650 (6 U.S.C. 15))

Subpart I—Construction, Equipment and Security

§ 19.271 Construction of buildings.

Buildings in which spirits (including denatured spirits), articles, or wines are produced, stored, or processed shall be constructed with substantial material (e.g., masonry, concrete, wood, metal, etc.), and arranged, equipped, and protedted to provide adequate security to the revenue.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1353, as amended (26 U.S.C. 5178))

§ 19.272 Equipment.

The proprietor shall provide equipment suitable for the operations conducted on the distilled spirits plant. The equipment shall also meet the needs for revenue protection.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1353, as amended (26 U.S.C. 5178))

§ 19.273 Tanks.

(a) *General.* (1) Tanks used as receptacles for spirits (including denatured spirits) or wines shall be located, constructed, and equipped to be suitable for the intended purpose and to allow ready examination the intended purpose and to allow ready examination.

(2) An accurate means of measuring the contents of each tank shall be provided by the proprietor.

(3) When a means of measuring is not a permanent fixture of the tank, the tank shall be equipped with a fixed device to allow the approximate contents to be determined readily.

(4) Tanks used for determining the tax imposed by 26 U.S.C. 5001 shall be mounted on scales and an additional suitable device shall be provided so that the volume of the contents can be quickly and accurately determined.

(5) The proprietor shall install walkways, landings, and stairways which will permit safe access to all parts of a tank.

(6) Tanks in which gauges required by this part are to be made shall not be used until they are accurately calibrated and a statement of certification of acccurate calibration is included in the notice of registration.

(7) If tanks or their fixed gauging devices are moved in location or position subsequent to original calibration, the tanks shall not be used until recalibrated.

(8) All openings in the tanks shall be equipped for locking or have a similar means of revenue protection.

(9) Any tank vents, flame arresters, foam devices, or other safety devices shall be constructed to prevent extraction of spirits or wines.

(b) *Scale tanks.* (1) Beams or dials of scale tanks used for determining the tax imposed by 26 U.S.C. 5001 shall have minimum graduations not greater than the following:

Quantity to be weighed	Minimum graduation
Not exceeding 2,000 pounds	½ pound
Between 2,000 and 6,000 pounds	1 pound
Between 6,000 and 20,000 pounds	2 pounds
Between 20,000 and 50,000 pounds	5 pounds
Over 50,000 pounds	10 pounds

(2) For scales having a capacity greater than 2,000 pounds, the minimum quantity which may be entered onto the weighing tank scale for gauging for tax determination shall be the greater of (i) 1,000 times the minimum graduation of the scale or (ii) 5 percent of the total capacity of the weighing tank scale.

(3) The weighing of lesser quantities for determination of tax may be authorized by the regional regulatory administrator where the beam of the scale is calibrated in ½ pound or 1 pound graduations and it is found by actual test that the scales break accurately at each graduation.

(4) Lots of spirits weighing 1,000 pounds or less shall be weighed on scales having ½ pound graduations.

(c) *Testing of scale tanks.* (1) Proprietors shall ensure the accuracy of scales used for weighing lots of spirits (including denatured spirits) through tests conducted by responsible scale companies or governmental agencies at intervals of not more than 6 months.

(2) When a scale is tested, adjusted or repaired, the proprietor shall prepare or secure a signed statement certifying that the scale has been tested, adjusted, or repaired, as the case may be, and found to be accurate.

(3) Proprietors shall also test, at least once a month, the gallonage represented to be in a scale tank against the gallonage indicated by volumetric determination of the contents of the tank. However, if the scale is not used during a month the volumetric determination need only be verified at the next time actually used.

(4) The volumetric determination shall be made in accordance with Part 13 of this chapter, and if the variation exceeds 0.5 percent of the quantities shown to be in the tank, the proprietor shall take appropriate steps to have the accuracy of the scale verified.

(5) When an ATF officer determines that a tank scale may be inaccurate, the proprietor shall have the accuracy of the scale tested.

(6) A record shall be maintained of test results at the distilled spirits plant.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1320, as amended, 1358, as amended, 1391, as amended (26 U.S.C. 5006, 5204, 5505))

§ 19.274 Pipelines.

(a) *General.* (1) Pipelines for the conveyance of spirits (including denatured spirits), articles, or wines shall be of permanent character and constructed, connected, arranged, and secured so as to afford adequate protection to the revenue and to permit ready examination. However, the regional regulatory administrator may approve pipelines which may not be readily examined if no jeopardy to the revenue is created.

(2) Where a pipeline connection must be flexible, a hose may be used if connected and secured so as to protect the revenue.

(b) *Identification.* The regional regulatory administrator may require permanent pipelines for conveyance of spirits (including denatured spirits) to be color coded to provide identification.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1353, as amended (26 U.S.C. 5178))

§ 19.275 Continuous distilling system.

The distilling system shall be continuous, and designed, constructed, and connected in such a manner as to prevent the unauthorized removal of distilled spirits. Security of the distilling system shall be maintained by locks, or by other methods affording comparable protection.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1353, as amended (26 U.S.C. 5178))

§ 19.276 Package and case scales.

The proprietor shall provide a scale suitable for the weighing of packages. The proprietor shall, not less than once each month, test the accuracy of the scales. However, if the scales are not used during a month, the scales need only be tested prior to use. A record shall be maintained of test results. Scales used to weigh packages or cases designed to hold 10 wines gallons or less shall indicate weight in ounces or in hundredths of a pound.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5204))

§ 19.277 Measuring devices and proofing instruments.

The proprietor shall provide for his own use accurate hydrometers, thermometers, and other necessary equipment to determine proof or volume.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5204))

§ 19.278 Identification of structures, areas, apparatus, and equipment.

(a) Each room or enclosed area where spirits (including denatured spirits), articles, wine, distilling or fermenting materials, or containers are held, and each building, within the plant, shall be appropriately marked with a distinguishing number or letter.

(b) Each tank or receptacle for spirits (including denatured spirits) or wine shall be marked to show its serial number and capacity.

(c) Each still, fermenter, cooker, and yeast tank shall be numbered and marked to show its use.

(d) All other major equipment used for processing or containing spirits (including denatured spirits) or wine, or distilling or fermenting material, and all

other tanks, shall be identified as to use unless the intended purpose is readily apparent.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1353, as amended (26 U.S.C. 5178))

§ 19.279 Government office.

The proprietor shall provide an office at the distilled spirits plant for the exclusive use of ATF officers in performing supervisory and administrative duties and safeguarding Government records and property. The office shall be provided with adequate office furniture, lighting, ventilation, heating, and toilet and lavatory facilities. A secure cabinet, fitted for locking with a Government lock and of adequate size, shall also be provided by the proprietor. The office and facilities provided by the proprietor shall be subject to the approval of the regional regulatory administrator. Where suitable facilities are otherwise available, the regional regulatory administrator may waive the requirements for a separate Government office.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1353, as amended (26 U.S.C. 5178))

§ 19.280 Signs.

The proprietor shall place a sign conspicuously on the outside entrance to the distilled spirits plant. The sign shall have legible and durable characters that state:

(a) The real name of the proprietor. However, where registered to operate under a basic operating name (i.e., the name of a division of a corporation or the name of a partnership), the operating name shall be on the sign;

(b) The distilled spirits plant number; and

(c) The operations conducted (distiller, warehouseman, or processor) or designations which have obtained public and commercial significance (i.e., industrial alcohol plant, registered distillery).

(Sec. 201, Pub. L. 85–859, 72 Stat. 1355, as amended (26 U.S.C. 5180))

§ 19.281 Security.

(a) *General.* The proprietor shall provided adequate security measures at the distilled spirits plant to protect the revenue. The proprietor shall upon request of the regional regulatory administrator file a statement of security. After the regional regulatory administrator approves the statement of security prescribed in this section, the proprietor shall affix his locks to buildings, rooms and outside tanks as designated in the statement of security.

(b) *Buildings.* The buildings, rooms, and partitions shall be constructed of substantial materials. Doors, windows, or any other openings to the building shall be locked or fastened during times when distilled spirits plant operations are not being conducted.

(c) *Outdoor tanks.* Outdoor tanks in use for the storage of spirits (including denatured spirits), or wine shall remain locked unless operations are involving the tanks. The outdoor tanks need not be locked if another secure barrier (i.e., tank farm fence) has been provided and the entrance is locked when no outdoor tank operations are occurring.

(d) *Indoor tanks.* Tanks used for the storage of spirits (including denatured spirits), or wines, which are located in a secure room or building, shall be equipped for locking or affixing other similar security devices. Indoor tanks need not be locked if the entrances to rooms or buildings are secured with locks when no tank operations are occurring.

(e) *Approved locks.* Locks, which proprietors affix in place of Government locks on outside tanks or outside doors to rooms or buildings containing bulk distilled spirits in storage, shall meet the following minimum specifications:

(1) Corresponding serial number on the lock and on the key;

(2) Case hardened shackle at least one-fourth inch in diameter, with heel and toe locking;

(3) Body width of at least 2";

(4) Captured key feature (key may not be removed while shackle is unlocked);

(5) Tumbler with at least 5 pins; and

(6) Lock or key contains no bitting data. Master key locking systems may be used at the option of the proprietor. Locks meeting the specifications in this section are approved locks for the purpose of 26 U.S.C. 5682. Proprietors who wish to use locks of unusual design, which do not meet the specifications in this part, shall submit an example or prototype of the lock to the Director with a request that the lock be approved for use.

(f) *Additional security.* Where the regional regulatory administrator finds the construction, arrangement, equipment, or protection inadequate, additional security shall be provided (i.e., fences, flood lights, alarm systems, watchman services) or changes in construction, arrangement, or equipment shall be made to the extent necessary to protect the revenue.

(g) *Statement of security.* Prior to commencing operations, or as provided in § 19.922, the proprietor shall submit a statement of security describing the security measures at the distilled spirits plant to the regional regulatory administrator for approval. The regional regulatory administrator may require that the statement of security be modified prior to approval. The statement of security shall include:

(1) A general description of the physical security at the distilled spirits plant, including methods utilized to secure buildings and outdoor tanks;

(2) If guard personnel are employed, the number of guards and their shifts and responsibilities;

(3) If any electronic or mechanical alarm system is used, how this system works;

(4) The type of locks used (including brands, models, and serial numbers);

(5) A statement certifying that locks used meet the specifications provided in paragraph (e) of this section;

(6) A list of persons by position or title having responsibility for the custody of and access to keys for approved locks used at the distilled spirits plant.

The proprietor shall report to the regional regulatory administrator any change in personnel or procedures as contained in the statement of security on file. The proprietor shall fully comply with the approved statement of security.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1353, as amended, 1410, as amended (26 U.S.C. 5178, 5682); Sec. 806, Pub. L. 96–39, 93 Stat. 279 (26 U.S.C. 5202))

Subpart J—Production

§ 19.311 Notice by proprietor.

(a) *Commencement of operations.* The proprietor shall, before commencing production operations or resuming production operations after having given notice of suspension, file a notice on Form 5110.34 with the area supervisor, specifying the date on which he desires to commence or resume operations for the production of spirits. The notice shall be filed in accordance with the instructions on the form. The proprietor shall not commence or resume operations prior to the time specified in the notice.

(b) *Suspension of operations.* Any proprietor desiring to suspend production operations for a period of 90 days or more shall file notice on Form 5110.34 with the area supervisor specifying the date on which he will suspend operations. The notice shall be filed in accordance with instructions on the form. In case of an accident which makes it apparent that operations cannot be conducted for 90 days or more, the proprietor shall give immediate notice of suspension on Form 5110.34.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1364, as amended (26 U.S.C. 5221))

§ 19.312 Receipt of materials.

The quantities of fermenting and distilling materials received shall be determined by the proprietor and reported as provided in Subpart W of this part. Distilling materials, as used in this section, means: spirits (including denatured spirits), articles and spirits residues, for redistillation, and extracted oils of juniper berries and other natural aromatics to be used in the course of original and continuous distillation of gin and, nonpotable chemical mixtures containing spirits produced in accordance with § 19.66. Fermented material (except apple cider exempt from tax under 26 U.S.C. 5042(a)(1)) to be used in the production of spirits shall be produced on the bonded premises where used or must be received on the premises from (a) a bonded wine cellar, in the case of wine, or (b) a contiguous brewery where produced, in the case of beer.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended, 1365, as amended (26 U.S.C. 5201, 5222, 5223))

§ 19.313 Use of materials in production of spirits.

The proprietor may produce spirits from any suitable material in accordance with statements of production procedure in his notice of registration. The distillation of nonpotable chemical mixtures received pursuant to application as provided in § 19.66 shall be deemed to be the original and continuous distillation of the spirits in such mixtures and to constitute the production of spirits. Materials from which alcohol will not be produced may be used in production only if the use of the materials is described in approved statements of production procedure.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1349, as amended, 1353, as amended (26 U.S.C. 5172, 5178))

§ 19.314 Removal of fermenting material.

Material received for use as fermenting material may be removed from or used on bonded premises for other purposes. A record of use or removal shall be kept, as provided in Subpart W.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended, (26 U.S.C. 5201); Sec. 807, Pub. L. 96–39, 93 Stat. 284 (26 U.S.C. 5207))

§ 19.315 Removal or destruction of distilling material.

Except as provided in this section, distilling material shall not be removed from bonded premises before being distilled. On submission of a letter notice to the area supervisor, the proprietor may remove mash, wort wash or other distilling material—(a) to plant premises, other than bonded premises for use in such businesses as may be authorized under § 19.73; (b) to other premises for use in processes not involving the production of (1) spirits (2) alcoholic beverages, or (3) vinegar by the vaporizing process; (c) for destruction. The residue of distilling material not introduced into the production system may be removed from the premises if the liquid is expressed from the material before removal and such liquid is not received at any distilled spirits plant or bonded wine cellar. Residue of beer used as distilling material may be returned to the producing brewery. Distilling material produced and wine and beer received for use as distilling material may be destroyed. A record of removal or destruction shall be kept as provided in Subpart W of this Part.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1365, as amended, 1381, as amended (26 U.S.C. 5222, 5370))

§ 19.316 Distillation procedure.

The procedure for distillation shall be such that the spirits pass through a continuous system from the first still where entry into the system would constitute a jeopardy to the revenue until the production procedure is completed. The distiller may, in the course of production, convey the product through as many distilling operations as desired, provided the operations are continuous. Distilling operations are continuous when the spirits are conveyed through the various steps of production as expeditiously as plant operation will permit. The collection of unfinished spirits for the purpose of redistillation is not deemed to be a break in the continuity of the distilling procedure. However, the quantity and proof of any unfinished spirits produced from distilling materials, the quantity of which was ascertained in the manner authorized in § 19.752(c) for such materials, shall be determined and recorded before any mingling with other materials or before any further operations involving the unfinished spirits. Spirits may be held, prior to the production gauge, only for so long as is reasonably necessary to complete the production procedure.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1353, as amended, 1362, as amended, 1365, as amended (26 U.S.C. 5178, 5211, 5222))

§ 19.317 Treatment during production.

Spirits may, in the course of original and continuous distillation, be purified or refined through, or by use of, any material which will not remain incorporated in the finished product. Juniper berries and other natural aromatics, or the extracted oils of such, may be used in the distillation of gin. Spirits may be percolated through or treated with oak chips which have not been treated with any chemical. Materials used in treatment of spirits, and which do not remain in the spirits, shall be destroyed or so treated as to preclude the extraction of potable spirits therefrom.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

§ 19.318 Addition of caramel to rum or commercial brandy and addition of oak chips to spirits.

Caramel possessing no material sweetening properties may be added to rum or commercial brandy on bonded premises prior to production gauge. Oak chips which have not been treated with any chemical may be added to packages prior to or after production gauge; however, notation to that effect shall be made on the gauge form prescribed by § 19.319.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

§ 19.319 Production gauge.

(a) *General.* All spirits shall be gauged (by measuring and proofing) within a reasonable time after production is completed. Except as otherwise specifically provided in this section, quantities may be determined by volume or by weight, by meter, or, when approved by the Director, by another method which accurately determines the quantities. If caramel is added to brandy or rum, the proof of the spirits shall be determined after the addition. Spirits in a tank shall be gauged before and after each removal of spirits therefrom. The gauges shall be recorded by the proprietor in the records required by § 19.756.

(b) *Tax to be determined on production gauge.* Tax may be determined on the basis of the production guage if:

(1) Spirits are weighed into bulk conveyances; or

(2) Spirits are uniformly filled by weight into metal packages.

Production and deposit forms shall be marked "Withdraw on Original Gauge."

(c) *Tax not to be determined on production gauge.* If spirits are drawn from the production system into barrels, drums, or similar portable containers of the same rated capacity and the containers are filled to capacity, and the tax is not to be determined on the basis of the production gauge, the gauge may be made by: (1) Weighing in a tank, converting the weight into proof gallons,

and determining the average content of each container; or

(2) Measuring volumetrically, in a calibrated tank, converting the wine gallons determined into proof gallons, and determining therefrom the average content of each container. However, the regional regulatory administrator may require the use of meters or other measuring devices in lieu of a calibrated tank; or

(3) Converting the rated capacity into proof gallons to determine the average content of each container; or

(4) Determining by a device or method approved under the provisions of paragraph (a) of this section, the total quantity filled into containers, and determining therefrom the average content of each container.

Rated capacity of new cooperage shall be as prescribed by specifications of the manufacturer, or in the case of used cooperage, as determined by the proprietor.

(d) *Records of production gauge.* In computing the production gauge on the basis of average content of packages as provided in paragraph (c) of this section, fractional proof gallons shall be rounded to the nearest one-tenth and the average content so determined shall be used in computing the quantity produced. A separate Form 5110.26 shall be prepared for each lot of packages filled (see § 19.593(b)) and for each removal by pipeline or bulk conveyance for deposit in bond on the same plant premises. Form 5110.26 shall indicate "Deposit in storage" or "Deposit in processing." If spirits are to be transferred in bond, or withdrawn from bond, as authorized by this part, the production gauge shall be made on the form required by this part for the transaction (accompanied by Form 5110.45, if required). Each transaction form and Form 5110.45, if any, shall show:

(1) The real name (or basic operating name as provided in § 19.280) of the producer, and, if the spirits are produced under a trade name, the trade name under which produced.

(2) For each remnant container, the actual proof gallons in the container.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended, 1362, as amended (26 U.S.C. 5204, 5211))

§ 19.320 Identification of spirits.

At the time of production gauge, containers of spirits shall be identified by the proprietor in accordance with Subpart Q of this part. When the proprietor desires to enter spirits into bonded storage for subsequent packaging in wooden packages, he may identify such spirits with the specific designation to which they would be entitled if drawn into wooden packages, followed by the word "Designate", for example, "Bourbon Whisky Designate."

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended, 1360, as amended (26 U.S.C. 5201, 5206))

§ 19.321 Entry.

Pursuant to the production gauge, the proprietor shall make appropriate entry for (a) deposit of the spirits on bonded premises for storage or processing, (b) withdrawal of the spirits on determination of tax, (c) withdrawal of the spirits free of tax, (d) withdrawal of the spirits without payment of tax, or (e) transfer of the spirits for redistillation. Entry for deposit on the bonded premises of the same plant premises shall be made on Form 5110.26. When spirits are entered for deposit on another plant premises or are entered for withdrawal or redistillation, the provisions of Subpart O of this part shall be followed.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1362, as amended (26 U.S.C. 5211))

§ 19.322 Receipts for redistillation.

A proprietor authorized to produce distilled spirits may receive and redistill spirits (including denatured spirits), which: (a) have not been removed from bond; (b) have been withdrawn from bond on payment or determination of tax, and are eligible for return to bond as provided in Subpart U of this part; (c) have been withdrawn from bond free of tax or without payment of tax, and are eligible for return to bond as provided in Subpart U; or (d) have been abandoned to the United States and sold to the proprietor without the payment of internal revenue tax. The proprietor may also receive and redistill recovered denatured spirits and recovered articles returned under the provisions of § 19.703, and articles and spirits residues received under the provisions of § 19.704.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1365, as amended, 1370, as amended (26 U.S.C. 5223, 5243); Sec. 807, Pub. L. 96–39, 93 Stat. 285 (26 U.S.C. 5215))

§ 19.323 Redistillation.

Spirits shall not be redistilled at a proof lower than that prescribed for the class and type at which such spirits were originally produced, unless the redistilled spirits are to be used in wine production, to be used in the manufacture of gin or vodka, or to be designated as alcohol. Different kinds of spirits must be redistilled separately, or with distilling material of the same kind or type as that from which the spirits were originally produced. However, such restriction shall not apply when (a) brandy is redistilled into "spirits-fruit" or "neutral spirits-fruit" (not for use in wine production), (b) whisky is redistilled into "spirits-grain" or "neutral spirits-grain", (c) spirits originally distilled from different kinds of material are redistilled into "spirits-mixed" or "neutral spirits-mixed", or (d) the spirits are redistilled into alcohol. All spirits redistilled subsequent to production gauge shall be treated the same as if such spirits had been originally produced by the redistiller and all provisions of this part and 26 U.S.C. Chapter 51 (including liability for tax attaching to spirits at the time of production) applicable to the original production of spirits shall be applicable thereto, except that spirits recovered by redistillation of denatured spirits, articles, or spirits residues may not be withdrawn from bonded premises except for industrial use or after denaturation thereof. Any redistillation of spirits, unless accomplished pursuant to § 19.383 shall be done as a production operation by a person qualified as a distiller. Nothing in this section shall be construed as affecting any provision of this chapter or of 27 CFR Part 5 relating to the labeling of distilled spirits.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1365, as amended (26 U.S.C. 5223))

§ 19.324 Losses in production.

The distiller shall report any unusual loss of distilling material or spirits in the production facilities to the area supervisor as soon as practical after discovery of the loss. The regional regulatory administrator may require the distiller to submit proof as to the cause of such loss and, where deemed necessary, to file a claim for remission of tax, as provided in Subpart C of this part. In every case where it appears that the loss was by theft, the burden shall be on the proprietor to establish to the satisfaction of the regional regulatory administrator that such theft did not occur as a result of connivance, collusion, fraud, or negligence on his part or on the part of any of his employees or agents.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1323, as amended (26 U.S.C. 5008))

§ 19.325 Distillates containing extraneous substances.

(a) *Use in production.* Distillates containing substantial quantities of fusel oil, aldehydes, or other extraneous substances may be removed from the distilling system prior to the production gauge for addition to fermenting or distilling material at the distillery where produced. Distillates removed from the distilling system under the provisions of

this paragraph shall be added promptly to the fermenting or distilling material.

(b) *Use at bonded wine cellar.* Distillates containing aldehydes may be removed, without payment of tax, to an adjacent bonded wine cellar for use therein for fermentation of wine to be used as distilling material at the distilled spirits plant from which the distillates were removed. The gauge and removal of distillates to an adjacent bonded wine cellar shall be in accordance with the applicable provisions of Subpart O of this part relating to withdrawal of wine spirits for use in wine production and the receipt and use of such distillates at an adjacent bonded wine cellar shall be in accordance with the provisions of 27 CFR Part 240.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended, 1365, as amended, 1382, as amended (26 U.S.C. 5201, 5222, 5273))

Chemical By products

§ 19.326 Spirits content of chemicals produced.

All chemicals produced, including chemical by-products of the spirits production system, shall be substantially free of spirits before being transferred to tanks or removed from the bonded premises of the distilled spirits plant. Except as authorized by the Director, the spirits content of such chemicals shall not exceed 10 percent by volume. Proprietors will test chemicals for spirits content in accordance with methods approved by the Director. Records of the tests will be maintained as prescribed by Subpart W.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

§ 19.327 Disposition of chemicals.

Chemical by-products of the spirits production system may be removed from the plant premises by pipeline or in such containers as the proprietor may desire. The quantities of such chemicals removed from the plant premises shall be determined by the proprietor and records of removals maintained as prescribed by Subpart W. Packages of such chemicals shall be appropriately marked by the proprietor to show the nature of the contents. Products to be removed shall be subject to such sampling by ATF officers as may be deemed necessary.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended, 1365, as amended (26 U.S.C. 5201, 5222))

§ 19.328 Wash water.

Water used in washing chemicals to remove spirits therefrom may be run into a wash tank or a distilling material tank, or otherwise properly destroyed or disposed of on the premises.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1323, as amended, 1356, as amended (26 U.S.C. 5008, 5201))

Inventories

§ 19.329 Inventories.

Each distiller shall take a physical inventory of the spirits and denatured spirits in tanks and other vessels at the close of each calendar quarter. The inventory shall differentiate between spirits and denatured spirits received for redistillation and other spirits.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

Subpart K—Storage

§ 19.341 General.

Proprietors who are qualified as warehousemen as provided in this part, and who have otherwise complied with the requirements of this part for the storage of bulk distilled spirits and wines, may conduct such operations pursuant to the provisions of this part. Proprietors shall not conduct storage operations except as provided in this part.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

§ 19.342 Receipt and storage of bulk spirits and wines.

(a) *Deposit.* All spirits entered for deposit in storage after production as provided in Subpart J shall be deposited on the bonded premises designated in the entry for deposit. Spirits withdrawn from customs custody without payment of tax under the provisions of this part shall be received on the bonded premises to which so withdrawn and (unless to be immediately redistilled) shall be deposited on such premises. Spirits transferred in bond as provided in Subpart O shall be deposited on the bonded premises designated on the transfer form.

(b) *Tanks.* If spirits or wines are being deposited in a partially filled tank in storage on bonded premises, simultaneous withdrawals may not be made therefrom unless the flow of spirits or wines into and out of the tank is being measured by meters or other devices approved by the Director which permit a determination of the quantity being deposited and the quantity being removed. Proprietors shall maintain Form 5110.29 in accordance with the instructions on the form, for each tank in which spirits of less than 190 degrees of proof or wines are stored.

(c) *Storage.* Spirits or wines may be stored on bonded premises in tanks or portable bulk containers into which spirits or wines may be filled on bonded premises. Containers used for such storage shall be so stored that they can be readily inspected or inventoried by ATF officers. The provisions of § 19.133 are applicable to storage of bulk spirits or wines in portable containers. However, on application submitted to, and approval by, the regional regulatory administrator, the proprietor may be authorized to store packages in any manner which adequately safeguards the interests of the Government.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended, 1362, as amended, 1366, as amended, 1398, as amended (26 U.S.C. 5201, 5211, 5212, 5232, 5601); sec. 806(a), Pub. L. 96–39, 93 Stat. 279 (26 U.S.C. 5202); sec. 807 (a), Pub. L. 96–39, 93 Stat. 286 (26 U.S.C. 5231))

§ 19.343 Addition of oak chips to spirits and addition of caramel to brandy and rum.

Oak chips which have not been treated with any chemical may be added to packages either prior to or after filling; if added prior to gauge for withdrawal from storage notation shall be made on the deposit form and, if transferred, on the transfer form. Caramel possessing no material sweetening properties may be added to rum or commercial brandy in packages or tanks.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

Filling and Changing Packages

§ 19.344 Filling of packages from tanks.

Spirits or wines may be drawn into packages from storage tanks on bonded premises. The spirits or wines in the tank shall be gauged prior to filling of packages, and when only a portion of the contents of the tank is packaged, the spirits or wines remaining in the tank shall be again gauged and such gauges shall be recorded by the proprietor in the records required by § 19.760. The provisions of § 19.319 regarding the filling of packages, the taking of production gauge of packages, and the preparation of gauge reports shall be applicable to the filling and gauging of packages of spirits under this section.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

§ 19.345 Change of packages.

Spirits or wines in storage may be transferred from one package to another. Except in the case of spirits of 190 degrees or more of proof, each new package shall contain spirits from only one package. Packages shall be marked and branded as provided in Subpart Q of this part. The proprietor shall note the record covering the deposit of the spirits in bond to show the proof gallons contained in each new package. In the

case of wines, each package shall bear the same marks as the package from which the wine was transferred.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

Mingling of Blending or Spirits

§ 19.346 Mingling or blending of spirits for further storage.

The following mingling or blending operations are permissible in the storage account of a warehouseman:

(a) *Mingling of spirits distilled at 190 degrees or more of proof.* Spirits distilled at 190 degrees or more of proof, whether or not subsequently reduced, may be mingled in storage.

(b) *Mingling of spirits distilled at less than 190 degrees of proof.* Spirits distilled at less than 190 degrees of proof may be mingled for withdrawal or further storage if—

(1) In the case of dometic spirits:

(i) Such spirits are of the same kind; and

(ii) Such spirits were produced by the same proprietor (under his own or any trade name) at the same distillery.

(2) In the case of imported spirits:

(i) Such spirits are of the same kind;

(ii) Such spirits were produced by the same proprietor at the same foreign distillery; and

(iii) Such spirits were treated, blended, or compounded at the same foreign plant by the same person, and the duty was paid at the same rate.

(c) *Permissible blending of beverage rums or brandies.* Fruit brandies distilled from the same kind of fruit at not more than 170 degrees of proof may, for the sole purpose of perfecting such brandies according to commercial standards, be blended with each other, or with any blend of such fruit brandies in storage. Rums may, for the sole purpose of perfecting them according to commercial standards, be blended with each other, or with any blend of rums.

(d) *Packaging of mingled spirits or blended rums and brandies.* Packaging after mingling or blending shall be conducted under the provisions of § 19.344. If so desired, the mingled or blended spirits may be returned to the packages from which they were dumped for mingling or blending, or as many of such packages as are necessary.

(Sec. 201, Pub L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

§ 19.347 Packages dumped for mingling or blending.

When dumping packages of spirits of less than 190 degrees of proof in storage for mingling or blending, the proprietor shall record such mingling or blending on Form 5110.29 in accordance with the instructions on the form. When packages of spirits of 190 degrees or more of proof are to be mingled, the proprietor shall prepare Form 5110.26 to reflect the dumping of the packages for mingling and, when applicable, the repackaging, of the spirits. Each package of spirits to be mingled or blended under this subpart shall be examined by the proprietor, and if any package bears evidence of loss due to theft or unauthorized voluntary destruction, such package shall not be dumped until the area supervisor has been notified and releases the package. Each disposition of spirits of less than 190 degrees of proof from a tank shall be recorded on Form 5110.29 as it occurs.

(Sec. 201, Pub. L. 85–859, 72 Stat 1356, as amended (26 U.S.C. 5201))

§ 19.348 Determining age of mingled or blended spirits or date of fill for imported spirits.

(a) *Age.* When spirits are mingled or blended in accordance with § 19.346 (b) or (c), the age of the spirits for the entire lot shall be the age of the youngest spirits contained in the lot. Age shall be stated in years, months and days.

(b) *Date of fill for imported spirits.* For purposes of this part, the date of fill for spirits imported in packages shall be the date of release from customs custody.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201); Sec. 807, Pub. L. 96–39 (26 U.S.C. 5207))

§ 19.349 Mingled or blended spirits or wines held in tanks.

When spirits of less than 190 degrees of proof or wines are mingled or blended in a tank, the proprietor shall gauge the spirits or wines in the tank and record the mingling gauge on Form 5110.29.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

§ 19.350 Transfer, withdrawal, or movement between accounts.

Spirits mingled or blended under the provisions of § 19.346 may be transferred in bond, moved between accounts or withdrawn from bond for any purpose for which the spirits could have been withdrawn before mingling or blending. Transfer forms, except as to spirits mingled under § 19.346(a) shall be noted to show the age of the spirits after mingling, determined as provided in § 19.348.

(Sec. 201, Pub. L. 85–859, 72 Stat 1356, as amended 1362, as amended (26 U.S.C. 5201, 5212))

Inventories

§ 19.353 Inventories.

Each warehouseman shall take a physical inventory of all spirits and wines in storage tanks and other vessels (except packages) at the close of each calendar quarter and at such other times as the regional regulatory administrator may require. The inventory shall separately identify spirits and wines. The results of the inventory shall be recorded in accordance with Subpart W of this part.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

Subpart L—Processing Operations Other Than Denaturation and Manufacture of Articles

§ 19.371 General.

Proprietors, who are qualified as processors as provided in this part, shall conduct operations relating to the manufacture, treatment, mixing or bottling of distilled spirits on bonded premises pursuant to the provisions of this subpart. Proprietors, who conduct operations relating to the denaturation of spirits or the manufacture of articles on bonded premises, pursuant to the provisions of Subpart M of this part, shall be qualified as processors.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

Receipt of Spirits and Wines

§ 19.376 Receipt of spirits and wines for processing.

(a) Proprietors may receive into the processing account—

(1) Bulk spirits (i) from the production or storage account at the same plant, (ii) by transfer in bond from another distilled spirits plant, or (iii) on withdrawal from customs custody under 26 U.S.C. 5232;

(2) Wines (i) from the storage account at the same plant, or (ii) by transfer in bond from a bonded wine cellar or another distilled spirits plant;

(3) Spirits returned to bond under the provisions of 26 U.S.C. 5215; or

(4) Nonbeverage products manufactured under 26 U.S.C. 5131–5134.

(b) Spirits and wines received in bulk containers shall be recorded as dumped on receipt, but may be retained in the containers in which received until used. Spirits and wines received by pipeline or in bulk conveyances shall be deposited in tanks, gauged by the proprietor, and recorded as dumped. Alcoholic flavoring materials may be retained in the containers in which received or may be transferred to another container if the proprietor marks or otherwise indicates thereon,

the full identification of the original container, the date of receipt, and the quantity deposited. Alcoholic flavoring materials and nonalcoholic ingredients shall be considered dumped when mixed with spirits or wines. The proof gallon content of spirits, wines, and alcoholic flavoring materials shall be determined at the time of dumping.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

§ 19.377 Receipt of Puerto Rican and Virgin Islands spirits.

Proprietors shall maintain a separate accounting in proof gallons of Puerto Rican or Virgin Islands spirits received in the processing account for nonindustrial use, showing spirits from the storage account of the same or another plant or from customs custody. Each month proprietors shall determine the percentage of overall monthly processing gains or losses of nonindustrial spirits. The proof gallons of Puerto Rican or Virgin Islands spirits received in processing during any month shall be adjusted by the percentage of overall gains or losses for the month. Proprietors shall file monthly reports on Form 5110.28 showing separately the adjusted proof gallons of Puerto Rican rum, other Puerto Rican spirits, and Virgin Islands spirits received in processing as provided in § 19.786.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1394, as amended (26 U.S.C. 5555))

§ 19.378 Tank record of alcoholic flavoring materials.

When alcoholic flavoring materials are deposited in a tank for storage prior to dumping, the proprietor shall prepare a tank record showing the consignor, the date and quantity received, and the name of the product. The proprietor shall enter on such record the date and quantity of each removal from the tank and each loss ascertained to have occurred therefrom.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

§ 19.379 Containers bearing evidence of theft or unusual loss.

The proprietor shall inspect containers of spirits or wines at the time of their receipt for processing. If the proprietor finds evidence of unusual loss or loss due to theft, he shall promptly report the matter to the area supervisor and hold the container pending the area supervisor's advice as to its disposition. If the proprietor finds that any container is missing from the shipment, he shall promptly report such fact to the area supervisor.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1323, as amended, 1356, as amended (26 U.S.C. 5008, 5201))

Use of Alcoholic Ingredients

§ 19.381 Record of use.

(a) *Dump record.* When spirits, wines, and alcoholic flavoring materials are dumped for use in the manufacture of a distilled spirits product, and spirits are to be removed by pipeline or bulk conveyance, the proprietor shall prepare a dump record.

(b) *Batch record.* Proprietors shall prepare a batch record to report—

(1) The dumping of spirits which are to be used immediately and in their entirety in preparing a batch of a product manufactured under an approved formula;

(2) The use of spirits or wines previously dumped, reported on dump records and retained in tanks or receptacles; and

(3) Any combination of ingredients in paragraphs (b) (1) and (2) of this section used in preparing a batch of a product manufactured under an approved formula. Batch records shall be annotated to separately identify alcoholic flavoring materials.

(c) *Format of dump/batch records.* Proprietor's dump/batch records shall contain, as applicable, the following—

(1) Serial number;

(2) Name and distilled spirits plant number of the processor;

(3) Kind of spirits used, with a notation to indicate treatment with oak chips, addition of caramel, imported spirits, and spirits from Puerto Rico and the Virgin Islands;

(4) Serial number of tank or container to which ingredients are added for use;

(5) Serial or identification number of tank or container from which spirits are removed;

(6) Quantity of each alcoholic ingredient used, identifying any alcoholic flavoring materials;

(7) Serial number of source transaction record (e.g., record covering spirits previously dumped);

(8) Date of each transaction;

(9) Quantity, by ingredient, of nonalcoholic ingredients used;

(10) Formula number;

(11) Quantity of ingredients used in the batch that have been previously dumped, reported on dump records, and retained in processing;

(12) Total quantity of all ingredients used;

(13) Identification of each form or record to which spirits are transferred;

(14) Quantity in each lot transferred;

(15) Date of each transfer;

(16) Total quantity transferred; and

(17) Gain or loss.

(Sec. 807, Pub. L. 96–39, 92 Stat. 284 (26 U.S.C. 5207))

§ 19.382 Manufacture of nonbeverage or intermediate products.

Spirits and wines may be used for the manufacture of flavors or flavoring extracts as intermediate products to be used exclusively in the manufacture of other distilled spirits products on bonded premises. Nonbeverage products (alcoholic flavoring materials) on which drawback under 26 U.S.C. 5131–5134 is to be claimed may not be manufactured on bonded premises. Premises used for the manufacture of nonbeverage products eligible for drawback shall be completely separated from any contiguous bonded premises.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

§ 19.383 Production of gin or vodka in processing.

The production of gin or vodka by other than original and continuous distillation is a processing operation. Such production requires an approved formula on Form 5110.38. Formulas on Form 5110.38 shall be filed as required by Part 5 of this chapter.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

Bottling, Packaging, and Removal of Products

§ 19.391 Removals from processing.

Spirits shall not be transferred from processing to the storage account. Processors may remove—

(a) Spirits upon tax determination or withdrawal under the provisions of 26 U.S.C. 5214 or 26 U.S.C. 7510;

(b) Spirits to the production account at the same plant for redistillation;

(c) Bulk spirits by transfer in bond to the production or the processing account at another distilled spirits plant for redistillation or further processing;

(d) Spirits or wines for authorized voluntary destruction; or

(e) Wines by transfer in bond to a bonded wine cellar or to another distilled spirits plant. Spirits may be bottled and cased for removal. Spirits and wines may be removed in any approved bulk container, by pipeline or in bulk conveyances on compliance with the provisions of this part.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1314, as amended, 1320, as amended, 1323, as amended, 1356, as amended, 1360, as amended, 1362, as amended, 1365, as amended, 1380, as amended (26 U.S.C. 5001, 5006, 5008, 5201, 5206, 5212, 5214, 5223, 5362))

§ 19.392 Bottling tanks.

All spirits shall be bottled from tanks certified as being accurately calibrated

and suitable for the intended purpose. However, the regional regulatory administrator may authorize bottling from original packages or special containers where it is impracticable to use a bottling tank. Bottlers desiring to bottle from packages or special containers shall make application to the regional regulatory administrator under Subpart D. The application shall show the necessity for the operation.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

§ 19.393 Bottling tank gauge.

When distilled spirits products are to be bottled or packaged, the proprietor shall make an actual gauge of the product, on completion of any filtering, reduction, or other treatment, and prior to commencement of bottling or packaging. Any gauge made under this section shall be made at bottling proof in the tank from which the product is to be bottled or packaged, and the details of the gauge shall be entered on the bottling record prescribed in § 19.394.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

§ 19.394 Bottling record.

Each proprietor shall maintain a record for each lot of spirits bottled or packaged. This record shall contain the following information:

(a) Tank number(s);

(b) Serial number of the record (beginning with "1" each January 1);

(c) Formula number (if any) of the lot;

(d) Serial number of the dump/batch record;

(e) Kind of product (including age, if claimed);

(f) Details of the tank gauge (including proof, wine gallons, proof gallons, and, if applicable, obscuration);

(g) The date the cases or packages were filled;

(h) The size of the bottles or packages, the number of bottles or containers per case, and the number of cases filled;

(i) The serial numbers of the cases or other containers filled;

(j) The proof of the spirits bottled or packaged (if different from subsection (f));

(k) The total quantity bottled or packaged in wine gallons and proof gallons; and

(l) Gain or loss for each tank.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201); Sec. 807(a), Pub. L. 96–39, 93 Stat. 284 (26 U.S.C. 5207))

§ 19.395 Labels to agree with contents of tanks and containers.

Labels affixed to bottles shall agree in every respect with the spirits in the tanks from which the containers were filled, if they do not the proprietor shall relabel such spirits with a proper label. The proprietor's records shall be such that they will enable ATF officers to readily determine, by case serial number, which label was used on any given filled container.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

§ 19.396 Liquor bottles.

Liquor bottles may be used, but need not be used, in bottling spirits for export. (See Subpart R of this part for provisions respecting liquor bottles.)

(Sec. 201, Pub. L. 85–859, 72 Stat. 1374, as amended (26 U.S.C. 5301))

§ 19.397 Filling of bottles.

(a) *Proof and fill tests.* (1) Proprietors shall test and examine bottles of spirits bottled at frequent intervals during bottling operations to determine whether the spirits contained in such bottles agree in proof and quantity (fill) with that stated on the label or bottle.

(2) If the regional regulatory administrator finds that a proprietor's test procedures do not protect the revenue and insure the label accuracy of the bottled product, he may require corrective measures.

(b) *Variations in proof and fill.* If the contents do not agree with the respective data on the label or bottle as to—

(1) Quantity (fill), except for such variations in measuring as may occur in filling conducted in compliance with good commercial practice with the overall objective of maintaining 100 percent fill for all bottled products; and/or

(2) Proof, subject to a normal drop in proof occurring during bottling operations not to exceed three-tenths of a degree of proof—the proprietor shall rebottle, recondition, or relabel the spirits in such manner that the label will correctly describe the contents.

(c) *Proof and fill test records.* (1) Proprietors shall record the results of all proof and fill tests made.

(2) The daily record shall be maintained in a manner and provide information that will enable ATF officers to determine whether the proprietor—

(i) Monitors filling operations by conducting proof and fill tests, and

(ii) Employs procedures to correct variations in proof and fill described in paragraph (b).

(3) Proof and fill test records shall contain, at a minimum, the following information—

(i) Date and time of test,

(ii) Serial number of bottling record,

(iii) Size of bottle,

(iv) Label proof,

(v) Test proof,

(vi) Percentage of variation from 100 percent fill, and

(vii) Corrective action taken (if any).

(4) Where the content, format and arrangement of the daily records does not comply with the provisions of (c)(2) or (c)(3) of this section, the regional regulatory administrator may require a format or arrangement which will clearly and accurately reflect proof and fill test information.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended, 1394, as amended, 1395, as amended (26 U.S.C. 5201, 5301, 5555); Sec. 807(a), Pub. L. 96–39 (26 U.S.C. 5207))

§ 19.398 Completion of bottling.

When the contents of a bottling tank are not completely bottled at the close of the day, the bottler shall make entries on the bottling record covering the total quantity bottled that day from the tank. Entries shall be made not later than the morning of the following business day unless the bottler maintains auxiliary or supplemental records as provided in § 19.751.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

§ 19.399 Strip stamps or alternative devices.

The proprietor shall affix to each bottle of spirits filled under the provisions of this subpart a red or green strip stamp or approved alternative device. Such stamps shall be procured, overprinted (when required), affixed, and accounted for as provided in Subpart S of this part.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5205))

§ 19.400 Cases.

On completion of bottling, the filled bottles with labels and properly affixed strip stamps or alternative devices shall be placed in cases, and the cases shall be sealed. However, the proprietor may be authorized to retain, on bonded premises, unsealed cases, pending the affixing of brand labels or State stamps, upon approval of written application to the area supervisor. Where the mandatory information required by Part 5 of this chapter appears on the brand label rather than a separate label, the brand label shall be affixed at the time of bottling. Each case of spirits filled shall be marked as prescribed by Subpart Q of this part before removal from such premises.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended, 1360, as amended (26 U.S.C. 5201, 5206))

§ 19.401 Remnants.

Where on completion of bottling there remain bottles less than the number necessary to fill a case, the bottles, after being stamped or affixed with alternative devices and labeled, may be marked as a remnant case as provided in Subpart Q of this part or kept uncased on the bonded premises until spirits of the same kind are again bottled. Appropriate notation shall be made on the bottling record to cover the bottling and disposition of the remnant. If the remnant is subsequently used to complete the filling of a case, an accounting shall be made on the subsequent bottling record showing the use of the remnant by adding the remnant gallonage to the quantity to be accounted for, together with an appropriate notation explaining the transactions.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended, 1360, as amended (26 U.S.C. 5201, 5206))

§ 19.402 Filling packages.

Spirits may be drawn into packages from a tank (conforming to the requirements of § 19.273). Such packages shall be gauged by the proprietor, and he shall report the details of such gauge on Form 5110.45 and attach a copy of Form 5110.45 to each copy of the bottling tank record covering the product. Such packages shall be marked as prescribed by Subpart Q of this part.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

§ 19.403 Removals in bulk.

Where spirits in processing are to be removed in bulk conveyances or by pipeline, the proprietor shall record the filling of the conveyance or the transfer by pipeline on the bottling record. The spirits shall be removed from bonded premises in accordance with Subpart O of this part. The consignor shall forward to the consignee a statement of composition or a copy of any formula under which such spirits were processed for determining the proper use of the spirits, or for the labeling of the finished product. Bulk conveyances shall be marked as provided in Subpart Q of this part, and distilled spirits stamps, if required, shall be affixed to the conveyances as provided in Subpart S of this part.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

§ 19.404 Rebottling.

When the spirits are dumped, bottlers desiring to rebottle distilled spirits shall prepare a bottling record, appropriately modified. If the spirits were originally bottled by another bottler, a statement from the original bottler consenting to the rebottling must be secured by the proprietor. When the spirits are rebottled, the strip stamps or alternative devices on the original bottles shall be destroyed and new strip stamps or alternative devices used. Liquor bottles used for rebottling shall comply with the provisions of Subpart R of this part. Bottlers shall have a certificate of label approval or certificate of exemption from label approval issued under 27 CFR Parts for labels used on rebottled spirits.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201); Sec. 807, Pub. L. 96–39, 93 Stat. 280 (26 U.S.C. 5215))

§ 19.405 Restamping, reaffixing alternative devices and relabeling.

The proprietor may restamp, reaffix alternative devices, or relabel distilled spirits, either before removal from bonded premises or after return thereto. Spirits returned to bonded premises for restamping, reaffixing of alternative devices, or relabeling must be promptly removed from bonded premises after such operation has been completed. When spirits were originally bottled by another bottler, the bottler shall have on file a statement from the original bottler consenting to any relabeling. When spirits are relabeled, bottlers shall have a certificate of label approval or certificate of exemption from label approval issued under 27 CFR Part 5 for labels used on relabeled spirits. Daily bottling records shall be prepared by the proprietor to cover the relabeling, restamping or the reaffixing of alternative devices. For spirits returned to bond under 26 U.S.C. 5215(c), the proprietor shall annotate such information on his daily bottling records.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended, 1358, as amended (26 U.S.C. 5201, 5205); Sec. 807 Pub. L. 96–39, 93 Stat. 280 (26 U.S.C. 5215))

§ 19.406 Bottled-in-bond spirits.

Spirits which are to be labeled and stamped as bottled-in-bond for domestic consumption shall meet the eligibility and labeling requirements in 27 CFR Part 5 and shall be stamped as provided in Subpart S of this part.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

§ 19.407 Labels for export spirits.

All bottles containing spirits bottled for export shall have securely affixed thereto a label showing the following:

(a) Kind of spirits;

(b) Proof of the spirits;

(c) Net contents, unless the markings on the bottle indicate such contents; and

(d) The name (or, if desired, the trade name) of the bottler.

The bottler may place on the label any additional information that he may desire if it is not inconsistent with the required information. The label information may be stated in the language of the country to which the spirits are to be exported provided the proprietor maintains on file an English translation of the information. The net contents and proof may be stated in the units of measurement of the foreign country provided the proprietor maintains a record of the equivalent units as they would be required to be expressed if bottled for domestic consumption. The Director may waive the requirement of showing any of the information required by this section, other than the kind of spirits, upon a showing that the country to which the spirits are to be exported prohibits the showing of such information.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended, 1374, as amended (26 U.S.C. 5201, 5301))

§ 19.408 Spirits removed for shipment to Puerto Rico.

Spirits removed for shipment to Puerto Rico with benefit of drawback or without payment of tax under the provisions of Part 252 of this chapter are subject to the provisions of Part 5 of this chapter in respect of labeling requirements and standards of fill for bottles.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

§ 19.409 Spirits not originally intended for export.

Spirits manufactured, produced, bottled in bottles, packed in containers, or which are packaged in casks or other bulk containers in the United States, originally intended for domestic use may be exported with benefit of drawback or without payment of tax if:

(a) The strip stamp or alternative device affixed to each bottle is legibly overprinted with the word "Export" by means of a rubber stamp or other suitable method; and

(b) Each case, package or other bulk container is marked as required by Part 252 of this chapter. The proprietor may relabel the spirits to show any of the information provided for in § 19.407. Where the proprietor desires to file claim for drawback on spirits prepared for export under this section, the provisions of § 252.195b of this chapter shall be followed. Where the proprietor desires to withdraw spirits without payment of tax, he shall file a notice in accordance with § 252.92 of this chapter.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1336, as amended, 1358, as amended, 1362, as amended (26 U.S.C. 5062, 5205, 5214))

Alcohol

§ 19.410 General.

(a) *Bottled alcohol.* Alcohol of 190 degrees or more of proof may be bottled in containers of 1 gallon or less, or in bottles complying with the provisions of § 19.584; however, the proprietor is required to comply with the provisions of Subpart R of this part where applicable. The proprietor shall prepare dump and batch records and bottling records as provided in this subpart.

(b) *Encased containers.* Containers of alcohol, authorized under § 19.584, which are enclosed in and attached to individual cartons, as provided in § 19.585, shall be filled and recorded as provided in paragraph (a) of this section, but the filled containers are not considered to be bottled alcohol, and are not subject to the provisions of § 19.411 relating to stamps, labels, and marks. The cartons or cases shall be marked in the manner provided in §§ 19.585 and 19.608.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended, 1369, as amended (26 U.S.C. 5201, 5235))

§ 19.411 Stamps, labels, marks and brands.

The proprietor shall affix to each bottle of alcohol filled by him a red strip stamp or alternative device procured and affixed as provided in Subpart S of this part. All bottles of alcohol shall have securely affixed thereto a label showing (a) alcohol and (b) the name, address, and plant number of the bottler. In addition, bottled alcohol to be withdrawn on tax determination shall be labeled in accordance with the provisions of Subpart R of this part or Part 5 of this chapter, as applicable. The proprietor may place on the label any additional information that he may desire if it is not inconsistent with the required information. Each case of bottled alcohol shall bear the marks and brands prescribed therefor by Subpart Q of this part.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended, 1369, as amended (26 U.S.C. 5205, 5235))

Records

§ 19.416 Daily summary record of spirits bottled or packaged.

The proprietor shall maintain a separate daily summary record of spirits bottled or packaged as provided in § 19.769.

(Sec. 807, Pub. L. 96–39, 93 Stat. 283 (26 U.S.C. 5207))

Inventories

§ 19.421 Inventories of wines and bulk spirits (except packages).

Each proprietor shall take a physical inventory of wines and bulk spirits (except packages) in the processing account at the close of each calendar quarter. The results of the inventory shall be recorded in accordance with Subpart W of this part.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

§ 19.422 Inventories of bottled and packaged spirits.

(a) *Physical inventories.* (1) Physical inventories of bottled and packaged spirits shall be taken for the return periods ending June 30 and December 31 of each year, and for other return periods as may be required by the regional regulatory administrator.

(2) On approval of an application filed with the regional regulatory administrator, required physical inventories may be taken on dates other than June 30 and December 31 if the dates established for taking such inventories:

(i) Coincide with the end of a return period, and

(ii) Are approximately six months apart.

(3) On approval of the application, the designated inventory dates shall take effect with the first inventory scheduled to be taken within six months of the previous June 30 or December 31 inventory.

(4) Physical inventories may be taken within a period of a few days before or after June 30 or December 31 (or other dates approved by the regional regulatory administrator), if:

(i) Such period does not include more than one complete weekend; and

(ii) Necessary adjustments are made to reflect pertinent transactions, so that the recorded inventories will agree with the actual quantities of bottled or packaged spirits on hand in processing at the prescribed times.

(b) *Waiver of physical inventory.* (1) The regional regulatory administrator, on receipt of an application, may relieve a proprietor of the requirement of taking the June 30 or December 31 physical inventory, (or other date approved under paragraph (a) of this section) if he finds that only one such inventory during any 24 consecutive return periods is necessary.

(2) The regional regulatory administrator may reimpose the requirement for the waived inventory if he finds that it is necessary for law enforcement or protection of the revenue.

(c) *Notification of physical inventory.* Whenever a physical inventory of bottled or packaged spirits is to be taken, the proprietor shall, at least 5 business days in advance, notify the area supervisor, of the date and time he will take such inventory.

(d) *Supervision of physical inventories.* Physical inventories required under the provisions of this section shall be taken under such supervision, or verified in such manner, as the regional regulatory administrator may require.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

Subpart M—Denaturing Operations and Manufacture of Articles

§ 19.451 General.

Proprietors who are qualified as processors may conduct denaturing operations or manufacture articles pursuant to the provisions of this part. Proprietors shall not conduct denaturing operations or manufacture articles except as provided in this part.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1353, as amended (26 U.S.C. 5178); Sec. 807(a), Pub. L. 96–39, 93 Stat. 286 (26 U.S.C. 5241))

Denaturation

§ 19.452 Formulas.

Spirits authorized under Part 212 of this chapter to be denatured, may be denatured in accordance with formulas prescribed in that part. Denaturing materials shall be thoroughly mixed with the spirits to be denatured.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1369, as amended (26 U.S.C. 5242))

§ 19.453 Testing of denaturants.

(a) *Testing.* Proprietors shall assure that the materials they receive for use in denaturing conform to the specifications prescribed therefor in Part 212 of this chapter. The regional regulatory administrator may require the testing of denaturants at any time.

(b) *Samples.* Samples of denaturants shall be taken in such manner as to represent a true composite of the total lot being sampled. When samples are tested by persons other than a proprietor, a copy of the analysis or a statement, signed by the chemist performing the test, shall be secured and filed by the proprietor for each test. Samples of denaturants may be taken by ATF officers at any time for testing by Government chemists.

(c) *Conformity.* When a denaturant does not conform to the specifications prescribed under Part 212 of this chapter, the proprietor shall not use the material unless he treats or manipulates

the denaturant to make it conform to such specifications. Such treated or manipulated denaturant shall again be tested.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1369, as amended (26 U.S.C. 5242))

§ 19.454 Gauge for denaturation.

(a) The proprietor shall gauge spirits before and after denaturation and record each gauge in a commercial record as prescribed in paragraph (b) of this section. However, spirits dumped from previously gauged containers or spirits transferred directly to mixing tanks from gauge tanks where they were gauged, need not again be gauged. Measurements of spirits and denaturants shall be made by volume, weight, by meter, or, another device when approved by the Director.

(b) The information to be recorded for each gauge shall include the formula number, the tank in which denaturation takes place, the proof gallons of spirits before denaturation, the quantity of each denaturant used (in gallons, or in pounds and ounces), and the wine gallons of denatured spirits produced.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended, (26 U.S.C. 5204); Sec. 807, Pub. L. 96–39, 93 Stat. 286 (26 U.S.C. 5241))

§ 19.455 Dissolving of denaturants.

Denaturants which are difficult to dissolve in alcohol at usual working temperatures, which are highly volatile, or which become solid at such usual temperatures may be liquefied or dissolved in a small quantity of alcohol or water in advance of their use in the production of specially denatured alcohol, pursuant to the prescribed formula, so long as the proof of the denatured spirits manufactured does not fall below the proof prescribed for the applicable formula in Part 212 of this chapter. Any ethyl alcohol used in dissolving denaturants and contained in the resulting solution shall be included as part of the total quantity of alcohol denatured in each batch.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1369, as amended (26 U.S.C. 5242))

§ 19.456 Adding denaturants.

Denaturants and spirits shall be mixed in packages, tanks, or bulk conveyances on bonded premises. The regional regulatory administrator may, on written application, authorize other methods of mixing denaturants and spirits if he deems such denaturation will not hinder effective administration of this part or jeopardize the revenue. If requested by the regional regulatory administrator, the proprietor shall submit a flow diagram of the intended process or method of adding denaturants.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1369, as amended (26 U.S.C. 5242))

§ 19.457 Restoration and redenaturation of recovered denatured spirits and recovered articles.

Recovered denatured spirits and recovered articles received on bonded premises, as provided in Subpart U of this part, for restoration (including redistillation, if necessary) and/or redenaturation may not be withdrawn from bonded premises except for industrial use or after denaturation thereof. If the recovered or restored denatured spirits or recovered articles are to be redenatured and do not require the full amount of denaturants for redenaturation, a notation to that effect will be made on the record required by § 19.454.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1369, as amended (26 U.S.C. 5242))

§ 19.458 Mixing of denatured spirits.

(a) Denatured spirits produced under the same formula may be mixed on bonded premises.

(b) Denatured spirits may be mixed on bonded premises for immediate redistillation at the same plant or at another plant in accordance with the provisions of §§ 19.322 and 19.323. If such denatured spirits are to be redistilled at another plant, the transfer form shall show that the spirits are for redistillation.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1369, as amended (26 U.S.C. 5242); Sec. 807, Pub. L. 96–39, 93 Stat. 286 (26 U.S.C. 5241))

§ 19.459 Conversion of specially denatured alcohol.

(a) *Conversion to Formula No. 1.* Any specially denatured alcohol, except Formulas No. 3–A and No. 30, may be converted into specially denatured alcohol, Formula No. 1, by the addition of methyl alcohol and denatonium benzoate, N.F. (Bitrex) or methyl isobutyl ketone in accordance with the formulations prescribed in § 212.16 of this chapter. For specially denatured alcohol Formulas No. 3–A and No. 30, the methyl alcohol content shall be reduced to the level prescribed for specially denatured alcohol Formula No. 1 by the addition of ethyl alcohol before adding the other ingredient prescribed in § 212.16 of this chapter.

(b) *Conversion to Formula No. 29.* Any specially denatured alcohol may be converted to specially denatured alcohol, Formula No. 29, by the addition of acetaldehyde or ethyl acetate, in accordance with the formulations prescribed in § 212.39(a) of this chapter.

(c) *Conditions governing conversion and use.* The quantities of denaturants required for conversions authorized in paragraphs (a) and (b) of this section shall be determined on the basis of the alcohol in the formulations. Specially denatured alcohol resulting from such conversions shall be manufactured into articles or used in processes by the proprietor who converted it, or by his controlled or wholly owned subsidiaries (as defined in § 19.242), unless the Director authorizes its use by another manufacturer or user (as defined in Part 211 of this chapter). Specially denatured alcohol converted to Formula No. 29 may be used as authorized in § 212.39(b) of this chapter except that it shall not be used in the manufacture of vinegar, drugs, or medicinal chemicals, and the conditions governing use provided in § 212.39(c) of this chapter shall apply.

(d) *Conversion to completely denatured alcohol.* Any specially denatured alcohol not containing methanol or wood alcohol may be converted to any one of the completely denatured alcohol formulas, prescribed in Part 212 of this chapter, by adding the required denaturants.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1369, as amended (26 U.S.C. 5242))

§ 19.460 Receipt and storage of denatured spirits.

(a) *Deposit.* Denatured spirits produced, received in bond as provided in Subpart O or returned to bonded premises as provided in Subpart U of this part, shall be deposited on the bonded premises.

(b) *Tanks.* If denatured spirits are being deposited in a partially filled tank on bonded premises, simultaneous withdrawals may not be made therefrom unless the flow of denatured spirits both into and out of the tank is being measured by meters, or other devices approved by the Director, which permit a determination of the quantity being deposited and the quantity being removed. Proprietors shall maintain a record in accordance with § 19.770 for tanks in which denatured spirits are stored.

(c) *Storage.* Denatured spirits may be stored on bonded premises in any container into which denatured spirits may be filled on bonded premises. Such containers shall be so stored that they can be readily inspected by ATF officers and inventoried. The provisions of § 19.133 are applicable to storage of denatured spirits in portable containers. However, upon application, the regional regulatory administrator may authorize the proprietor to store packages and cases in any manner which safeguards the interests of the Government.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

§ 19.461 Filling of packages from tanks.

Denatured spirits may be drawn into packages from tanks on bonded premises. The denatured spirits in the tanks shall be gauged prior to filling of packages, and when only a portion of the contents of the tank is packaged, the denatured spirits remaining in the tank shall be again gauged and such gauges shall be recorded by the proprietor. The provisions of § 19.319 shall be applicable to the filling and gauging of packages under this section.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

§ 19.462 Containers for denatured spirits.

Packaging of denatured spirits and the marking of packages of such denatured spirits shall be in accordance with requirements of Subpart Q of this part.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended (26 U.S.C. 5206))

Inventories

§ 19.463 Inventories.

Each proprietor shall take a physical inventory of all denatured spirits on bonded premises at the close of each calendar quarter or at such other times as the regional regulatory administrator may require. The results of the inventory shall be recorded as provided in Subpart W of this part.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

Articles

§ 19.471 Manufacture of articles.

Proprietors use of denatured spirits in the manufacture, formulation, labeling, marking, and distribution of articles, shall be as provided in Part 211 of this chapter.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1372, as amended (26 U.S.C. 5273))

Subpart N—Importation

Spirits Imported Into the United States

§ 19.481 Importation of spirits.

The proprietor may withdraw from customs custody, without payment of the tax imposed on imported spirits by 26 U.S.C. 5001, imported spirits in bulk containers and transfer such spirits to his bonded premises in such bulk containers or by pipeline. A proprietor intending to receive imported spirits from customs custody shall obtain an approved application, Form 5100.16, in the manner provided in § 251.172 of this chapter. Imported spirits transferred to bonded premises, as provided in this section, (a) may be redistilled or denatured only if of 185 degrees or more of proof, and (b) may be withdrawn for any purpose authorized by 26 U.S.C. Chapter 51, in the same manner as domestic spirits. Imported spirits shall be kept separate at the bonded premises and shall not be mixed with domestic spirits or with other imported spirits, except as follows: imported spirits (1) may, if of 185 degrees or more of proof, be mingled with domestic spirits or with other such imported spirits if the mingled spirits are to be immediately denatured, (2) may, if eligible under § 19.346 be mingled with other imported spirits similarly eligible which have been duty paid at the same rate, and (3) may, if imported as beverage spirits, be mixed with other spirits in processing in accordance with Subpart L of this part or in storage in accordance with Subpart K of this part. Imported spirits shall not be filled into packages, or subjected to treatment, which would modify the taste, aroma, or other characteristics generally attributed to that class and type of spirits. The provisions of this section with respect to the separation from other spirits and of §§ 19.482 and 19.483 are applicable to imported spirits received on bonded premises under this section, whether or not redistilled. Imported spirits to be redistilled shall be appropriately identified on Form 5110.26

(Sec. 201, Pub. L. 85–859, 72 Stat. 1366, as amended (26 U.S.C. 5232))

§ 19.482 Transfers and withdrawals of imported spirits.

Imported spirits transferred to ATF bond under 26 U.S.C. 5232, may, under the provisions of Subpart O of this part, be transferred in bond or withdrawn from bond for any purpose authorized by 26 U.S.C. Chapter 51, in the same manner as domestic distilled spirits. The rates of duty specified by the customs officer at the time of release from customs custody shall be shown on transaction forms and records, which shall also be marked with the designation "IMPORTED" (see § 251.173 of this chapter).

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended, 1366, as amended (26 U.S.C. 5201, 5232))

§ 19.483 Markings for containers of imported spirits.

Each portable bulk container of imported spirits shall, when received on bonded premises under the provisions of § 19.481, or when filled on bonded premises, be marked with:

(a) The name of the importer;

(b) The country of origin;

(c) The kind of spirits;

(d) The package serial number;

(e) The date of release from customs custody, or if filled in ATF bond, the date of fill;

(f) The proof; and

(g) The proof gallons of spirits in the package. Packages of imported spirits received from customs custody or filled from tanks on bonded premises shall be assigned package identification numbers as provided in § 19.593. Such numbers shall be preceded by the symbol "IMP" and any distinguishing prefix of suffix used as provided in § 19594. The proprietor who files Form 5100.16 to receive packages of imported spirits under the provisions of § 19.481 shall be responsible for having the required marks placed on such packages. Package identification numbers assigned under the provisions of this section to packages of spirits received from customs custody shall be recorded on the deposit forms or records by the proprietor who filed the Form 5100.16 to receive the spirits.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended (26 U.S.C. 5206))

§ 19.484 Exceptions to specifications for package marking requirements.

The package marks prescribed by § 19.483 shall be placed on each package of imported spirits received from customs custody in the manner required by § 19.595, except that, proprietors are relieved from placing prescribed marks on such packages where the packages will be dumped within 30 days of the date of receipt at such distilled spirits plant. Packages not dumped as provided in this paragraph within the time prescribed must be promptly marked in the manner required by § 19.595. The provisions of this section shall not be construed to waive, or authorize the waiver of, the requirements of this part for the assigning of package identification numbers or for the recording of such package identification numbers on deposit forms or records, and the required recording of lot identification numbers and related information on other transaction forms, records, or reports.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended (26 U.S.C. 5206))

§ 19.485 Recording gauge.

At the time of receipt into ATF bond of packages of imported spirits, the proprietor shall use the last official gauge to compute and record on deposit forms or records for each entry the average content of the packages being received, in the manner provided for package summary accounts in § 19.761. If the last official gauge indicates a substantial variation in the contents of the packages, the proprietor shall group

the packages into lots according to their approximate contents, and assign a separate lot identification to each group of packages, based on the date the packages were received on bonded premises.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended (26 U.S.C. 5206))

Deposit, Storage, Transfer, and Withdrawal of Puerto Rican and Virgin Islands Spirits

§ 19.486 Transaction forms and records.

Deposit, transfer, and withdrawal forms, and records pertaining to spirits transferred to ATF bond from Puerto Rico or the Virgin Islands shall be marked to show that the spirits are from Puerto Rico or the Virgin Islands. Separate records shall be maintained for Puerto Rican or Virgin Islands spirits in the same manner as for imported spirits, except that the record of deposits and the summary of deposits and withdrawals, Form 5110.37, shall be arranged alphabetically by name of producer in Puerto Rico or the Virgin Islands.

(Sec. 807, Pub. L. 96–39, 93 Stat. 284 (26 U.S.C. 5207))

§ 19.487 Marks on containers.

(a) *Packages received in bond.* (1) When packages of Puerto Rican spirits are received on the bonded premises of a distilled spirits plant under the provisions of this subpart, the markings prescribed by § 250.40 of this chapter, modified to show the serial number of the Form 4776 prefixed by "Form 4776", rather than the serial number and identification of the Form 487–B, shall be accepted in lieu of the markings prescribed in § 19.483. On receipt of packages so marked the proprietor of the distilled spirits plant shall show on such packages the date of entry for deposit of the spirits, and the words "PUERTO RICAN" or the abbreviation "P.R.".

(2) When packages of Virgin Islands spirits are received on the bonded premises of a distilled spirits plant under the provisions of this subpart, the markings prescribed by § 250.206 of this chapter that are on such packages shall be accepted in lieu of the markings prescribed in § 19.483. On receipt of packages so marked the proprietor of the distilled spirits plant shall show on such packages the date of entry for deposit of the spirits and the words "VIRGIN ISLANDS" or the abbreviation "V.I."

(b) *Portable bulk containers.* Portable bulk containers of Puerto Rican or Virgin Islands spirits filled in ATF bond shall, in addition to the required marks prescribed in § 19.596, be marked to show the serial number of the approved formula under which produced, and with the words "PUERTO RICAN" or "VIRGIN ISLANDS" or the abbreviation thereof. Portable bulk containers containing spirits received in ATF bond under the provisions of this subpart shall, in addition to other required marks, be marked with the words "PUERTO RICAN" or "VIRGIN ISLANDS" or the abbreviation thereof.

(c) *Cases of bottled alcohol.* In addition to other mandatory marks prescribed by § 19.608 for cases of bottled alcohol, the words "PUERTO RICAN" or "VIRGIN ISLANDS", as appropriate, or the abbreviation "P.R." or "V.I." shall precede or follow the word "alcohol" on cases of alcohol from Puerto Rico or the Virgin Islands that are bottled and cased on bonded premises.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended, 1369, as amended (26 U.S.C. 5206, 5235))

§ 19.488 Additional tax on nonbeverage spirits.

The additional tax imposed by 26 U.S.C. 5001(a)(9), on imported spirits withdrawn from customs custody without payment of tax and thereafter withdrawn from bonded premises for beverage purposes, and the related provisions of § 19.517, are not applicable to Puerto Rican or Virgin Islands spirits brought into the United States and transferred to bonded premises under the provisions of this part.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

Miscellaneous Provisions

§ 19.489 Abatement, remission, credit, or refund.

The provisions of 26 U.S.C. 5008, authorizing abatement, remission, credit and refund for loss or destruction of distilled spirits, shall apply to spirits brought into the United States from Puerto Rico or the Virgin Islands, with respect to the following:

(a) Spirits lost while in ATF bond;

(b) Voluntary destruction of spirits in bond;

(c) Spirits returned to bonded premises; and

(d) Spirits returned to bonded premises after withdrawal upon tax determination.

Claims relating to spirits lost in bond, in addition to the information required by § 19.41 of this chapter, shall show the name of the producer, and the serial number and date of the Form 5110.38 (Form 27–B Supplemental), where required, under which produced.

(Sec. 201, Pub. L. 95–859, 72 Stat. 1323, as amended (26 U.S.C. 5008); Sec. 807, Pub. L. 96–39, 93 Stat. 285 (26 -U.S.C. 5215))

General

§ 19.501 Authority to withdraw

Spirits (including denatured spirits) and wines shall be removed from bonded premises only as provided in this subpart. Spirits entered into bonded storage for subsequent packaging in wooden packages, as provided in § 19.320, which have not been drawn into such packages at the time of withdrawal from bond shall be redesignated to conform to the classes and types set out in Subpart Q of this part and in Part 5 of this chapter.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended 1362, as amended (26 -U.S.C. 5201, 5212, 5214); Sec. 807(a), Pub. L. 96–39, 93 Stat. 285 (26 26 U.S.C. 5213))

§ 19.502 Examination of containers.

Each bulk container of spirits (including denatured spirits) or wine to be removed from bonded premises, or to be dumped on bonded premises, shall be examined by the proprietor. If any bulk container bears evidence of loss due to theft or unauthorized voluntary destruction, or loss in excess of normal storage losses, such container shall not be removed or dumped until the area supervisor has been notified and releases such container.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1323, as amended, 1381, as amended (26 -U.S.C. 5008, 5370))

§ 19.503 Withdrawal of spirits on original gauge.

When the filling or production gauge is made under the provisions of § 19.319(b), spirits may be withdrawn from bonded premises for any lawful purpose on the filling or production gauge. Spirits not so filled or produced must be gauged when they are withdrawn from bonded premises on determination of tax. When spirits which are to be withdrawn on determination of tax on the original gauge are transferred in bond, all copies of Form 5110.27 shall be marked by the proprietor "Withdraw on Original Gauge".

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5204))

§ 19.504 Determination of tare.

When packages are to be individually gauged for withdrawal from bonded premises, actual tare shall be determined in accordance with Part 13 of this chapter.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26- U.S.C. 5204))

Transfers Between Bonded Premises

§ 19.505 Authorized transfers.

(a) *Spirits.* Pursuant to approval of an application therefor as provided in § 19.506, bulk spirits (including denatured spirits) may be transferred in bond between bonded premises in bulk conveyances, or by pipeline, or in bulk containers into which spirits may be filled on bonded premises.

(b) *Wine.* (1) Wines may be transferred (i) from a bonded wine cellar to the bonded premises of a distilled spirits plant, (ii) from the bonded premises of a distilled spirits plant to a bonded wine cellar, or (iii) between the bonded premises of distilled spirits plants.

(2) Wines transferred to the bonded premises of a distilled spirits plant may be used in the manufacture of a distilled spirits product, and may not be removed from such bonded premises for consumption or sale as wine.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1362, as amended, 1380, as amended (26 U.S.C. 5212, 5362))

§ 19.506 Application to receive spirits in bond.

When a proprietor desires to have spirits or denatured spirits transferred to him in bond he shall make application for such transfer to the regional regulatory administrator on Form 5100.16. Application to receive such spirits by transfer in bond shall not be approved unless the applicant's operations or unit bond is in the maximum penal sum, or, if in less than the maximum- penal sum, is sufficient to cover the tax on the spirits (including denatured spirits) to be transferred in addition to all other liabilities chargeable against such bond. The applicant shall deliver one of the approved copies of the application to the consignor proprietor.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1318, as amended, 1362, as amended (26 -U.S.C. 5005, 5212))

§ 19.507 Termination of application.

A proprietor may terminate an approved application, Form 5100.16, at any time by (a) retrieving the consignor's copy, and (b) returning this copy, together with his own, to the regional regulatory administrator for cancellation.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1318, as amended (26 -U.S.C. 5005))

§ 19.508 Consignor premises.

(a) *General.* (1) Form 5110.27 shall be prepared by the consignor proprietor of a distilled spirits plant (i) to cover the transfer of spirits or denatured spirits in bond, pursuant to an approved application on Form 5100.6, or (ii) to cover the transfer of wine in bond to the bonded premises of a distilled spirits plant or bonded wine cellar. Except as otherwise provided herein, a Form 5110.27 shall be prepared for each conveyance. Each Form 5110.27 shall show the real name (or the basic operating name as provided in § 19.280) of the producer (or the name of the importer in the case of imported spirits or the name of the packaging proprietor in the case of spirits of 190 degrees or more of proof) and, if the spirits were produced under a trade name, shall also show the trade name under which produced. The proprietor shall also enter on Form 5110.27 the serial numbers of any seals or other devices affixed to a conveyance used for shipment of spirits, or denatured spirits. On completion of lading (or completion of transfer by pipeline), the proprietor shall dispose of the remaining copies of Form 5110.27 as provided in the instructions on the form.

(2) The proprietor may cover on one Form 5110.27 all packages of spirits shipped by truck on the same day from his bonded premises to another distilled spirits plant located in the same region. In such case, the proprietor shall prepare a shipment and delivery order for each shipment, showing the number of packages, their package identification numbers, the name of the producer, and the serial numbers of the seals or other devices (if any) applied to the truck. Such shipping and delivery order shall be properly authenticated, and shall constitute a complete record of the spirits so transferred in each truck each day. A copy of each shipping and delivery order shall be retained by the consignor. On completion of the lading of the last truck for the day, the Form 5110.27 shall be disposed of as provided in the instructions on the form.

(b) *Packages.* When spirits are to be transferred in bond in packages, the consignor proprietor shall weigh each package, except (1) when the transfer is to be made in a sealed conveyance, (2) when the individual packages have been securely sealed by the proprietor, or (3) when this requirement has been waived by the regional regulatory administrator on a finding that, because of the location of the premises and the proposed method of operation, there will be no jeopardy to the revenue. When packages are weighed at the time of shipment, the proprietor shall list the package identification number of each package and its gross shipment weight on Form 5110.45. A copy of Form 5110.45 shall accompany each copy of Form 5110.27.

(c) *Bulk conveyances and pipelines.* When spirits, denatured spirits, or wines are to be transferred in bond in bulk conveyances or by pipelines, the consignor shall gauge the spirits, denatured spirits, or wines and record the quantity so determined on Form 5110.27. Bulk conveyances of spirits shall be sealed by the proprietor.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1367, as amended, 1380, as amended (26 U.S.C. 5212, 5362))

§ 19.509 Reconsignment in transit.

Where, prior to or on arrival at the premises of a consignee, spirits transferred in bond (including denatured spirits) or wines are found to be unsuitable for the purpose for which intended, were shipped in error, or, for any other bona fide reason, are not accepted by such consignee, or are not accepted by a carrier, they may be reconsigned, by the consignor, to himself, or to another consignee on notification to the regional regulatory administrator of the consignor's region of such reconsignment. In such case, application to receive spirits by transfer in bond (on Form 5100.16) shall have been previously approved for the consignee (not required in the case of wines) and the bond of the proprietor to whom the spirits or wines are reconsigned shall cover such spirits while in transit after reconsignment. Notice of cancellation of the Form 5110.27 covering the shipment to the original consignee shall be made by the consignor to each person receiving a copy of Form 5110.27. Where the reconsignment is to another proprietor, a new Form 5110.27 shall be prepared and prominently marked with the word "Reconsignment".

(Sec. 201, Pub. L. 85–859, 72 Stat. 1367, as amended, 1380, as amended (26 U.S.C. 5212, 5362))

§ 19.510 Consignee premises.

(a) *General.* When spirits, denatured spirits, or wines are received by transfer in bond the consignee proprietor shall examine each conveyance to determine whether the seals, if any, are intact upon arrival at his premises. If the seals are not intact, he shall immediately notify the area supervisor before removal of any spirits from the conveyance. The proprietor shall follow the provisions of Subpart P of this part to determine, record and report losses, if any. After execution on the transfer forms of his receipt of the shipment of spirits, denatured spirits, or wines the consignee shall dispose of Form 5110.27 or (in the case of wines from a bonded wine cellar) Form 703, as provided in the instructions on the respective forms.

(b) *Packages.* When spirits are received in packages, the consignee proprietor shall weigh each package, except (1) when the transfer is made in a sealed conveyance and the seals or other devices are intact on arrival, (2) when the individual packages have been sealed by the consignor proprietor and are intact on arrival, or (3) when the requirement for weighing the packages at the consignor premises has been waived under the provisions of § 19.508(b)(3). The proprietor shall record the receiving weight of each package on Form 5110.45 (if any) which accompanied the shipment or on a list showing the identification number and receiving weight of each package. A copy of such list or Form 5110.45 shall be attached to each copy of Form 5110.27 in his possession.

(c) *Bulk conveyances and pipelines.* When spirits, denatured spirits, or wines are received in bulk conveyances or by pipeline, the consignee shall gauge the spirits, denatured spirits, or wines and record the gauge on Form 5110.27 or, in the case of wines received from a bonded wine cellar, on Form 703. However, the regional regulatory administrator may waive the requirement for gauging spirits, denatured spirits, or wines on receipt by pipeline if he finds that, because of the location of the premises, there will be no jeopardy to the revenue.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended, 1380, as amended (26 U.S.C. 5204, 5362); Sec. 807(a), Pub. L. 96–39, 93 Stat. 285 (26 U.S.C. 5213))

Removal of Spirits to Production

§ 19.511 Removal of spirits for redistillation.

A proprietor intending to remove spirits (including denatured spirits) from processing or storage to production on the same bonded premises for redistillation, in accordance with the provisions of §§ 19.322 and 19.323, shall prepare Form 5110.26 to cover such removal. Each lot of spirits (except bottled spirits) shall be gauged by the proprietor. Such gauge shall be recorded on Form 5110.26. The packages or cases shall be examined by the proprietor, and if any package or case bears evidence of loss due to theft or unauthorized destruction, such loss shall be reported to the area supervisor and the package or case shall not be dumped until released by him; Form 5110.26 shall be amended when necessary.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

Withdrawals on Determination and Payment of Tax

§ 19.512 Determination and payment of tax.

(a) *General.* Distilled spirits may be withdrawn from bonded premises on determination of tax in approved containers, or, to the contiguous premises of a manufacturer of nonbeverage products, by pipeline.

(b) *Record of tax determination.* A serially numbered invoice or shipping document, signed or initialed by an agent or employee of the proprietor, shall constitute the record of tax determination. For purposes of this part, the total proof gallons determined from each numbered invoice or shipping document shall constitute a single withdrawal and is the basis for computation of the tax. All tax which is to be prepaid or deferred shall be determined prior to the physical removal of the spirits from bonded premises.

(c) *Payment of tax.* The tax on the spirits shall be paid on Form 5110.32 before removal of the spirits from bonded premises unless the proprietor has furnished a withdrawal or unit bond to secure payment of the tax. Where such bond is in less than the maximum penal sum, the proprietor shall prepay the tax for any withdrawal which would cause the outstanding liability for tax to exceed the limits of coverage under the bond. Where the payment of tax is to be deferred, the proprietor shall keep the daily summary record of tax determinations as required by § 19.518.

(Sec. 807, Pub. L. 96–39, 93 Stat. 285, (26 U.S.C. 5213))

§ 19.513 Bond account.

Where the proprietor has furnished a withdrawal or unit bond to cover the tax on spirits withdrawn on determination of tax, and such bond is in less than the maximum penal sum, he shall maintain an account of his bond and he shall charge the bond with the amount of liability incurred on each withdrawal on determination of tax. He shall credit the bond on payment of the amount of tax required to be remitted with a return and by authorized credits taken on a return. Where a bond in less than the maximum penal sum has been allocated among two or more plants, as provided in §§ 19.243 and 19.244, the proprietor shall maintain an account at each plant of that part of the penal sum allocated to that plant.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

§ 19.514 Proprietor's statement.

When tax is to be paid pursuant to a return on Form 5110.35, the proprietor shall execute on all copies of the daily summary record of tax determinations, as prescribed in § 19.518, a statement in which he (a) agrees to pay, in accordance with law and this part, the amount of tax shown on such summary record, or to be shown thereon, and (b) certifies, under the penalties of perjury, that he is not in default in any payment of tax chargeable against his withdrawal or unit bond, as applicable, and that the penal sum of such bond (1) is in the maximum penal sum or (2) is sufficient to cover such amount in addition to all other amounts chargeable against such bond. When tax is to be prepaid on return Form 5110.32, the proprietor shall note the serial number of the return and the date and time such return was filed on the individual record of tax determination. The full amount of tax determined shall be included for payment in a tax return on Form 5110.32 or Form 5110.35 filed as provided in §§ 19.522 and 19.523. Nothing in this part shall be construed as precluding an adjustment after tax payment, pursuant to law and regulations, of any overpayment or underpayment of tax.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

§ 19.515 Gauge for tax determination.

(a) *Packages.* When spirits in packages are to be withdrawn from bonded premises on determination of tax on the basis of an individual package gauge, each package shall be gauged unless the tax is to be determined on the original gauge. When the packages are to be withdrawn, the proprietor shall prepare Form 5110.45 in such a manner as to reflect the identification and gauge of each package. On completion of gauge (if any) and computation of tax, the Form 5110.45 shall be attached to the appropriate record of tax determination, and a copy of each shall be furnished to the consignee.

(b) *Tanks.* Spirits in tanks which are to be withdrawn on determination of tax shall be gauged (by weighing and proofing) as prescribed in § 19.92, and the elements of the gauge shall be recorded on the record of tax determination or on a separate record of the gauge for attachment to the record of tax determination.

(c) *Cases.* Cases of distilled spirits to be withdrawn from bonded premises shall be tax determined on the basis of the contents thereof. The proof gallonage contained in cases shall be determined in accordance with Part 13 of this chapter and the method prescribed in § 19.742. The record of tax determination shall contain all data

necessary to calculate the amount of spirits tax determined.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358 (26 U.S.C. 5204); Sec. 807, Pub. L. 96–39, 93 Stat. 285 (26 U.S.C. 5213))

§ 19.517 Imported spirits.

When spirits which have been imported for non-beverage purposes and transferred to bonded premises pursuant to 26 U.S.C. 5232 are withdrawn for beverage purposes, there shall be paid, in addition to the internal revenue tax imposed by 26 U.S.C. 5001, a tax equal to the duty which would have been paid had the spirits been imported for beverage purposes, less the duty already paid thereon. The additional tax shall be referred to as "additional tax—less duty", and shall be paid at the time and in the manner that the basic tax is paid. The total quantity in proof gallons withdrawn shall be the basis of computing the tax at the rates indicated. The amount of the "additional tax—less duty" shall be stated separately and identified as such on the tax return.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1314, as amended (26 U.S.C. 5001))

§ 19.518 Daily summary record of tax determinations.

Every proprietor of a distilled spirits plant who withdraws distilled spirits on determination, but before payment, of tax shall maintain a daily summary record of tax determinations. The summary record shall show, for each day on which tax determinations occur, (a) the serial number of each record of tax determination, (b) the total proof gallons on which tax was determined, and (c) the total tax. The proprietor shall execute on the daily summary record the statement required by § 19.514. The daily summary record of tax determinations shall be maintained in accordance with Subpart W of this part.

(Sec. 807, Pub. L. 96–39, 93 Stat. 285 (26 U.S.C. 5213))

§ 19.519 Methods of tax payment.

The tax on spirits shall be paid pursuant to a return on Form 5110.32 or on Form 5110.35, filed as provided in §§ 19.523 and 19.524. Remittance for the tax in full shall accompany the return and may be in any form which the district director is authorized to accept under the provisions of 26 CFR 301.6311–1 and which is acceptable to him. However, where a check or money order tendered in payment for taxes is not paid on presentment, or where the taxpayer is otherwise in default in payment, any remittance made during the period of such default, and until the regional regulatory administrator finds that the revenue will not be jeopardized by the acceptance of a personal check (if acceptable to the district director), shall be in cash or in the form of a certified, cashier's, or treasurer's check drawn on any bank or trust company incorporated under the laws of the United States, or under the laws of any State, territory, or possession of the United States, or a money order, as provided in 26 CFR 301.6311–1. Checks and money orders shall be made payable to "Internal Revenue Service".

(Act of August 16, 1954, Ch. 736, 68A Stat. 777, as amended (26 U.S.C. 6311); Sec. 201, Pub. L. 85–859, 72 Stat. 1335, as amended (26 U.S.C. 5061))

§ 19.520 Employer identification number.

The employer identification number (defined at 26 CFR 301.7701–12) of the taxpayer who has been assigned such a number shall be shown on each return on Form 5110.32 or Form 5110.35 filed pursuant to the provisions of this part. Failure of the taxpayer to include his employer identification number on Form 5110.32 or Form 5110.35 may result in assertion and collection of the penalty specified in 26 CFR 301.6676–1.

(Sec. 1, Pub. L. 87–397, 75 Stat. 828, as amended (26 U.S.C. 6109, 6676))

§ 19.521 Application for employer identification number.

(a) An employer identification number will be assigned pursuant to application on Form SS–4 filed by the taxpayer. Form SS–4 may be obtained from the director of the service center or from the district director.

(b) An application on Form SS–4 for an employer identification number shall be made by every taxpayer who files a return on Form 5110.32 or Form 5110.35, but who prior to the filing of his first return on Form 5110.32 or Form 5110.35 has neither secured an employer identification number nor made application therefor. Such application on Form SS–4 shall be filed on or before the seventh day after the date on which such first return on Form 5110.32 or Form 5110.35 is filed.

(c) Each taxpayer shall make application for and shall be assigned only one employer identification number, regardless of the number of places of business for which the taxpayer is required to file a tax return under the provisions of this part.

(Sec. 1, Pub. L. 87–397, 75 Stat. 828, as amended (26 U.S.C. 6109))

§ 19.522 Taxes to be collected by returns.

(a) *Semimonthly periods.* The tax on spirits to be withdrawn from bond for deferred payment of tax shall be paid pursuant to a return on Form 5110.35. The periods to be covered by returns on Form 5110.35 shall be semimonthly; such periods to run from the 1st day through the 15th day of each month, and from the 16th day through the last day of each month. A return, Form 5110.35, shall be executed and filed to cover each return period notwithstanding that no tax is due for payment for such period. The proprietor of each bonded premises shall include, for payment, on his return on Form 5110.35 the full amount of distilled spirits tax determined in respect of all spirits released for withdrawal from the bonded premises on determination of tax during the period covered by the return (except spirits on which tax has been prepaid).

(b) *Conditions under which deferral is denied.* Notwithstanding the posting of a withdrawal or unit bond by the proprietor, the tax shall be prepaid as provided in paragraph (c) of this section—

(1) Where a proprietor has defaulted in any payment of tax under this section, during the period of such default and until the regional regulatory administrator finds that the revenue will not be jeopardized by deferral; and

(2) Where a proprietor, who, after having been notified of his deficiency by the regional regulatory administrator (i) fails to maintain records required by this part to substantiate the correctness of his tax returns or (ii) otherwise fails to comply with any provisions of this part, is so notified by the regional regulatory administrator.

(c) *Prepaid taxes.* The tax on distilled spirits shall be paid pursuant to a return on Form 5110.32 in all cases where the tax is required to be paid before the spirits are withdrawn from bond. A single return on Form 5110.32 may cover one or more transactions.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1335, as amended, 1395, as amended (26 U.S.C. 5061, 5555))

§ 19.523 Time for filing returns.

(a) *Payment pursuant to semimonthly return, Form 5110.35.* Where the proprietor of bonded premises has withdrawn spirits from such premises on determination and before payment of tax, he shall file a tax return covering such spirits on Form 5110.35, with remittance, as follows:

(1) If the return period is in calendar year 1980, not later than the last day of the first succeeding return period plus five days;

(2) If the return period is in calendar year 1981, not later than the last day of the first succeeding return period plus ten days;

(3) If the return period is in calendar year 1982 or in any year thereafter, not later than the last day of the second

succeeding return period. Where the due date for filing a return falls on a Saturday, Sunday, or legal holiday, the time for filing is extended to the first succeeding day which is not a Saturday, Sunday, or legal holiday.

(b) *Payment pursuant to prepayment return, Form 5110.32.* If the proprietor of a distilled spirits plant desires to withdraw spirits from bonded premises on determination of tax and does not have on file an approved withdrawal or unit bond of sufficient penal sum to cover the withdrawal, if there is default by him in any payment of tax under this part, or the proprietor is notified by the regional regulatory administrator as provided in § 19.522(b)(2), the proprietor shall not remove the spirits from the bonded premises until the tax thereon has been paid. To pay the tax, the proprietor of the bonded premises shall file a prepayment return, Form 5110.32, with remittance, before removal of the spirits.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1335, as amended (26 U.S.C. 5061))

§ 19.524 Manner of filing returns.

(a) *General.* All returns on Form 5110.32 and Form 5110.35 with remittance shall be filed with the district director or an ATF officer designated by the regional regulatory administrator.

(b) *Filing with district director.* Where the remittance is in cash, the return and remittance shall be filed directly with the district director. Where the return and remittance are delivered by U.S. mail to the office of the district director, the date of the official postmark of the U.S. Postal Service stamped on the cover in which the return and remittance were mailed shall be deemed to be the date of filing. However, if the postmark on the cover is illegible, the burden of proving when the postmark was made will be on the proprietor. If the return is sent by registered mail or by certified mail, the date of registry postmark or the sender's receipt, as applicable, shall be treated as the filing date of the return and remittance.

(c) *Filing with an ATF officer.* Where the return and remittance are to be filed with a designated ATF officer, the proprietor shall file the return and remittance no later than 2 p.m. on the date the return is required to be filed.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1335, as amended (26 U.S.C. 5061))

§ 19.525 Removal of spirits on tax determination.

No spirits shall be removed from bonded premises, except as otherwise provided by law, unless the tax thereon has been paid or determined. A record of tax determination shall be prepared for each removal of spirits as provided in § 19.512. The proprietor shall apply distilled spirits stamps to the packages or bulk conveyances of spirits to be removed from bonded premises. Distilled spirits stamps shall be affixed, canceled, and protected in the manner provided in Subpart S of this part. When the distilled spirits stamps have been affixed by the proprietor to the containers and the containers have been properly marked, they shall be promptly removed from the bonded premises.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5205); Sec. 807, Pub. L. 96–39, 93 Stat. 285 (26 U.S.C. 5213))

Withdrawal of Spirits Without Payment of Tax

§ 19.531 Authorized withdrawals without payment of tax.

Spirits may be withdrawn from bonded premises, without payment of tax for:

(a) Export, as authorized under 26 U.S.C. 5214(a)(4);

(b) Transfer to customs manufacturing bonded warehouses, as authorized under 19 U.S.C. 1311;

(c) Transfer to foreign-trade zones, as authorized under 19 U.S.C. 81c;

(d) Supplies for certain vessels and aircraft, as authorized under 19 U.S.C. 1309;

(e) Transfer to customs bonded warehouses, as authorized under 26 U.S.C. 5066 or 5214(a)(9);

(f) Use in wine production, as authorized under 26 U.S.C. 5373;

(g) Transfer to any university, college of learning, or institution of scientific research for experimental or research use as authorized under 26 U.S.C. 5312(a); or

(h) Research, development or testing, as authorized under 26 U.S.C. 5214(a)(10). The withdrawal of spirits as provided in paragraphs (a) through (e) of this section shall be in accordance with the regulations in Part 252 of this chapter.

(Sec. 311, Tariff Act of 1930, 46 Stat. 691, as amended (19 U.S.C. 1311); Sec. 201 Pub. L. 85–859, 72 Stat. 1362, as amended, 1375, as amended, 1382, as amended (26 U.S.C. 5214, 5312, 5373); Sec. 3, Pub. L. 91–659, 84 Stat. 1965, as amended (26 U.S.C. 5066))

§ 19.532 Withdrawals of spirits for use in wine production.

Wine spirits withdrawn without payment of tax for use in wine production may be removed, in accordance with Part 240 of this chapter, to a bonded wine cellar.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1362, as amended, 1382, as amended (26 U.S.C. 5214, 5373))

§ 19.533 Withdrawal of spirits without payment of tax for experimental or research use.

Any scientific university, college of learning, or institution of scientific research (which has qualified under the provisions of § 19.72 to withdraw spirits from a bonded premises), desiring to withdraw a specific lot of spirits for experimental or research use, shall file a letterhead application with the regional regulatory administrator of the region in which the applicant's premises are located.

(Sec. 201, Pub. L. 85–859), 72 Stat. 1975, as amended (26 U.S.C. 5312))

Withdrawal of Spirits Free of Tax

§ 19.536 Authorized withdrawals free of tax.

Pursuant to the regulations in this chapter, spirits may be withdrawn from bonded premises free of tax—

(a) On receipt of a valid permit, issued under Part 213 of this chapter, to procure spirits for nonbeverage purposes and not for resale or use in the manufacture of any product for sale, as provided in 26 U.S.C. 5214(a)(3);

(b) On receipt of a valid permit, issued under Part 213 of this chapter, to procure spirits by and for the use of the United States or any governmental agency, any State, any political subdivision of a State, or the District of Columbia, for nonbeverage purposes as provided in 26 U.S.C. 5214(a)(2);

(c) On receipt of a valid permit, issued under this part, to procure spirits by and for the use of the United States, under the provisions of 26 U.S.C. 7510, for purposes other than as provided in paragraph -(b) of this section and 26 U.S.C. 5214(a)(2);

(d) After being specially denatured—

(1) On receipt of a valid permit to procure such spirits, issued under Part 211 of this chapter;

(2) For export;

(e) After being completely denatured, for any lawful purpose;

(f) When contained in an article.

(Act of August 16, 1954, Ch. 736, 68A Stat. 900 (26 U.S.C. 7510); Sec. 201, Pub. L. 85–859, 72 Stat. 1362, as amended (26 U.S.C. 5214))

§ 19.537 Withdrawal of spirits free of tax.

Spirits withdrawn free of tax under § 19.536 (a), (b), and (c) shall be withdrawn in approved containers and shipped to the consignee designated in the permit. Unless the spirits are in cases or are to be withdrawn on the original gauge, the proprietor shall gauge each container. For each shipment, the proprietor shall prepare Form 1473 and distribute the form in accordance with the instructions thereon. Bulk

conveyances used to transport spirits withdrawn free of tax under this section shall be sealed. (See § 19.96.)

(Sec. 201, Pub. L. 85–859, 72 Stat. 1362, as amended (26 U.S.C. 5214))

§ 19.538 Permits for withdrawal of spirits by the United States.

Where the United States or a governmental agency thereof intends to procure spirits free of tax for nonbeverage purposes, application for a permit shall be filed on Form 1444 under the provisions of Part 213 of this chapter. Where the United States or a governmental agency thereof intends to procure spirits free of tax for other purposes, application for a permit shall be filed on Form 1444 under the provisions of this part. The application shall be signed by the head of the department, independent bureau, or agency to which such spirits are to be shipped, or by some person duly authorized by such head of a department, independent bureau, or agency, and forwarded to the Director. Evidence of authority to sign for the head of a department, independent bureau, or agency shall be furnished to the Director. If the Director finds the application in order, he will issue a permit to the applicant. At the time the spirits are to be procured, the permit on Form 1444 and a purchase order shall be submitted by the governmental agency to the proprietor. At the time of shipment, the consignor shall return the permit to the governmental agency unless he has been authorized by such governmental agency to retain the permit for the purpose of making future shipments. On receipt of a shipment of spirits, the representative of the governmental agency receiving the same shall execute the certificate of receipt on both copies of Form 1473 received from the plant proprietor, after noting thereon any loss or deficiency in the shipment, and shall forward one copy to the regional regulatory administrator of the region in which the plant proprietor is located and shall retain the other copy for his files. Every appropriate precaution shall be taken by the governmental agency to ensure that the procured spirits will be used only for governmental purposes. When no more spirits will be procured under a permit, the governmental agency shall return it to the Director for cancellation.

(Act of August 16, 1954, Ch. 736, 68A Stat. 900 (26 U.S.C. 7510))

§ 19.539 Disposition of excess spirits.

Any excess spirits in the possession of a governmental agency shall be disposed of to another agency of the United States holding a permit, shall be returned to a plant on approval of the regional regulatory administrator of the region in which the plant is located, or shall be disposed of otherwise as may be authorized by the Director. In no case may such spirits be disposed of to the general public, or otherwise, than as provided in this section.

(Act of August 16, 1954, Ch. 736, 68A Stat. 900 (26 U.S.C. 7510))

§ 19.540 Removal of denatured spirits and articles.

(a) *Specially denatured spirits.* Specially denatured spirits withdrawn free of tax under § 19.536(d) shall be shipped in approved containers to the consignee designated in the permit. If such spirits are for export or for transfer to a foreign-trade zone, they shall be withdrawn under the applicable provisions of Part 252 of this chapter. If such spirits are for shipment to a qualified user or a bonded dealer, the proprietor shall prepare a notice of shipment on Form 1473 and distribute the copies of the form in accordance with the instuctions thereon. Bulk conveyances used to transport specially denatured spirits shall be sealed in accordance with the provisions of § 19.96.

(b) *Completely denatured alcohol.* No permit, application, or notice is required for removal of completely denatured alcohol from bonded premises, except that completely denatured alcohol may be transferred from bonded premises by pipeline only when the consignee has obtained authority to receive completely denatured alcohol by such means pursuant to the provisions of Part 211 of this chapter. The proprietor is required to keep a record of such removals, as prescribed in Subpart W of this part.

(c) *Samples of denatured spirits.* The proprietor may take samples of denatured spirits free of tax which may be necessary for the conduct of business. The proprietor may furnish samples of specially denatured spirits: (1) To dealers in, and users of, specially denatured spirits in advance of sales; and (2) to users and to applicants or prospective applicants for permits to use specially denatured spirits, for experimental purposes or for use in preparing samples of a finished product for submission to the Director. Samples for these purposes, in excess of 1 liter, shall be furnished only after a permit on Form 1512 is issued to the consignee. Form 1473 shall be prepared to cover shipment of samples of a size in excess of 1 liter. Form 1473 shall show the permit number of the Form 1512. The proprietor shall retain the Form 1512 on file as a part of the record transaction.

(d) *Labels for samples of denatured spirits.* Each sample of denatured spirits withdrawn under the provisions of paragraph (c) of this section shall have a label affixed showing the following information: (1) The word "Sample", and the words "Specially Denatured Alcohol", "Specially Denatured Spirits", or "Completely Denatured Alcohol", whichever is applicable; (2) the name, address, and plant number of the proprietor; (3) the formula number; and (4) the name and address of the consignee.

(e) *Articles.* Removal of articles from bonded premises shall be in accordance with the provisions of Part 211 of this chapter.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1382, as amended (26 U.S.C. 5214))

§ 19.541 Reconsignment in transit.

Where, prior to or on arrival at the consignee's premises, spirits (including specially denatured spirits) withdrawn free of tax under § 19.536 are not accepted by the consignee or by a carrier, they may be reconsigned by the proprietor making the shipment on notification to the proprietor's regional regulatory- administrator of the reconsignment. Such reconsignment may be made to himself or to another proprietor for return to bonded premises under the provisions of § 19.705 or to another person holding an industrial use permit authorizing receipt or use of such spirits or specially denatured spirits. In case of reconsignment to bonded premises, the provisions of § 19.705, relating to consents of surety in respect of return of spirits (including denatured spirits) withdrawn free of tax shall be applicable. Notice of cancellation of Form 1473 covering the shipment to the original consignee shall be given by the proprietor to each person receiving a copy of the form. Where reconsignment is to another person as provided in this section, a new Form 1473 shall be prepared and the word "Reconsignment" placed thereon. The entry on the permit covering the original withdrawal shall be voided.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

Withdrawals Authorized by Puerto Rico

§ 19.546 Withdrawals authorized by Puerto Rico.

Distilled spirits (including denatured spirits) may be withdrawn from the bonded premises of a distilled spirits plant in Puerto Rico pursuant to authorization issued under the laws of the Commonwealth of Puerto Rico; such spirits so withdrawn and products containing such spirits so withdrawn,

may not be brought into the United States free of tax.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1375, as amended (26 U.S.C. 5314))

Subpart P—Losses and Shortages

§ 19.561 Allowable losses.

Tax shall not be collected (or, if paid, such tax shall be refunded) with respect to spirits (including denatured spirits) or wines lost or destroyed while in bond, except that such tax shall be collected in the case of—

(a) Theft, unless the regional regulatory administrator finds that the theft occurred without connivance, collusion, fraud, or negligence on the part of the proprietor, owner, consignor, consignee, bailee, or carrier, or the employees or agents of any of them. The abatement, remission, credit, or refund of taxes on spirits (including denatured spirits) or wines, lost by theft shall only be allowed to the extent that the claimant is not indemnified against or recompensed for such tax.

(b) Voluntary destruction, unless such destruction is carried out as provided in Subpart T of this part.

(c) Unexplained shortage of bottled distilled spirits.

In every case where it appears that the loss was by theft, the burden shall be on the proprietor of the distilled spirits plant or other person responsible for the distilled spirits tax or wine tax to establish to the satisfaction of the regional regulatory administrator that such loss did not occur as the result of connivance, collusion, fraud, or negligence on the part of the proprietor of the distilled spirits plant, owner, consignor, consignee, bailee, or carrier, or the employees or agents of any of them. Claims in respect of losses allowable under this section shall be filed in accordance with the applicable provisions of Subpart C of this part.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1323, as amended, 1381, as amended (26 U.S.C. 5008, 5370))

§ 19.562 Loses of spirits from packages.

(a) *Original quantity.* Where there is evidence satisfactory to the regional regulatory administrator that any loss of spirits (including denatured spirits) from any package deposited on bonded premises is due to theft (except where the regional regulatory administrator has made the finding provided for in § 19.561(a)) or is due to unauthorized voluntary destruction, the regional regulatory administrator may require the immediate taxpayment of the quantity of spirits lost, except where the extent of any loss from causes other than theft or unauthorized voluntary destruction can be established by the proprietor to the satisfaction of the regional regulatory administrator, the regional regulatory administrator may credit the tax on the loss so established against the tax on the original quantity.

(b) *Alternative method.* Where there is evidence satisfactory to the regional regulatory administrator that there has been access, other than as authorized by law, to the contents of packages entered for deposit on bonded premises, and the extent of such access is such as to evidence a lack of due diligence or a failure to employ necessary and effective controls on the part of the proprietor, the regional regulatory administrator may (in lieu of the procedure prescribed in paragraph (a) of this section) assess an amount equal to the tax on 5 proof gallons of spirits on each of the total number of such packages as determined by him.

(c) *Applicability to packages filled after entry.* The provisions of this section apply to spirits (including denatured spirits) which are filled into casks or packages as authorized by law, after entry and deposit on bonded premises, whether by recasking, filling from tanks, mingling, or otherwise. The quantity filled into those casks or packages is considered to be the original quantity for the purpose of this section in the case of loss from those casks or packages.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1320, as amended (26 U.S.C. 5006))

§ 19.563 Losses in bond.

(a) *General.* Where a bulk container of spirits (including denatured spirits) or wines in bond sustains a loss in excess of normal storage or transit losses, or as a result of theft or unauthorized voluntary destruction, the loss shall be determined at the time of discovery. When it appears that any container in bond has sustained a loss resulting from theft or unauthorized voluntary destruction, such loss shall be taxpaid or reported promptly by the proprietor to the area supervisor. Proprietors shall record on deposit and transfer forms for each container sustaining such a loss, the container identification number, the quantity lost, and the apparent cause of the loss. If the proprietor pays the tax as provided in § 19.562, such fact, including the details of the method used to determine the tax to be paid, shall be shown on the record of deposit, and the tax shall be included on the next tax return filed. Unusual losses from obvious cause other than theft or unauthorized voluntary destruction occurring or discovered at the time of withdrawal from bond or transfer in bond shall be noted on the appropriate withdrawal or transfer form in the manner prescribed in this paragraph. When a loss appears to be due to theft or unauthorized voluntary destruction, the container shall be segregated (if applicable) and the area supervisor shall be notified, unless the proprietor acknowledges liability and elects to pay the tax on the quantity lost. Where it is found that the contents of a container have been tampered with, or where a material deficiency is found without evidence of loss by leakage or casualty, or where deterioration in proof not accountable by variation in gauge is disclosed, the container shall be segregated (if applicable) and the area supervisor shall be notified, unless the proprietor acknowledges liability and elects to pay the tax on the quantity lost. In any case in which spirits (including denatured spirits) are lost or destroyed in bond, whether by theft or otherwise, the regional regulatory administrator may require the proprietor or other person liable for the tax to file a claim for relief from the tax in accordance with the applicable provisions of Subpart C of this part. Losses of spirits (including denatured spirits) sustained from the tanks and bulk conveyances in bonded warehouses shall be determined by the proprietor each time a tank or bulk conveyance is emptied and on the basis of the physical inventories required by §§ 19.329, 19.353, 19.421, and 19.463. All losses of spirits, whether by theft, voluntary destruction, or otherwise, shall be recorded on the date of discovery in the records prescribed by § 19.781. If at any time any package recorded as deposited on bonded premises cannot be located or otherwise lawfully accounted for, such fact shall be immediately reported to the area supervisor, and the proprietor shall either pay the tax or file a claim with respect thereto under the provisions of § 19.41.

(b) *Storage account loss limitation.* When the quantity lost from all the storage tanks and bulk conveyances exceeds 1 percent of the total quantity contained in the tanks and bulk conveyances during the calendar quarter, or where any loss from storage tanks or bulk conveyances is due to illegal withdrawal, the loss shall be taxpaid unless a claim for remission is filed in accordance with the provisions of § 19.41 and is allowed by the regional regulatory administrator.

(c) *Bottled distilled spirits.* In any case where bottled distilled spirits are lost or destroyed in bond, whether by theft or otherwise, the regional regulatory administrator may require the

proprietor to file a claim for relief from the tax in accordance with the applicable provisions of Subpart C of this part. All losses of spirits, whether by theft, voluntary destruction, or otherwise, shall be recorded on the date of discovery, in the records prescribed by § 19.416.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1323, as amended (26 U.S.C. 5008, 5201))

§ 19.564 Shortages of bottled distilled spirits.

Any unexplained shortage of bottled distilled spirits shall be taxpaid on Form 5110.32 or Form 5110.35. Unexplained shortages shall be determined by comparing the bottled spirits recorded to be on hand (book figure) with the results of any quantitative determination of any part of the bottled spirits found to be on hand by actual count (physical inventory). When the record balance of spirits is greater than the actual count, the difference shall be taken as an unexplained shortage. Whether the record balance is larger or smaller than the actual count, any overage or shortage shall be recorded in the records prescribed in § 19.769, and the record balance shall be adjusted accordingly.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1323, as amended (26 U.S.C. 5008))

§ 19.565 Losses after tax determination.

In the case of spirits lost after determination of tax and before completion of physical removal from bonded premises, the tax thereon may, pursuant to claim filed in accordance with Subpart C, be abated, remitted, or, without interest, refunded or credited to the proprietor of the bonded premises where the loss occurred, provided the tax would not, by reason of the provisions of 26 U.S.C. 5008(a)(1) have been collectible if such loss had occurred on bonded premises before determination of tax.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1323, as amended (26 U.S.C. 5008))

§ 19.566 Losses of wine in bond.

In the case of wine lost or destroyed in bond other than by theft, whether disclosed by examination of records, inventories, or otherwise, the regional regulatory administrator may require the proprietor to file a claim for remission of tax in accordance with the applicable provisions of Subpart C of this part. In any case where wine is lost by theft and the proprietor has not paid the tax, a claim for remission of tax shall be filed in accordance with the provisions of Subpart C of this part. All losses shall be recorded in the records prescribed by Subpart W of this part on the date of discovery of the loss.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1331, as amended, 1332, as amended, 1380, as amended, 1381, as amended (26 U.S.C. 5041, 5043, 5362, 5370))

Subpart Q—Containers and Marks and Brands

Containers

§ 19.581 General.

Proprietors shall use for any purpose of containing, storing, transferring, conveying, removing, or withdrawing spirits or denatured spirits under this part only containers which are authorized by, or under the provisions of this part for such purpose, and a container so authorized will be deemed to be an approved container for such purpose. Except where stated otherwise, the provisions of Part 211 of this chapter apply to containers used for containing, storing and shipping of articles, and the provisions of Part 240 of this chapter apply to containers used for storage or transfer of wine. In addition to the types of containers specifically authorized by this part for a particular purpose, a container- of another type may be authorized for that purpose by the Director on a finding by him that the use of such container will afford protection to the revenue equal to or greater than that afforded by the containers specifically authorized by this part, and that the use will not cause administrative difficulty. If another container- is so authorized by the Director, he shall prescribe the detail and manner in which such container shall be constructed, protected, marked, and branded, consistent with the provisions of this part and the extent of such use. Similarly, where a container- authorized for a particular purpose is required by this subpart to be made of specified materials, the Director may authorize the use of containers made of other materials which he has found to be suitable for the intended purpose. This subpart does not regulate or prohibit the use on plant premises of any container for purposes other than containing alcholic substances.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended, 1362, as amended, 1374, as amended- (26 U.S.C. 5206, -5212, 5214, 5301); Sec. 805, Pub. L. 96–39, 93 Stat. 279 (26 U.S.C. 5002); Sec. 807, Pub. L. 96–39, 93 Stat. 285 (26 U.S.C. 5213))

§ 19.582 Containers of 1 gallon (3.785 liters) or less.

The provisions of Subpart L of this part govern the containers to be used in bottling alcohol under 26 U.S.C. 5235. The provisions of Subpart R of this part govern the containers to be used in bottling spirits for domestic use. Denatured spirits may be filled on bonded premises into metal or glass containers of a capacity of 1 gallon (3.785 liters) or less. The provisions of Part 211 of this chapter apply to containers to be used for packaging articles. Liquor bottles shall not be used for bottling denatured spirits or articles. Spirits in bottles of a capacity of 1 gallon (3.785 liters) or less, except anhydrous spirits and spirits to be withdrawn from bond free of tax, are deemed to be for nonindustrial use.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended- 1374, as amended, (26 U.S.C. 5206, 5301); Sec. 805, Pub. L. 96–39, 93 Stat. 278 (26 U.S.C. 5002))

§ 19.583 Cases.

Spirits or denatured spirits which have been filled in containers of 1 gallon (3.785 liters) or less, in accordance with the provisions of § 19.582, shall be placed in cases so constructed as to afford reasonable protection against breakage or theft. Pursuant to the provisions of this part, cases of spirits, including denatured spirits may be stored on bonded premises or withdrawn from bond.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended (26 U.S.C. 5206))

§ 19.584 Containers holding from 1 gallon to 10 gallons.

(a) *Spirits for industrial use.* Spirits in bond, including denatured spirits, for industrial use, may be filled into glass containers of a capacity greater than 1 gallon but not greater than 10 gallons, and metal containers of a capacity of 1 gallon but not greater than 10 gallons.

(b) *Spirits for nonindustrial use.* Spirits in bond, for nonindustrial use, may be filled into metal containers holding 10 gallons and, if for export, such spirits may be filled into metal containers holding 5 gallons. Spirits may be filled into glass containers of a capacity greater than 1 gallon but not greater than 5 gallons and into metal containers of a capacity greater than 1 gallon but not greater than 10 gallons during bottling operations. Pursuant to the provisions of this part, and of Part 5 of this chapter, containers filled in bond under this section may be stored on bonded premises, transferred in bond (except containers holding 1 gallon or less may not be transferred in bond), or withdrawn from bonded premises.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended (26 U.S.C. 5206); Sec. 805, Pub. L. 96–39, 93 Stat. 278 (26 U.S.C. 5002))

§ 19.585 Encased containers.

Unlabeled containers of denatured spirits and spirits of 190 degrees of proof or more for industrial use filled in

accordance with the provisions of § 19.584 may be completely encased in wood, fiberboard, or similar material in such a manner that the surface (including opening) of the actual container is not exposed. Required marks, brands, and stamps (if any) shall be applied to an exposed surface of the case, and the case shall be so constructed that the portion containing such marks, brands, and stamps will remain attached to the inner container until all of the contents have been removed therefrom. A statement reading "Do Not Remove Inner Container Until Emptied" or of similar import, shall be placed on the portion of the case bearing the marks, brands, and stamps.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended (26 U.S.C. 5206))

§ 19.586 Packages.

Packages of more than 10 gallons capacity may be used on bonded premises for original entry of spirits, and for packaging from tanks, storing, transferring in bond, and withdrawing from bonded premises of spirits and denatured spirits. Metal drums shall be so constructed that all openings therein may be sealed and other packages shall be constructed so as to be capable of secure closure.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended (26 U.S.C. 5206))

§ 19.587 Bulk conveyances.

Bulk conveyances which conform to the requirements of § 19.590 may be used on bonded premises for original entry of spirits, and for filling from tanks, storing, transferring in bond, and withdrawing from bond of taxpaid spirits and of denatured spirits. Spirits may be withdrawn free of tax, pursuant to the provisions of this part, in a bulk conveyance only for use of the United States, or if the Director has authorized the proprietor, as provided in § 19.581, to so withdraw such spirits to a specified consignee. Spirits may be withdrawn without payment of tax, pursuant to the provisions of this part, in bulk conveyances for the purposes provided in § 19.531(a), (b), (c), (e), and (f).

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended (26 U.S.C. 5206))

§ 19.588 Tanks.

Tanks which conform to the requirements of § 19.273 may be used on bonded premises as containers for distilled spirits, denatured spirits, articles, and wines.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended (26 U.S.C. 5206))

§ 19.589 Pipelines.

Pursuant to the provisions of this part, pipelines which conform to the requirements of § 19.274 may be used for (a) the conveyance on bonded premises of spirits, denatured spirits, articles, and wines, and (b) the conveyance to and from bonded premises of spirits, denatured spirits, articles, and wines, where the premises from or to which conveyed is in the immediate vicinity.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended (26 U.S.C. 5206))

§ 19.590 Construction of bulk conveyances.

(a) *Construction.* All bulk conveyances authorized by this part shall conform to the following:

(1) If the conveyance consists of two or more compartments, each shall be so constructed or arranged that emptying of any compartment will not afford access to the contents of any other compartment.

(2) The conveyance (or in the case of compartmented conveyances, each compartment) shall be so arranged that it can be completely drained.

(3) Each tank car or tank truck shall have permanently and legibly marked thereon its number, capacity in wine gallons, and the name or symbol of its owner.

(4) If the conveyance consists of two or more compartments, each compartment shall be identified and the capacity of each shall be marked thereon.

(5) Permanent facilities shall be provided on tank trucks and tank cars to permit ready examination of manholes or other openings.

(6) A route board, or other suitable device, for carrying required marks, brands, and stamps shall be provided on each bulk conveyance.

(7) Calibrated charts, prepared or certified by competent and recognized authorities or engineers, showing the capacity of each compartment in wine gallons for each inch of depth, shall be carried with each tank truck, tank ship, or barge.

(b) *Proprietor's responsibility.* Before filling any bulk conveyance, the proprietor shall examine it to ascertain that it meets the requirements of this section and is otherwise suitable for receiving the spirits, denatured spirits, or wines, and he shall refrain from, or discontinue, using any such conveyance found by him or by an ATF officer to be unsuitable.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended, 1362, as amended (26 U.S.C. 5206, 5212, 5214); Sec. 807, Pub. L. 96–39, 93 Stat. 285 (26 U.S.C. 5213))

§ 19.591 Restrictions on disposition of bulk spirits.

(a) *For nonindustrial use.* Spirits for nonindustrial use may be sold or disposed of in containers holding more than 1 wine gallon only to the persons and for the purposes set forth in Part 3 of this chapter.

(b) *For industrial use.* Shipment or delivery of spirits (other than alcohol or neutral spirits) withdrawn from bond in containers holding more than 1 wine gallon for industrial use shall, as provided in Part 3 of this chapter, be made directly to the user of the spirits.

(Sec. 201, Pub. L. 85–895, 72 Stat. 1356, as amended (26 U.S.C. 5201))

Marks and Brands

§ 19.592 General.

Proprietors shall mark, brand, identify, label, and stamp all containers of spirits (including denatured spirits) as provided by this part. Containers of wine shall be marked and branded in accordance with Part 240 of this chapter. Containers of articles shall be marked and branded in accordance with Part 211 of this chapter.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended, 1360, as amended (26 U.S.C. 5204, 5206))

§ 19.593 Package identification numbers.

(a) *General.* Packages of spirits filled during production or storage operations after December 31, 1979, shall be marked with a package identification number, consisting of a lot identification and serial number as follows:

(1) A lot identification representing the date the package is filled, and consisting in the order shown, of—

(i) The last two digits of the calendar year;

(ii) An alphabetical designation from "A" through "L", representing January through December, in that order;

(iii) The digits corresponding to the day of the month; and

(iv) When more than one lot is filled into packages during the same day, for successive lots after the first lot, a letter suffix, in alphabetical order, with "A" representing the second lot, "B" representing the third lot, and so forth. The first three lots filled into packages on January 2, 1980, would be identified as "80A02", "80A02A", "80A02B".

(2) A serial number for each package of spirits within a lot consecutively numbered by the proprietor commencing with "1" for each lot and appearing adjacent to the lot identification as "80A02–1" or "80A02A–25".

(b) *Packages constituting a lot.* Packages of spirits filled during any one day shall be given the same lot

identification subject to the following conditions:

(1) They are of the same type and either are of the same rated capacity or are uniformly filled with the same quantities by weight or other method provided in § 19.319;

(2) They are filled with spirits of the same kind and same proof;

(3) They are filled with spirits which are mingled or blended in accordance with § 19.346; and

(4) They are filled with imported spirits, Puerto Rican spirits, or Virgin Islands spirits, as applicable.

Any remnant package shall itself constitute a lot.

(c) *Waiver of requirement for serial numbers.* Notwithstanding the provisions of paragraph (a) of this section, the regional regulatory administrator may, upon application from the proprietor, waive the requirement for assigning serial numbers to packages of spirits at the time of filling or receipt on bonded premises if he finds that the revenue will not be jeopardized, and no administrative difficulties will be caused by such waiver. When such waiver has been granted, the lot identification shall constitute the package identification number. When it becomes necessary, as a result of a transaction (such as the transfer in bond of the packages in an unsealed conveyance, withdrawal of the packages from bond on the basis of an individual package gauge, etc.) occurring after deposit of such unnumbered packages, the proprietor who is conducting the transaction shall consecutively number each package involved in the transaction and such number, in conjunction with the lot identification, shall thereafter constitute the package identification number.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended (26 U.S.C. 5206))

§ 19.594 Numbering of packages and cases.

Packages of spirits filled during processing operations, including packages of denatured spirits, and cases containing bottles or other containers of spirits (including denatured spirits) shall, when filled, be consecutively numbered in a separate series by the proprietor commencing with "1" in each series of serial numbers, except that any series of such numbers in use may be continued. When the numbering in any series reaches "1,000,000", the proprietor may recommence the series. However, a new series for packages of spirits filled during processing operations, including packages of denatured spirits, shall be given an alphabetical prefix or suffix. For additional identification, separate series of serial numbers, distinguished from each other by the use of alphabetical prefixes or suffixes, may be established to identify size of bottles, brand names, or other information, on written notice to the regional regulatory administrator. Remnant cases shall be given the serial number of the last full case followed by the letter R. Where there is a change in the individual, firm, corporate name, or trade name, all series in use at that time shall be continued. However, for a change in proprietorship, a new series shall be commenced.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended (26 U.S.C. 5206))

§ 19.595 Specifications for marks and brands.

The proprietor shall place the prescribed marks and brands on cases and encased containers of spirits by printing, stenciling, or stamping and shall place the prescribed marks and brands on packages of spirits by burning, cutting, printing, or stenciling; the prescribed marks and brands may also be made by any equally legible and durable method approved by the regional regulatory administrator. The marks required to be placed on packages by this subpart shall be placed on one head, which shall be called the Government head, and the marks for other containers, and for cases, on one side, which shall be called the Government side. However, the proprietor may, on application, to, and approval by, the regional regulatory administrator, locate the required marks on a container at a place other than that prescribed by this section. The letters and figures shall be large enough to be easily read and, when printed, stamped, or stenciled, shall be in permanent ink and in a color distinctly in contrast to that of the background. The prescribed marks on packages, cases, and encased containers of specially denatured spirits may be placed thereon in the manner provided in this section, or may be placed thereon by means of labels if the labels are clearly legible and securely affixed to the package, case, or container.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended (26 U.S.C. 5206))

§ 19.596 Marks on packages of spirits filled on bonded premises.

(a) *Packages filled in production or storage.* Except as otherwise provided in this part packages of spirits filled in production or storage shall be marked with—

(1) The name of the producer, or his trade name as provided in paragraph (c) of this section;

(2) The plant number of the producer, such as "DSP–KY–708";

(3) The kind of spirits or, in the case of distillates removed under § 19.325, the kind of distillates such as "Grape distillate", "Peach distillate", etc;

(4) The package identification number;

(5) The date of fill;

(6) "BSA" or "OC" when spirits are treated with caramel or oak chips, as the case may be;

(7) The rated capacity of the package in gallons shown as "RC–G"; and

(8) If packages of spirits of 190 degrees or more of proof are filled by other than the producer, the name (or trade name) and plant number of the packaging proprietor shall be substituted for that of the producer.

(b) *Packages filled in bond during processing.* Except as otherwise provided in this part, packages of spirits filled on bonded premises during processing shall be marked with—

(1) The name of the processor, or his trade name as provided in paragraph (c) of this section;

(2) The plant number of the processor, such as "DSP–KY–708";

(3) The kind of spirits (in the case of an intermediate, the product name shown on Form 5110.38);

(4) The serial number, as applicable;

(5) The date of filling; and

(6) If manufactured under an approved formula, the serial number of the formula.

(c) *Real or trade names.* The producer's real name or any trade name authorized (as provided in § 19.165), at the time of production, may be placed on any package filled at the time of production gauge, or at the time of original packaging of the spirits in wood when, as provided in § 19.320, the spirits were not filled into wooden packages at the time of production gauge. When spirits have been mingled under § 19.346, the proprietor may use any of the names represented in the mingled spirits, but no other name, as the name of the producer to be marked on packages filled with such mingled spirits. However, if the proprietor was the actual producer of the spirits, he may in any case use his real name. The processor's real name or any trade name authorized (as provided in § 19.165) may be placed on any package filled with spirits during processing operations.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended (26 U.S.C. 5206))

§ 19.597 Kind of spirits.

(a) *Designation.* The designations as to kind of spirits required by § 19.596 shall be in accordance with the classes and types of spirits set out in Part 5 of this chapter, except that:

(1) Spirits distilled at more than 160 degrees of proof, which lack the taste, aroma, and other characteristics generally attributed to whisky, brandy, rum, or gin, and which are substantially neutral in character, may be designated as "Alcohol". When alcohol is withdrawn on determination of tax, the designation shall consist of the word "Alcohol" preceded or followed by a word or phrase descriptive of the material from which the alcohol was produced.

(2) The designations for vodka, neutral spirits, or gin shall include a word or phrase descriptive of the material from which the spirits so designated were produced.

(3) Spirits distilled at less than 190 degrees of proof which lack the taste, aroma, and other characteristics generally attributed to whisky, brandy, rum, or gin, may be designated "Spirits", preceded or followed by a word or phrase descriptive of the material from which produced. However, spirits distilled on or after July 1, 1972, distilled as provided in this paragraph may not be designated "Spirits grain" or "Grain spirits".

(4) Spirits distilled from fruit at or above 190 degrees of proof, if intended for use in wine production, shall be designated "Neutral Spirits—Fruit", preceded or followed by the name of the fruit from which produced.

(5) Spirits distilled at not more than 160 degrees of proof from a fermented mash of not less than 51 percent rye, corn, wheat, malted barley, or malted rye grain, packaged in reused cooperage, may be designated "Whisky" if further qualified with the words "Distilled from rye mash" (or bourbon, wheat, malt, or rye malt mash, as the case may be). However, such spirits shall, if distilled from a fermented mash of not less than 80 percent corn, be designated "Corn Whisky."

(b) *Change of designation.* A proprietor may, on written application to, and approval of the regional regulatory administrator, change the original designation for spirits at any time, before their withdrawal from bonded premises, to a new designation properly describing the spirits in accordance with the provisions of this section.

(c) *Other designations.* If the proprietor proposes to produce spirits for which a designation has not been prescribed, he shall first make written application to the Director for a designation for such spirits and such spirits shall be branded accordingly.

(d) *Spirits for nonindustrial use.* The provisions of this section shall not be construed as authority for applying designations to spirits withdrawn for nonindustrial use which designations do not comply with provisions of 27 CFR Part 5.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended (26 U.S.C. 5206))

§ 19.598 Authorized abbreviations to identify spirits.

The following abbreviations may be used, either alone or in conjunction with descriptive words, to identify the kind of spirits on transaction forms and records:

Kind of spirits:	*Abbreviations*
Alcohol	A
Brandy	BR
Bourbon Whisky	BW
Canadian Whisky	CNW
Completely Denatured Alcohol	CDA
Corn Whisky	CW
Grain Spirits	GS
Irish Whisky	IW
Light Whisky	LW
Malt Whisky	MW
Neutral Spirits	NS
Neutral Spirits Grain	NSG
Rye Whisky	RW
Scotch Whisky	SW
Specially Denatured Alcohol	SDA
Specially Denatured Rum	SDR
Tequila	TEQ
Vodka	V
Whisky	W

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended (26 U.S.C. 5206))

§ 19.599 Change of packages.

When spirits are transferred from one package to another as authorized in § 19.345, each new package shall be given the same package identification number, marks, and brands as the original package. The proprietor shall prepare and sign a label to be affixed to the head of each new package in the manner prescribed for affixing distilled spirits stamps. The label shall be in the following form:

The spirits in this
,_____,
(Kind of cooperage)
,_____,
(Barrel or drum)
,_____
,package identification No.,
,_____
,were transferred from a
,_____,
(Kind of cooperage)
,_____,
(Barrel or drum)
on
,_____,
(Date)
,_____,
(Proprietor)

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended (26 U.S.C. 5206))

§ 19.600 Packages of blended brandy or rum.

When brandy or rum is blended in accordance with the provisions of § 19.346(c), packages containing such spirits shall be marked to show the words "Blended by" followed by the name and the plant number of the blending proprietor in lieu of showing the name and plant number of the producer. However, if the blender was the actual producer of the spirits, he may mark the packages to show "Produced and Blended by" followed by his name and plant number where the spirits were blended. Such packages shall otherwise be marked in accordance with the provisions of this subpart.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended (26 U.S.C. 5206))

§ 19.601 Marks on approved containers of specially denatured spirits.

(a) *General.* Each package, case, and encased container of specially denatured spirits filled on bonded premises shall be marked or labeled to show:

(1) Quantity in gallons;

(2) Serial number;

(3) Plant number of the denaturer;

(4) Designation or abbreviation of the specially denatured spirits by kind (alcohol or rum);

(5) Formula number; and

(6) Proof of spirits which were denatured at other than 190 degrees of proof.

(b) *Location of marks.* Marks or labels shall be affixed to the head of the package or side of the container or case.

(c) *Alternate formulations.* When spirits are denatured under a formula authorizing a choice of types and quantities of denaturants, the container or case shall be marked to show actual types and quantities of denaturants used.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended (26 U.S.C. 5206))

§ 19.602 Marks on containers of completely denatured alcohol.

Each approved container of completely denatured alcohol (except pipelines and bulk conveyances) shall have marked on the head of the package (or side of the can or casing) the name of the proprietor by whom the containers were filled, the plant number where filled, the contents in wine gallons, the apparent proof, the words "Completely Denatured Alcohol", and the formula number.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended (26 U.S.C. 5206))

§ 19.603 Marks on tanks.

When denatured spirits or articles are held in a tank, the formula number of the denatured spirits or article (if applicable) shall be marked or otherwise indicated on the tank.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended (26 U.S.C. 5206))

§ 19.604 Caution label.

Each container of completely denatured alcohol containing 5 gallons or less, sold or offered for sale, shall be labeled to show in plain, legible letters (red or white) the words "Completely Denatured Alcohol" and the following statement: Completely denatured alcohol; contains ingredients which render the product wholly unfit for beverage purposes; if taken internally, will cause serious consequences to health. The name and address of the denaturer may be printed on such label, but no other extraneous matter will be permitted thereon without the approval of the Director. The word "pure", qualifying denatured alcohol, will not be permitted to appear on the label or the container.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended (26 U.S.C. 5206))

§ 19.605 Additional marks on portable containers.

In addition to the other marks required by this part, portable containers (other than bottles enclosed in cases) of spirits (including denatured spirits, as applicable) to be withdrawn from the bonded premises—

(a) Without payment of tax, for export, transfer to customs manufacturing bonded warehouses, transfer to foreign-trade zones or supplies for certain vessels and aircraft, shall be marked as provided in 27 CFR Part 252; or

(b) Tax-free alcohol shall be marked to show the number of the permit of the tax-free user and the date of withdrawal.

The proprietor may show on the Government head or side other information such as brand or trade name; caution notices and other material required by Federal, State, or local law or regulations; wine or proof gallons; and plant control data. However, marks or attachments shall not conceal, obscure, interfere with or conflict with the markings required by this subpart.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended (26 U.S.C. 5206))

§ 19.606 Marks on bulk conveyances.

The provisions of 27 CFR Part 240 apply to marks on bulk conveyances used to transport wine. The provisions of 27 CFR Part 211 apply to marks on bulk conveyances used to transport articles. The proprietor shall securely attach to the route board, or other suitable device, of each bulk conveyance used to transport spirits (including denatured spirits) a label (coated with transparent shellac or otherwise adequately protected) to identify each conveyance or, when applicable, each compartment as follows:

(a) In-bond shipments and shipments of spirits on which the tax has been determined shall bear a label showing the name, plant number, location (city or town and State) of both the consignor and the consignee, and the date of shipment. In the case of in-bond shipments, the words "Shipped in bond by" shall precede the name of the consignor. In addition, such label shall show the quantity in proof gallons (wine gallons for denatured spirits), and the formula number for denatured spirits.

(b) Shipments of spirits (including denatured spirits) for tax-free use shall bear a label showing the name, location (city or town and State) of both the consignor and the consignee, the plant number of the consignor, the permit number the consignee, the date of shipment, the quantity in proof gallons (wine gallons for denatured spirits), and the formula number for denatured spirits.

(c) Shipment of spirits withdrawn without payment of tax, for export, transfer to customs manufacturing bonded warehouses, transfer to foreign-trade zones, or for use in wine production, shall bear a label showing the name and location (city or town and State) of both the consignor and consignee, the plant number of the consignor, the registry number, if any, of the consignee, the quantity in proof gallons, the date of shipment, and the purpose of the withdrawal, as, for example, "For Export", "For Deposit in CMBW Cl. 6", "For Trans. to F.T.Z. No. ———", or "For Use in Wine Production". In addition export shipments shall conform to the requirements of Part 252 of this chapter.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended (26 U.S.C. 5206))

§ 19.607 Marks on cases.

(a) *Mandatory marks.* Except for cases marked as provided in §§ 19.601, 19.602, and 19.608, the following information shall be plainly marked on the Government side of each case of spirits filled in processing:

(1) Serial number;
(2) Kind of spirits;
(3) Plant number where bottled;
(4) Date filled;
(5) Proof; and
(6) Proof gallons.

Cases removed for export, transfer to customs bonded warehouses or customs manufacturing bonded warehouses transfer to foreign-trade zones, or for use as supplies on certain vessels and aircraft, shall bear the additional marks required by 27 CFR Part 252.

(b) *Other marks.* In addition to the required marks on cases filled in processing, the proprietor may include on the Government side of cases, marks as follows:

(1) Name or trade name, and location if desired of the bottler, and in conjunction therewith the word "Bottler";

(2) For products actually distilled or processed by the proprietor, his name or trade name, and location, if desired, and in conjunction therewith the words "Distiller" or "Processor" as applicable;

(3) For products actually imported and bottled by the proprietor, the words "Imported and Bottled By", followed by his name or trade name, and location if desired;

(4) For products bottled for a dealer, the words "Bottled For", followed by the name of such dealer;

(5) Other material required by Federal or State law and regulations.

The marks authorized by this paragraph shall not interfere with or detract from the mandatory marks prescribed in paragraph (a) of this section. No other marks may be placed on the Government side except as authorized by the Director as provided in § 19.609.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended (26 U.S.C. 5206); Sec. 3(a), Pub. L. 91–659, 84 Stat. 1965, as amended (26 U.S.C. 5066))

§ 19.608 Cases of bottled alcohol.

(a) *Mandatory marks.* The Government side of each case of alcohol bottled for industrial use in accordance with Subpart L shall be marked as applicable, to show—

(1) Designation as "alcohol";
(2) Serial number;
(3) Plant number;
(4) Proof;
(5) Proof gallons;
(6) Permit number of the tax-free user;
(7) Information required by 27 CFR Part 252, for cases withdrawn for export, transferred to customs bonded warehouses, transferred to foreign trade zones, or supplies for certain vessels and aircraft.

(b) *Other marks.* (1) The Government side of cases may be marked to show the brand or trade name, or information required by Federal, State, or local law and regulations.

(2) Other marks shall not interfere with or distract from mandatory case marks.

(3) Additional marks may be placed on the Government side of cases if authorized by the Director pursuant to § 19.609.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended, 1369, as amended (26 U.S.C. 5206, 5235))

§ 19.609 Additional marks for cases.

Labels or data describing the contents for commercial identification purposes, or indicating payment of State or local taxes, may appear on the Government side of cases. The Director may authorize designs or other marks on the Government side of cases. Labels, marks, or designs shall not conflict with, or obscure, the markings required by this part. Applications for approval of designs or other marks shall be submitted through the regional regulatory administrator and be accompanied by drawings or other representations showing the proposed marks and the colors in which they will appear.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended (26 U.S.C. 5206))

§ 19.610 Obliteration of marks, brands, stamps, and labels.

Except as to change of designation as provided in § 19.597(b), the marks, brands, stamps, and labels required on any container or case by this part shall not be destroyed or altered until the container or case is emptied. When the proprietor empties any container, the stamps shall be destroyed, and the marks, brands, and labels shall be effaced or obliterated. However, the marks and brands on packages emptied on distilled spirits plant premises need not be effaced or obliterated until the packages are reused or removed from the plant. The provisions of this section shall not apply to containers stamped with strip stamps or alternative devices, or to the permanent marks on tanks required by § 19.278.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5205))

§ 19.611 Relabeling and restamping off bonded premises.

The proprietor of a distilled spirits plant may relabel, affix brand labels, reaffix alternative devices, or restamp bottled taxpaid spirits on wholesale liquor dealer premises or at a taxpaid storeroom on, contiguous to, adjacent to, or in the immediate vicinity of the plant, if such wholesale liquor dealer premises or taxpaid storeroom is operated in connection with the plant.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

§ 19.612 Authorized abbreviations to identify required marks.

In addition to the abbreviations and symbols which are authorized in this part for use in marking containers, the following abbreviations may be used to identify certain required marks:

Required Mark	Abbreviation
Completely denatured alcohol	CDA
Distilled spirits stamps	DSS
Gallon or wine gallon	WG
Gross weight	G
Proof	P
Specially denatured Alcohol	SDA
Specially denatured Rum	SDR
Tare	T
Tax determined	TD
Wine spirits addition	WSA

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended (26 U.S.C. 5206))

§ 19.613 Identification marks on devices other than strip stamps.

Devices approved by the Director as an alternative to strip stamps when affixed to containers of distilled spirits shall be marked at the distilled spirits plant with a permanent and legible identification as follows:

(a) An abbreviation of the State in which the plant is located; and

(b) The plant number.

For example, the identification on devices other than strip stamps for DSP–VA–280 would be identified on the device as "VA280".

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5205))

Subpart R—Liquor Bottle and Label Requirements

§ 19.631 Scope of subpart.

The provisions of §§ 19.632 through 19.640 of this subpart shall apply only to liquor bottles having a capacity of 200 ml or more except where expressly applied to liquor bottles of less than 200 ml capacity. The provisions of §§ 19.641 through 19.650 of this subpart shall apply to all liquor bottles, regardless of size.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended, 1374, as amended (26 U.S.C. 5206, 5301))

Liquor Bottle Requirements

§ 19.632 Bottles authorized.

Liquor bottles shall conform to the applicable standards of fill provided in Subpart E of 27 CFR Part 5, including those for liquor bottles of less than 200 ml capacity. The use of any bottle size other than as authorized in Subpart E of 27 CFR Part 5 is prohibited for the packaging of distilled spirits for domestic purposes. Bottles bearing the indicia required under 27 CFR Part 173 may be used, but need not be used, in bottling spirits for export.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1374, as amended (26 U.S.C. 5301))

§ 19.633 Indicia for bottles.

Except as provided in § 19.634, liquor bottles used for packaging spirits for domestic use shall bear the indicia prescribed in § 173.33 or § 173.34 of this chapter. Additional information may, as provided in Part 173 of this chapter, be permanently marked on such liquor bottles.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1374, as amended (26 U.S.C. 5301))

§ 19.634 Distinctive liquor bottles.

A proprietor desiring approval of a domestic liquor bottle of distinctive shape or design, including bottles of less than 200 ml capacity, whether or not such bottles bear the indicia required under 27 CFR Part 173, or, to use such distinctive liquor bottle, shall submit a letter application to the Director for approval. Each application shall be accompanied by ten 5" × 7" photographs and, if the bottle has not previously been declared distinctive, an actual bottle or an authentic model or other representation acceptable to the Director. Each application shall contain the following information as applicable:

(a) Date of application;

(b) Name, address and permit number of applicant;

(c) Description of the bottle;

(d) Size of the bottle;

(e) Kind of spirits to be contained in the bottle;

(f) A request to have the bottle declared distinctive (if the bottle has not previously been so declared by the Director);

(g) Distinctive container number (if the bottle has been previously declared distinctive by the Director);

(h) A request to have the bottle declared distinctive, and names, addresses and distilled spirits plant numbers of the plants where the bottle will be used;

(i) A request for waiver of headspace requirements, as provided in § 5.48 of this chapter; and

(j) Signature and title of applicant.

Properly submitted applications for approval of a distinctive liquor bottle, or for use of a distinctive liquor bottle, will be approved provided such bottles are found by the Director to meet the requirements of 27 CFR Part 5, to be distinctive, not to jeopardize the revenue, to be suitable for their intended purpose, and not to be deceptive to consumers. If the application is approved, the Director will send one photocopy of the approved application and one approved photograph of the distinctive bottle to the applicant and to each regional regulatory administrator.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1374, as amended (26 U.S.C. 5301))

§ 19.635 Receipt and storage of liquor bottles.

No proprietor shall accept shipment or delivery of liquor bottles except from the manufacturer thereof, a supplier abroad, or another proprietor. However, the Director may, pursuant to letterhead application, authorize a proprietor to receive and reuse liquor bottles assembled for such proprietor as provided in 27 CFR 194.263. Liquor bottles, including those of less than 200 ml capacity, shall be stored in a safe and secure place, either on the proprietor's qualified premises or at another location.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1374, as amended (26 U.S.C. 5301))

§ 19.636 Bottles to be used for display purposes.

Liquor bottles may be furnished to liquor dealers for display purposes, provided that each bottle is marked to show that it is to be used for such purpose. Any paper strip used to seal the bottle shall be of solid color and without design or printing, except that the use of a border or a design, formed entirely of the legend, "not genuine—for display purposes only" is permissible. The Disposition of such bottles, showing names and addresses of consignees, dates of shipment, and size, quantity, and description of bottles, shall be included in the records required under § 19.779.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1374, as amended (26 U.S.C. 5301))

§ 19.637 Bottles for testing purposes.

A proprietor may, on notice to the regional regulatory administrator of the region in which the plant is located, ship a reasonable number of liquor bottles for bona fide testing purposes, such as the testing of bottling machinery by the manufacturer thereof. The notice shall show the name and address of the person to whom the bottles are shipped and the number of bottles shipped. Such shipments shall be reflected in the records required under § 19.779.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1374, as amended (26 U.S.C. 5301))

§ 19.638 Bottles not constituting approved containers.

The Director may disapprove for use as a liquor bottle any bottle, including a bottle of less than 200 ml capacity, which he determines to be deceptive. Any such bottle, whether or not it bears the indicia required under 27 CFR Part 173, is not an approved container for the purposes of § 19.581 of this part, and shall not be used for packaging distilled spirits for domestic purposes.

(Sec. 201, Pub. L. 859, 72 Stat. 1374, as amended (26 U.S.C. 5301))

§ 19.639 Disposition of stocks of liquor bottles.

When a proprietor discontinues operations, or permanently discontinues the use of a particular size or type of liquor bottle, the stocks of such bottles on hand shall either be disposed of to another person authorized to receive liquor bottles, or destroyed (including disposition for purposes which will render them unusable as bottles). However, on approval of a written application by the regional regulatory administrator of the region in which the proprietor's plant is located, liquor bottles may be otherwise disposed of.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1374, as amended (26 U.S.C. 5301))

§ 19.640 Use and resale of liquor bottles.

No proprietor shall use any liquor bottle except for packaging distilled spirits, or dispose of any empty liquor bottle except to another person authorized to receive liquor bottles or as provided in § 19.639. Bottles may be furnished to others for display and testing purposes as provided in §§ 19.636 and 19.637, respectively.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1374, as amended (26 U.S.C. 5301))

Bottle Label Requirements

§ 19.641 Certificate of label approval or exemption.

Proprietors are required by 27 CFR Part 5 to obtain approval of labels, or exemption from label approval, for any label to be used on bottles of spirits for domestic use and shall exhibit evidence of label approval, or of exemption from label approval, on request of an ATF officer.

(Sec. 201, Pub. L. 85–859, 72 Stat 1356, as amended (26 U.S.C. 5201))

§ 19.642 Statements required on labels under an exemption from label approval.

All labels to be used on bottles of spirits for domestic use under an exemption from label approval shall contain the applicable information required in §§ 19.643 through 19.650. Where a statement of age or age and percentage is required, it shall have the meaning given, and be stated in the manner provided in 27 CFR Part 5.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

§ 19.643 Brand name, class and type, alcohol content, and State of distillation.

The brand name, class and type as set out in 27 CFR Part 5, and alcohol content of the distilled spirits, by proof, shall be shown on the label except that on labels for liqueurs, cordials, bitters, cocktails, highballs, or other such specialties, the alcohol content may be stated in percentage by volume. Except in the case of "light whisky", "blended light whisky", "blended whisky", "a" "blend of straight whiskies", or "spirit whisky", the State of distillation shall be shown on the label of any whisky produced in the United States if the whisky is not distilled in the State given in the address on the brand label. The Director may, however, require the State of distillation to be shown on the label or permit such other labeling as may be necessary to preclude any misleading or deceptive impression which might otherwise be created as to the actual State of distillation. In the case of "light whisky", as defined in 27 CFR 5.22(b)(3), the State of distillation shall not appear in any manner on any label if the Director finds such State is associated by consumers with an American type whisky (as provided in 27 CFR 5.22), except as part of a name and address as set forth in 27 CFR 5.36(a).

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

§ 19.644 Net contents.

The net contents of liquor bottles shall be shown on the label, unless the statement of the net contents is permanently marked on the side, front, or back of the bottle.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

§ 19.645 Name and address of bottler.

There shall be stated on the label of distilled spirits the phrase "Bottled by", "Packed by", or "Filled by" immediately followed by the name (or trade name) of the bottler and the place where such spirits are bottled. If the bottler is the actual bona fide operator of more than one distilled spirits plant engaged in bottling operations, there may, in addition, be stated immediately following the name (or trade name) of such bottler the addresses of such other plants. However—

(a) Where distilled spirits are bottled by or for the distiller thereof, there may be stated, in lieu of the phrase "Bottled by", "Packed by", or "Filled by", followed by the bottler's name (or trade name) and address, the phrase "Distilled by", followed by the name (or trade name) under which the particular spirits were distilled, or any trade name shown on the distiller's permit (covering the premises where the particular spirits were distilled), and the address (or addresses) of the distiller;

(b) Where distilled spirits are bottled by or for the proprietor of a distilled spirits plant, there may be stated, in lieu of the phrase "Bottled by", "Packed by", or "Filled by", followed by the bottler's name (or trade name) and address, the phrase "Blended by", "Made by", "Prepared by", "Manufactured by", or "Produced by" (whichever may be appropriate to the process involved), followed by the name (or trade name) and the address (or addresses) of the distilled spirits plant proprietor; and

(c) On labels of distilled spirits bottled for a retailer or other person who is not the actual distilled spirits plant proprietor of such distilled spirits, there may also be stated the name and address of such retailer or other person, immediately preceded by the words "Bottled for", or "Distributed by", or other similar statement.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

§ 19.646 Age of whisky containing no neutral spirits.

In the case of whisky containing no neutral spirits, statements of age and percentage shall be stated on the label as provided in 27 CFR Part 5.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

§ 19.647 Age of whisky containing neutral spirits.

In the case of whisky containing neutral spirits, the age of the whisky or whiskies and the respective percentage by volume of whisky or whiskies and neutral spirits, shall be stated on the label as provided in 27 CFR Part 5.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

§ 19.648 Age of brandy.

If brandy is aged for a period of less than two years, the age thereof shall be shown on the label.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

§ 19.649 Presence of neutral spirits and coloring, flavoring, and blending materials.

The presence of neutral spirits or coloring, flavoring, or blending materials shall be stated on labels in the manner provided in 27 CFR Part 5.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

§ 19.650 Country of origin.

On labels of imported distilled spirits there shall be stated the country of origin in substantially the following form: Product of ....," the blank to be filled in with the name of the country of origin.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

Subpart S—Stamps

Strip Stamps and Alternative Devices

§ 19.661 General.

(a) *Spirits bottled-in-bond.* Each bottle of spirits, qualified for the labeling designation "bottled-in-bond" under 27 CFR Part 5, shall when filled, be stamped by the proprietor with a green strip stamp or affixed with an approved alternative device.

(b) *Alcohol and other distilled spirits.* Each bottle or other container of alcohol bottled under 26 U.S.C. 5235, and other distilled spirits bottled on bonded premises, except spirits which are eligible for the labeling designation "bottled-in-bond" under 27 CFR Part 5, as described in paragraph (a) of this section, shall, when filled, be stamped by the proprietor with a red strip stamp or affixed with an approved alternative device.

(c) *Overprinting.* If bottled spirits are to be exported, the word "EXPORT" shall be legibly and durably overprinted on the strip stamp or alternative device. Subject to approval by the Director, strip stamps or alternative devices may be similarly overprinted with the class and type of product or with an appropriate abbreviation or symbol (for example, "BW" for bourbon whisky).

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended, 1369, as amended (26 U.S.C. 5205, 5235))

§ 19.662 Strip stamp format.

All prescribed strip stamps shall be issued in (a) a standard size for bottles or containers of 200 ml capacity or more, and in (b) a small size for bottles or containers of less than 200 ml capacity.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5205))

§ 19.663 Alternative devices.

(a) *Application to use alternative devices in lieu of red or green strip stamps.* Distilled spirits plant proprietors who wish to use devices other than red or green strip stamps on containers of distilled spirits shall file an application with the Director. The application shall contain:

(1) The name, address, and distilled spirits plant number;

(2) A description of the alternative device and method of affixing to containers. Two samples of the proposed alternative device (including designs and lettering) affixed to empty containers shall accompany the application; and

(3) The signature of the proprietor or authorized agent.

(b) *Alternative devices used as an alternative to red or green strip stamps.* (1) Alternative devices shall be approved by the Director prior to use;

(2) Alternative devices, after the containers are filled, shall:

(i) Be marked as required by § 19.613,

(ii) Be securely affixed, and

(iii) Leave a portion of the device remaining on the container after opening.

(3) Any designs or lettering appearing on the alternative device shall also be approved by the Director prior to use.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5205))

§ 19.664 Procurement of strip stamps.

(a) *General.* Strip stamps may be obtained, without charge, by the proprietor, in reasonable anticipation of current needs, from the regional regulatory administrator of the region in which the plant is located, by requisition on Form 428. Stamps may not be procured by one proprietor from another or transferred to another plant operated by the same proprietor, except on authorization by the regional regulatory administrator. Requisitions shall be for full sheets of such stamps. On receipt of the stamps the proprietor shall verify the quantity received and acknowledge receipt, noting any discrepancies, on both copies of Form 428 returned by the regional regulatory administrator, forward one copy of the Form 428 to the regional regulatory administrator and retain one copy on file.

(b) *Alternative method.* When the regional regulatory administrator determines that the interests of the Government will be best served, the stamps may be shipped directly to the proprietor from a location other than the office of the regional regulatory administrator. In that case, the regional regulatory administrator shall notify the proprietor that the strip stamps will be delivered by an alternative method and the minimum quantity, if any, of each size stamp which may be requisitioned on any particular Form 428. Upon approval of Form 428, two copies of the form shall be returned to the proprietor. Upon receipt of the stamps, the proprietor shall (1) indicate the quantity of stamps received and acknowledge receipt, noting any discrepancies, on both copies of Form 428 and (2) return one copy to the regional regulatory administrator, and retain one copy.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5205))

§ 19.665 Affixing stamps or alternative devices.

The proprietor shall affix strip stamps to containers with a suitable adhesive.

The proprietor shall affix alternative devices to containers of distilled spirits as described in the approved application. Upon opening the container, the stamp or alternative device shall be broken and a portion shall remain attached to the container. Strip stamps or alternative devices affixed to containers shall not be concealed or obscured in any manner except that (a) the Director may authorize labels or State stamps to be so affixed as to partially obscure strip stamps or alternative devices, if a need exists, and the manner of affixing the labels or State stamps does not obscure essential information on the strip stamps which is not clearly shown on the bottle or on the labels affixed to the bottle, and (b) a stamp or alternative device may be covered by a cup, cap, seal, carton, wrapping, or other item which can readily be removed without injury to the stamp or which is sufficiently transparent- to be able to read all data on the stamp or alternative device. If a cup, cap, or seal is placed over a stamp or alternative device, a portion of the stamp or alternative device must remain plainly visible. If containers are enclosed in sealed opaque cartons or wrappings, the cartons or wrappings must bear the words, "This package may be opened for examination by ATF Officers". ATF officers have the right to open the cartons and wrappings and examine the containers. Where there is doubt as to the propriety of the use of any cup, cap, or seal, the closure and container should be submitted to the Director for approval.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5205))

§ 19.666 Strip stamp and alternative device accounting.

Proprietors are responsible for the proper control of and accounting for all strip stamps or alternative devices. Strip stamps that have been mutilated shall be destroyed by the proprietor, and unused stamps for which the proprietor has no use, shall be disposed of in accordance with the instructions of the regional regulatory administrator.

Proprietors shall not transfer or dispose of strip stamps charged to their account except as provided in this part. Proprietors shall keep records and submit reports relating to strip stamps and alternative devices in accordance with Subpart W of this part.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5205); Sec. 807, Pub. L. 96–39, 93 Stat. 284 (27 U.S.C. 5207))

§ 19.667 Restamping of spirits.

Bottles of distilled spirits filled on bonded premises may be restamped under the provisions of Subpart L of this part. Bottles of distilled spirits to which strip stamps or alternative devices have been affixed may also be restamped under the provisions of § 19.611. Replacement of mutilated or missing strip stamps or alternative devices by persons other than proprietors of plants shall be made in accordance with 27 CFR Part 194.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5205))

Distilled Spirits Stamps

§ 19.668 General.

(a) *Containers to be stamped.* Except for containers required to be stamped under § 19.661 and pipelines for the conveyance of spirits, containers of spirits withdrawn from bonded premises on determination of tax, or without payment of tax for the purposes authorized in § 19.531(a)–(d), shall be stamped with a prescribed distilled spirits stamp evidencing compliance with the provisions of 26 U.S.C. Chapter 51, and this part.

(b) *Information on stamp.* The prescribed distilled spirits stamp is serially numbered. It shall be marked, in the space provided, by the proprietor withdrawing or removing the spirits, to show the name and plant number of such proprietor, the date of affixing the stamp to the container, and the serial number or package identification number, as applicable, of the container. When spirits are withdrawn under the provisions of § 19.531(a)–(d), the proprietor shall insert the word "Export" on the stamp.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5205))

§ 19.669 Procurement of distilled spirits stamps.

(a) *General.* Distilled spirits stamps may be obtained by the proprietor, without charge, in reasonable anticipation of current needs, from the regional regulatory administrator of the region in which the plant is located, by requisition on Form 428. Such stamps may not be procured by one proprietor from another proprietor or transferred between plants operated by the same proprietor, except on authorization by the regional regulatory administrator. On receipt of the stamps from the regional regulatory administrator, the proprietor shall (1) verify the quantity received, (2) acknowledge receipt thereof, noting any discrepancies on both copies of Form 428 returned by the regional regulatory administrator, (3) forward one copy of the receipted Form 428 to the regional regulatory administrator, and (4) retain a copy for his files.

(b) *Alternate method.* When the regional regulatory administrator determines that the interests of the Government will be best served, the distilled spirits stamps may be supplied to the proprietor from a location other than the office of the regional regulatory administrator. In such case, the regional regulatory administrator shall notify the proprietor that the stamps will be supplied from an alternate location and inform him of the minimum or maximum quantity, if any, which may be requisitioned on any particular Form 428. Upon approval of Form 428, two copies of the form will be returned to the proprietor. Upon receipt of the stamps, the proprietor shall (1) verify the quantity received, (2) acknowledge receipt thereof, noting any discrepancies on both copies of Form 428 returned, (3) forward one copy of Form 428 to the regional regulatory administrator, and (4) retain a copy for his files.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5205))

§ 19.670 Affixing of distilled spirits stamps.

Distilled spirits stamps shall be affixed and canceled by the proprietor before packages or conveyances are removed from the bonded premises. The stamps shall be securely affixed to the Government head of the package, or the route board, or other suitable device of the bulk conveyance, or to an appropriate part of any other approved container, and thereupon canceled by drawing or otherwise imprinting a line (not less than one-eighth inch wide) in durable red ink diagonally across the stamp. Such stamps (except in the case of packages to be transferred to contiguous premises) shall be covered with a transparent coating of shellac, lacquer, varnish, or equally suitable material to protect the markings on the stamp. Where the bulk conveyance consists of separate compartments, a separate stamp shall be canceled and affixed to the appropriate route board for each compartment. Distilled spirits stamps shall remain on the containers or conveyances until the spirits therein are emptied. Such stamps shall be destroyed, as provided in § 19.610, when the containers are emptied.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5205))

§ 19.671 Restamping packages, conveyances, or other containers.

Any package, conveyance, or other container of spirits which has been duly stamped with a distilled spirits stamp, but from which the stamp has been lost

or destroyed by accident, shall, except as otherwise provided in this chapter, be restamped with another distilled spirits stamp. Notice of restamping shall be made in writing to the regional regulatory administrator for the region in which the package, conveyance, or other container to be restamped is located. The notice, which shall be executed under the penalties of perjury, shall set forth the following:

(a) The package identification number or serial number, as applicable, of each package, conveyance or other container (and proprietor's name thereon);

(b) The location of the package, conveyance, or other container;

(c) A description of the contents;

(d) The applicant's interest in the property;

(e) The tax status of the spirits (supported by certified copies of the withdrawal forms);

(f) Statement by the applicant (or person having knowledge of the facts) that the package, conveyance, or other container was once duly stamped (and evidence thereof); and

(g) The circumstances connected with the destruction or loss of the stamps.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5205))

§ 19.672 Distilled spirits stamp accounting.

Proprietors are responsible for proper control of and accounting for all distilled spirits stamps received. Stamps that have been mutilated shall be destroyed by the proprietor and unused stamps for which the proprietor has no use shall be disposed of in accordance with the instructions of the regional regulatory administrator. Proprietors shall not transfer or dispose of distilled spirits stamps charged to their account except as provided in this part. Proprietors shall keep records and submit reports relating to such stamps in accordance with the provisions of Subpart W.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5205))

Imitation Stamps

§ 19.673 Imitation of prescribed stamps prohibited.

No person shall affix to any container containing or intended to contain distilled spirits, any stamp, mark, brand, or label, in imitation or simulation of any prescribed ATF stamp required to be affixed to any container of distilled spirits.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5205))

Subpart T—Voluntary Destruction

§ 19.681 General.

The tax liability terminates on spirits (including denatured spirits), articles, or wines when voluntarily destroyed in accordance with this part.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1323, as amended, 1381, as amended (26 U.S.C. 5008, 5370))

§ 19.682 Voluntary destruction procedures.

(a) *Notice required.* A proprietor who desires to destroy spirits (including denatured spirits), articles or wines shall file a notice of his intention with the area supervisor at least 7 days prior to the proposed date of destruction. However, the notice may be submitted directly to an ATF officer present at the distilled spirits plant, who may either supervise the destruction or transmit the notice to the area supervisor. The notice shall include, as applicable, the information required for the record of voluntary destruction in § 19.683.

(b) *Destruction.* If, by the date and time specified in the notice, an ATF officer has not supervised the destruction and the area supervisor has not advised the proprietor that the destruction must be supervised, the proprietor may complete the destruction in the manner stated in the notice.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1323, as amended, 1381, as amended (26 U.S.C. 5008, 5370))

§ 19.683 Record of destruction.

The proprietor shall record details of the voluntary destruction of spirits (including denatured spirits), articles, or wines as follows:

(a) Identification of the spirits (including denatured spirits), articles, or wines to include, as applicable, kind, quantity, elements of gauge, name, and permit number of the producer, and identification and type of container;

(b) The reason for the destruction;

(c) The date, time, place, and manner of the destruction;

(d) A statement of whether or not the spirits had previously been withdrawn and returned to bond; and

(e) The name and title of the proprietor's representative who accomplished or supervised the destruction.

(Sec. 807, Pub. L. 96–39, 93 Stat. 284 (26 U.S.C. 5207))

Subpart U—Return of Spirits to Bonded Premises

§ 19.701 Return of taxpaid spirits to bonded premises.

(a) *Taxpaid spirits returned for destruction, denaturation, redistillation, reconditioning, or rebottling.* Distilled spirits on which tax has been paid or determined may be returned to the bonded premises of a distilled spirits plant only for:

(1) Destruction in accordance with § 19.682;

(2) If eligible for denaturation, denaturation in accordance with Subpart M of this part;

(3) Redistillation in accordance with Subpart J of this part;

(4) Reconditioning; or

(5) Rebottling.

Spirits returned under this paragraph shall be gauged upon receipt on bonded premises and the gauge recorded in the appropriate records maintained under Subpart W of this part.

(b) *Restrictions.* When containers of spirits are emptied, the proprietor shall comply with the applicable provisions of § 19.610. Distilled spirits products to which alcoholic ingredients other than distilled spirits have been added and which were withdrawn from a distilled spirits plant before January 1, 1980, may be returned only to the bonded premises of the distilled spirits plant from which withdrawn, for disposition as authorized by this section.

(c) *Applicability of 26 U.S.C. Chapter 51.* All provisions of 26 U.S.C. Chapter 51 and this part, applicable to spirits in ATF bond, shall be applicable to spirits when returned to bonded premises under this section. The provisions of this subpart do not apply to taxpaid bottled spirits returned to bond solely for relabeling or restamping and under the provisions of Subpart L of this part.

(Sec. 807, Pub. L. 96–39, 93 Stat. 285 (26 U.S.C. 5215))

§ 19.702 Receipt and disposition of returned taxpaid spirits.

(a) *General.* (1) Spirits returned to bonded premises pursuant to § 19.701 shall be immediately dumped.

(2) All returned spirits shall be supported by credit memoranda or other documents evidencing the return.

(b) *Gauge and disposition.* (1) On receipt of taxpaid spirits returned to bonded premises, the proprietor shall gauge the spirits for immediate disposition as provided in § 19.701.

(2) The receipt and report of gauge shall be reported on ATF F 5110.17.

(3) The completed ATF F 5110.17 shall be prepared and filed in accordance with instructions on the form.

(4) ATF F 5110.17 shall have attached to it sufficient evidence to establish:

(i) Class and type of the product;

(ii) Proof;

(iii) Distilled spirits plant number from which the spirits were withdrawn upon tax determination;

(iv) Date of tax determination;

(v) If processed under ATF F 5110.38 (Form 27–B Supplemental), the serial number of the form and if withdrawn from a distilled spirits plant prior to January 1, 1980, data sufficient to establish the distilled spirits (and wine, if returned during a calendar year 1980) taxes paid.

(5) A copy of ATF F 5110.17 shall accompany any claim filed under § 19.42 for spirits returned in accordance with this section.

(Sec. 807, Pub. L. 96–39, 93 Stat. 285 (26 U.S.C. 5215))

§ 19.703 Return of recovered denatured spirits and recovered articles.

Recovered denatured spirits and recovered articles may be returned for restoration or redenaturation to the bonded premises of any plant authorized to denature spirits, in accordance with the provisions of Part 211 of this chapter. When containers are emptied, the proprietor shall comply with the applicable requirements of § 19.610. If restoration requires redistillation, the recovered denatured spirits or recovered articles may be returned for that purpose to bonded premises of a plant authorized to produce spirits. When recovered denatured spirits or recovered articles are received, the proprietor shall gauge the materials and record the gauge on Form 5110.26. Spirits recovered by the redistillation of recovered denatured spirits and recovered articles may not be withdrawn from bonded premises except for industrial use or after denaturation. All spirits redistilled under the provisions of this subpart shall be treated the same as if the spirits had been originally produced by the redistiller. These spirits and articles shall be kept apart from all other spirits (including denatured spirits and recovered articles) and shall be promptly redenatured and removed.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1363, as amended, 1372, as amended (26 U.S.C. 5223, 5273))

§ 19.704 Articles and spirits residues received for redistillation.

Articles manufactured under Part 211 of this chapter, and spirits residues of manufacturing processes related thereto, may be received on the bonded premises of a distilled spirits plant authorized to produce distilled spirits, for the recovery by redistillation of the distilled spirits contained in those materials. The proprietor shall gauge the materials when received and record the gauge on Form 5110.26. Spirits recovered by the redistillation of articles and spirits residues may not be withdrawn from bonded premises except for industrial use or after denaturation. All spirits redistilled under the provisions of this subpart shall be treated the same as if the spirits had been originally produced by the redistiller.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1365, as amended (26 U.S.C. 5223))

§ 19.705 Return of recovered tax-free spirits, and spirits and denatured spirits withdrawn free of tax.

(a) *General.* Specially denatured spirits withdrawn free of tax under the applicable provisions of Part 252 of this chapter for exportation or for deposit in a foreign-trade zone, and spirits (including denatured spirits) withdrawn free of tax under the applicable provisions of Part 211 or 213 of this chapter, may be returned: (1) To bonded premises of any distilled spirits plant authorized to produce distilled spirits, for redistillation; or (2) To any bonded premises of a distilled spirits plant pending subsequent lawful withdrawal free of tax. Recovered tax-free spirits may, as provided in Part 213 of this chapter, be returned for redistillation to bonded premises of any distilled spirits plant authorized to produce distilled spirits or to any bonded premises of a distilled spirits plant for restoration (not including redistillation). The return shall be made under the applicable provisions of this part and Part 211, 213, or 252 of this chapter, as appropriate.

(b) *Bonding requirements.* Before spirits (including denatured spirits) are returned to bonded premises, except spirits (including denatured spirits) returned for redistillation, the proprietor shall file a consent of surety on Form 1533 to extend the terms of the operations or unit bond to cover the return of the spirits. The proprietor may file one consent of surety on the bond to extend the terms thereof to cover all spirits which may be returned.

(c) *Procedure.* If the shipment was reported on a Form 1473, the proprietor shall execute the certificate of receipt on that form and forward the original to the regional regulatory administrator. When recovered tax-free spirits, spirits, or denatured spirits are received, they shall be gauged, and the gauge shall be recorded on Form 5110.26. When containers of spirits are emptied, the proprietor shall comply with the applicable provisions of § 19.610. When containers of spirits removed for export are returned to bond, pending subsequent removal for a purpose other than export, the export marks shall be destroyed.

(d) *Limitation.* Spirits recovered by the redistillation of denatured spirits may not be withdrawn from bonded premises except for industrial use or after denaturation. All spirits redistilled under the provisions of this subpart shall be treated the same as if the spirits had been originally produced by the redistiller.

(Sec. 3, Act of June 13, 1934, 48 Stat. 999, as amended (19 U.S.C. 81c); Sec. 201, Pub. L. 85–859, 72 Stat. 1365, as amended (26 U.S.C. 5223))

§ 19.706 Return of spirits withdrawn without payment of tax.

(a) *Spirits withdrawn for export.* Spirits lawfully withdrawn without payment of tax under the provisions of Part 252 of this chapter for exportation, or for transfer to a customs bonded warehouse or a customs manufacturing bonded warehouse, or for deposit in a foreign-trade zone, or for use on vessels and aircraft, and not so exported, transferred, deposited, or used (or laden for use) on a vessel or aircraft, may be returned, under the applicable provisions of this part and Part 252 of this chapter: (1) To the bonded premises of any plant authorized to produce distilled spirits, for redistillation; or (2) To the bonded premises from which withdrawn pending subsequent removal for a lawful purpose.

(b) *Spirits withdrawn for use in wine production.* Wine spirits withdrawn under § 19.532 for use in wine production, and not so used, may be returned to the bonded premises of a distilled spirits plant. The consignee proprietor shall obtain approval, as provided in § 19.506. The wine spirits shall be removed from the winery in accordance with the provisions of Part 240 of this chapter.

(c) *Spirits withdrawn for research, development, or testing.* Spirits withdrawn without payment of tax, under the provisions of Subpart V of this part, for research, development, or testing may be returned to the bonded premises of the distilled spirits plant from which withdrawn. After returning these spirits to bonded premises, they shall be destroyed or returned to vessels in the distilling system containing similar spirits.

(d) *Procedure.* When spirits are received, they shall be gauged by the proprietor; and the gauge shall be recorded on Form 5110.26. When containers of spirits are emptied, the proprietor shall comply with the applicable provisions of § 19.610. When

containers of spirits removed for export are returned to bond pending subsequent removal for a purpose other than export, the export marks and the stamps, if any, shall be destroyed.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1362, as amended, 1365, as amended, 1382, as amended (26 U.S.C. 5214, 5223, 5373); Sec. 3, Pub. L. 91–659, 84 Stat. 1965, as amended (26 U.S.C. 5066))

§ 19.707 Abandoned spirits.

Spirits abandoned to the United States may be sold, without payment of the tax, to a proprietor of a plant for denaturation or for redistillation and denaturation, if the plant is authorized to denature or redistill and denature spirits. These spirits shall be kept apart from all other spirits (including denatured spirits) until denatured. The receipt, gauging, handling, and recordkeeping provisions of § 19.703 are applicable to these spirits.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1370, as amended (26 U.S.C. 5243))

Subpart V—Spirits Withdrawn for Research, Development or Testing

§ 19.721 General.

(a) *Withdrawal of spirits without payment of tax.* Subject to the conditions prescribed in this subpart, spirits may be withdrawn from the bonded premises of a distilled spirits plant by the proprietor without payment of tax for testing or laboratory analysis, in accordance with § 19.724, or for research, development, or testing, in accordance with § 19.725.

(b) *Withdrawal of brandy or wine spirits free of tax.* In addition to being withdrawn under the provisions of paragraph (a) of this section, brandy or wine spirits may be withdrawn from the bonded premises of a distilled spirits plant by the proprietor free of tax for testing or laboratory analysis, in accordance with § 19.724.

(c) *Restrictions.* Distilled spirits shall not be withdrawn under the provisions of this subpart in containers which have been filled and stamped with the strip stamp or affixed with the alternative device as provided in Subpart S.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1318, as amended, 1362, as amended, 1382, as amended (26 U.S.C. 5005, 5214, 5373))

§ 19.722 Taxable withdrawals.

Spirits withdrawn from bonded premises for research, development, or testing are taxable if the spirits are found to have been withdrawn, used, or disposed of in a manner not authorized by this part. If the proprietor is qualified to defer payment of the tax, the tax due shall be included in the proprietor's tax return on Form 5110.35. If a proprietor is not qualifed to defer the payment of tax, the tax on spirits shall be paid by return on Form 5110.32.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1314, as amended, 1318, as amended, 1362, as amended, 1382, as amended (26 U.S.C. 5001, 5005, 5214, 5373))

§ 19.723 Labels.

On each container of spirits to be withdrawn under the provisions of § 19.724 or § 19.725, the proprietor shall affix a label showing the following information:

(a) The words "Research", "Development", or "Testing", as appropriate;

(b) The kind of spirits (and for imported spirits, the word "Imported");

(c) The size of the container and the proof of the spirits;

(d) If the spirits are to be removed to other than the immediate or contiguous premises of the proprietor, the name and address of the consignee;

(e) The name of the proprietor and the plant number;

(f) The date of the sample taken.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended, 1362, as amended, 1382, as amended (26 U.S.C. 5206, 5214, 5373))

§ 19.724 Withdrawals for testing or laboratory analysis.

(a) *General.* Subject to the conditions prescribed in this subpart, the proprietor may withdraw spirits without payment of tax, or wine spirits or brandy free of tax, from the bonded premises, for testing or laboratory analysis (other than consumer testing or other market analysis) to determine the quality or character of the finished product. A quantity of spirits not exceeding 1 liter may be furnished to a prospective purchaser for quality testing, if a bona fide written or oral purchase agreement exists which is contingent upon quality approval by a prospective purchaser of spirits or denatured spirits.

(b) *Limitations.* Except for spirits furnished to a prospective customer, as provided in paragraph (a) of this section, spirits withdrawn for testing or laboratory analysis shall be removed to the proprietor's laboratory located at the same distilled spirits plant or to a laboratory located at the distilled spirits plant of an affiliated or subsidiary corporation, to the proprietor's central laboratory, or, if approved by the regional regulatory administrator to a recognized commercial laboratory. These spirits shall be withdrawn in containers not exceeding 1 liter, unless the regional regulatory administrator has authorized removal in larger containers. Taxes shall be paid when the spirits are used for any purpose other than the purpose authorized under this section. Taxes shall also be paid when the quantities of spirits withdrawn under this section are in excess of the amount necessary for the conduct of the proprietor's operations.

(c) *Recording samples.* At the time of withdrawal, the proprietor shall record the removal in the record required by § 19.776.

(d) *Disposition.* Remnants or residues of spirits remaining after testing may not be accumulated beyond a reasonable time. Accumulated spirits shall be destroyed or returned to the continuous distilling system containing similar spirits. If the spirits are tested in a laboratory at the plant premises from which removed, the date and manner of disposition shall be recorded in the record maintained under § 19.776.

(e) *Losses.* When spirits are lost prior to their use in testing or laboratory analysis, the proprietor shall either pay the tax or file a claim for remission of tax, as prescribed by § 19.41.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1318, as amended, 1362, as amended, 1382, as amended (26 U.S.C. 5005, 5214, 5373))

§ 19.725 Withdrawals for research, development or testing.

(a) *General.* Subject to the conditions prescribed in this subpart, spirits may be withdrawn from the bonded premises of a distilled spirits plant without payment of tax for research, development, or testing (other than consumer testing or other market analysis) of processes, systems, materials or equipment relating to distilled spirits or distilled spirits plant operations. The amount withdrawn shall be limited to an amount necessary for conduct of the proprietor's operations.

(b) *Consignee's statement.* The proprietor shall secure a written statement, executed by the consignee under the penalties of perjury, agreeing that he will maintain records of the receipt, use, and disposition of all spirits received by him and that those records and operations will be available during regular business hours for inspection by ATF officers. However, a statement will not be required when the spirits are removed to the proprietor's laboratory located at the same plant, or to a laboratory located at the distilled spirits plant of an affiliated or subsidiary corporation.

(c) *Limitation.* The regional regulatory administrator shall proceed to collect the tax on any spirits withdrawn under this section which are found to have been used or disposed of in a manner not authorized by this subpart.

(d) *Losses.* When spirits are lost prior to being used for the authorized purpose, the proprietor shall either pay the tax or file a claim for remission of tax, prescribed by § 19.54.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1318, as amended, 1362, as amended (26 U.S.C. 5005, 5214))

Subpart W—Records and Reports

General

§ 19.741 Records.

(a) *In general.* The records required by this part to be maintained by proprietors shall include:

(1) All records and summaries specifically required by this part;

(2) All supplemental, auxiliary, and source data utilized in the compilation of required forms, records, and summaries, and for preparation of reports, returns, and claims;

(3) Substitute records authorized under the provisions of this part;

(4) Copies of notices, reports, returns, and approved applications and other documents relating to operations and transactions; and

(5) Proprietor's copies of individual transaction forms.

(b) *Accounts.* The records required by this part to be maintained by proprietors shall be arranged into three primary operational accounts:

(1) Production,

(2) Storage, and

(3) Processing. Records shall indicate receipts, movements between accounts, transfers in bond, or withdrawals of spirits, denatured spirits, articles, or wines.

(c) *Exceptions.* The term "records" as used in this subpart does not include copies of qualifying documents required under Subpart G or of bonds required under subpart H of this part.

(d) *Special provisions.* See 27 CFR 70.22 for information with respect to ATF examination of financial records and books of account.

(Sec. 807, Pub. L. 96–39, 93 Stat. 284 (26 U.S.C. 5207))

§ 19.742 Conversion between metric and U.S. units.

Whenever liters are converted to wine gallons, the quantity in liters shall be multiplied by 0.264172 to determine the equivalent quantity in wine gallons. If the conversion from liters to U.S. units is made before multiplying by the number of cases, the quantity in U.S. units shall be rounded off to the nearest sixth decimal place. If the conversion is made after multiplying by the number of cases, the quantity in U.S. units shall be rounded off to the nearest hundredth.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

§ 19.743 Maintenance and preservation of records.

Records required by this part shall be prepared and kept by the proprietor at the plant where the operation or transaction occurs and shall be available for inspection by any ATF officer during business hours. Whenever any record, because of its condition, becomes unsuitable for its intended or continued use, the proprietor shall reproduce such record, by a process approved by the regional regulatory administrator under § 19.746 for reproducing records, and such reproduction shall be treated and considered for all purposes as though it were the original record, and all provisions of law applicable to the original shall be applicable to such reproduction. Records required by this part shall be preserved for a period of not less than four years from the date thereof or the date of the last entry required to be made thereon, whichever is later. Notwithstanding any other provision of this section, record data maintained on data processing equipment may be kept at a location other than the plant premises if the original transaction (source) records required by §§ 19.756–19.778 and the reports required by § 19.786 are kept available for inspection at the plant premises. Data which has been accumulated on cards, tapes, discs, or other accepted record media must be retrievable within five business days. The applicable data processing program shall be made available for examination if requested by an ATF officer.

(Sec. 807, Pub. L. 96–39, 93 Stat. 284 (26 U.S.C. 5207))

§ 19.744 Variations from prescribed forms or records.

(a) *Notice.* Proprietors may, upon the filing of a serially numbered letter notice to the Director, modify certain prescribed forms, or maintain substitute records in lieu thereof, or may, upon the filing of a serially numbered letter notice to the regional regulatory administrator, maintain substitute records in lieu of the records required by this part in order to adapt the use of such forms and records to data processing equipment or special operations, to provide additional information, or for other good cause, if such changes are not inconsistent with the general requirements of clarity and accuracy and do not result in difficulty in processing or filing such forms or difficulty in maintaining and examining such records. Such modified forms or substitute records shall (1) contain the information which would have been on the prescribed form or record, (2) constitute the record or report required by this part, and (3) be subject to the same requirements as the prescribed forms or records. Copies of modified forms or substitute records shall be filed with the applicable notice.

(b) *Exceptions.* No modification shall be permitted on qualification documents, bond forms, claim forms, tax return forms, or forms covering the reports required by § 19.786, unless such modification has been approved by the Director as provided in paragraph (c) of this section.

(c) *Application.* An application to use a modified form in an excepted category shall be submitted to the Director through the regional regulatory administrator. It shall be accompanied by (1) three copies of each proposed form with typical entries thereon and (2) a statement explaining the need for the use of the modified forms. Such modified forms shall not be used until approved by the Director.

(d) *Restrictions.* The use of substitute records or modified forms shall not relieve a proprietor from any requirements of this part. The Director or the regional regulatory administrator, as applicable, may require a proprietor to immediately discontinue the use of any modified form or substitute record when in his opinion the administration of this part will be served thereby.

(Sec. 807, Pub. L. 96–39, 93 Stat. 284 (26 U.S.C. 5207))

§ 19.745 Symbols for proof of distillation.

Where the proof of distillation is required by this part to be shown, the following symbols may be used to designate the proof of distillation: "D190P" for "Distilled 190 proof or over"; "D160P–190P" for "Distilled between 160 and 190 proof"; and "D160P" for "Distilled not over 160 proof"; or in the case of spirits derived from fruit, "D170–190P" for "Distilled between 170 and 190 proof"; and "D170P" for "Distilled not over 170 proof". However, brandy distilled between 140 and 170 proof, not reduced with water, and intended for use in wine production, shall be marked "D–140–170P."

(Sec. 807, Pub. L. 96–39, 93 Stat. 284 (26 U.S.C. 5207))

§ 19.746 Photographic copies of records.

Proprietors who desire to record, copy, or reproduce records, required by this part, by any process which accurately reproduces or forms a durable medium for so reproducing the original of such records, shall apply to

the regional regulatory administrator for permission to do so, describing:

(a) The records to be reproduced,

(b) The reproduction process to be employed,

(c) The manner in which the reproductions are to be preserved, and

(d) The provisions to be made for examining, viewing, and using such reproductions.

The regional regulatory administrator shall not approve any application unless the manner of preservation of the reproductions and the provisions for examining, viewing, and using such reproductions are satisfactory. Whenever records are reproduced under this section, the reproduced records shall be preserved in conveniently accessible files, and provisions shall be made for examining, viewing, and using the reproduced record the same as if it were the original record, and it shall be treated and considered for all purposes as though it were the original record. All provisions of law and regulations applicable to the original shall be applicable to the reproduced record. As used in this section, "original record" shall mean the record required by this part to be maintained or preserved by the proprietor, even though it may be an executed duplicate or other copy of the document.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1395, as amended (26 U.S.C. 5555))

Daily Records

§ 19.751 General.

(a) *Entries.* (1) Each entry required by this part to be made in daily records shall be made on the day on which the operation or transaction occurs.

(2) When the proprietor prepares supplemental or auxiliary records concurrent with the individual operation or transaction, and these records contain all the required information with respect to the operation or transaction, entries in daily records may be deferred not later than the close of business the third business day succeeding the day on which the operation or transaction occurs.

(b) *Content.* (1) All entries in the daily records required by this subpart shall show the date of the operation or transaction.

(2) Daily records shall accurately and clearly reflect the details of each operation or transaction and, as applicable, contain all data necessary to enable—

(i) identification and proper marking, branding, and labeling of spirits, denatured spirits, or wines;

(ii) proprietors to prepare summaries, reports, and returns required by this part; and

(iii) ATF officers to—

(A) verify and trace the quantity and movement of materials, spirits, denatured spirits, wines, or alcoholic flavoring materials involved in each transaction or operation;

(B) verify tax determinations and claims; and

(C) ascertain whether there has been compliance with law and regulations.

(c) *Format.* (1) Proprietor's copies of prescribed forms which bear all required details shall be utilized as daily records.

(2) In instances when a form is not prescribed, the proprietor's commercial records (e.g., invoices, bills of lading) which bear all required details shall be utilized as required daily records.

(3) Daily records required by this part shall be so maintained that they clearly and accurately reflect all mandatory information. Where the format or arrangement of the daily records is such that the information is not clearly or accurately reflected, the regional regulatory administrator may require a format or arrangement which will clearly and accurately reflect the information.

(Sec. 807, Pub. L. 96–39, 93 Stat. 284, (26 U.S.C. 5207))

§ 19.752 Details of daily records.

The daily records required by this part shall conform to the following requirements:

(a) Spirits shall be recorded by kind and by quantity in proof gallons, except that removals of bottled products from bonded premises shall be either in wine gallons or liters and proof.

(b) Denatured spirits shall be recorded by formula number and by quantity in wine gallons.

(c) Distilling materials produced on the premises shall be recorded by kind and by quantity in wine gallons. Chemical byproducts containing spirits, articles, spirits residues, and distilling materials received on the premises shall be recorded by kind, by percent of alcohol by volume, and by quantity in wine gallons. When nonliquid distilling materials which are not susceptible to such quantitative determination are received, the quantity of such materials may be determined by weight and shall be so recorded, and the alcohol content need not be recorded. When it can be shown that it is impractical to weigh or otherwise determine the exact quantity of such nonliquid materials, the proprietor may estimate the weight or volume of the material.

(d) Wines received for and used in processing operations shall be recorded by quantity in proof gallons.

(e) Alcoholic flavoring materials shall be recorded by kind (and formula number, if any) and by quantity in proof gallons.

(f) Containers (other than packages bearing package identification numbers) or cases involved in each operation or transaction shall be recorded by type, serial number, and the number of containers (including identifying marks on bulk conveyances), or cases. Package identification numbers, number of packages, and proof gallons per package shall be recorded on storage deposit records reflecting production gauges or filling of packages from tanks; however, only the lot identification numbers, number of packages, and proof gallons per package need be shown for transactions in packages of spirits unless package identification numbers are specifically required by this part.

(g) Materials intended for use in the production of spirits shall be recorded by kind and by quantity, recording liquids in gallons and other materials in pounds, and giving the sugar content for molasses.

(h) The name and address of the consignee or conignor, and if any, the plant number or industrial use permit number of such person, shall be recorded for each receipt or removal of materials, spirits (including denatured spirits), articles, spirits residues, and wine.

(i) The serial number of the tank used for each operation or transaction.

(j) All records shall be specifically noted to indicate spirits designated for bottling-in-bond, or for bottling of industrial alcohol.

(k) When spirits are required to be gauged, all elements of the gauge shall be shown on the required records.

(l) The rate of duty paid on imported spirits shall be shown on the transaction forms or records.

(Sec. 807, Pub. L. 96–39, 93 Stat. 284 (26 U.S.C. 5207))

Production Account

§ 19.756 Daily production records.

(a) *Spirits production.* Each proprietor shall maintain daily records of production operations showing:

(1) The receipt of fermenting material or other nonalcoholic material intended for use in the production of spirits.

(2) The receipt and use of spirits, denatured spirits , articles, and spirits residues received for redistillation.

(3) The receipt and use of extracted oils of juniper berries and other natural

aromatics received for use in gin production.

(4) The fermenting material set in each fermenter or other material used in the production of spirits.

(5) The distilling material produced, received for production, and used in production of spirits, or destroyed or removed from the premises before being distilled (including the residue of beer returned to the producing brewery).

(6) The gauge of spirits in each receiving tank both before and after the production gauge of spirits removed therefrom, the production gauge (in proof gallons) of spirits removed from each tank, the purpose for which removed, and the transaction form and its serial number covering each removal. The details of packages filled pursuant to production gauge shall also be recorded.

(7) The fermenting materials or other nonalcoholic materials removed from the premises.

(8) The quantity and alcoholic content of fusel oil or other chemicals removed from the production system and the disposition thereof with the name of the consignee, if any.

(9) The kind and quantity of distillates removed from the production system.

(10) The kind and quantity of spirits lost or destroyed prior to production gauge.

Records pertaining to production shall be maintained in such a manner that the spirits produced may be traced through the distilling system to the mash or other material from which produced, and the identity of the spirits thus traced may be clearly established.

(b) *Byproduct spirit production.* Each proprietor who manufactures substances other than spirits, in a process which produces spirits as a byproduct, shall maintain daily production records as to each such process showing:

(1) The kinds and quantity of materials received, unless included in records maintained under paragraph (a) of this section.

(2) The spirits produced and disposed of.

(3) The kind and quantity of other substances produced.

(Sec. 807, Pub. L. 96–39, 93 Stat. 284, (26 U.S.C. 5207))

Storage Account

§ 19.760 Daily storage records.

Each warehouseman shall maintain daily transaction records which shall show as applicable:

(a) Spirits or wines received in storage;

(b) Spirits mingled or blended;

(c) Spirits or wines filled into packages from tanks and retained for storage;

(d) Spirits of less than 190 degrees of proof or wines transferred from one tank to another;

(e) Spirits returned to bond;

(f) Spirits or wines voluntarily destroyed;

(g) Spirits or wines lost during storage;

(h) The change of packages;

(i) Addition of oak chips to spirits and the addition of caramel to brandy or rum; and

(j) Disposition of spirits or wines.

(Sec. 807, Pub. L. 96–39, 93 Stat. 284, (26 U.S.C. 5207))

§ 19.761 Storage summary records.

Each warehouseman shall keep current summary records of spirits and wines in storage as follows:

(a) Package accounts shall be maintained on Forms 5110.37, and shall show the number of packages and proof gallons received in and withdrawn from storage as follows:

(1) Separate accounts for—

(i) domestic spirits;

(ii) imported spirits;

(iii) Virgin Islands spirits;

(iv) Puerto Rican spirits; and

(v) wines.

(2) The spirits accounts shall be arranged by—

(i) producer, blender, or warehouseman;

(ii) kind of spirits;

(iii) season or year of filling; (for imported spirits by (A) date of release from customs custody or (B) if filled in ATF bond, the date of fill); and

(iv) except for spirits of 190 degrees or more of proof, (A) state (alphabetically) and (B) plant number (numerically).

(3) The wine accounts shall be composite accounts of each wine by kind in packages.

(b) Tank accounts shall show the proof gallons deposited, in, withdrawn from, and remaining in the tank or tanks covered by such account as follows:

(1) Wines or spirits of less than 190° of proof. Separate accounts shall be maintained on Form 5110.29 for each tank (including tank cars, tank trucks, and similar vessels) containing wines or spirits of less than 190° of proof.

(2) Spirits of more than 190° of proof. A separate account shall be maintained on Form 5110.37 for each kind (class) of spirits of 190° or more of proof, stored in tanks (including tank cars, tank trucks, or similar vessels).

(c) *Summarization.* Package accounts and tank account records shall—

(1) Be summarized at the end of each month to show for each type of container, by each kind, the total proof gallons received in, withdrawn from, and remaining in storage;

(2) Be summarized for lesser periods when required by the regional regulatory administrator; and

(3) Include all losses and gains.

(Sec. 807, Pub. L. 96–39, 93 Stat. 284, (26 U.S.C. 5207))

Processing Account

§ 19.766 Processing.

Each processor shall maintain daily records of transactions and operations with respect to:

(a) Manufacture and bottling of distilled spirits products;

(b) Production of gin or vodka by other than original and continuous distillation;

(c) Finished products in inventory;

(d) Denaturation of spirits; and

(e) Manufacture of articles.

(Sec. 807, Pub. L. 96–39, 93 Stat. 284, (26 U.S.C. 5207))

§ 19.767 Daily records of bottling operations.

Each processor shall maintain daily records of the details of his manufacturing and bottling operations, showing:

(a) The spirits, wines, and alcoholic flavoring materials received from all sources.

(b) The spirits, wines, and alcoholic flavoring materials and nonalcoholic flavoring materials and other ingredients used in the manufacture of a distilled spirits product, as required by § 19.381.

(c) The bottling or packaging of each lot of spirits as required by § 19.394.

(d) The results of bottling proof and fill tests as required by § 19.397.

(e) The rebottling, relabeling, and restamping (including reaffixing alternative devices) of bottled products as required by §§19.404 and 19.405.

(f) The spirits, wines, and alcoholic flavoring materials removed from the premises. The total removals for each day shall be summarized by showing (1) the spirits and wines removed without bottling or packaging, (2) spirits products removed after bottling or packaging, (3) the spirits and wines transferred in bond, and (4) alcoholic flavoring materials removed.

(g) The samples of spirits and wines transferred or withdrawn, and the name and address of the consignee of such samples.

(h) The spirits moved to the production account for redistillation.

(i) The voluntary destruction of spirits, in accordance with Subpart T of this part.

(j) The losses as provided in Subpart P of this part.

The records required by paragraph (a) of this section shall also show the name and plant number of the producer or processor (warehouseman in the case of blended beverage rums or brandies or spirits of 190 degrees or more of proof received from storage) for domestic spirits, the name of the importer and the country of origin for imported spirits, and the name and address of the producer of wines and alcoholic flavoring materials.

(Sec. 807, Pub. L. 96–39, 93 Stat. 284 (26 U.S.C. 5207))

§ 19.768 Production of gin or vodka.

Each processor shall maintain daily records in addition to the record required by § 19.381, of the production of gin or vodka, by means other than original and continuous distillation, as follows:

(a) Spirits used in the production of gin or vodka;

(b) Receipt and use of extracted oils of juniper berries and other natural aromatics; and

(c) Gin or vodka produced.

(Sec. 807, Pub. L. 96–39, 93 Stat. 284 (26 U.S.C. 5207))

§ 19.769 Records of finished products.

Each processor shall maintain daily records and a summary of spirits bottled or packaged in processing as follows:

(a) A beginning quantity of bottled or packaged spirits on hand (book record);

(b) The quantity of spirits bottled or packaged;

(c) The quantity of bottled or packaged spirits disposed of by:

(1) Withdrawal on tax determination;

(2) Transfer in bond (in bulk containers);

(3) Withdrawal free of tax or without payment of tax;

(4) Dumping to bulk for further processing;

(5) Transfer to the production account for redistillation;

(6) Voluntary destruction;

(7) Accountable breakage;

(8) Sampling;

(9) Inventory shortages, overages, and losses; and

(10) Other dispositions.

(d) An ending quantity of bottled or packaged spirits on hand (book record). Daily summary records shall be totaled monthly and used to compile the report required by § 19.786.

(Sec. 807, Pub. L. 96–39, 93 Stat. 283, as amended (26 U.S.C. 5207))

§ 19.770 Records of denaturation operations.

Each processor qualified to denature spirits shall maintain the following daily records of denaturation:

(a) The kind and quantity of denaturants received, used in denaturation of spirits, or otherwise disposed of;

(b) The spirits used;

(c) The quantity of denatured spirits produced, received, removed, or otherwise disposed of;

(d) The recovered denatured spirits or recovered articles received, restored, and/or redenatured;

(e) Packages of denatured spirits filled with a separate record for each formula number and filed in numerical order according to the serial number of the packages;

(f) Losses; and

(g) Disposition of denatured spirits.

(Sec. 807, Pub. L. 96–39, 93 Stat. 284 (26 U.S.C. 5207))

§ 19.771 Records for manufacture of articles.

Each processor qualified to manufacture articles shall maintain daily records arranged by the name and authorized use code of the article to show the following:

(a) Quantity, by formula number of denatured spirits used in the manufacture of the article.

(b) Quantity of each article manufactured; and

(c) Quantity of each article removed, or otherwise disposed of, including the name and address of the person to whom sold or otherwise disposed of.

(Sec. 807, Pub. L. 96–39, 93 Stat. 284 (26 U.S.C. 5207))

Other Records

§ 19.776 Record of spirits withdrawn for research, development, or testing, or laboratory analysis.

The proprietor shall maintain a record of spirits withdrawn without payment of tax or free of tax under the provisions of § 19.724 or § 19.725. The record shall show for each withdrawal—

(a) Date sample taken;

(b) Full identity of the laboratory in which to be tested or consignee;

(c) Whether withdrawn without payment of tax or free of tax;

(d) Kind of spirits;

(e) Identification of container from which withdrawn;

(f) Description of the purpose for which withdrawn;

(g) The size of container(s) in which withdrawn;

(h) The wine gallons and proof withdrawn; and

(i) Date and manner of final disposition after testing (unless withdrawn free of tax).

(Sec. 201, Pub. L. 85–859, 72 Stat. 1362, as amended (26 U.S.C. 5214); Sec. 807, Pub. L. 96–39, 93 Stat. 284 (26 U.S.C. 5207))

§ 19.777 Daily record of strip stamps and alternative devices.

Each proprietor bottling spirits shall maintain, for each day a transaction in strip stamps or alternative devices occurs, a daily record showing the following for:

(a) *Strip stamps.* A record by kind (green or red) and by size (small or standard) showing, by quantity, the strip stamps—

(1) Received,

(2) Affixed (by bottle size),

(3) Lost,

(4) Multiated,

(5) Unaccounted for,

(6) Destroyed or otherwise disposed of, and

(7) On hand at the beginning and at the end of the day.

(b) *Alternative devices.* The number of alternative devices affixed by size of bottle. The record shall be in sufficient detail to enable proprietors to prepare the semiannual report, Form 5100.8, for strip stamps as required by § 19.786.

(Sec. 807, Pub. L. 96–39, 93 Stat. 284 (26 U.S.C. 5207))

§ 19.778 Daily record of distilled spirits stamps.

Each proprietor of bonded premises shall maintain, for each day a transaction in distilled spirits stamps occurs, a daily record of distilled spirits stamps, showing the quantity—

(a) Received;

(b) Used, with annotation to show the applicable transaction form or record and its serial number (if any);

(c) Destroyed or otherwise disposed of; and

(d) On hand at the beginning of the day and at the end of the day.

(Sec. 807, Pub. L. 96–39, 93 Stat. 284 (26 U.S.C. 5207))

§ 19.779 Record of liquor bottles.

Proprietors who bottle distilled spirits shall keep records covering the receipt, use, and disposition of liquor bottles in such manner as to enable any ATF officer to verify and trace the receipt and disposition of such bottles.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1374, as amended (26 U.S.C. 5301))

§ 19.780 Daily record of wholesale liquor dealer and taxpaid storeroom operations.

Where the proprietor, in connection with his plant, conducts wholesale liquor dealer operations, or operates a taxpaid storeroom, on, contiguous to, adjacent to, or in the immediate vicinity of plant premises, or operates taxpaid storage premises at another location from which distilled spirits are not sold at wholesale, he shall maintain daily records of the receipt and disposition of

all distilled spirits and wines at such premises, and of all restamping or relabeling operations. The provisions of this section shall also apply to products returned to a wholesale liquor dealer or taxpaid storeroom from the market. A separate record shall be kept for each such premises. The records in respect of the receipt and disposition of distilled spirits and wines shall contain all data necessary (supported by records including bills of lading and invoices) to enable ATF officers to identify and trace such receipts and dispositions and to ascertain whether there has been compliance with all laws and regulations relating thereto. In addition to any other information shown therein, such records shall include:

(a) *As to receipts and dispositions*—

(1) The date of the transaction (or date of discovery in the case of casualty or theft);

(2) The name and address of each consignor or consignee, as the case may be;

(3) The brand name;

(4) The kind of spirits;

(5) The actual quantity of distilled spirits involved (proof and proof gallons if in packages; wine gallons or liters and proof if in bottles);

(6) The package identification numbers or serial numbers of packages involved;

(7) The name of the producer; and

(8) The country of origin, if imported spirits.

(b) *As to case dispositions*—In addition to the requirements listed in paragraph (a) of this section, the serial numbers of cases involved; however, the regional regulatory administrator may, upon receipt of an application and a finding that such recording is not necessary to law enforcement or protection of the revenue, relieve a dealer from the requirement of recording such case serial numbers.

(c) *As to restamping or relabeling operations*—

(1) The date of the transaction;

(2) The serial numbers of cases involved;

(3) The total number of bottles;

(4) The name of the bottler; and

(5) The number and kind of strip stamps used and/or the number of alternative devices used.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1395, as amended (26 U.S.C. 5555))

Procedures Which Affect All Account Categories

§ 19.781 Inventories.

(a) *General.* Each proprietor shall make a record of inventories of spirits, denatured spirits, and wines required by §§ 19.329, 19.353, 19.421, 19.422, and 19.463. The following information shall be shown:

(1) Date taken;

(2) Identification of container(s);

(3) Kind and quantity of spirits, denatured spirits, and wines;

(4) Losses, gains or shortages; and

(5) Signature, under penalties of perjury, of the proprietor or person taking the inventory.

(b) *Production.* Each proprietor shall record the quarterly inventory of spirits as provided in paragraph (a) of this section.

(c) *Storage.* (1) Each proprietor shall record the quarterly inventory of spirits and wines (except those in packages) as provided in paragraph (a) of this section.

(2) Gains or losses disclosed for each container shall be recorded on the current Form 5110.29 or 5110.37.

(d) *Processing.* Each proprietor shall record inventories as provided in paragraph (a) of this section, and for—

(1) Bulk spirits and wines in process, any gains or losses shall be recorded on the individual dump, batch, or bottling record;

(2) Finished products in bottles and packages, any overages, losses, and shortages shall be recorded in records required by § 19.769; and

(3) Denatured spirits, any gains or losses shall be recorded in the record prescribed by § 19.770.

(e) *Retention.* Inventory records shall be retained by the proprietor and made available for inspection by ATF officers.

(Sec. 807, Pub. L. 96–39, 93 Stat. 284 (26 U.S.C. 5207))

§ 19.782 Submission of transaction forms, records, and reports.

(a) *Transaction forms.* Completed copies of transaction forms and records which must be submitted under the provisions of this part shall be submitted by the proprietor no later than the close of the business day next succeeding the date of the transaction, as provided by this part and by instructions on the individual forms.

(b) *Timely submission of operational notices.* Where this part requires an advance copy of a notice to be submitted before commencing an operation, such notice shall be submitted at such time to provide the area supervisor sufficient opportunity to determine whether such operation should be conducted under supervision.

(c) *Reports.* Reports required by this part shall be submitted by the proprietor in accordance with this part and the instructions on the form.

(Sec. 807, Pub. L. 96–39, 93 Stat. 284 (26 U.S.C. 5207))

§ 19.786 Reports.

(a) Reports required by this section shall be prepared as of the end of the applicable reporting period. The original shall be submitted to the regional regulatory administrator and a copy retained by the proprietor.

(b) Proprietors shall submit the following reports of their operations:

Title and function	Form No.	Reporting period
(1) Production report: Summary of production operations.	5110.40	Monthly
(2) Storage report: Summary of storage operations.	5110.11	Monthly
(3) Processing reports: Summary of processing operations.		
(i) Manufacture/bottling	5110.28	Monthly
(ii) Denaturation (including article manufacture).	5110.43	Monthly
(4) Report of stamps and alternative devices: Summary of strip stamp, alternative device, and distilled spirits stamp activities.	5100.8	Quarterly

(c) All reports required by this part shall be prepared and submitted to the regional regulatory administrator not later than the 15th day of the month following the close of the reporting period.

(Sec. 807, Pub. L. 96–39, 93 Stat. 284 (26 U.S.C. 5207))

Subpart X—Transitional Rules for the All-In-Bond Method of Distilled Spirits Plant Operation

§ 19.901 Scope of subpart.

This subpart provides regulations for conversion to the all-in-bond method of producing, storing, and processing of distilled spirits, denatured spirits, articles, and wines at distilled spirits plants. This subpart addresses the continued operation of distilled spirits plants qualified to operate on December 31, 1979, and includes provisions for (a) filing of new bonds; (b) filing of applications for registration and necessary operating permits; (c) conversion of controlled stock and bulk wines; (d) filing of final returns; and (e) the payment of taxes determined but not paid by the close of business on December 31, 1979.

§ 19.902 Filing of final returns.

(a) *General.* Applicable taxes paid or determined on converted controlled stock and bulk wine under § 19.906, may be taken as an offset for taxes that will be paid with final returns filed under this section. Such credits (without interest) determined under § 19.907 shall first be applied by proprietors to the tax payable with any final returns provided for in this subpart. Any excess credit remaining after the filling of final returns may be applied to returns filed on ATF Form 5110.35. For each amount of tax

credit taken on filed returns, proprietors shall show on the return "credit taken as provided in 27 CFR 19.902".

(b) *ATF Form 4077.* A final return on ATF Form 4077 shall be filed by proprietors on January 15, 1980, to pay all outstanding unsatisfied liability on tax determined distilled spirits which have been withdrawn from bond under 26 U.S.C. 5174(a)(2) through December 31, 1979.

(c) *ATF Form 2527.* A final tax return on ATF Form 2527 shall be filed by proprietors on January 15, 1980, to pay all outstanding unsatisfied liability for taxes incurred under 26 U.S.C. 5021, 5022 and/or 5041 on bulk spirits and wines at distilled spirits plants at the close of business on December 31, 1979. In the remarks section on the ATF Form 2527, proprietors shall show the total taxes reported at line 17, columns (d), (e), and (f). The total taxes shall be reduced by (1) the amount of taxes determined as prescribed in § 19.905, and (2) any taxes determined on rectified spirits and wines on hand at the time of the inventory prescribed in § 19.904 which were reported on ATF Form 2637 but which were not bottled. The difference thus determined shall be reported at line 18 of ATF Form 2527 as the "adjusted total tax" to be paid with the final return.

(d) *ATF Form 2522.* A final return on ATF Form 2522 shall be filed by proprietors on January 15, 1980, to pay all outstanding unsatisfied liability on tax determined distilled spirits which have been withdrawn from bond under 26 U.S.C. 5174(a)(1) through December 31, 1979.

(e) *Returns to be filed and marked.* Final returns shall be filed whether or not taxes are due, and each return shall be conspicuously marked "Final Return".

§ 19.903 Liability for payment of tax.

Except as otherwise provided in this subpart, the tax on all distilled spirits which have been withdrawn from bond on determination of tax, and on which tax has not been paid by the close of December 31, 1979, shall become due on January 1, 1980, and shall be payable, in accordance with 26 U.S.C. 5061, on the applicable final return, as provided in § 19.902.

§ 19.904 Physical inventory.

A physical inventory of all distilled spirits which were designated as controlled or taxpaid stock on December 31, 1979, and bulk wine on distilled spirits plant premises, shall be taken to establish the quantities of each to remain on bonded premises after December 31, 1979, and to provide the basis for filing final claim for operational loss. The inventory shall differentiate between products to be converted to bonded stock and taxpaid products that will remain on bonded premises. The physical inventory may be taken within a period of a few days before or after December 31, 1979, if such period does not include more than one complete weekend and if necessary adjustments are made to reflect pertinent transactions, so that the recorded inventory will agree with the actual quantities of converted bonded stock and taxpaid stock on hand as of close of business December 31, 1979. Records of the inventory shall be prepared and shall indicate the tax established on converted products in accordance with § 19.907(b). All inventory records shall be maintained in sufficient detail to enable ATF officers to verify the amount of any tax established for the purpose of a return, claim, or credit, and shall be executed under the penalties of perjury, as provided in § 19.11.

19.905 Rectification and wine taxes.

When taking the inventory prescribed in § 19.904, proprietors shall determine all liability for taxes incurred under 26 U.S.C. 5021, 5022, and/or 5041 on bulk distilled spirits and wines which at the close of business on December 31, 1979, were not determined and reported on ATF Form 2637. Such taxes not yet determined shall be determined for all bulk spirits and wines and reported on a modified ATF Form 2637. Inventory records shall be kept to support taxes reported on the modified ATF Form 2637, and such taxes shall be included with other taxes to be shown on the final return prescribed in § 19.902.

§ 19.906 Election to convert controlled stock and bulk wine.

Proprietors may, subject to the provisions in Section 808 of The Distilled Spirits Tax Revision Act of 1979, elect to convert to bonded stock any controlled stock or bulk wine on distilled spirits plant premises at the beginning of business on January 1, 1980. Proprietors may elect to convert all or any part of such controlled stock or wine by designating in the final inventory under § 19.904 the applicable portion thereof as bonded stock. Controlled stock which is not designated as converted to bonded stock becomes taxpaid stock, subject to the filing of returns and payment of tax as prescribed in 27 CFR 19.903. Any distilled spirits, wine, or rectification tax previously paid or determined on controlled stock or wine which is converted shall be without interest, credited, or refunded. At the time of election, converted products shall become distilled spirits or wines in bond on which tax has not been paid or determined. Proprietors shall establish the amount of tax to be credited or refunded on products to be converted as provided in § 19.907.

§ 19.907 Tax on converted products.

(a) *Credit or refund.* The amount of tax to be credited or refunded on products converted to bonded stock, as provided in § 19.906, shall be established by the proprietor making the election, as follows:

(1) The tax on products containing only distilled spirits shall be established by determining the quantity and proof of such products, and calculating the proof gallons and tax therefrom. The quantity and proof of bottled products shall be based on the case markings or label information.

(2) The tax on bulk wines shall be established by determining the quantity in wine gallons of each tax rate of wines to be converted, and calculating the total tax on all wines therefrom.

(3) The tax on products containing alcoholic ingredients, other than distilled spirits which were withdrawn from bond on payment or determination of tax shall be established on the basis of the formulation under which such products were manufactured. The amount of tax to be credited or refunded shall be the taxes which were actually paid or determined on the distilled spirits and wines contained in a product, plus applicable rectification tax. The taxes on spirits and wines in these products shall be established as follows:

(i) The taxes actually paid or determined may be calculated for the spirits and wines contained in each lot of product bottled, and therefrom the taxes to be credited or refunded may be established for any part of the lot remaining in the controlled stock to be converted.

(ii) The taxes on products, regardless of kind or brand, which were manfactured under a standard formulation, (i.e., always manfactured with the same amount of spirits and wines) may be established by calculating the actual rate of taxes paid or determined on the spirits and wines in a typical product and then applying the rate to all such product remaining in the controlled stock to be converted.

(iii) The taxes on products that are formulated with varying amounts of spirits and wines may be established by first determining the total wines (at each tax rate) and the total spirits used in each product, from July 1, 1979, to September 30, 1979, then calculating

from the totals an average rate of taxes paid or determined on the spirits and wines in the product, and then applying the average rate to the remaining product in the controlled stock to be converted. If the product to be converted was not manfuactured during the period from July 1, 1979 to September 30, 1979, the proprietor may make the same calculations from the last batch of the product produced prior to July 1, 1979.

(b) *Amount of Tax.* The total distilled spirits, wine, and rectification taxes paid or determined, as established in this section, may be credited or refunded as provided in § 19.902 upon conversion of controlled stock and bulk wine to which the tax pertains. Credit for converted stock may be taken on returns without filing a claim for credit on Form 2635.

§ 19.908 Nondrawback alcoholic flavoring ingredients.

Alcoholic flavoring ingredients on which drawback of tax has not and will not be claimed may be considered distilled spirits in controlled stock for the purpose of conversion of controlled stock for tax credit. Proprietors with such nondrawback alcoholic flavoring ingredients on their control premises on December 31, 1979, may convert the ingredients for tax credit in the same manner as provided for distilled spirits in controlled stock in § 19.906.

§ 19.909 Taxpayment from Customs bond.

Bulk distilled spirits which were withdrawn on payment or determination of tax from Customs bond to the control premises of a distilled spirits plant may be considered controlled stock for the purpose of conversion of controlled stock for tax credit. Proprietors who on December 31, 1979, have such bulk spirits, shall remove the spirits prior to January 1, 1980, or convert the spirits to bonded stock as provided in § 19.906.

§ 19.910 Disposition of on-hand bulk spirits.

Entries in the records of processors after December 31, 1979, for all operations involving the bottling and packaging of distilled spirits shall be made as bonded operations in the bonded processing account. Therefore, all bulk distilled spirits in controlled stock and bulk wine on distilled spirits plant premises on December 31, 1979, must be removed from the bonded premises prior to January 1, 1980, or be converted to bonded stock as provided in § 19.906.

§ 19.911 Spirits in export storage.

Distilled spirits held in an export storage facility at the close of business on December 31, 1979, shall be treated as any other distilled spirits in bond, and may, subject to the provisions of this chapter, be withdrawn for any purpose authorized by 26 U.S.C. Chapter 51.

§ 19.912 Final operational loss claim.

On or after January 1, 1980, proprietors may file final claims for operating losses incurred from July 1, 1979, through December 31, 1979. Such claims shall be filed in the manner provided for final computational year claims in Subpart O of 27 CFR Part 201 in effect on December 31, 1979, and shall be supported by the physical inventory prescribed in § 19.904.

§ 19.913 Continuation of business under new bond.

As provided in Section 809(c) of The Distilled Spirits Tax Revision Act of 1979, each proprietor who is qualified to operate a distilled spirits plant on December 31, 1979, shall, prior to continuing operations on the premises of such plant, furnish a bond as provided in 26 U.S.C. 5173 to cover the operations to be continued. No person shall continue operations on a distilled spirits plant after December 31, 1979, unless the person has a valid operations or unit bond.

§ 19.914 Qualification of distilled spirits plants in existence on December 31, 1979.

(a) *New application.* Each proprietor (and alternate proprietor) of a distilled spirits plant who intends to continue operation after December 31, 1979, shall file a new application for registration with the regional regulatory administrator before January 1, 1980. The approved registration in effect on December 31, 1979, shall remain in effect until the new application is acted upon by the regional regulatory administrator.

(b) *Continuing operations.* With respect to any operation which was permitted to be conducted on May 1, 1979, at premises which were registered on such date under Section 5171 of the Internal Revenue Code of 1954, the determination of whether such premises qualify for registration under such section as a distilled spirits plant shall be made without regard to whether or not—

(1) the person engaged in operations at such premises is registered under such section as a distiller or warehouseman, and

(2) such premises meet the capacity requirements for a bonded warehouse.

An example of such an application would be one filed by a distilled spirits plant proprietor qualified as a rectifier and bottler, without bonded premises.

§ 19.915 Establishment of finished products records.

Records of finished products in bond shall be established January 1, 1980, to include—

(a) Stock held in an export storage facility at the close of business December 31, 1979;

(b) Other stock on bonded premises at the close of business on December 31, 1979; and

(c) Controlled stock converted in accordance with § 19.906 on January 1, 1980.

Subsequent entries in finished products records shall be made in accordance with Subpart W of this part.

§ 19.916 Taxpaid stock on bonded premises.

(a) *Retention of stocks.* Distilled spirits and wines on which the tax has been paid, and distilled spirits in controlled stock on which the tax will be paid, may remain on the bonded premises of the distilled spirits plant during calendar year 1980.

(b) *Separation of stocks.* Such taxpaid spirits and wines shall be physically separated from other distilled spirits and wines on bonded premises. Separation shall be accomplished by the use of separate tanks, rooms, or buildings, or by partitioning, or by such other methods equally protective of the revenue which the regional regulatory administrator finds will properly distinguish between bonded and taxpaid distilled spirits or wines. The locations on bonded premises where taxpaid stock will be kept shall be appropriately identified to show the tax status of the stock held there.

(c) *Special conditions.* The taxpaid stock referred to in this section shall consist of all distilled spirits and wine on which tax has been paid or is due on January 1, 1980, and which are stored in buildings or rooms on distilled spirits plant premises that become bonded premises as of January 1, 1980.

§ 19.917 Records of taxpaid stock remaining on bonded premises during 1980.

Records shall be kept to show full accountability for taxpaid distilled spirits and wines that remain on bonded premises, as provided in § 19.916, and they shall be maintained separately from the records required to be kept for taxpaid storeroom and wholesale liquor dealer operations. When taxpaid distilled spirits and wines are removed from the bonded premises of a distilled spirits plant to a taxpaid storeroom or wholesale liquor dealer premises, operated in connection with a distilled spirits plant, during 1980, the receipt of

the products shall be shown in the records required by § 19.780 (records of taxpaid storeroom and wholesale liquor dealer operations).

§ 19.918 Filing of tax return, ATF Form 5110.35.

Every proprietor, who on January 1, 1980, is qualified under a withdrawal or unit bond to defer payment of distilled spirits tax, shall file a tax return on ATF Form 5110.35, as provided in this section, and in § 19.522. Such return shall be filed for each prescribed return period, whether or not liability is incurred during a period, with the first return to be filed by February 5, 1980, for the return period inclusive of January 1 through January 15, 1980.

§ 19.919 Return of products containing taxpaid wine.

With respect to distilled spirits returned to the bonded premises of a distilled spirits plant during calendar year 1980, the proprietor may claim a credit or refund of the tax imposed under 26 U.S.C. 5001(a)(1) (or the tax equal to such tax imposed under 26 U.S.C. 7652) on the spirits so returned as well as any tax imposed under 26 U.S.C. 5041 on the wine contained in the product. With respect to such spirits returned after calendar year 1980, the proprietor may claim a credit or refund of only the tax imposed under 26 U.S.C. 5001(a)(1) (or the tax equal to such tax imposed under 26 U.S.C. 7652) on the spirits so returned.

§ 19.920 Curtailment and extension of distilled spirits plant and bonded wine cellar premises.

A proprietor of a contiguous or adjacent distilled spirits plant and bonded wine cellar which on December 31, 1979, are subject to alternate curtailment and extension of premises for the conduct of operations required to be carried on under the opposite registration may continue such curtailment and extension to conduct the operations for which they were qualified on December 31, 1979, until the required new application for registration of the distilled spirits plant has been acted upon by the regional regulatory administrator.

§ 19.921 Continuation of alternate methods or procedures.

Proprietors following alternate methods or procedures which were approved prior to January 1, 1980, shall determine the propriety of continued operation under the methods or procedures. If any approved alternate method or procedure is inconsistent with any regulatory provisions in this chapter after January 1, 1980, operations under the approval shall be immediately discontinued.

§ 19.922 Supervision.

(a) *General.* Notwithstanding the provisions in Subpart E of this part, the same degree and extent of on-premises ATF supervision exercised at distilled spirits plants under law and regulations in effect prior to January 1, 1980, shall be continued at each plant until the regional regulatory administrator requests, receives, and approves a proprietor's statement of security as provided in § 19.281. Such on-premises supervision by ATF officers shall include, but is not limited to, the gauging or the supervision of the gauge of spirits transferred to or received in a processing account and the affixing of Government locks to tanks of spirits and rooms or buildings containing packages of spirits.

(b) *Curtailment.* The regional regulatory administrator may curtail ATF on-premises supervision at a proprietor's distilled spirits plant, after approval of the proprietor's statement of security.

(c) *Notification.* The proprietor shall be notified, in writing, of any intended curtailment of supervision.

(d) *Statement of security.* Upon request of the regional regulatory administrator, the proprietor shall promptly prepare and submit a statement of security as required by § 19.281.

§ 19.923 Removal of seals from the distilling system and other equipment.

Government cap seals affixed to a distilling system and other equipment prior to January 1, 1980, may be removed by the proprietor. Proprietors shall destroy Government cap seals when they are removed.

§ 19.924 Approval of locks.

Proprietors who, on January 1, 1980, do not have approved locks that may be utilized as required by this part, shall submit to the regional regulatory administrator for approval, a timetable for the acquisition of such locks. The timetable shall be prepared according to guidelines established by the regional regulatory administrator for the replacement of Government locks with the approved locks of distilled spirits plant proprietors at plants where direct supervision is to be suspended.

§ 19.925 Pilot operations.

Proprietors authorized under pilot operations to affix their locks on tanks, rooms, buildings, pipelines, etc., in place of Government locks affixed by ATF officers may continue the use of their locks for such purposes, subject to a determination of the need therefor by the regional regulatory administrator, and pending final approval of the locks as provided in § 19.924.

§ 19.926 New sign.

Proprietors, who were qualified to conduct business on May 1, 1979, who qualify to conduct business after December 31, 1979, and whose required sign does not conform to the requirements in § 19.280, may continue to conduct business during 1980 with the existing sign after which time they must place the new sign.

Section D. Part 170 is amended as follows:

PART 170—MISCELLANEOUS REGULATIONS RELATING TO LIQUOR

Paragraph 1. The table of contents is amended to delete Subparts C, F, G and W and to amend the contents of Subpart U. As amended, the table of contents reads as follows:

* * * * *

Subparts B–D—[Reserved]

* * * * *

Subparts F–N—[Reserved]

* * * * *

Subpart U—Manufacture and Sale of Certain Compounds, Preparations, and Products Containing Alcohol

Sec.

170.611 Scope of subpart.
170.612 Meanings of terms.
170.613 Products to which exemptions relate.
170.614 U.S.P. and N.F. preparations.
170.615 Change of formula; when required.
170.616 Products classed as liquors.
170.617 Apothecaries and manufacturers exempt from qualification.
170.618 Sale of products for beverage use; special tax.

Subparts V–Y—[Reserved]

* * * * *

Paragraph 2. Section 170.2 is revised to change a law citation. As revised, § 170.2 reads as follows:

§ 170.2 Statutory authority.

Section of 5205(d), 26 U.S.C., provides that the Secretary may, under regulations prescribed by him, issue stamps for restamping packages of distilled spirits which have been duly stamped, but from which the stamps have been lost or destroyed by unavoidable accident.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5205))

Paragraph 3. Section 170.3 is revised to reflect revised withdrawal procedures under the all-in-bond system. As revised, § 170.3 reads as follows:

§ 170.3 Applications.

Applications for restamping packages of distilled spirits should be made in writing to the regional regulatory administrator. The applicant should state in detail the number of packages, description of the contents, the place where the packages are located, the kind of stamps lost or destroyed, and the nature of the applicant's interest in the property. The applicant shall submit with his application a certified copy of the document showing lawful withdrawal of the packages of spirits from a distilled spirits plant.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5205))

Paragraph 4. Subpart C is revoked in its entirety. The center headings "Subpart B—[Reserved]" and "Subpart D—[Reserved]" are combined to read as follows:

Subparts B–D—[Reserved]

Paragraph 5. Subparts F and G are revoked in their entirety; however, provisions in these Subparts are being incorporated into 27 CFR Parts 19 and 250 as applicable. As amended, the center heading "Subparts H–N—[Reserved]" reads as follows:

Subparts F–N—[Reserved]

§ 170.30 [Amended]

Paragraph 6. Section 170.301 is amended to delete the term "rectified products," in paragraph (a), and the term "rectified products," in paragraph (c).

Paragraph 7. Section 170.303 is amended to update definitions by deleting references to rectified products and by amending the definition of distilled spirits. As amended, § 170.303 reads as follows:

§ 170.303 Meaning of terms.

* * * * *

Alcoholic liquors or liquors. Distilled spirits, wines, and beer, lost, made unmarketable, or condemned, as provided in this subpart.

* * * * *

Distilled spirits, or spirits. Ethyl alcohol and other distillates, such as whisky, brandy, rum, gin, and vodka, in any form (including all dilutions and mixtures thereof, from whatever source or by whatever process produced), on which the internal revenue tax has been paid or determined and, if imported, on which duties have been paid.

* * * * *

Major disaster. * * *

Region. * * *

* * * * *

Tax. (a) With respect to distilled spirits, "tax" means the internal revenue tax that is paid or determined on the spirits.

* * * * *

(c) With respect to beer, "tax" means the internal revenue tax that is paid or determined on the beer.

United States. * * *

* * * * *

§ 170.304 [Amended]

Paragraph 8. Section 170.304 is amended by deleting the term "rectified products," in paragraphs (a) and (b).

Paragraph 9. Section 170.611 is revised to reflect the repeal of the commodity and occupational taxes relating to rectification. As revised, § 170.611 reads as follows:

§ 170.611 Scope of subpart.

This subpart contains provisions relating to persons who compound, mix, manufacture, or sell compounds, mixtures, preparations, or products containing taxpaid distilled spirits or wines.

(Sec. 805, Pub. L. 96–39, 93 Stat. 278 (26 U.S.C. 5002))

Paragraph 10. Section 170.612 is revised to bring the definitions of certain terms into conformity with 26 U.S.C. Chapter 51, as amended. As revised, § 170.612 reads as follows:

§ 170.612 Meanings of terms.

When used in this subpart, where not otherwise distinctly expressed or manifestly incompatible with the intent thereof, term shall have the meaning ascribed in this section. Words in the plural form shall include the singular, and vice versa, and words importing the masculine gender shall include the feminine. The terms "includes" and "including" do not exclude things not enumerated which are in the same general class.

Director. The Director, Bureau of Alcohol, Tobacco and Firearms, the Department of the Treasury, Washington, D.C.

Distilled spirits, or spirits. That substance known as ethyl alcohol, ethanol, or spirits of wine, in any form, including all dilutions and mixtures thereof, from whatever source or by whatever process produced.

Liquors. Distilled spirits and/or wines.

Person. An individual, trust, estate, partnership, association, company, or corporation.

Processor. Except as otherwise provided under 26 U.S.C. 5002(a)(6), any person qualified under Part 19 of this chapter who manufactures, mixes, or otherwise processes distilled spirits (including denatured spirits), or manufactures any article.

Regional regulatory administrator. The principal ATF regional official responsible for administering regulations in this part.

Special tax. The special (occupational) tax imposed by 26 U.S.C. 5111 and 5121 on dealers in liquors.

Taxpaid distilled spirits or wines. Distilled spirits or wines as the case may be, on which the distilled spirits tax imposed by 26 U.S.C. 5001, or the wine taxes imposed by 26 U.S.C. 5041, have been paid or determined.

This chapter. Title 27, Code of Federal Regulations, Chapter I (27 CFR Chapter I).

U.S.C. The United States Code.

Paragraph 11. The center heading immediately preceding § 170.613 is deleted and § 170.613 is amended due to the repeal of rectification taxes. As amended, the introductory clause in paragraph (a) and paragraph (b) of § 170.613 reads as follows:

§ 170.613 Products to which exemptions relate.

(a) *Products meeting requirements.* Apothecaries, pharmacists, and manufacturers are not required to qualify as processors under 26 U.S.C. 5171 before manufacturing or compounding medicines, medicinal preparations, food products, flavors, and flavoring extracts, if the tax has been paid or determined on all of the distilled spirits and/or wines contained therein, as follows:

* * * * *

(b) *Formulas and samples; when required.* On request of the Director, or when in doubt as to the classification of a product, the manufacturer shall submit to the Director the formula for and a sample of the product for examination to verify the manufacturer's claim of exemption from qualification requirements.

(Sec. 805, Pub. L. 96–39, 93 Stat. 275, 278 (26 U.S.C. 5002, 5171))

Paragraph 12. Section 170.614 is revised due to repeal of rectification taxes. As revised, § 170.614 reads as follows:

§ 170.614 U.S.P. and N.F. preparations.

The following United States Pharmacopoeia and National Formulary preparations which are used by physicians and pharmacists principally as vehicles may be made with distilled spirits without qualification by the manufacturer as a processor under 26 U.S.C. 5171 and without incurring liability for special taxes for their sale:

Elixir aromaticum.
Elixir aromaticum rubrum.
Elixir aurantii amari.

Elixir cardamom compositum.
Elixir glycyrrhizae.
Elixir taraxaci compositum.
Elixir terpini hydratis.
Spiritus aetheris.
Spiritus myrciae compositus.
Tinctura aurantii dulcis.
Tinctura limonis.

(Sec. 805, Pub. L. 96-39, 93 Stat. 275, 278 (26 U.S.C. 5002, 5171))

Paragraph 13. Section 170.615 is revised due to repeal of rectification taxes. As revised, § 170.615 reads as follows:

§ 170.615 Change of furmula; when required.

If the regional regulatory administrator finds at any time that any product manufactured under this subpart as an unfit product is being used for beverage purposes, or for mixing with beverage liquors other than by a processor, he shall notify the manufacturer to desist from manufacturing the prouduct until the formula is changed to make the product not susceptible of beverage use and the change is approved by the Director. However the provisions of this section shall not prohibit the use of unfit products in small quantities for flavoring drinks at the time of serving for immediate consumption. Where, pursuant to notice, the manufacturer does not desist, or the formula is not so modified as to make the product unsusceptible of beverage use, the manufactuer shall immediately qualify as a processor.

(Sec. 805, Pub. L. 96-39, 93 Stat. 275, 278 (26 U.S.C. 5002, 5171))

Paragraph 14. Section 170.616 is revised due to repeal of rectification taxes. As revised, § 170.616 reads as follows:

§ 170.616 Products classed as liquors.

United States Pharmacopoeia tincture of ginger is held to be liquor. Bitters, patent medicines, and similar alcoholic preparations which are fit for beverage purposes, although held out as having certain medicinal properties, are also classed as liquors. These preparations are required to be manufactured on the bonded premises of a distilled spirits plant, bottled or packaged, stamped, recorded, and disposed of in accordance with the procedure prescribed in Part 19 of this chapter for other distilled spirits products. Sellers of such preparations shall be subject to the provisions of Part 194 of this chapter with respect to special taxes.

(Sec. 201, Pub. L. 85-859, 72 Stat. 1340, as amended, 1343, as amended (26 U.S.C. 5111, 5121); Sec. 805, Pub. L. 96-39, 93 Stat. 275 (26 U.S.C. 5171))

Paragraph 15. The center heading immediately preceding § 170.617 is deleted and § 170.617 is revised due to repeal of the rectifier's occupational tax. As revised, paragraphs (a) and (b) of § 170.617 reads as follows:

§ 1790.617 Apothecaries and manufacturers exempt from qualification.

(a) *Compounders or manufacturers.* An apothecary, a pharmacist, or a manufacturer is not required to qualify as a processor or, except as provided in § 170.618, to qualify as a dealer in liquors in order to prepare, manufacture, or sell products described in § 170.613 or § 170.614, or products declared by the Director to be unfit for use for beverage purposes.

(b) *Manufacturers recovering taxpaid alcohol.* A manufacturer who recovers taxpaid distilled spirits from dregs or marc of percolation or extraction, or from medicines, medicinal preparations, food products, flavors, or flavoring extracts, which do not meet the manufacturer's standards, is not required to qualify as a processor if such manufacturer uses the recovered distilled spirits exclusively in the manufacture of medicine, medicinal preparations, food products, flavors, or flavoring extracts, which are unfit for use for beverage purposes.

* * * * *

(Sec. 805, Pub. L. 96-39, 93 Stat. 275, 278 (26 U.S.C. 5002, 5171))

Paragraph 16. Section 170.618 is revised due to repeal of the rectifier's occupational tax. As revised, § 170.618 reads as follows:

§ 170.618 Sale of products for beverage use; special tax.

Any person (including the manufacturer) who sells for beverage purposes any of the products described in §§ 170.613 to 170.614, or any other product declared by the Director to be unfit for use for beverage purposes, or any distilled spirits recovered as provided in § 170.617(b), or who sells any such substance under circumstances from which it might reasonably appear that it is the intention of the purchaser to procure the same for sale or use for beverage purposes, is required to pay special tax as a wholesale dealer in liquors or a retail dealer in liquors, as the case may be.

(Sec. 201, Pub. L. 85-859, 72 Stat. 1340, as amended, 1343, as amended (26 U.S.C. 5111, 5121))

Paragraph 17. Subpart W is obsolete and is revoked in its entirety. The center headings "Subpart V—[Reserved]" and "Subparts X-Y—[Reserved]" are combined to read as follows:

Subparts V-Y—[Reserved]

§ 170.683 [Amended]

Paragraph 18. Section 170.683 is amended to delete the phrase "Form 2601" and to insert in lieu thereof the phrase "operations or unit bond". Section E, Part 173 is amended as follows:

PART 173—RETURNS OF SUBSTANCES, ARTICLES, OR CONTAINERS

§ 173.35 [Deleted]

Paragraph 1. The table of contents of 27 CFR Part 173 is amended to delete § 173.35.

Paragraph 2. Section 173.5 is amended to delete a reference to rectified distilled spirits in the definitions. As amended, § 173.5 reads as follows:

§ 173.5 Meaning of terms.

* * * * *

Distilled spirits or spirits. That substance known as ethyl alcohol, ethanol, or spirits of wine, including all dilutions and mixtures thereof, from whatever source or by whatever process produced, and shall include whisky, brandy, rum, gin, and vodka.

* * * * *

§ 173.33 [Amended]

Paragraph 3. Section 173.33 is amended to delete the phrase "Parts 201" and to insert in lieu thereof the phrase "Parts 19".

Paragraph 4. Section 173.34 is amended to delete reference to Part 201 and insert the recodified Part 19. As amended, paragraph (c) of § 173.34 reads as follows:

§ 173.34 Indicia for imported liquor bottles.

* * * * *

(c) *Additional information permanently marked on liquor bottles.* Additional information, such as the name of the foreign manufacturer of the spirits or of the exporter abroad, or the symbol and permit number of the domestic bottler, as applicable, may be permanently marked on liquor bottles provided the information does not conflict with information required to be placed on labels and is so located as not to obscure indicia required by this section or interfere with the labeling or stamping of the bottle, when filled, as provided in Parts 19, 250, and 251 of this chapter.

(46 Stat. 690, as amended, 48 Stat. 999, as amended, 72 Stat. 1336, as amended (19 U.S.C. 1309, 81c, 26 U.S.C. 5062))

§ 173.35 [Deleted]

Paragraph 5. Section 173.35 is obsolete and is deleted in its entirety.

Section F. Part 194 is amended as follows:

PART 194—LIQUOR DEALERS

Paragraph 1. The table of contents is amended to reflect a change in the wording of a subpart and a few sections, and the deletion of a section. As amended, the table of contents reads as follows:

* * * * *

Sec.
194.38 [Deleted]
* * * * *

Subpart P—Strip Stamps or Alternative Devices

194.251 Strip stamps or alternative devices required on all bottles.
194.252 Breaking of strip stamp or alternative device on opening bottle.
194.253 Mutilated or missing strip stamps or alternative devices.
194.254 Affixing strip stamps on containers found to have missing strip stamps or alternative devices.
194.255 Strip stamps or alternative devices found by ATF officers to be mutilated or missing.
194.256 Strip stamp or alternative device replacement not required.
* * * * *

Subpart T—Miscellaneous

* * * * *
194.293 Mixing cocktails in advance of sale.
* * * * *

Paragraph 2. Section 194.11 is amended to change the definitions of "Distilled spirits or spirits" and "Distilled spirits plant" to conform to the all-in-bond concept of operation. As amended, § 194.11 reads as follows:

§ 194.11 Meaning of terms.

* * * * *

Distilled spirits or spirits. That substance known as ethyl alcohol, ethanol, or spirits of wine in any form, including all dilutions and mixtures thereof, from whatever source or by whatever process produced.

Distilled spirits plant. An establishment qualified under Part 19 of this chapter for the production, storage or processing of distilled spirits.

* * * * *

§ 194.38 [Deleted]

Paragraph 3. Section 194.38 is deleted because special occupational tax for a rectifier has been repealed.

Paragraph 4. Section 194.224 is revised to delete reference to Part 201 and to insert the recodified Part 19. As revised, § 194.224 reads as follows:

§ 194.224 Records to be kept by proprietors of distilled spirits plants.

Wholesale liquor dealer operations conducted by proprietors of distilled spirits plants shall be recorded and reported in accordance with the applicable provisions of Part 19 of this chapter.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1342, as amended (26 U.S.C. 5114); Sec. 807, Pub. L. 96–39, 93 Stat. 284 (26 U.S.C. 5207))

Paragraph 5. Section 194.251 and the title to Subpart P are revised to include the use of alternative devices. As revised, the title to Subpart P and § 194.251 read as follows:

Subpart P—Strip Stamps or Alternative Devices

§ 194.251 Strip stamps or alternative devices required on all bottles.

Except as provided in §§ 194.264, 194.271, and 194.272, all distilled spirits in the possession of wholesale or retail dealers in liquors shall be in bottles or similar containers of a capacity of 1 gallon (3.785 liters) or less and shall have the prescribed strip stamps or alternative devices evidencing bottling in compliance with internal revenue law. The strip stamp or alternative device shall be affixed in such manner as to be broken when the container is opened.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5205))

Paragraph 6. Section 194.252 is revised to include the use of alternative devices in lieu of strip stamps. As revised, § 194.252 reads as follows:

§ 194.252 Breaking of strip stamp or alternative device on opening bottle.

The strip stamp or alternative device affixed to a container of distilled spirits (whether affixed over the mouth of the container or in some other authorized manner) shall be broken on opening the container. A portion of the strip stamp or alternative device shall remain attached to the container while any part of the contents remain.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5205))

Paragraph 7. Section 194.253 is revised to include the use of alternative devices in lieu of strip stamps. As revised, § 194.253 reads as follows:

§ 194.253 Mutilated or missing strip stamps or alternative devices.

Any unopened bottle or other approved container of distilled spirits—

(a) From which the strip stamp or alternative device is missing,

(b) On which the strip stamp or alternative device is mutilated to the extent that the genuineness of the stamp or device cannot be determined, or

(c) The contents of which are accessible without breaking the stamp or device, shall be restamped under §§ 194.254–194.255, or be returned to a distilled spirits plant for restamping or to have alternative devices replaced. Where the containers of distilled spirits are to be returned to a distilled spirits plant for restamping or to have devices replaced, the dealer shall record the transaction in his record of disposition and include in this record an accurate description of the containers of distilled spirits to be restamped or to have devices replaced, and the name and address of the proprietor who has agreed to accept the liquors for restamping or for reaffixing alternative devices.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5205))

Paragraph 8. Section 194.254 is revised to include provisions for alternative devices to be used in lieu of strip stamps. As revised, § 194.254 reads as follows:

§ 194.254 Affixing strip stamps on containers found to have mutilated or missing strip stamps or alternative devices.

Containers requiring restamping, as described in § 194.253, shall be set aside by the dealer and an application for necessary stamps submitted with Form 428, Requisition for Bottle Strip Stamps, to the regional regulatory administrator. Copies of Form 428 may be obtained from the regional regulatory administrator. The application shall state the cause of mutilation or absence of stamps or alternative devices and contain evidence that the spirits are eligible for stamping under 26 U.S.C. 5205. The evidence may consist of invoices covering purchase of the spirits, in addition to other available documents. The application shall be signed by the dealer or his authorized agent under the penalties of perjury immediately below a declaration, worded as follows:

> I declare under the penalties of perjury that I have examined this application and to the best of my knowledge and belief it is true and correct.

If the regional regulatory administrator is satisfied from the evidence submitted that the mutilation or absence of the strip stamps or alternative devices has been satisfactorily explained, he will approve the requisition for stamps, Form 428, and deliver the stamps to the applicant by mail or by a representative of his office, with instructions for affixing them to the containers. If an overprinted stamp is to be replaced by

the dealer, the word "Restamped," the name of the dealer, and the date of restamping shall be imprinted, or written in ink, in lieu of overprinting the replacement stamp.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5205))

Paragraph 9. Section 194.255 is revised to include provisions for alternative devices to be used in lieu of strip stamps. As revised, § 194.255 reads as follows:

§ 194.255 Strip stamps or alternative devices found by ATF officers to be mutilated or missing.

When an ATF officer discovers an unopened bottle of distilled spirits which requires restamping or replacement of an alternative device due to conditions specified in § 194.253, the bottle will be set aside. If the officer is satisfied that the spirits are eligible for restamping or for having an alternative device replaced, he will secure from the dealer the application for strip stamps and Form 428 required under the provisions of § 194.254 and forward this information to the regional regulatory administrator. When the ATF officer has reason to believe that the distilled spirits have not been lawfully marked with a strip stamp or alternative device, or that the original contents of the bottle have been replaced or increased by the addition of any substance whatsoever, the spirits will be seized for forfeiture.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended, 1404 (26 U.S.C. 5205, 5613))

Paragraph 10. Section 194.256 is revised to include the use of alternative devices in lieu of strip stamps. As revised, § 194.256 reads as follows:

§ 194.256 Strip stamp or alternative device replacement not required.

Where a minor portion of the stamp or alternative device is missing, or where the strip stamp has dropped off a container and may be reaffixed by the dealer, it will not be necessary to restamp the container or to replace the alternative device.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5205))

Paragraph 11. Section 194.264 is amended to change a reference citation. As amended, § 194.264 reads as follows:

§ 194.264 Mixed cocktails.

A retail liquor dealer who mixes cocktails or compounds any alcoholic liquors in advance of sale, as provided in § 194.293, may not use liquor bottles in which distilled spirits have been previously packaged for the storage of the mixture pending sale.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1374, as amended (26 U.S.C. 5301))

Paragraph 12. Section 194.271 is revised to conform to the changes made in 27 CFR Part 19, and to include the use of althernative devices in lieu of strip stamps. As revised, § 194.271 reads as follows:

§ 194.271 Requirements and procedure.

On compliance with the provisions of Part 19 of this chapter applicable to persons repackaging distilled spirits, a dealer in liquor engaged in the business of supplying alcohol for industrial use may obtain bulk alcohol on which the tax has been paid or determined and repackage the alcohol for sale for industrial use in containers of a capacity in excess of 1 wine gallon and not more than 5 wine gallons.

(a) *Qualification procedure.* Application for registration, Form 5110.41, and application for an operating permit, Form 5110.25, modified in accordance with instructions of the regional regulatory administrator, shall be executed and filed with the regional regulatory administrator. No alcohol shall be repackaged until the approved application for registration and the operating permit are received.

(b) *Operations.* Repackaging operations shall be conducted in accordance with the bottling and packaging requirements of Part 19 of this chapter, except—

(1) Requisitions for strip stamps on Form 428 shall be submitted directly to the regional regulatory administrator, and

(2) Packaging and labeling operations may be carried on without supervision of an ATF officer unless the regional regulatory administrator requires supervision.

(c) *Records.* The dealer shall keep records, daily, showing the bulk alcohol received, dumped for packaging, packaged, strip stamped, and disposed of, including the name and address of each consignor and consignee. A report, on Form 5100.8, of strip stamp transactions shall be prepared as of the close of business March 31, June 30, September 30, and December 31 of each year. The dealer shall also prepare a monthly report on Form 5110.28 of bulk alcohol received, packaged, and disposed of. Reports on Form 5100.8 and Form 5110.28 shall be submitted to the regional regulatory administrator not later than the 15th day of the month succeeding the period for which rendered. Records, documents, or copies of documents supporting the records, and copies of reports submitted to the regional regulatory administrator shall be filed and retained as prescribed in §§ 194.241 and 194.242.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1343, as amended, 1358, as amended, 1360, as amended (26 U.S.C. 5116, 5205, 5206))

Paragraph 13. Section 194.281 is revised to include the use of alternative devices in lieu of strip stamps. As revised, § 194.281 reads as follows:

§ 194.281 General.

A State, or political subdivision thereof, or a person holding a wholesale liquor dealer's basic permit issued pursuant to Part 1 of this chapter may export bottled taxpaid distilled spirits with benefit of drawback to the extent provided in § 252.171 of this chapter. The overprinting of stamps or alternative devices, restamping of bottles, marking of cases, preparation of notice of shipment on Form 5110.30, the removal and exportation of the distilled spirits, and the filing of claims by the processor of the spirits shall be in accordance with the applicable provisions of Parts 19 and 252 of this chapter.

Paragraph 14. Section 194.292 is revised to delete a distilled spirits plant as a place to bottle taxpaid wines. As revised, § 194.292 reads as follows:

§ 194.292 Wine bottling.

Each person desiring to bottle, package, or repackage taxpaid wines shall, before carrying on such operations, apply and receive permission from the regional regulatory administrator, as required under Part 231 of this chapter. The decanting of wine by caterers or other retail dealers for table or room service, banquets, and similar purposes shall not be considered as "bottling," if the decanters are not furnished for the purpose of carrying wine away from the area where served.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1378, as amended (26 U.S.C. 5352))

Paragraph 15. Section 194.38 was deleted because of a reference to rectification tax. However, other requirements of § 194.38 have been retained and appear as a new section, § 194.293. As added, § 194.293 reads as follows:

§ 194.293 Mixing cocktails in advance of sale.

A retail liquor dealer shall not mix cocktails, or compound any alcoholic liquors in advance of sale, except for the purpose of filling, for immediate consumption on the premises, orders received at the bar or in the expectation of the immediate receipt of orders. (For further provisions, see § 194.264.)

(Sec. 805, Pub. L. 96-39, 93 Stat. 277 (26 U.S.C. 5002))

Section G. Part 195 is amended as follows:

PART 195—PRODUCTION OF VINEGAR BY THE VAPORIZING PROCESS

Section 195.10 is amended to update the definition of distilled spirits. As amended, § 195.10 reads as follows:

§ 195.10 Meaning of terms.

* * * * *

Distilled spirits. "Distilled spirits" shall mean that substance known as ethyl alcohol, ethanol, spirits, or spirits of wine in any form (including all dilutions and mixtures thereof, from whatever source or by whatever process produced), and includes low wines produced by the vaporizing process in the manufacture of vinegar.

* * * * *

Section H. Part 196 is amended as follows:

PART 196—STILLS

Section 196.5 is amended to update the definitions of distilled spirits or spirits, and distilling. As amended, § 196.5 reads as follows:

§ 196.5 Meaning of terms.

* * * * *

Distilled spirits or spirits. Distilled spirits or spirits shall mean that substance known as ethyl alcohol, ethanol, or spirits of wine in any form (including all dilutions and mixtures thereof, from whatever source or by whatever process produced).

Distilling. "Distilling" shall mean the distillation of spirits as defined by 26 U.S.C. 5002. Such distillation shall include: (a) the original manufacture of distilled spirits from mash, wort, or wash, or any material suitable for the production of spirits; (b) the redistillation of spirits in the course of original manufacture; (c) the redistillation of spirits, or products containing spirits; (d) the distillation, redistillation, or recovery of spirits or of completely or specially denatured spirits, or of articles containing spirits or completely or specially denatured spirits; and (e) the redistillation or recovery of tax-free spirits.

* * * * *

Section I. Part 197 is amended as follows:

PART 197—DRAWBACK ON DISTILLED SPIRITS USED IN MANUFACTURING NONBEVERAGE PRODUCTS

Paragraph 1. Section 197.5 is amended to change the definition of distilled spirits to conform with the new statutory definition. As amended, § 197.5 reads as follows:

§ 197.5 Meaning of terms.

* * * * *

Distilled spirits. Distilled spirits shall mean that substance known as ethyl alcohol, ethanol, spirits, or spirits of wine in any form (including all dilutions and mixtures thereof, from whatever source or by whatever process produced), which are fully taxpaid or tax-determined at the distilled spirits rate.

* * * * *

Paragraph 2. Section 197.112 is amended to eliminate references to Form 179. As amended, § 197.112 reads as follows:

§ 197.112 Distilled spirits received in tank cars or tank trucks.

Each claim covering distilled spirits received in tank cars or tank trucks shall be accompanied by a statement showing in respect of each shipment received: The date or receipt; the name and address of the vendor; the number or other identification mark of the tank car or tank truck; the serial number of the distilled spirits stamp and the date it was affixed to the tank car or tank truck; the name of the producer, blender, or warehouseman, and the kind, quantity, and proof of the spirits. If the tank car or tank truck is received without the stamp affixed, the vendee shall note the fact on the bill of lading and immediately notify the regional regulatory administrator. (The distilled spirits stamp shall be completely destroyed when the distilled spirits have been removed from the tank car or tank truck.)

Paragraph 3. Section 197.113 is revised to delete a reference to Form 179. As revised, § 197.113 reads as follows:

§ 197.113 Distilled spirits received in barrels, drums, or other portable containers.

Each claim covering distilled spirits received in barrels, drums, or other portable containers bearing distilled spirits stamps shall be accompanied by a statement showing: the date of receipt; the name and address of the vendor; the kind and serial number of the stamp affixed to the container and the date the stamp was issued or affixed as stated on the stamp; the serial number, if any, of the container; the name of the producer, blender, or warehouseman as shown on the commercial invoice provided for in § 197.130b; and the kind, quantity, and proof of the spirits. (When the container is emptied, the stamp shall be completely destroyed.)

Paragraph 4. Section 197.115 is revised to limit the requirement for showing eligible and ineligible proof gallon content to rectified products taxpaid before January 1, 1980. As revised, § 197.115 reads as follows:

§ 197.115 Use of distilled spirits.

Each claim covering the use of distilled spirits in the manufacture of nonbeverage products shall be accompanied by a statement showing the name, description, and formula number, if any, of each nonbeverage product in the manufacture of which distilled spirits were used, the alcoholic content by volume of each product, the number of proof gallons and kind of distilled spirits used in the manufacture, and the quantity produced. If a rectified product containing alcoholic ingredients (other than spirits) on which the tax was paid or determined prior to January 1, 1980, was used as an ingredient in the manufacture of a nonbeverage product, the statement shall show, as to such ingredient, the proof gallon content eligible for drawback and the proof gallon content ineligible for drawback.

Paragraph 5. Section 197.130 is revised due to the repeal of rectification provisions and the elimination of the requirement for strip stamp serial numbers from regulations. As revised, paragraphs (c) and (e) of § 197.130 reads as follows:

§ 197.130 Nature of records.

* * * * *

(c) Kind and serial number of container (such as tank car, drum, case of bottles) and the kind and serial number, if any, of the stamp or alternative device affixed to the container.

* * * * *

(e) Number of proof gallons and kind of distilled spirits used in the manufacture of each product, and the date of use. (The record of rectified distilled spirits products which were taxpaid or tax-determined at the premises of a distilled spirits plant prior to January 1, 1980, and contain spirits not fully taxpaid (or tax-determined) at the distilled spirits rate shall also show the percent of spirits fully taxpaid at the distilled spirits rate and the percent of spirits not so taxpaid.)

* * * * *

Paragraph 6. Section 197.130a is revised to delete references to Form 179 and to reflect recodification of the

Gauging Manual as 27 CFR Part 13. As revised, § 197.130a reads as follows:

§ 197.130a Distilled spirits received and used.

(a) *Receipts.* Each manufacturer shall, at the time of receipt, determine, preferably by weight, and record in his permanent records, the exact quantity of distilled spirits received: *Provided,* That if the spirits are received in a tank car or tank truck and the result of the manufacturer's gauge of the spirits is within 0.2 percent of the quantity reported on the invoice covering the tax-determination of the spirits, the quantity reported on the invoice may be recorded in the manufacturer's permanent records as the quantity received. However, the receiving gauge shall be noted on the record of receipt. Losses in transit, other than those attributable to variations in gauge not exceeding the 0.2 percent limitation as provided in this paragraph, shall be determined but shall not be recorded in the manufacturer's permanent records as distilled spirits received.

(b) *Use.* Each manufacturer shall accurately determine, by weight or volume, the quantity of all distilled spirits used and enter the quantity in the permanent records. Where the quantity used is determined by volume, adjustments shall be made if the temperature of the spirits is above or below 60 degrees Fahrenheit. A correction table, Table No. 7, is available in 27 CFR Part 13, Gauging Manual. Losses after receipt, due to leakage, spillage, evaporation, or other causes shall be accurately recorded in the manufacturer's permanent records at the time the losses are determined.

Paragraph 7. Section 197.130b is amended to reflect replacement of Form 179 by commercial records. As amended, paragraph (a) of § 197.130b reads as follows:

§ 197.130b Evidence of tax payment of distilled spirits.

(a) *Domestic spirits.* All shipments of spirits made from a distilled spirits plant shall be supported by the vendor's commercial invoice which must bear a certification as to tax payment by the person who paid the tax, and include the following information:

(1) The name and address of vendor;

(2) The registry number of the distilled spirits plant from which the spirits were withdrawn on determination of tax;

(3) The number of the applicable invoice;

(4) the name of the producer, blender, or warehouseman of the spirits;

(5) The serial number of the container;

(6) The serial number and date of the distilled spirits stamp; and

(7) The kind of spirits, proof, and proof gallons in the container.

* * * * *

Paragraph 8. Section 197.133 is revised due to the elimination of Form 179. As revised, § 197.133 reads as follows:

§ 197.133 Retention of records.

Each manufacturer shall retain for a period of not less than 2 years all records required by this part, all commercial invoices or shipping documents, and all bills of lading received evidencing receipt and tax determination of the spirits. In addition, a copy of each approved formula returned to the manufacturer shall be retained for not less than 2 years from the date he files his last claim for drawback under the formula. The records, forms and formulas shall be readily available during the manufacturer's regular business hours for examination and taking abstracts by ATF officers.

Section J. Part 200 is amended as follows:

PART 200—RULES OF PRACTICE IN PERMIT PROCEEDINGS

Section 200.16 is amended to incorporate the correct statutory citation for operating permits. As amended, paragraph (c) of § 200.16 reads as follows:

§ 200.16 Other terms.

* * * * *

Permit. (a) * * *

* * * * *

(c) *Operating permit.* "Operating permit" shall mean the document issued pursuant to 26 U.S.C. 5171, authorizing the person named therein to engage in the business described therein.

* * * * *

Section K. Part 211 is amended as follows:

PART 211—DISTRIBUTION AND USE OF DENATURED ALCOHOL AND RUM

Paragraph 1. Section 211.3 is revised to show recodification of Part 201 of this chapter as Part 19. As revised, § 211.3 reads as follows:

§ 211.3 Related regulations.

Regulations relating to this part are listed below:

27 CFR Part 19—Distilled Spirits Plants.
27 CFR Part 196—Stills.
27 CFR Part 200—Rules of Practice in Permit Proceedings.
27 CFR Part 212—Formulas for Denatured Alcohol and Rum.
27 CFR Part 250—Liquors and Articles from Puerto Rico and the Virgin Islands.
27 CFR Part 251—Importation of Distilled Spirits, Wines, and Beer.
27 CFR Part 252—Exportation of Liquors.
31 CFR Part 225—Acceptance of Bonds, Notes, or Other Obligations Issued or Guaranteed by the United States as Security in Lieu of Surety or Sureties on Penal Bonds.

Paragraph 2. Section 211.11 is amended to conform with statutory changes and amendments to distilled spirits plant regulations. As amended, § 211.11 reads as follows:

§ 211.11 Meaning of terms.

* * * * *

Alcohol. Those spirits known as ethyl alcohol, ethanol, or spirits of wine in any form, from whatever source or by whatever process produced; the term does not include such spirits as whisky, brandy, rum, gin, or vodka.

* * * * *

Denaturer. The proprietor of a distilled spirits plant who denatures alcohol or rum pursuant to 27 CFR Part 19.

* * * * *

Manufacturer or user. A person who holds an industrial use permit to use specially denatured alcohol or specially denatured rum or to recover completely or specially denatured alcohol, specially denatured rum, or articles, or a distilled spirits plant proprietor qualified as a processor.

* * * * *

Paragraph 3. Section 211.42 is revised to reflect new provisions allowing distilled spirits plant proprietors to use denatured spirits in the manufacture of articles. As revised, § 211.42 reads as follows:

§ 211.42 Application, Form 1479, for permit to use or recover.

Each person, except a distilled spirits plant proprietor qualified under Part 19 of this chapter, desiring to use specially denatured alcohol or specially denatured rum, or both, and each person desiring to recover denatured alcohol, specially denatured rum, or articles shall, before commencing business, apply for and obtain an industrial use permit, Form 1481. Except as provided in § 211.42a, application for an industrial use permit shall be on Form 1479. The application, and necessary supporting documents as required by this subpart for the permit, shall be filed with the regional regulatory administrator. All data, written statements, affidavits, and other documents submitted in support of the application shall be a part of the application. The application shall be accompanied by evidence which will

establish the authority of the officer or other person who executes the application to execute the same and, where applicable, by the application for a withdrawal permit, Form 1485, required by § 211.161.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1370 as amended (26 U.S.C. 5271))

Paragraph 4. Section 211.215 is revised to reflect recodification of Part 201 of this chapter as Part 19. As revised, § 211.215 reads as follows:

§ 211.215 Denaturants.

Manufacturers shall comply with the applicable requirements of Part 19 of this chapter governing the procurement, use and recordkeeping of denaturants by denaturers.

Paragraph 5. Section 211.219 is revised to reflect recodification of Part 201 of this chapter as Part 19. As revised, § 211.219 reads as follows:

§ 211.219 Shipment of articles and spirits residues for redistillation.

Articles, containing denatured spirits, manufactured under this part, and spirits residues of manufacturing processes related thereto, may, on receipt of an approved copy of the application filed under the provisions of Part 19 of this chapter by the proprietor of a distilled spirits plant authorized to produce distilled spirits, be shipped to the distilled spirits plant for redistillation. Packages of articles or spirits residues shall be identified as to contents and shall otherwise be marked and serially numbered in the manner provided in § 211.217. Notice of shipment shall be prepared on Form 1473, appropriately modified, in the manner provided in § 211.218.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1365, as amended (26 U.S.C. 5223))

Section L. Part 212 is amended as follows:

PART 212—FORMULAS FOR DENATURED ALCOHOL AND RUM

Paragraph 1. Section 212.1 is revised to show the distilled spirits plant regulations as recodified into Part 19 of this chapter. As revised, § 212.1 reads as follows:

§ 212.1 Formulas for denatured spirits.

The regulations in this part relate to the formulation of completely denatured alcohol, specially denatured alcohol, and specially denatured rum; to the specifications for denaturants; and to the uses of denatured spirits. The procedural and substantive requirements relative to the production of denatured alcohol and specially denatured rum are prescribed in Part 19 of this chapter and those relative to the distribution and use of denatured alcohol and specially denatured rum are prescribed in Part 211 of this chapter.

Paragraph 2. Section 212.4 is revised to show the distilled spirits plants regulations as recodified into 27 CFR Part 19. As revised, § 212.4 reads as follows:

§ 212.4 Related regulations.

Regulations related to this part are listed below:

27 CFR Part 19—Distilled Spirits Plants.
27 CFR Part 211—Distribution and Use of Denatured Alcohol and Rum.

Paragraph 3. Section 212.5 is amended to reflect modified definitions for the terms "alcohol" and "manufacturer or user." As amended, § 212.5 reads as follows:

§ 212.5 Meaning of terms.

* * * * *

Alcohol. Those spirits known as ethyl alcohol, ethanol, or spirits of wine in any form, from whatever source or by whatever process produced; the term does not include such spirits as whisky, brandy, rum, gin, or vodka.

* * * * *

Manufacturer or user. A person who holds an industrial use permit to use specially denatured alcohol or specially denatured rum, or to recover completely or specially denatured alcohol, specially denatured rum, or articles manufactured with denatured spirits, or a distilled spirits plant proprietor qualified as a processor.

* * * * *

Section M. Part 213 is amended as follows:

PART 213—DISTRIBUTION AND USE OF TAX-FREE ALCOHOL

Section 213.3 is revised due to recodification of Parts 186 and 201 as 27 CFR Parts 13 and 19, respectively. As revised, § 213.3 reads as follows:

§ 213.3 Related regulations.

Regulations related to this part are listed below:

27 CFR Part 13—Gauging Manual.
27 CFR Part 19—Distilled Spirits Plants.
27 CFR Part 196—Stills.
27 CFR Part 200—Rules of Practice in Permit Proceedings.
27 CFR Part 250—Liquors and Articles from Puerto Rico and the Virgin Islands.
27 CFR Part 251—Importation of Distilled Spirits, Wines, and Beer.
31 CFR Part 225—Acceptance of Bonds, Notes, or Other Obligations Issued or Guaranteed by the United States as Security in Lieu of Surety or Sureties on Penal Bonds.

Section N. Part 231 is amended as follows:

PART 231—TAXPAID WINE BOTTLING HOUSES

Paragraph 1. The table of contents is amended to add Subpart K to provide for alternation of premises. As added, the Table of Contents reads as follows:

* * * * *

Subpart K—Alternation of Premises

231.140 Alternation.

* * * * *

Paragraph 2. Section 231.1 is revised to delete a reference to distilled spirits plant premises for the bottling of taxpaid wine. As amended, § 231.1 reads as follows:

§ 231.1 Bottling or packaging of taxpaid wine.

The regulations in this part relate to the bottling and packaging of taxpaid United States and foreign wines.

Paragraph 3. Section 231.30 is revised to allow for bottling of other than standard wine on taxpaid wine bottling premises. As amended § 231.30 reads as follows:

§ 231.30 General.

Each person desiring to bottle or package taxpaid wine shall provide premises, make application on Form 2975, and receive approval from the regional regulatory administrator, as required in § 231.50, to operate a taxpaid wine bottling house for that purpose. Notwithstanding the provisions of this section and of § 231.50, any proprietor of a taxpaid wine bottling house who has qualified under an application which was not made on Form 2975 need not make a new application on Form 2975 solely by reason of the Form being prescribed.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1378, as amended, 1379, as amended (26 U.S.C. 5352, 5356))

Paragraph 4. Section 231.81 is revised to delete a reference to rectification tax. As amended § 231.81 reads as follows:

§ 231.81 Prohibited practices.

While more than one lot of wine of the same kind (class and type), taxable grade, and country of origin, may be deposited in the same storage container or bottling tank to facilitate handling, the blending of taxpaid wine at a taxpaid wine bottling house is prohibited. Water shall not be added to wine nor the wine subjected to any treatment which will alter its basic character. Unauthorized treatment of wine may result in liability for additional wine tax. The proprietor of a

taxpaid wine bottling house may incur civil or criminal liability by reason of unauthorized treatment of wine.

(Sec. 201, Pub. L. 85-859, 72 Stat. 1407 (26 U.S.C. 5661))

Paragraph 5. Subpart K title and Section 231.140 are added to provide for an alternation of taxpaid wine bottling house premises and distilled spirits plant premises. As added, Subpart K and § 231.140 read as follows:

Subpart K—Alternation of Premises

§ 231.140 Alternation.

Each proprietor of a taxpaid wine bottling house operating a contiguous distilled spirits plant desiring to alternate the use of each premises by extension or curtailment shall file the necessary documents with the regional regulatory administrator as required by 27 CFR 19.204.

(Sec. 201, Pub. L. 85-859, 72 Stat. 1349, as amended, 1353, as amended, 1379, as amended (26 U.S.C. 5172, 5178, 5356))

Section O. Part 240 is amended as follows:

PART 240—WINE

Paragraph 1. The table of contents is revised to reflect a change in the wording of subparts and sections, and the deletion of several sections. As amended, the table of contents reads as follows:

* * * * *

Sec.

240.221a Operations bond or unit bond.

* * * * *

240.281 Amended Form 698 and basic permit.

* * * * *

240.311 Alternation of premises.

* * * * *

240.313 Pipeline change approvals.

* * * * *

240.351 [Deleted]

* * * * *

240.352 Production of other than standard wine.

* * * * *

240.355 [Deleted]

* * * * *

Use of Wine Spirits

240.374 General.
240.375 [Deleted]
240.376 [Deleted]
240.377 [Deleted]
240.378 [Deleted]
240.379 [Deleted]
240.380 [Deleted]

* * * * *

240.480 [Deleted]

* * * * *

240.491 Notice to use distillates containing aldehydes.

* * * * *

Sec.

240.575 [Deleted]

* * * * *

Subpart BB—Transfer of Wine in Bond

* * * * *

240.611 [Deleted]

* * * * *

Subpart PP—Receipt and Use of Wine Spirits

240.820 General.
240.821 Supervision requirements.
240.822 Withdrawal.
240.823 Annual withdrawals.

Receipt of Wine Spirits

240.824 Transfer of wine spirits by pipeline for immediate use.
240.825 Transfer of wine spirits by pipeline to wine spirits storage tank.
240.826 Tank car and tank truck requirements.
240.827 Examination of tank car or tank truck.
240.828 Wine spirits in packages.

Wine Spirits Additions

240.830 Wine spirits added to wine.
240.831 Gauge of wine spirits.
240.832 Report of addition of wine spirits.

Other Dispositions of Wine Spirits

240.835 Withdrawal from distilled spirits plant.
240.836 Application to dispose of wine spirits.
240.837 Disposition of spirits.
240.838 Taxpayment.
240.839 Transfer to a distilled spirits plant or wine cellar.

Samples of Wine Spirits

240.840 Limitations.
240.841 Notice.

Subpart QQ—Losses of Wine Spirits in Bond

* * * * *

240.854 Losses in wine cellar.

* * * * *

Subpart RR—[Reserved]

240.870 [Deleted]
240.871 [Deleted]
240.872 [Deleted]
240.873 [Deleted]
240.874 [Deleted]

* * * * *

240.890 Notice required.

* * * * *

240.904 Forms 5120.28 and 5110.26.

* * * * *

240.1041 Withdrawal.
240.1042 Notice on Form 5120.38.

* * * * *

Paragraph 2. Section 240.1 is revised to include all wine. As amended, § 240.1 reads as follows:

§ 240.1 Production and removal of wine.

Regulations in this part relate to the production and removal of wine from bonded wine cellars. The regulations cover the establishment and operation of bonded wine cellars for the production, amelioration, sweetening, addition of wine spirits, blending, and other cellar treatment, storage, taxpayment, transfer to customs manufacturing warehouse and removal for exportation, for experimental or research purposes by scientific institutions, for analysis or testing by or for the proprietor of a bonded wine cellar, for use of the Government of the United States, for analysis, testing, research or experimentation by the governments of the several States, for use as distilling material, or for use in the manufacture of vinegar.

Paragraph 3. Section 240.10 is amended, in alphabetical order, by revising the definitions of "Distilled spirits plant" and "Wine". As amended, § 240.10 reads as follows:

§ 240.10 Meaning of terms.

* * * * *

Distilled spirits plant. "Distilled spirits plant" shall mean an establishment qualified under 27 CFR Part 19 for the production, warehousing, or processing of spirits (including denatured spirits), or articles.

* * * * *

Wine. "Wine", when used without qualification, includes all still wines, champagne and other sparkling wines, artificially carbonated wine and special natural wine or other wine products produced on bonded wine cellar premises.

* * * * *

Paragraph 4. Section 240.124 is revised to delete a reference to bottling taxpaid wine on a distilled spirits plant premises. As amended, § 240.124 reads as follows:

§ 240.124 Bottling of taxpaid wine.

Each person desiring to bottle or rebottle taxpaid wine shall establish taxpaid wine bottling house premises in compliance with the provisions of regulations set forth in 27 CFR Part 231.

Paragraph 5. Section 240.130 is revised to delete reference to standard wine. As amended, § 240.130 reads as follows:

§ 240.130 Activity on bonded wine cellar premises.

Except as authorized in this subpart, bonded wine cellar premises shall be used exclusively for 9(a) the receipt, production, blending, packaging, repackaging and removal of untaxpaid wine, and (b) the receipt, preparation, use, or removal of fruit, concentrated or unconcentrated fruit juice, or other materials authorized by this part or an approved formula under Subpart U of this part, for use in the production and cellar treatment of wine.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1378, as amended, 1386, as amended (26 U.S.C. 5351, 5361))

Paragraph 6. Section 240.142 is revised to delete a reference to Government locks and the wine spirits storage room sign. As amended, § 240.142 reads as follows:

§ 240.142 Wine spirits storage room.

Where wine spirits are to be received and stored in packages at a bonded wine cellar for use in wine production, a wine spirits storage room shall be provided. The room shall be securely constructed of substantial material so as to prevent unlawful access to the wine spirits. The door shall be equipped with a hasp and staple for locking.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1379, as amended (26 U.S.C. 5357))

Paragraph 7. Section 240.143 is revised to liberalize the Government office requirements at a bonded wine cellar using wine spirits. As amended, § 240.143 reads as follows:

§ 240.143 Office facilities.

Where wine spirits are to be used in the production of wine, other than use in small quantities for dosages or preparation of essences, the proprietor shall provide and maintain on the wine cellar premises in a convenient location a secure cabinet of adequate strength and size, suitably equipped for locking with a Government lock, for use in safeguarding Government property. Each cabinet shall contain shelving or compartments of proper size for the filing of Government records. Conveniently located toilet and lavatory facilities shall also be provided and made available for the use of ATF officers. The facilities shall be subject to approval by the regional regulatory administrator.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1379, as amended (26 U.S.C. 5357))

Paragraph 8. Section 240.169 is revised to change old Part 201 to the recodified Part 19 and delete pipeline color identification. As amended, § 240.169 reads as follows:

§ 240.169 Wine spirits pipelines.

Pipelines used for the conveyance of wine spirits from the bonded premises of a distilled spirits plant to wine spirits storage tanks, measuring tanks, weighing tanks, and wine spirits addition tanks shall be constructed in accordance with the requirements of regulations prescribed in 27 CFR Part 19. If wine spirits are to be received by tank car or tank truck, a secure pipeline shall be provided from the unloading point to the storage tank, measuring tank, weighing tank or wine spirits addition tank. Where wine spirits are stored in wine spirits storage tanks, a fixed pipeline, unbroken except for necessary short hose connections to pumps or weighing tanks, shall be provided from the wine spirits storage tank to the wine spirits addition tank. All joints in the pipelines shall be brazed, welded, or otherwise permanently joined. Valves, suitably equipped for locking, shall be provided to control the flow of the wine spirits from or into each tank.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1395, as amended (26 U.S.C. 5552))

Paragraph 9. Section 240.171 is revised to delete reference to taxpaid wine bottled at a distilled spirits plant. As amended, § 240.171 reads as follows:

§ 240.171 Taxpaid wine pipeline.

The pipeline used to transfer taxpaid wine from the bonded wine cellar to a taxpaid wine bottling house shall be a fixed unbroken line of permanent character, securely constructed and connected, and so arranged as to be exposed to view throughout its entire length. The pipeline shall be permanently connected with the taxpayment tank, or tanks, required by § 240.170. The valves in the pipeline shall be equipped for locking. The pipeline shall be shown on the bonded wine cellar plat.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1395, as amended (26 U.S.C. 5552))

Paragraph 10. Section 240.190 is revised to delete a reference to standard wine premises. As amended, § 240.190 reads as follows:

§ 240.190 Application, Form 698.

Each person establishing a bonded wine cellar premises shall file application on Form 698 with the regional regulatory administrator. Except as provided in § 240.199, in the case of amended or supplemental applications, all the information required by this part and by the instructions on the form shall be furnished. Application on Form 698 (including all attachments and inserts) shall contain or be verified by a written declaration that it is made under the penalties of perjury. Applications shall be numbred serially, starting with "1", and continuing in numerical sequence for all applications filed, whether amended or supplemental, and shall indicate the purpose of the application. All data, written statements, and other documents submitted in support of the application, shall be a part of the application.

(Act of August 16, 1954, 68A Stat. 749, as amended (26 U.S.C. 6065); Sec. 201, Pub. L. 85–859, 72 Stat. 1379, as amended (26 U.S.C. 5356))

Paragraph 11. Section 240.198 is revised to delete the need to return tank gauge sheets. As amended, § 240.198 reads as follows:

§ 240.198 Wine spirits addition tanks.

If tanks are to be used for the addition of wine spirits to wine, the proprietor shall ensure that tanks are accurately calibrated and shall maintain accurate calibration charts at the bonded wine cellar.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1379, as amended (26 U.S.C. 5356))

Paragraph 12. Section 240.202 is revised to delete a reference to the number of documents filed with Form 698. As amended, § 240.202 reads as follows:

§ 240.202 Individual owners, partnerships, or associations.

Where application, Form 698, is filed by an individual owner, partnership, or association, the name and address of each person interested in the bonded wine cellar, whether active, passive, or silent, shall be given on Form 698. If there are articles of partnership or association, copies shall be submitted with the Form 698.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1378, as amended (26 U.S.C. 5351))

Paragraph 13. Section 240.203 is revised to delete a reference to the number of documents filed with Form 698. As amended, § 240.203 reads as follows:

§ 240.203 Corporate documents.

Where application, Form 698, is filled by a corporation, there shall be filed with the original or initial application copies of the following documents: (a) articles of incorporation; (b) certificate of incorporation; (c) certificate authorizing the corporation to operate in the State where the bonded wine cellar is located, if other than that in which incorporated; (d) certified extracts of the minutes of meetings of the board of directors authorizing certain officers or other persons to sign for the corporation and specifying what documents may be signed; and (e) a list of the names and addresses (business and residence) of the officers, directors, and stockholders as required by § 240.204. Where these documents have been filed with the regional regulatory administrator in connection with qualification of other premises in the same region, and a statement to that effect is made on Form 698, additional copies of the documents are not required.

Paragraph 14. Section 240.204 is revised to delete a reference to the number of documents filed with Form 698. As amended, § 240.204 reads as follows:

§ 240.204 List of officers, directors, and stockholders.

In the case of corporations and similar legal entities, there shall be submitted with Form 698 at the commencement of business, a list giving the names and addresses (business and residence) of all officers, directors, stockholders, and other persons interested in the corporation, or other legal entity, and the amount and nature of the stock holding or other interests of each, whether the interest appears in the name of the interested party or in the name of another for him. However, if there are more than ten holders of any class of stock, only the names, addresses and holdings of the ten persons having the largest ownership or other interest in each of the classes of stock need be included in the list of stockholders.

Paragraph 15. Section 240.209 is revised to delete the reference to the number of copies of plats required. As amended, § 240.209 reads as follows:

§ 240.209 Plat.

Each person filing an application to establish a bonded wine cellar shall file with the regional regulatory administrator an accurate plat conforming to the requirements of Subpart J of this part.

Paragraph 16. Section 240.221 is revised to delete a reference to rectification tax. As amended, § 240.221 reads as follows:

§ 240.221 Bond, Form 700.

Each proprietor of a bonded wine cellar shall give bond on Form 700 for the payment of taxes imposed by the United States for which the proprietor shall become liable. This includes liability for occupational taxes and penalties and interest. The bond on Form 700 shall apply to wine and wine spirits and the operation of the bonded wine cellar, whether the transaction or operation upon which the liability is based occurred on the bonded wine cellar premises (including transfers between noncontiguous portions) or in transit. The bond shall also be for the faithful compliance, without fraud or evasion, with all requirements of the laws of the United States and regulations respecting wine and wine spirits and the operation of the bonded wine cellar. The penal sum of the bond shall be not less than the tax on all wine and wine spirits possessed at the bonded wine cellar, in transit to the bonded wine cellar, wine spirits authorized to be withdrawn under approved applications, or wine or wine spirits unaccounted for, at any one time. The penal sum of the bond shall also cover the tax on all wine removed for export or for use as supplies on vessels or aircraft, but not exported or otherwise accounted for. The penal sum of the bond shall be not less than $1,000 or more the $50,000, except that where the amount of tax exceeds $250,000, the penal sum of the bond shall be $100,000. However, the obligation on any bond on Form 700, shall apply with respect to taxes not in excess of $100, which have been determined on wine removed from the bonded wine cellar or transferred to a taxpaid wine room on the bonded wine cellar premises and which have not been paid.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1379, as amended (26 U.S.C. 5354))

Paragraph 17. Section 240.221a is revised to include the new distilled spirits operations bond or unit bond. As amended § 240.221a reads as follows:

§ 240.221a Operations bond or unit bond.

Notwithstanding the provisions of §§ 240.208 and 240.221, each person intending to commence or continue business as a proprietor of a bonded wine cellar with an adjacent distilled spirits plant qualified under 27 CFR Part 19 for the production of distilled spirits shall, in lieu of the bond on Form 700 and the bonds required under the provisions of 26 U.S.C. 5173 as amended, give an operations bond or unit bond in accordance with the applicable provisions of 27 CFR Part 19.

(Sec. 805(c), Pub. L. 96–39, 93 Stat. 276 (26 U.S.C. 5173))

Paragraph 18. Section 240.270 is revised to reduce the number of plat sheets required. As amended, § 240.270 reads as follows:

§ 240.270 Plat required.

Each person intending to establish a bonded wine cellar shall, as required by § 240.209, file an accurate plat of the premises with the regional regulatory administrator.

Paragraph 19. Section 240.281 is revised to delete a reference to the number of Forms 698 required. As amended, § 240.281 reads as follows:

§ 240.281 Amended Form 698 and basic permit.

Where there is a change in the individual, firm, or corporate name, the proprietor shall submit to the regional regulatory administrator an amended Form 698 for the new name. The Form 698 shall be approved before operations are commenced under the new name. The proprietor shall also obtain from the regional regulatory administrator an amended basic permit under the Federal Alcohol Administration Act authorizing operations under the new name.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1379, as amended (26 U.S.C. 5356))

Paragraph 20. Section 240.282 is revised to delete a reference to the number of documents filed with Form 698. As amended, § 240.282 reads as follows:

§ 240.282 Amended articles of incorporation, etc.

Where there is a change in the corporate name, the proprietor shall submit to the regional regulatory administrator copies of the amended articles of incorporation, and the amended certificate of incorporation issued under the laws of the State in which incorporated covering the change in the corporate name. If the operations are conducted in a State other than the State in which incorporated, there shall also be submitted to the regional regulatory administrator copies of the amended certificate issued under the laws of the State in which the operations are conducted authorizing the corporation to operate under its new name in the State. If documents other than those specified are required under the laws of the State to effect a change in the name of the corporation, copies of the documents shall be submitted.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1379, as amended (26 U.S.C. 5356))

Paragraph 21. Section 240.283 is revised to delete a reference to the number of documents required. As amended, § 240.283 reads as follows:

§ 240.283 Amended articles of partnership or association.

Where there is a change in the name of a partnership or association, the proprietor shall submit to the regional regulatory administrator copies of the amended articles of partnership or association, if any.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1379, as amended (26 U.S.C. 5356))

Paragraph 22. Section 240.286 is revised to delete a reference to the number of documents required. As amended, § 240.286 reads as follows:

§ 240.286 Fiduciary.

If the bonded wine cellar is to be operated by an administrator, executor, receiver, trustee, assignee, or other fiduciary, the fiduciary shall comply with provisions of Subpart G of this part to the extent that the provisions are

applicable, except that in lieu of filing a new bond and a new plat, the fiduciary may furnish a consent of surety extending the terms of the predecessor's bond, may adopt the plat of the predecessor, and, as provided in § 240.290a, may also adopt the formulas of the predecessor. The fiduciary shall furnish certified copies of the order of the court, or other pertinent documents, showing qualification as a fiduciary. The effective date of the qualifying documents filed by a fiduciary shall be the same as the date of the court order, or the date specified for assuming control. If the fiduciary was not appointed by the court, the date of assuming control shall coincide with the effective date of the qualifying documents filed.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1379, as amended (26 U.S.C. 5354, 5356))

Paragraph 23. Section 240.290 is revised to delete a reference to the number of plat certificates. As amended, § 240.290 reads as follows:

§ 240.290 Plat.

The adoption by a successor of the plat of a predecessor shall be in the form of a certificate in which shall be set forth the name of the predecessor, registry number and address of the bonded wine cellar, the date of preparation, and the date of approval of the plat, and a certification as to the accuracy of the plat adopted.

Paragraph 24. Section 240.292 is revised to delete a reference to the number of application copies required. As amended, § 240.292 reads as follows:

§ 240.292 Successor to bonded wine cellar with bonded wine warehouse.

Where a bonded wine warehouse has been established at a bonded wine cellar under the provisions of § 240.201, and it is desired to continue the operation of the bonded wine warehouse subsequent to a change in proprietorship of the bonded wine cellar, the proprietor of the bonded wine warehouse shall file a new letter application accompanied by a statement from the new proprietor (applicant) of the bonded wine cellar requesting the continuation of the warehouse, and a consent of surety.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1379, as amended (26 U.S.C. 5353))

Paragraph 25. Section 240.296 is revised to delete a reference to the number of document copies. As amended, § 240.296 reads as follows:

§ 240.296 Change in officers, directors, or stockholders of a corporation.

Where there is a change in officers or directors, or in the stockholders required to be listed under § 240.204, the proprietor shall submit, within 10 days of the change, a written notice to the regional regulatory administrator. However, changes in the list of stockholders may be submitted annually on May 1, except where the sale or transfer of capital stock results in a change in the control or management of a business. The notice shall describe the changes and be prepared as required by § 240.204.

Paragraph 26. Section 240.311 is revised to provide for alternation of bonded wine cellar premises with taxpaid wine bottling house premises or distilled spirits plant premises. As amended, § 240.311 reads as follows:

§ 240.311 Alternation of premises.

Each proprietor desiring to curtail or extend the bonded wine cellar premises shall file an amended Form 698 and plat with the regional regulatory administrator. An additional bonded wine cellar premises created by extension shall not be used for the proposed purposes, and the portion to be excluded by curtailment shall not be used for other than the approved purposes, prior to the approval of the amended Form 698 and plat. Proprietors of a bonded wine cellar desiring to extend or curtail a contiguous distilled spirits plant premises shall also comply with 27 CFR 19.203. Proprietors desiring to extend or curtail a contiguous taxpaid wine bottling house shall also comply with 27 CFR 231.140.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1379, as amended (26 U.S.C. 5356))

Paragraph 27. Section 240.313 is revised to clarify the language of the section. As amended, § 240.313 reads as follows:

§ 240.313 Pipeline change approvals.

No change shall be made in any wine or wine spirits pipeline not wholly on the bonded wine cellar premises prior to the approval of the changes by the regional regulatory administrator. A letterhead application filed with the regional regulatory administrator shall be serially numbered in sequence with serial numbers required by § 240.312, identify the premises by name and registry number, and describe in detail the changes to be made. A sketch should accompany the application where it will be helpful to an understanding of the changes desired.

§ 240.351 [Deleted]

Paragraph 28. Section 240.351 is deleted as a reference to a standard bonded wine cellar is no longer applicable.

Paragraph 29. Section 240.352 is revised to allow the use of a bonded wine cellar premises for both standard and other than standard wine production. As amended, § 240.352 reads as follows:

§ 240.352 Production of other than standard wine.

Wine which is other than standard as a result of fermentation with sugar and water in excess of limitations prescribed for standard wine shall have a basic character derived from the primary winemaking material. The aggregate weight of the sugar used before and during fermentation shall be less than the weight of the primary wine producing material. Molasses, malts, cereals, and grains shall not be used in the production of wine.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1331, as amended, 1380, as amended (26 U.S.C. 5041, 5361))

§ 240.355 [Deleted]

Paragraph 30. Section 240.355 is deleted as a reference to rectification tax is no longer applicable.

Paragraph 31. Section 240.356 is amended by changing the last sentence to delete a reference to rectification tax. As amended, the last sentence in § 240.356 reads as follows:

§ 240.356 Use of essences, flavors, or coloring.

* * * The use in wine of essences, flavoring, or coloring, other than as authorized in this part, results in the production of an other than standard wine and is subject to the formula requirements of § 240.482.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1383, as amended, 1386, as amended (26 U.S.C. 5382, 5386, 5387))

Paragraph 32. Section 240.374 is revised to delete the Government supervision requirement for wine spirits additions. As amended, § 240.374 reads as follows:

Use of Wine Spirits

§ 240.374 General.

Grape wine spirits may be added only to natural grape wine in a bonded wine cellar, the proprietor of which produces natural wine by fermentation of juice or must, and which is located in the same State as the bonded wine cellar where the natural grape wine was produced. If the wine has been ameliorated, wine spirits may be added (whether or not wine spirits were previously added)

only if the wine contains not more than 14 percent of alcohol by volume derived from fermentation. The wine spirits shall be received and used as provided in Subpart PP of this part.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1381, as amended, 1382, as amended, 1383, as amended, 1384, as amended (26 U.S.C. 5366, 5373, 5382, 5383))

§§ 240.375, 240.376, 240.377, 240.378, and 240.379 [Deleted]

Paragraph 33. Sections 240.375, 240.376, 240.377, 240.378 and 240.379 are deleted and the requirements of these sections moved to Subpart PP—Receipt and Use of Wine Spirits.

§ 240.380 [Deleted]

Paragraph 34. Section 240.380 is deleted because Government samples are no longer required for each wine spirits addition.

Paragraph 35. Section 240.381 is revised to reference Subpart PP. As amended, § 240.381 reads as follows:

§ 240.381 Addition of wine spirits to other grape wine.

The provisions of Subpart PP of this part shall be followed where proprietors desire to use wine spirits in the production of heavy bodied blending wine, Spanish type blending sherry and similar products produced under the provisions of Subpart U of this part.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1380, as amended, 1382, as amended, 1383, as amended (26 U.S.C. 5361, 5373, 5382).)

Paragraph 36. Section 240.382 is revised to delete a reference to standard wine premises. As amended, § 240.382 reads as follows:

§ 240.382 Addition of wine spirits to juice or concentrated juice.

Wine spirits may be added to the juice or concentrated juice of grapes in the same manner as to wine, as provided in Subpart PP of this part. The alcohol content of the juice or concentrated juice shall not exceed 24 percent by volume after the addition of wine spirits. Juice or concentrated juice to which wine spirits have been added is not wine, but shall be accounted for as wine.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1382, as amended, 1383, as amended (26 U.S.C. 5373, 5382))

Paragraph 37. Section 240.406 is revised to change the wine spirits addition procedure references. As amended, § 240.406 reads as follows:

§ 240.406 Use of pure dry sugar or liquid sugar.

A winemaker producing wine from fruit or berries, other than grapes, or from mixtures (which may include grapes) of two or more fruits or berries, with the addition of pure dry sugar or liquid sugar, but without water added to reduce acid content, may add pure dry sugar or liquid sugar to the juice in the fermenters, or to the wine after fermentation. However, such wine shall have not more than 14 percent alcohol by volume after complete fermentation, or after complete fermentation and sweetening, and a total solids content not in excess of 21 percent by weight. The use of liquid sugar under this section shall be limited so that the resultant volume will not exceed the volume which could result from the maximum authorized use of pure dry sugar only. Where pure dry sugar or liquid sugar is added to the juice in the fermenters, the winemaker shall maintain a separate record showing the kind and quantity of juice (exclusive of pulp) deposited in fermenters and the quantity of pure dry sugar or liquid sugar added. Where wine produced as provided in this section is sweetened after complete fermentation with liquid sugar, a record of sweetening shall be kept in accordance with § 240.914b. Where wine produced as provided in this section is sweetened after complete fermentation with pure dry sugar, the gallons of wine before and after sweetening shall be determined and entered on the record provided for in § 240.908. After completion of fermentation of the wine, wine spirits may be added in accordance with the provisions of Subpart PP of this part.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1383, as amended, 1385, as amended (26 U.S.C. 5382, 5384))

Paragraph 38. Section 240.411 is revised to reflect the deletion of §§ 240.375 thru 240.380. As amended, § 240.411 reads as follows:

§ 240.411 Addition of wine spirits.

To fruit wine produced from one kind of fruit under the provisions of § 240.401 or § 240.407, wine spirits from the same kind of fruit may be added according to the procedures prescribed in Subpart PP of this part. Wine spirits may not be added to fruit wine made from mixtures of two or more fruits. Where the proprietor desires to add wine spirits made from the same kind of fruit to juice or concentrated juice, the provisions of §§ 240.382 and 240.383 (relative to the addition of wine spirits to grape juice or concentrated grape juice) shall be followed.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1382, as amended, 1383, as amended (26 U.S.C. 5373, 5382))

Paragraph 39. Section 240.460 is revised to delete a reference to standard wine premises. As amended, § 240.460 reads as follows:

§ 240.460 General.

Agricultural wine may be made on bonded wine cellar premises from suitable agricultural products other than the juice of fruit. Water or pure dry sugar, or both, or liquid sugar or invert sugar syrup may be used within the limitations of this subpart in the production of agricultural wine. Agricultural wine shall not be flavored or colored, except that hops may be used in the production of honey wine; wine spirits shall not be used in the production of the wine; and a wine made from one agricultural product shall not be blended with a wine made from another agricultural product. Agricultural wine made with sugar other than pure dry sugar; or with pure dry sugar or water, liquid sugar, or invert sugar syrup in excess of the limitations of this subpart shall be segregated as required by § 240.131.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1386 as amended (26 U.S.C. 5387))

§ 240.480 [Deleted]

Paragraph 40. Section 240.480 is deleted because a reference to standard wine is no longer needed.

Paragraph 41. Section 240.481 is revised to delete a reference to standard wine premises. As amended, § 240.481 reads as follows:

§ 240.481 Classes of wine other than standard wine.

The following classes of wine are not standard wines:

(a) High fermentation wine, produced as provided in § 240.483;

(b) Heavy bodied blending wine, produced as provided in § 240.484;

(c) Spanish type blending sherry, produced as provided in § 240.485;

(d) Wine products not for beverage use, produced as provided in § 240.485a;

(e) Distilling material, produced as provided in § 240.486;

(f) Vinegar stock, produced as provided in § 240.487;

(g) Wines other than those in classes listed in paragraphs (a), (b), (c), (d), (e), and (f) of this section, not produced within the limitations for standard wine; and

(h) Spoiled wine, of the kind described in § 240.489.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1387 as amended (26 U.S.C. 5388))

Paragraph 42. Section 240.483 is revised to delete a reference to standard wine premises. As amended, § 240.483 reads as follows:

§ 240.483 High fermentation wine.

High fermentation wine is a wine made within the limitations of § 240.365 for grape wine or § 240.405 for fruit wine, except (a) that the alcohol content after complete fermentation or complete fermentation and sweetening is more than 14 percent; and (b) that wine spirits are not added. While high fermentation wine is not a natural wine or a standard wine, it is produced, stored, and handled on bonded wine cellar premises, subject to appropriate marking or labeling.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1381, as amended, 1387, as amended (26 U.S.C. 5365, 5388))

Paragraph 43. Section 240.484 is revised to delete a reference to standard wine premises. As amended, § 240.484 reads as follows:

§ 240.484 Heavy bodied blending wine.

Wine made from grapes or other fruit without added sugar, and with or without added wine spirits, may be made for blending purposes with a total solids content in excess of 21 percent. Heavy bodied blending wine may be used in blending with other wine made from the same kind of fruit, or for removal upon payment of tax, not for sale or consumption as beverage wine. A separate record shall be kept showing the quantities of heavy bodied blending wine produced, received, used, shipped, and on hand. Upon removal, the shipping containers (and Form 703, if in bond) shall be marked "Heavy Bodied Blending Wine—Not for Sale or Consumption as Beverage Wine."

(Sec. 201, Pub. L. 85–859, 72 Stat. 1380, as amended, 1387, as amended (26 U.S.C. 5361, 5388))

Paragraph 44. Section 240.488 is revised to delete a reference to standard wine premises. As amended, § 240.488 reads as follows:

§ 240.488 Other wines.

Wine produced with sugar, water, liquid sugar, or invert sugar syrup beyond the limitations prescribed for standard wine, or wine made with sugar other than pure sugar, or wine made with materials not authorized for use in standard wine, may be produced on bonded wine cellar premises, but shall remain segregated from other wines. Upon removal, the wine shall be marked or labeled with a designation which will adequately disclose the nature and composition of the wine.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1381, as amended,1387, as amended (26 U.S.C. 5365, 5388))

Paragraph 45. Section 240.489 is amended by revising the first sentence of such section and reads as follows:

§ 240.489 Spoiled wine.

Whenever a standard wine becomes spoiled by reason of its condition, the spoiled wine shall be immediately removed from the bonded wine cellar, unless the condition is corrected, the wine is removed in due course for redistillation, or is destroyed under government supervision. * * *

Paragraph 46. Section 240.490 is revised to change old Part 201 to the recodified Part 19. As amended, § 240.490 reads as follows:

§ 240.490 General.

Distillates containing aldehydes, withdrawn under the provisions of 27 CFR Part 19, may be used in fermentation of wine to be used as distilling material at the distilled spirits plant from which distillates were withdrawn. Distillates produced from one kind of fruit shall not be used in the fermentation of wine made from a different fruit.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1382, as amended (26 U.S.C. 5373))

Paragraph 47. Section 240.491 is revised to change Part 201 to the recodified Part 19 and change an application to a notice. As amended, § 240.491 reads as follows:

§ 240.491 Notice to use distillates containing aldehydes.

Where a distillate containing aldehydes is to be used in fermentation of wine to be used as distilling material the proprietor of the bonded wine cellar, unless he is also the proprietor of the distilled spirits plant from which the distillates are to be withdrawn, shall submit a notice to the regional regulatory administrator stating: (a) the name, address, and registry number of the distilled spirits plant from which the distillate is to be withdrawn, (b) the kind of distillate, (c) the kind of wine in which the distillate will be used, and (d) a statement decribing the method by which the distillate will be added in fermentation of wine to be used as distilling material. Where the proprietor of the bonded wine cellar is also the proprietor of the distilled spirits plant, the notice required under 27 CFR Part 19 shall also be for the receipt and use of the distillates at the bonded wine cellar. Distillates containing aldehydes shall be received and used as provided by Subpart YY of this part. Record of receipt and use of distillates shall be kept in accordance with Subpart UU of this part and reported on Form 5720.17(702).

(Sec. 201, Pub. L. 85–859, 72 Stat. 1381, as amended 1382, as amended (26 U.S.C. 5367, 5373))

Paragraph 48. Section 240.537 is revised to change the size of samples. As amended, § 240.537 reads as follows:

§ 240.537 Application.

When a proprietor desires to reduce the acid content of wine below 5 parts per thousand, other than as authorized in § 240.1051, an application shall be submitted in letter form to the regional regulatory administrator. The application shall contain the following information:

(a) Name, address, and registry number of the proprietor;

(b) Statement of process or method to be used in effecting the acid reduction;

(c) Gallons of wine to be treated; and

(d) Kind of wine to be treated.

A 125 ml sample of the wine prior to treatment shall be submitted by the proprietor direct to the regional laboratory at the same time the application is filed. The sample shall be labeled and marked in a manner that it may be readily identified. The proprietor shall not proceed to reduce the acid content of the wine until receiving approval from the regional regulatory administrator.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1383, as amended (26 U.S.C. 5382))

Paragraph 49. Section 240.538 is revised to change the size of the sample. As amended, § 240.538 reads as follows:

§ 240.538 Sample of treated wine.

After completion of the acid reduction treatment a 125 ml sample of the wine shall be submitted by the proprietor to the regional laboratory. The sample will be labeled and marked in a manner that it may be readily identified and associated with the sample submitted prior to treatment.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1363, as amended (26 U.S.C. 5382))

Paragraph 50. Section 240.562 is revised to include a reference to wine products made with other than natural materials. As amended, paragraph (a)(3) of § 240.562 reads as follows:

§ 240.562 Marks.

(a) Required marks.* * *

(3) The kind (class and type) and the alcohol content of the wine. The kind of wine shall be stated in accordance with 27 CFR Part 4. The formula number shall be marked on bulk containers of special natural wine or wine produced under § 240.488.

* * * * *

Paragraph 51. Section 240.574 is revised to delete a reference to

rectification tax. As amended, § 240.574 reads as follows:

§ 240.574 Reused barrels.

Barrels previously used for the storage of distilled spirits may be used by proprietors as storage and shipping containers for wine, provided the barrels are treated to remove distilled spirits from the heads and staves before the deposit of wine. The spirits extracted from the barrels shall be destroyed in each instance. This authorization to use barrels should not be construed as relieving proprietors from tax liability in the event barrels are not treated to remove the distilled spirits. A person mixing distilled spirits with wine shall incur distilled spirits tax liability on the entire contents of the barrel.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1314, as amended, 1383, as amended (26 U.S.C. 5001, 5381))

§ 240.575 [Deleted]

Paragraph 52. Section 240.575 is deleted.

Paragraph 53. Section 240.590a is revised to include the new distilled spirits plant operations bond or unit bond. As amended, § 240.590a reads as follows:

§ 240.590a Qualification for extended deferral.

(a) *Deferral covered by operating bond only.* A proprietor who has not given a tax deferral bond on Form 2053, may file returns, Form 2050, with remittances, with benefit of extended deferral under an existing bond Form 700, operations bond or unit bond without further qualification provided the amount of tax unpaid at any one time does not exceed $100.

(b) *Deferral covered by bond on Form 2053.* A proprietor who desires to file returns, Form 2050, with remittances, with benefit of the extended deferral prescribed by § 240.591, and who has on file a tax deferral bond on Form 2053 in a penal sum which is less than that required under § 240.222, shall give a new bond in a sufficient penal sum on Form 2053 or give a strengthening bond to increase the total penal sum of the bonds in force to a sufficient penal sum.

(c) *Consents of surety.* A proprietor who desires to file returns or Form 2050, with benefit of extended deferral under an existing bond on Form 2053, shall file a consent of surety on Form 1533 to extend the terms of the bond. Each consent on Form 1533 shall identify the particular bond to which it applies and contain a statement of purpose as follows:

To continue in effect said bond (including all extensions or limitations of terms and conditions previously consented to and approved), notwithstanding that the time for payment of the tax may be deferred as provided by 27 CFR 240.591(d).

(d) *Commencement of extended deferral.* A proprietor may file returns with benefit of extended deferral only after the applicable bonds and consents of surety required by this section have been filed with and approved by the regional regulatory administrator. However, a proprietor qualified for extended deferral on the date immediately preceding the effective date of this section is qualified for deferral as of the effective date of this section without further qualification under this section. The benefit of extended deferral shall commence with the return for the first return period fully covered by the bonds and consents of surety.

Paragraph 54. Section 240.598 is revised to delete a reference to case marking requirements. As amended, § 240.598 reads as follows:

§ 240.598 Marking of containers.

Each container of wine removed taxpaid, except cases, shall be marked with the word "Taxpaid" in addition to the marks required by § 240.562.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1381, as amended (26 U.S.C. 5368))

Paragraph 55. Section 240.599 is revised to delete a reference to taxpaid wine being sent to the bottling premises of a distilled spirits plant. As amended, § 240.599 reads as follows:

§ 240.599 General.

The proprietor may remove tax determined wine by pipeline from a bonded wine cellar to a taxpaid wine bottling house, contiguous to, or in the immediate vicinity of the bonded wine cellar.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1331, as amended (26 U.S.C. 5041))

Paragraph 56. The title of Subpart BB is revised to delete "to other bonded wine cellars" because wine may also be transferred in bond to distilled spirits plants. As revised, the title of Subpart BB reads as follows:

Subpart BB—Transfer of Wine in Bond

Paragraph 57. Section 240.610 is revised to add a reference to distilled spirits plants for wine transferred in bond. As amended, § 240.610 reads as follows:

§ 240.610 General.

Wine may be removed for transfer in bond, from one bonded wine cellar to another bonded wine cellar, or a distilled spirits plant, as provided in this subpart.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1380, as amended (26 U.S.C 5362))

§ 240.611 [Deleted]

Paragraph 58. Section 240.611 is deleted.

Paragraph 59. Section 240.612 is revised to add a reference to a distilled spirits plant for wine transferred in bond. As amended, § 240.612 reads as follows:

§ 240.612 Transfer of wine by pipeline.

Wine may be transferred in bond between contiguous or adjacent bonded wine cellars or to a contiguous or adjacent distilled spirits plant by a pipeline constructed and approved as provided in § 240.172, provided one or more accurately calibrated tanks for measuring the wine have been installed on at least one of the premises. The quantity of wine transferred by pipeline shall be recorded to the nearest whole gallon, 5 tenths gallons being converted to the next full gallon.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1380, as amended, 1395, as amended (26 U.S.C 5362, 5552))

Paragraph 60. Section 240.613 is revised to update the information included in the transfer in bond Form 703. As amended, § 240.613 reads as follows:

§ 240.613 Use of Form 703.

When wine is transferred in bond from a bonded wine cellar to other premises, the proprietor shall prepare Form 703, showing the date of transfer; name, address and registry number of the consignee and of the consignor; the number of cases, packages or tanks; serial numbers (except where not required for cases by § 240.561); gallons; percentage of alcohol; and kind of wine shipped. However, when wine (including distilling material and vinegar stock) is transferred in bond by pipeline to adjacent premises, and commercial records are kept to show details of each shipment as would appear on a separate Form 703, a monthly Form 703 may be prepared for shipments to each premises instead of a separate Form 703 for each shipment. The alcohol content of the wine shall be stated on Form 703 as 13 percent, 18 percent, etc., rather than by taxable grade. The kind of wine shall be stated according to class and type, including vintage and varietal designation, if applicable, except in the case of unfinished grape wine, distilling material, or vinegar stock.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1380, as amended (26 U.S.C 5362))

Paragraph 61 Section 240.615 is revised to add a reference to a distilled spirits plant for wine received in bond. As amended, § 240.615 reads as follows:

§ 240.615 Receipt of wine in bond.

When wine is received in bond from a bonded wine cellar or a distilled spirits plant, the proprietor shall check the shipment against a copy of Form 703 or Form 5110.27, as applicable, and determine by measure or weight the quantity received, except that packages received without apparent loss need not be measured or weighed. A record of wine received in bond shall be maintained as required by Subpart UU of this part.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1380, as amended (26 U.S.C 5362))

Paragraph 62. Section 240.616 is revised to include a distilled spirits plant proprietor for filing claims on any wine losses in transit. As amended, § 240.616 reads as follows:

§ 240.616 Losses in transit.

The proprietor of the premises to which the wine is shipped in bond shall be liable for the tax on any wine lost in transit. The tax on wine lost in transit shall be assessed or remitted in accordance with the provisions of Subpart NN of this part. Where there is a loss in transit from any shipment, the consignee shall, as required by § 240.785, file a claim for allowance of the loss.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1381, as amended (26 U.S.C. 5370))

Paragraph 63. Section 240.618 is revised to liberalize the provisions for reconsignment of wine shipments. As amended, § 240.618 reads as follows:

§ 240.618 Reconsignment by consignor.

When a consignor reconsigns a shipment of wine, the consignor shall notify the regional regulatory administrator of the consignor region by preparing a new Form 703 and attaching a statement of diversion. The substitute consignee is liable for the tax on all losses sustained in shipment, and shall file a consent of surety with the regional regulatory administrator of his region, in accordance with § 240.231, extending the terms of his bond to cover any losses.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1380, as amended (26 U.S.C. 5362))

Paragraph 64. Section 240.619 is revised to add a reference to the Form 5110.27 for wine transferred in bond from a distilled spirits plant. As amended, § 240.619 reads as follows:

§ 240.619 Reconsignment by consignee.

When a consignee reconsigns a shipment of wine, the consignee shall notify the regional regulatory administrator of his region by acknowledging receipt of the full amount on Form 703 or Form 5110.27, at which point the reconsignment is a shipment in bond subject to the requirements of §§ 240.613 to 240.616. The substitute consignee is liable for tax on all losses sustained in shipment, and shall file a consent of surety with the regional regulatory administrator of his region, in accordance with § 240.231 extending the terms of his bond to cover any losses.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1380, as amended (26 U.S.C. 5362))

Paragraph 65. Subpart PP is revised to consolidate all provisions relating to the receipt and use of wine spirits within a single subpart. The title of Subpart PP is changed to "Receipt and Use of Wine Spirits." Provisions formerly included at sections 240.375 through 240.379 and in Subpart RR are included in Subpart PP as revised. In addition, the following specific changes have been made: (1) government supervision of the receipt and use of wine spirits is no longer mandatory but may be required by the regional regulatory administrator; (2) references to 27 CFR Part 201 are changed to the recodified Part 19; (3) provisions requiring an application for taking samples of wine spirits are changed to provide for a notice; and (4) Forms 2629, 257, and 275 are designated as ATF Forms 5110.26, 5120.38, and 5120.28, respectively, in order to conform with the ATF subject classification system. As revised, Subpart PP reads as follows:

Subpart PP—Receipt and Use of Wine Spirits

§ 240.820 General.

The wine spirits authorized for use in wine production shall be produced from the distilling material authorized for use in distillery operations under 26 U.S.C. 5373, but shall not be reduced with water from distillation proof, nor be distilled at less than one hundred forty degrees proof. However, commercial brandy aged in wood for a period of not less than two years and barreled at not less than one hundred degrees proof shall be deemed wine spirits for purposes of this part.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1382, as amended (26 U.S.C. 5373))

§ 240.821 Supervision requirements.

The regional regulatory administrator may require that the receipt and use of wine spirits at a bonded wine cellar be supervised by an ATF officer.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1381, as amended (26 U.S.C. 5366))

§ 240.822 Withdrawal.

The proprietor of any bonded wine cellar may withdraw and receive wine spirits without payment of tax from the bonded premises of a distilled spirits plant for use in the production of natural wine, or for addition to concentrated or unconcentrated juice for use in wine production, or for other uses as are authorized in this part.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1382, as amended (26 U.S.C. 5373))

§ 240.823 Annual withdrawals.

(a) *Contiguous premises.* If the distilled spirits plant and the wine cellar are located on contiguous premises and wine spirits are to be transferred to the bonded wine cellar from time to time, the Form 5120.38 may cover all wine spirits to be transferred to the wine cellar during the calendar year. However, if the bond of the proprietor is not in the maximum penal sum, the proprietor shall specify on Form 5120.38 the maximum quantity of wine spirits that will be on hand, removed from the distilled spirits plant, and unaccounted for, on any one day.

(b) *Noncontiguous premises.* If the distilled spirits plant and the wine cellar are not located on contiguous premises, and the proprietor's bond is in the maximum penal sum, the proprietor's Form 5120.38 may cover all wine spirits to be transferred from the noncontiguous distilled spirits plant to the wine cellar during the calendar year. A separate Form 5120.38 shall be submitted for each noncontiguous distilled spirits plant from which wine spirits will be transferred during the calendar year.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1382, as amended (26 U.S.C. 5373))

Receipt of Wine Spirits

§ 240.824 Transfer of wine spirits by pipeline for immediate use.

Wine spirits transferred by pipeline for immediate use shall be gauged either by weight or by volume in the bonded premises of the distilled spirits plant. Where the spirits are gauged in the bonded premises of the distilled spirits plant, the pipeline shall be directly connected, as provided in § 240.169, with wine spirits addition tanks. The valves in the pipeline shall be closed and locked with a lock at all times except when necessary to be opened for the transfer of wine spirits. Where the proprietor has placed wine in a wine

spirits addition tank and has ascertained the quantity of wine spirits to be added, the wine spirits may be transferred.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1382, as amended (26 U.S.C. 5373))

§ 240.825 Transfer of wine spirits by pipeline to wine spirits storage tank.

Where it is desired to transfer wine spirits by pipeline to bonded wine cellar premises and store the spirits prior to use, there shall be provided a suitable tank for storing the wine spirits. The pipeline from the adjacent bonded premises of the distilled spirits plant shall be connected to the tank as provided in § 240.169. The wine spirits to be transferred, if not gauged in the bonded premises of the distilled spirits plant, shall be gauged by weight or volume on the bonded wine cellar premises.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1382, as amended (26 U.S.C. 5373))

§ 240.826 Tank car and tank truck requirements.

Railroad tank cars and tank trucks used to transport wine spirits for use in wine production shall be constructed, marked, filled, labeled, and inspected, in the manner required by regulations in 27 CFR Part 19.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended, 1362, as amended (26 U.S.C. 5206, 5214))

§ 240.827 Examination of tank car or tank truck.

Upon arrival of the tank car or tank truck at the bonded wine cellar, the proprietor shall carefully examine the car or truck to see whether the seals are intact and whether there is any evidence of tampering or loss by leakage or otherwise. Any evidence of loss shall be reported to the area supervisor. The contents of the tank car or tank truck shall be gauged by weight or volume at the time of receipt by the proprietor. If the tank car or tank truck has been accurately calibrated, and the calibration chart is availabe at the wine cellar, the wine spirits may be gauged by volume in the tank car or tank truck. In any case where a volume gauge is made, the actual measurements of the spirits in the gauging tank, tank car, or tank truck, and the temperature of the spirits shall be recorded on Form 5110.26. The label attached to the tank car or tank truck at the distilled spirits plant shall be destroyed by the proprietor immediately after the car or truck is emptied.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1360, as amended, 1362, as amended, 1381, as amended (26 U.S.C. 5206, 5214, 5366))

§ 240.828 Wine spirits in packages.

The proprietor shall gauge (proof and weigh) each package to be used for the wine spirits addition, except that if a metal gauging tank accurately calibrated or mounted on scales is provided, the contents of the packages may be transferred into the gauging tank and a bulk gauge obtained by weight or by volume. If the packages have been received from contiguous bonded premises of a distilled spirits plant for immediate use, the packages need not be regauged in the bonded wine cellar unless there is some indication that the contents of the packages are not in agreement with the withdrawal gauge. If the quantity of wine spirits needed for the wine spirits addition is not equal to the contents of full packages, a portion of one package may be used and the remnant package returned to the wine spirits storage room. The proprietor shall weigh and proof the remnant package and attach a label showing the date of gauge, serial number of the Form 5120.28, the gross weight, and proof. The remnant shall be used at the first opportunity. The proprietor shall prepare Form 5110.26 for each release of wine spirits and attach a copy to each Form 5120.28.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1381, as amended, 1382, as amended (26 U.S.C. 5366, 5367, 5368, 5373))

Wine Spirits Additions

§ 240.830 Wine spirits added to wine.

Prior to the addition of wine spirits, the wine shall be placed in tanks (approved for the addition of wine spirits) located, equipped, and calibrated as provided in Subpart F of this part. The proprietor shall accurately measure the wine, determine its alcohol content, determine the proof of the wine spirits to be added, calculate the quantity of wine spirits required, and enter the details on Form 5120.28. The alcohol content of the wine after the addition of wine spirits shall not exceed 24 percent by volume. The proprietor shall certify on Form 5120.28 that the wine has been produced in accordance with the requirements of this subpart and is eligible for the addition of wine spirits.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1381, as amended, 1382, as amended (26 U.S.C. 5367, 5373))

§ 240.831 Gauge of wine spirits.

(a) If the wine spirits to be used are in a wine spirits storage tank on the bonded wine cellar premises, or received immediately prior to use from a distilled spirits plant not adjacent to the bonded wine cellar, the proprietor shall determine the quantity used, by volume gauge or by weight, and the proof of the spirits. Upon completion of the transfer of wine spirits from the wine spirits storage tank to the wine spirits addition tank, the proprietor shall lock the wine spirits storage tank. The proprietor shall prepare Form 5110.26 according to the instructions on the form.

(b) If the wine spirits made on the adjacent bonded premises of a distilled spirits plant are transferred directly into a wine spirits addition tank, the gauge of the wine spirits made on the distilled spirits plant premises shall be used. The proprietor at the distilled spirits plant premises shall deliver two copies of Form 5110.26 to the proprietor of the bonded wine cellar who shall acknowledge receipt of the wine spirits on both copies of the form and forward one copy to the regional regulatory administrator.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1381, as amended, 1382, as amended (26 U.S.C. 5367, 5373))

§ 240.832 Report of addition of wine spirits.

After the wine spirits have been added to the wine, the proprietor shall thoroughly agitate the contents of the tank to assure a complete mixture of the wine and wine spirits. The proprietor shall then measure the quantity of wine in the tank, take a representative sample of the wine, and test for alcohol content. The result of the measurement and test and the quantity of wine spirits added as shown by Form 5110.26 shall be recorded on Form 5120.28. The original of Form 5120.28 (with Form 5110.26, if the wine spirits have been regauged) shall be submitted to the regional regulatory administrator and the other copy retained for the proprietor's files. The quantity of wine and wine spirits used, and the quantity of wine resulting from addition of wine spirits, shall be entered in the cellar records.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1381, as amended, 1382, as amended, 1383, as amended (26 U.S.C. 5367, 5373, 5382))

Other Dispositions of Wine Spirits

§ 240.835 Withdrawal from distilled spirits plant.

Proprietors of bonded wine cellars engaged in the production of sparkling wine, or artificially carbonated wine, or special natural wine, or any other wine products, for which wine spirits are required for dosage, or for the preparation of approved essences or

similar approved flavorings on the wine cellar premises, may make application on Form 5120.38 to withdraw tax-free wine spirits. The wine spirits shall be received by the proprietor and placed under his lock in a secure room or locker on the bonded premises. The wine spirits shall remain in the original packages in the storeroom until withdrawn for use. Record of receipt and use shall be kept in accordance with Subpart UU of this part.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1382, as amended, 1383, as amended (26 U.S.C. 5373, 5382))

§ 240.836 Application to dispose of wine spirits.

Application for permission to transfer wine spirits to the bonded premises of a distilled spirits plant or bonded wine cellar or to taxpay or destroy wine spirits, shall be filed with the regional regulatory administrator. The application shall set forth the serial numbers of the packages or storage tanks in which the wine spirits are contained, the kind and quantity of wine spirits involved, the name and registry number of the distilled spirits plant, the date of receipt of the wine spirits in the wine cellar, and the reason it is desired to taxpay, destroy, or transfer the wine spirits.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1382, as amended (26 U.S.C. 5373))

§ 240.837 Disposition of spirits.

If the application is approved, the proprietor shall dispose of the spirits in accordance with the application and any instructions given by the regional regulatory administrator.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1382, as amended (26 U.S.C. 5373))

§ 240.838 Taxpayment.

When it is desired to taxpay the wine spirits, the application shall describe the containers in which the spirits will be removed upon taxpayment and the name and address of the person or persons to whom the spirits will be shipped and whether the spirits will be used for beverage or nonbeverage purposes.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1382, as amended (26 U.S.C. 5373))

§ 240.839 Transfer to a distilled spirits plant or wine cellar.

When it is desired to transfer wine spirits to the bonded premises of a distilled spirits plant or to a bonded wine cellar the application shall specify the name, number and location of the premises, and the means or containers by or in which it is proposed to transfer the wine spirits. The application shall also specify whether the proprietor of the designated distilled spirits plant or wine cellar has agreed to receive the wine spirits and file consent of surety on his bond, extending the terms of the bond to cover transfer to his premises and any storage.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1382, as amended (26 U.S.C. 5373))

Samples of Wine Spirits

§ 240.840 Limitations.

Samples of wine spirits may be withdrawn, free of tax, from any bonded wine cellar for analysis or testing. A sample may be withdrawn from each lot of wine spirits received, or from each wine spirits storage tank, or from a package representative of a lot of wine spirits on hand in the wine spirits storage room. Each sample shall be not more than 750 ml in size, and only one sample may be taken from any lot of wine spirits, unless authority is received from the regional regulatory administrator for larger or additional samples, upon a showing of necessity. All spirits produced at the same production facility of a distilled spirits plant on the same day, if received in the same shipment, will be considered as constituting a lot of spirits.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1382, as amended (26 U.S.C. 5373))

§ 240.841 Notice.

The proprietor shall file a notice with the regional regulatory administrator whenever samples of wine spirits are desired. The notice shall identify the lot or lots of spirits from which samples are desired, the size of the sample to be withdrawn from each lot, and the disposition to be made of the samples. Remnants or residues of samples remaining after analysis or testing, and which are not retained for laboratory specimens, shall be destroyed or returned to the bonded wine cellar for use in wine production.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1382, as amended (26 U.S.C. 5373))

Paragraph 66. Section 240.853 is revised to delete reference to two obsolete sections. As amended, § 240.853 reads as follows:

§ 240.853 In transit.

Losses in transit shall be ascertained at the time the wine spirits are received at the wine cellar.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1323, as amended (26 U.S.C. 5008))

Paragraph 67. Section 240.854 is revised to delete a reference to Government supervision. As revised, § 240.854 reads as follows:

§ 240.854 Losses in wine cellar.

Losses by theft, or from other causes, in the bonded wine cellar, shall be determined and reported at the time the losses are discovered. A physical inventory of wine spirits storage tanks shall be taken at the close of the month during which wine spirits are used in wine production, or upon completion of the use for the month and at any other time required by the regional regulatory administrator. Any losses which have not previously been reported shall be determined by the inventory. Where a loss is discovered requiring filing of a claim as provided in § 240.855, the proprietor shall gauge the contents of the container from which the loss occurred and prepare a report of gauge on Form 5110.26.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1323, as amended (26 U.S.C. 5008))

Paragraph 68. Subpart RR is deleted in its entirety and §§ 240.870 through 240.874 requirements have been moved to Subpart PP. As amended, the center heading "Subpart RR—Disposition of Unused Wine Spirits" reads as follows:

Subpart RR—[Reserved]

Paragraph 69. Section 240.890 is revised to change former part 198 to the recodified Part 18 and change the application to a notice. As amended, § 240.890 reads as follows:

§ 240.890 Notice required.

A proprietor desiring to produce or prepare for market commercial fruit products, or recover by-products (including volatile fruit-flavor concentrates) and store the products on bonded wine cellar premises shall file a notice with the regional regulatory administrator setting forth the details of the activity. In addition to the notice, if the proprietor desires to establish a volatile fruit flavor concentrate plant, he shall file Form 27–G and otherwise comply with the provisions of 27 CFR Part 18. Activities permitted shall be limited to those in which fruit or fruit juice is the principal material used in production. The operations shall not be conducted prior to the notice being submitted to the regional regulatory administrator. Wine shall not be used in the production of allied products.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1380, as amended (26 U.S.C. 5361))

Paragraph 70. Section 240.904 is revised to delete a reference to sections which are obsoleted. As amended, § 240.904 reads as follows:

§ 240.904 Forms 5120.28 and 5110.26.

Each proprietor of a bonded wine cellar using wine spirits in the production of wine shall prepare Forms 5120.28 and 5110.26 at the time wine spirits are gauged and added to wine.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1381, as amended (26 U.S.C. 5367))

Paragraph 71. Section 240.943 is revised to delete a reference to rectification tax. As amended, § 240.943 reads as follows:

§ 240.943 Assessment of tax.

If an investigation or an examination of records discloses that liability for wine tax, distilled spirits tax, or occupational tax has been incurred by the proprietor of a bonded wine cellar, the regional regulatory administrator will notify the proprietor by letter of the basis and the amount of the proposed assessment in order to afford the proprietor an opportunity to submit a protest, with supporting facts, within 45 days, or to request a conference with regard to the tax liability.

Paragraph 72. Section 240.1041 is revised to delete the requirements for Government supervision. As amended, § 240.1041 reads as follows:

§ 240.1041 Withdrawal.

The proprietor of a bonded wine cellar may, as provided in this part, withdraw, without payment of tax, distillates containing aldehydes for use in the fermentation of wine which is to be used as distilling material. Withdrawals shall be made only from an adjacent distilled spirits plant. A proprietor of a bonded wine cellar who is operating under bond, Form 700, and who intends to receive and use distillates containing aldehydes, shall furnish a consent of surety, Form 1533, which shall contain the following statement of purpose:

To extend the terms and conditions of said bond to cover payment of all taxes imposed by law now or hereinafter in force (plus penalties, if any, and interest) for which the principal may become liable on all distillates containing aldehydes removed from the bonded premises of a distilled spirits plant to his bonded wine cellar.

The facilities may include short detachable hose connections between pipelines and tanks on the bonded wine cellar premises.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1382, as amended (26 U.S.C. 5373))

Paragraph 73. Section 240.1042 is revised to change an application requirement to a notice. As amended, § 240.1042 reads as follows:

§ 240.1042 Notice on Form 5120.38.

A proprietor who intends to withdraw distillates containing aldehydes shall submit a notice on Form 5110.46.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1382, as amended (26 U.S.C. 5373))

Paragraph 74. Section 240.1043 is revised to update the section. As revised, § 240.1043 reads as follows:

§ 240.1043 Receipt and deposit of distillates containing aldehydes.

Distillates containing aldehydes which are received at the bonded wine cellar (if not immediately used) shall be placed under the proprietor's lock in a secure room or tank on the bonded premises. Distillates containing aldehydes shall not be mingled with wine spirits. If distillates contain less than one-tenth of one percent of aldehydes, they shall be subject to additional conditions relating to the receipt, storage, and use as the regional regulatory administrator shall require to assure that the distillates are properly used and accounted for.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1382, as amended (26 U.S.C. 5373))

Section P. Part 250 is amended as follows:

PART 250—LIQUORS AND ARTICLES FROM PUERTO RICO AND THE VIRGIN ISLANDS

Paragraph 1. The table of sections for Part 250 is amended to reflect (1) the addition of §§ 250.36c, 250.66a, 250.201c, and Subparts Ib and Oa, (2) the revision of Subparts D and K, (3) the revocation of §§ 250.83, 250.85, 250.96a, 250.112a, 250.204, and Subpart I, (4) the deletion of §§ 250.99, 250.100, and the undesignated center heading which preceded § 250.98, and (5) the amendment of the titles of §§ 250.66, 250.78, 250.98, 250.108, 250.110, 250.260 and Subpart E. As amended, the table of sections for Part 250 reads as follows:

* * * * *

250.36c Shipments of bulk distilled spirits to the United States without payment of tax.

* * * * *

Subpart D—Formulas for Products From Puerto Rico

Sec.

250.50 Formulas for liquors.
250.51 Formulas for articles and products manufactured with denatured spirits.
250.52 Still wines containing carbon dioxide.
250.53 Changes of formulas.
250.54 Filing and disposition of formulas.
250.55 Previously approved formulas.

Subpart E—Taxpayment of Liquors and Articles in Puerto Rico

Bonds

Sec.

* * * * *

250.66 Bond, ATF Form 5110.50—Distilled Spirits.
250.66a New bond required effective January 1, 1980.

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250.78 Application and permit, ATF Form 5110.51.

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Packages of Distilled Spirits

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250.98 Liqueurs, cordials and similar distilled spirits products containing wine.

Beer

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250.108 Application for permit, ATF Form 5110.51 and/or Form 2900.

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250.110 Release of articles or liquors.

* * * * *

Subpart Ib—Shipment of Bulk Distilled Spirits From Puerto Rico, Without Payment of Tax, for Transfer From Customs Custody to Internal Revenue Bond

250.196 General.
250.197 Furnishing formula to consignee.
250.198 Application to receive spirits in bond.
250.199 Application and permit to ship, ATF Form 5110.31.
250.199a Action by revenue agent.
250.199b Issuance and disposition of permit.
250.199c Action by carrier.
250.199d Customs inspection and release.
250.199e Transfer by pipeline at dock.
250.199f Consignee premises.

Subpart J * * *

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250.201c Shipments of bulk distilled spirits to the United States without payment of tax.

* * * * *

Subpart K—Formulas for Products From the Virgin Islands

250.220 Formulas for liquors.
250.221 Formulas for articles and products manufactured with denatured spirits.
250.222 Still wines containing carbon dioxide.
250.223 Changes of formulas.
250.224 Filing and disposition of formulas.
250.225 Previously approved formulas.

Subpart L * * *

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250.260 Certificate.

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Subpart Oa—Shipment of Bulk Distilled Spirits From the Virgin Islands, Without Payment of Tax, for Transfer From Customs Custody to Internal Revenue Bond

250.300 General.
250.301 Application, ATF Form 5100.16.
250.302 Gauge and certification.

Sec.
250.303 Customs inspection and release.
250.304 Bulk conveyances to be sealed.
250.305 Transfer by pipeline at dock.
* * * * *

Paragraph 2. Section 250.1 is amended to add reference to provisions which were redesignated from Subparts F and G of Part 170, to Subparts Ib and Oa of this part. As amended, § 250.1 reads as follows:

§ 250.1 Alcoholic products coming into the United States from Puerto Rico and the Virgin Islands.

This part, "Liquors and Articles from Puerto Rico and the Virgin Islands," relates to:

(a) The production, bonded warehousing, and withdrawal of distilled spirits, and denatured spirits, and the manufacture of articles in Puerto Rico and the Virgin Islands to be brought into the United States free of tax;

(b) The collection of internal revenue taxes on taxable alcoholic products coming into the United States from Puerto Rico and the Virgin Islands; and

(c) The transfer, without payment of tax, of Puerto Rican and Virgin Islands spirits in bulk containers or by pipeline from customs custody to the bonded premises of a distilled spirits plant qualified under Part 19 of this chapter.

Paragraph 3. Section 250.11 is amended (1) to add definitions of *Bottler, Bulk container, Bulk distilled spirits,* and *Rectifier,* (2) to amend the definitions of *Distilled spirits or spirits,* and *Wine,* and (3) to correct the statutory authority. As amended, § 250.11 reads as follows:

§ 250.11 Meaning of terms.

* * * * *

Bottler. Any person required to hold a basic permit as a bottler under 27 U.S.C. 203(b)(1).

Bulk container. Any container having a capacity of more than 1 gallon.

Bulk distilled spirits. The term "bulk distilled spirits" means distilled spirits in a container having a capacity in excess of 1 gallon.

* * * * *

Distilled spirits or spirits. That substance known as ethyl alcohol, ethanol, or spirits of wine, in any form (including all dilutions and mixtures thereof, from whatever source or by whatever process produced), but shall not include industrial spirits as defined in this part except when used in reference to such spirits which would be subject to tax if brought into the United States.

* * * * *

Rectifier. Any person required to hold a rectifier's basic permit under 27 U.S.C. 203(b)(1).

* * * * *

Wine. Still wine, vermouth, or other aperitif wine, imitation, substandard, or artificial wine, compounds designated as wine, flavored, rectified, or sweetened wine, champagne or sparkling wine, and artificially carbonated wine, containing not over 24 percent of alcohol by volume. Wines containing more than 24 percent of alcohol by volume are classed and taxed as distilled spirits.

* * * * *

(68A Stat. 917, as amended (26 U.S.C. 7805); 49 Stat. 981, as amended (27 U.S.C. 205))

§ 250.36b [Amended]

Paragraph 4. Section 250.36b is amended to reflect the addition of Subpart Ib to this part by deleting the last sentence.

Paragraph 5. Immediately after § 250.36b, a new § 250.36c is added to reflect the addition of Subpart Ib to this part. As added, § 250.36c reads as follows:

§ 250.36c Shipments of bulk distilled spirits to the United States without payment of tax.

Bulk distilled spirits may be brought into the United States from Puerto Rico without payment of tax for transfer from customs custody to the bonded premises of a distilled spirits plant qualified under Part 19 of this chapter. Such shipments are subject to the provisions of Subpart Ib.

Paragraph 6. Section 250.40 is amended to reflect the addition of Subpart Ib to this part by adding a new paragraph (e). As amended, § 250.40 reads as follows:

§ 250.40 Marking containers of distilled spirits.

* * * * *

(e) In the case of bulk containers shipped to the United States under Subpart Ib, the serial number of the application and permit to ship, ATF Form 5110.31, instead of the serial number of Form 487–B.

§ 250.41 [Amended]

Paragraph 7. Section 250.41 is amended to replace "Part 201" with "Part 19".

Paragraph 8. Subpart D is revised (1) to make formula requirements for Puerto Rican liquors and articles shipped to the United States conform with formula requirements for domestic manufacturers, (2) to add a requirement for a notice relating to still wines containing carbon dioxide, similar to the notice required for domestic winemakers, and (3) to add a qualification that previously approved formulas are valid. As revised, Subpart D reads as follows:

Subpart D—Formulas for Products From Puerto Rico

§ 250.50 Formulas for liquors.

(a) *Distilled spirits products.* Formulas are required by Part 5 of this chapter for distilled spirits products shipped to the United States from Puerto Rico. If any product contains liquors made outside of Puerto Rico, the country of origin for each such liquor shall be stated on the formula. These formulas shall be submitted on ATF Form 5110.38, in accordance with § 250.54.

(b) *Wine.* Persons in Puerto Rico who ship wine to the United States shall comply with the formula requirements of Part 240 of this chapter. If any wine contains liquors made outside of Puerto Rico, the country of origin for each such liquor shall be stated on the formula. All formulas required by this paragraph shall be submitted on ATF Form 698–A Supplemental, in accordance with § 250.54.

§ 250.51 Formulas for articles and products manufactured with denatured spirits.

(a) *Formulas for articles.* Formulas for articles made with distilled spirits must show the quantity and proof of the distilled spirits used, or the percentage of alcohol by volume contained in the finished product. Formulas for articles made with beer or wine must show the kind and quantity thereof (liquid measure), and the percent of alcohol by volume of such beer or wine.

(b) *Formulas for products manufactured with denatured spirits.* Formulas for products manufactured with denatured spirits shall be submitted as provided in Part 211 of this chapter for products manufactured in the United States with denatured spirits.

(c) *ATF Form 1479–A.* Formulas required by this section shall be submitted on ATF Form 1479–A, in accordance with § 250.54.

§ 250.52 Still wines containing carbon dioxide.

(a) *General.* Still wines may contain not more than 0.392 gram of carbon dioxide per 100 milliliters of wine; except that a tolerance to this maximum limitation, not to exceed 0.009 gram of carbon dioxide per 100 milliliters of wine, will be allowed where the amount of carbon dioxide in excess of 0.392 gram per 100 milliliters of wine was due to mechanical variations which could not be completely controlled under good commercial practices. Such tolerance

will not be allowed where it is found that the limitation of 0.392 gram of carbon dioxide per 100 milliliters of wine is continuously or intentionally exceeded, or where the variation results from the use of methods or equipment not in accord with good commercial practices.

(b) *Notice required.* Proprietors intending to add carbon dioxide to, or retain carbon dioxide in, still wines to be shipped to the United States shall submit a notice to the Chief, Puerto Rican Operations. The notice shall show the name and address of the proprietor and shall identify the method or process, the kinds (class and type) of wine, and the type of equipment to be used. A corrected notice shall be filed if there is any change (except for minor changes) in the information contained in the notice.

(c) *Filing and disposition of notice.* The notice required by paragraph (b) of this section shall be submitted in quintuplicate to the Chief, Puerto Rican Operations, who shall retain one copy, forward one copy to the Officer-in-Charge, one copy to the Secretary, and one copy to the revenue agent at the proprietor's premises, and return one copy to the proprietor. The proprietor shall keep the notice available for examination by revenue agents.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1331, as amended (26 U.S.C 5041))

§ 250.53 Changes of formulas.

Any change in the ingredients composing a product covered by an approved formula will necessitate the submission of a new formula.

§ 250.54 Filing and disposition of formulas.

Prior to shipment, formulas required by this subpart shall be submitted in quintuplicate to and approved by the Director. The Director shall retain one copy, forward one copy to the Officer-in-Charge, one copy to the Secretary, and one copy to the revenue agent at the premises of the applicant, and return one copy to the applicant. The applicant shall maintain copies of approved formulas available for examination by revenue agents.

§ 250.55 Previously approved formulas.

Any formula approved on Form 27–B Supplemental prior to January 1, 1980, shall continue to be valid until revoked or voluntarily surrendered. Any person holding such a formula is not required to submit a new formula. If an approved formula on Form 27–B Supplemental indicates that carbon dioxide will be added to, or retained in, still wine, the notice requirement of § 250.52 shall not apply.

Paragraph 9. The title of Subpart E is amended to delete reference to rectification and to add reference to taxpayment of articles in Puerto Rico. As amended, the title of Subpart E reads as follows:

Subpart E—Taxpayment of Liquors and Articles in Puerto Rico

Paragraph 10. Section 250.66 is amended (1) to clarify who is required to file a bond, (2) to change the number of an ATF form, (3) to revoke the bond requirement for rectification tax, and (4) to correct the statutory authority. As amended, § 250.66 reads as follows:

§ 250.66 Bond, ATF Form 5110.50—Distilled spirits.

(a) *General.* If any person intends to ship to the United States, distilled spirits products of Puerto Rican manufacture from bonded storage in Puerto Rico on computation, but before payment, of the tax imposed by 26 U.S.C. 7652(a), equal to the tax imposed in the United States by 26 U.S.C. 5001(a)(1), he shall, before making any such shipment, furnish a bond ATF Form 5110.50, for each premises from which shipment will be made, to secure payment of such tax, at the time and in the manner prescribed in this subpart, on all distilled spirits products shipped. The bond shall be executed in a penal sum not less than the amount of unpaid tax which, at any one time, is chargeable against the bond. The penal sum of such bond shall not exceed $1,000,000, but in no case shall the penal sum be less than $1,000.

(b) *Blanket bond.* Any person who is the proprietor of more than one premises in Puerto Rico from which shipment of spirits to the United States will be made, may, in lieu of furnishing two or more separate bonds on ATF Form 5110.50 as required by paragraph (a) of this section, furnish a blanket bond on ATF Form 5110.50. The penal sum of such blanket bond shall be equal to the sum of the penal sums of all the bonds in lieu of which it is given. Such blanket bond on ATF Form 5110.50 shall show each bonded warehouse and/or bonded processing room and/or rectifying plant to be covered by the bond, and the part of the total penal sum (computed in accordance with paragraph (a) of this section) to be allocated to each of the designated premises. If the penal sum of the bond allocated to a designated premises is in an amount less than the maximum prescribed in paragraph (a) of this section, transactions at such premises shall not exceed the quantity permissible, as reflected by the penal sum allocated in the bond to such premises. Such blanket bond shall contain the terms and conditions of the bonds in lieu of which it is given and shall be conditioned that the total amount of the bond shall be available for satisfaction of any liability incurred under the terms and conditions of such bond.

(Act of August 16, 1954, 68A Stat. 847, as amended, 907, as amended (26 U.S.C 7101, 7102, 7652))

Paragraph 11. Immediately after § 250.66, a new § 250.66a is added to require a new bond for persons who intend to continue deferral of taxes after January 1, 1980. As added, § 250.66a reads as follows:

§ 250.66a New bond required effective January 1, 1980.

Any person holding a valid bond on Form 2896 who desires to continue deferred payment of taxes on distilled spirits released for shipment on and after January 1, 1980, shall file and obtain approval of a new bond, ATF Form 5110.50, with an effective date of January 1, 1980. The new bond shall comply with the penal sum requirements prescribed by § 250.66 and shall be conditioned on compliance with the new tax deferral system prescribed by § 250.112. The proprietor shall prepay taxes, in accordance with § 250.113, if a new bond is not filed with and approved by the Officer-in-Charge.

Paragraph 12. Section 250.68a is amended (1) to delete reference to a revoked paragraph of regulation, (2) to change reference to a redesignated paragraph of regulation, and (3) to change the numbers of ATF forms. As amended, § 250.68a reads as follows:

§ 250.68a Bond account.

Every person who files a bond under this subpart shall keep an account of the charges against and credits to the bond if the penal sum of his bond is less than the maximum prescribed in §§ 250.66(a), 250.67, or 250.68, or if the penal sum allocated to his premises under § 250.66(b) is less than the prescribed maximum. He shall charge the bond with the amount of liability he accepts at the time he executes ATF Form 5110.51 or 2900, and shall credit the bond with the amount of the tax paid at the time he files each return, ATF Form 5110.32, 2927, or 2929, and remittance. The account shall also show the balance available under the bond at any one time.

§ 250.76 [Amended]

Paragraph 13. Section 250.76 is amended to replace "Form 2899" with "ATF Form 5110.51".

Paragraph 14. Section 250.77 is amended to reflect the imposition of distilled spirits tax on alcoholic ingredients added to distilled spirits products, and to delete references to rectification tax. As amended, § 250.77 reads as follows:

Distilled Spirits

§ 250.77 Subject to tax.

Distilled spirits of Puerto Rican manufacture, and any products containing such spirits, including any alcoholic ingredients added to such spirits or products, coming into the United States and withdrawn for consumption or sale are subject to a tax equal to the internal revenue tax imposed in the United States by 26 U.S.C. 5001(a)(1).

(Act of August 16, 1954, Pub. L. 591, 68A Stat. 907, as amended (26 U.S.C. 7652); Sec. 201, Pub. L. 85–859, 72 Stat. 1314, as amended (26 U.S.C. 5001))

Paragraph 15. Section 250.78 is amended to clarify who is required to obtain a permit to ship distilled spirits products to the United States and to change the number of an ATF Form. As amended, § 250.78 reads as follows:

§ 250.78 Application and permit, ATF Form 5110.51.

Application for permit to compute the tax on, and to withdraw, distilled spirits shall be made on ATF Form 5110.51, in sextuplicate, by the proprietor. The proprietor shall forward all copies of the form to the Secretary. If the application is properly prepared and is otherwise in order, the Secretary or his delegate shall execute the permit, retain one copy, and forward the original and remaining copies of the form to the revenue agent at the premises where the products are located.

§ 250.79 [Amended]

Paragraph 16. Section 250.79 is amended to change the numbers of ATF forms (1) by replacing "Form 2899" with "ATF Form 5110.51", (2) by replacing "Form 2630" with "ATF Form 5110.45", and (3) by replacing "Forms 2899 and 2630" with "ATF Forms 5110.51 and 5110.45".

Paragraph 17. Sections 250.80 and 250.81 are amended to reflect the new method of tax payment on finished distilled spirits products and to change the numbers of ATF forms. As amended, §§ 250.80 and 250.81 read as follows:

§ 250.80 Deferred payment of tax—release of spirits.

(a) *Action by proprietor.* Where the proprietor has furnished bond on ATF Form 5110.50, and payment of the tax is to be deferred, he shall execute an agreement on ATF Form 5110.51 to pay the amount of tax which has been computed and entered on the form. He shall also certify, under the penalties of perjury, that he is not in default of any payment of tax chargeable against his bond, and that his bond is in the maximum penal sum, or that it is sufficient to cover the amount of tax on the distilled spirits described on the form in addition to all other amounts chargeable against his bond. The proprietor shall deliver all copies of ATF Forms 5110.51 and 5110.45 to the revenue agent.

(b) *Action by revenue agent.* On receipt of the ATF Forms 5110.51 and 5110.45, the revenue agent shall verify the computation of the tax entered on the ATF Form 5110.51, and if the proprietor has on file a good and sufficient bond, ATF Form 5110.50, so indicate on ATF Form 5110.51. The revenue agent shall then execute his report of release on the ATF Form 5110.51 and release the spirits for shipment to the United States. He shall forward the original ATF forms 5110.51 and 5110.45 to the Officer-in-Charge, one copy of each form to the Bureau of Alcoholic Beverage Taxes, and one copy of each to the District Revenue Agent (Commonwealth of Puerto Rico), deliver one copy of each to the proprietor, and retain one copy of each for his file. Where the revenue agent finds that the proprietor does not have good and sufficient bond coverage, or where the revenue agent has received information that the proprietor is in default of payment of any taxes previously charged to his bond, he shall return all copies of ATF Forms 5110.51 and 5110.45 to the proprietor, giving his reasons for such action.

§ 250.81 Prepayment of tax and release of spirits.

(a) *Action by proprietor.* Where the distilled spirits are to be released after payment of the computed tax, the proprietor shall enter the amount of such computed tax on all copies of ATF Form 5110.51 and execute the statement that such tax is being prepaid. He shall then prepare ATF Form 5110.53 in quadruplicate, and send the original and two copies, with all copies of ATF Forms 5110.51 and 5110.45 and his remittance in full for the tax, to the Officer-in-Charge.

(b) *Action by Officer-in-Charge.* On receipt of ATF Forms 5110.51, 5110.53, and 5110.45, with remittance covering prepayment of tax, the Officer-in-Charge shall execute his receipt on all copies of ATF Form 5110.53 and his report of prepaid taxes on all copies of ATF Form 5110.51. He shall then forward one copy of ATF Form 5110.53 to the Secretary and one copy of ATF Form 5110.53 and four copies of ATF Forms 5110.51 and 5110.45 to the revenue agent, and retain the original of each form for his files.

(c) *Action by revenue agent.* On receipt of ATF Form 5110.51 executed by the Officer-in-Charge to show receipt of ATF Form 5110.53 and remittance, and a copy of the ATF Form 5110.53, the revenue agent shall execute his report of release on the ATF Form 5110.51 and release the spirits for shipment to the United States. He shall forward one copy of the ATF Form 5110.51 and one copy of ATF Form 5110.45 to the Bureau of Alcoholic Beverage Taxes and one copy of each to the District Revenue Agent (Commonwealth of Puerto Rico), deliver one copy of each to the proprietor, and retain one copy of each and the copy of ATF Form 5110.53 for his file.

§ 250.82 [Amended]

Paragraph 18. Section 250.82 is amended to reflect the new method of taxpayment on finished distilled spirits products by deleting the words "released from bonded storage under § 250.80 or § 250.81".

Paragraph 19. Section 250.84, relating to the stamping of bottles is amended to include the affixing of distilled spirits stamps on bulk containers. As amended, § 250.84 reads as follows:

§ 250.84 Stamping of bottles and bulk containers.

(a) *Bottles.* Every bottle of distilled spirits of Puerto Rican manufacture to be shipped to the United States must have affixed thereto a red strip stamp of proper size. Red strip stamps will be procured and used as provided in Subpart G of this part.

(b) *Bulk containers.* Where taxpaid distilled spirits intended for shipment to the United States are in containers of more than 1 gallon (3.785 liters), distilled spirits stamps shall be procured and affixed as provided in §§ 250.88 through 250.91.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5205))

§§ 250.83 and 250.85 [Revoked]

Paragraph 20. Section 250.83, relating to segregation of rectified and unrectified spirits, and § 250.85, relating to rectification tax, are revoked.

§ 250.87 [Amended]

Paragraph 21. Section 250.87 is amended (1) to delete reference to rectification tax by deleting the phrase, "and that all rectification taxes incurred have been paid or deferred in the same manner as provided in § 250.85 for

rectified spirits bottled and cased, or packaged," and, (2) to replace "Form 2899" with "ATF Form 5110.51".

Paragraph 22. Section 250.89 is amended to delete reference to rectification tax. As amended, § 250.89 reads as follows:

§ 250.89 Issurance of distilled spirits stamps.

On receipt of Form 3039, and the copy of the approved Form 487B, the Officer-in-Charge shall issue the required number of distilled spirits stamps. He shall enter, on each stamp, the name of the proprietor removing the spirits and the serial number of the container for which the stamp is issued. When the stamps have been issued, the issuing officer shall enter the serial numbers thereof on each copy of the Form 3039; return the copy of Form 487B and one copy of the Form 3039, with the stamps, to the applicant; forward one copy of Form 3039 to the Secretary; and retain the original of Form 3039 for his files.

Paragraph 23. Section 250.93 is amended to reflect the new tax computation procedure, whereby Form 2900 will be prepared only when wine is used in a finished product containing no distilled spirits. A sentence relating to "wines containing more than 24 percent of alcohol by volume" is deleted; since the definition of wine makes it clear that such products are not wines, but are rather distilled spirits. As amended, § 250.93 reads as follows:

§ 250.93 Application and permit, Form 2900.

When wine of Puerto Rican manufacture is to be withdrawn for shipment to the United States, or for use in an article made with wine only or with wine and beer only, for shipment to the United States, application for permit to compute the tax on, and to withdraw, the wine shall be made on Form 2900, in sextuplicate, by the proprietor of the bonded premises where the wine is stored. If the withdrawal is to be made in casks, barrels, kegs or similar containers, the proprietor shall enter the name of the winemaker producing the wine, the serial numbers of the packages, the total number of wine gallons contained therein, and the taxable grade of the wine, for example, "not more than 14 percent" if the wine contains not more than 14 percent of alcohol by volume, "14–21 percent" if the wine contains more than 14 percent and not exceeding 21 percent of alcohol by volume, "21–24 percent" if the wine contains more than 21 percent but not exceeding 24 percent of alcohol by volume. If the application covers more than one taxable grade of wine, the quantity in each taxable grade shall be reported separately. If the withdrawal is to consist of bottled wine, the proprietor shall show the number of cases, size of the bottles, the number of bottles per case, the total quantity in wine gallons, and the taxable grade of the wine in the manner stated above. The proprietor shall forward all copies of the form to the Secretary. If the application is properly prepared and is otherwise in order, the Secretary or his delegate shall execute the permit, retain one copy, and return the original and four copies to the proprietor.

§§ 250.95 and 250.96 [Amended]

Paragraph 24. Sections 250.95 and 250.96 are amended to replace "Form 2899" with "ATF Form 5110.51".

§ 250.96a [Revoked]

Paragraph 25. Section 250.96a, dealing exclusively with rectification tax, is revoked.

Paragraph 26. The undesignated center head immediately preceding § 250.98 is deleted. Section 250.98 is totally revised to indicate that all distilled spirits products containing wine are classed and taxed entirely at the distilled spirits rate. As revised, § 250.98 reads as follows:

§ 250.98 Liqueurs, cordials, and similar distilled spirits products containing wine.

The entire alcohol content of liqueurs, cordials, and similar distilled spirits products containing wine is taxable at the distilled spirits rate. The procedures for taxpayment, shipment, stamping containers, and release of such products shall be as prescribed in §§ 250.77 through 250.91.

§§ 250.99 and 250.100 [Revoked]

Paragraph 27. Sections 250.99 and 250.100, dealing with taxpayment and shipment of liqueurs, cordials, and similar products, are revoked. These products will be taxpaid and otherwise treated exactly the same as distilled spirits.

§§ 250.104 and 250.105 [Amended]

Paragraph 28. Sections 250.104 and 250.105 are amended to replace "Form 2899" with "ATF Form 5110.51".

Paragraph 29. Section 250.107 is revised to describe the new basis for taxation of articles. As revised, § 250.107 reads as follows:

Articles

§ 250.107 Taxable status.

Articles of Puerto Rican manufacture which are to be shipped to the United States and which are not exempt fom tax under the provisions of § 250.36 are subject, under section 7652(a) to a tax equal to the tax imposed by the internal revenue laws of the United States. If such articles contain distilled spirits, the tax will be collected at the rate prescribed by 26 U.S.C. 5001(a)(1) on all alcohol contained therein, regardless of the source. Such articles containing only wine and/or beer will be taxed at the rates prescribed by 26 U.S.C. 5041 and/or 5051, respectively. A formula covering the manufacture of each article shall be filed by the manufacturer in accordance with Subpart D of this part.

Paragraph 30. Section 250.108 is revised to conform the procedure, regarding application for permit to taxpay articles, to the new taxation structure. Form 2900 may be used only if the finished article contains no distilled spirits. As revised, paragraphs (a) and (b) of § 250.108 read as follows:

§ 250.108 Application for permit, ATF Form 5110.51 and/or Form 2900.

(a) *Distilled spirits.* Where distilled spirits of Puerto Rican manufacture are to be used in the manufacture of the articles to be shipped to the United States, the manufacturer shall make application on Form 5110.51, in accordance with the applicable provisions of § 250.78.

(b) *Wine and/or beer.* Where wine and/or beer of Puerto Pican manufacture is to be used in the manufacture of the articles to be shipped to the United States, the manufacturer shall make application on Form 2900, in accordance with the applicable provisions of §§ 250.93 and/or 250.102. Wine and beer may be included in the same application.

* * * * *

Paragraph 31. Section 250.109 is amended to conform to the new taxation structure and to the all-in-bond system to be imposed in the United States. The wine and beer tax rates may apply only if the finished article contains no distilled spirits. As amended, § 250.109 reads as follows:

§ 250.109 Taxpayment.

(a) *Distilled spirits.* The tax on distilled spirits contained in articles to be shipped to the United States, equal to the tax imposed in the United States by 26 U.S.C. 5001(a)(1), shall be computed in accordance with § 250.79 and paid in accordance with the applicable provisions of §§ 250.80, 250.81, and 250.111 through 250.113.

(b) *Wine.* The tax on wine used in the manufacture of articles to be shipped to the United States, equal to the tax imposed in the United States by 26 U.S.C. 5041, shall be computed in accordance with § 250.94 and paid in

accordance with the applicable provisions of §§ 250.95, 250.96, and 250.111 through 250.113.

(c) *Beer.* The tax on beer used in the manufacture of articles to be shipped to the United States, equal to the tax imposed in the United States by 26 U.S.C. 5051, shall be computed in accordance with § 250.103 and paid in accordance with the applicable provisions of §§ 250.104, 250.105, and 250.111 through 250.113.

Paragraph 32. Section 250.110 is amended to conform to the new taxation structure and the all-in-bond system being imposed in the continental United States. In the case of articles containing distilled spirits, release for shipment occurs after completion of the finished product, whereas for articles made only with beer and wine, release occurs when the liquors are withdrawn for use in manufacturing. As amended, § 250.110 reads as follows:

§ 250.110 Release of articles or liquors.

After determining that the proprietor has good and sufficient bond coverage, or, in the case of prepayment, on receipt of ATF Form 5110.51 or Form 2900 executed by the Officer-in-Charge to show receipt of ATF Form 5110.53, 2928, or 2930, and remittance, the revenue agent shall execute his report of release on ATF Form 5110.51 or Form 2900 and release the articles containing distilled spirits, or release the wine and/or beer for use in the manufacture of articles. He shall forward one copy of ATF Form 5110.51 or Form 2900, and of ATF Form 5110.45 (if any) to the Bureau of Alcoholic Beverage Taxes and one copy of each to the District Revenue Agent (Commonwealth of Puerto Rico), deliver one copy of each to the applicant, and retain one copy of each for his file. In the case of deferred payment, the original ATF Form 5110.51 or Form 2900 and the original ATF Form 5110.45 (if any) shall be forwarded to the Officer-in-Charge. A permit shall be obtained as provided in §§ 250.114 through 250.116 before the articles manufactured from such liquors may be shipped to the United States.

Paragraph 33. Section 250.112 is revised (1) to change the numbers of certain ATF Forms, (2) to eliminate reference to rectification tax, and (3) to impose the new extended deferral periods for distilled spirits prescribed by Pub. L. 96–39. As revised, § 250.112 reads as follows:

§ 250.112 Taxes to be collected by returns for semimonthly periods.

(a) *Distilled spirits.* The taxes imposed by 26 U.S.C. 7652(a), (equal to the taxes imposed in the United States by 26 U.S.C. 5001(a)(1)), the payment of which has been deferred under the provisions of § 250.80, shall be paid pursuant to a return on ATF Form 5110.52 prepared in quadruplicate. The proprietor shall list on his return the serial numbers of all ATF Forms 5110.51 covered by the return.

(b) *Wine.* The taxes imposed by 26 U.S.C. 7652(a), (equal to the taxes imposed in the United States by 26 U.S.C. 5041), the payment of which has been deferred under the provisions of § 250.95, shall be paid pursuant to a return on Form 2927 prepared in quadruplicate. The proprietor shall list on his return the serial numbers of all Forms 2900 covered by the return.

(c) *Beer.* The taxes imposed by 26 U.S.C. 7652(a), (equal to the taxes imposed in the United States by 26 U.S.C. 5051), the payment of which has been deferred under the provisions of § 250.104, shall be paid pursuant to a return on Form 2929 prepared in quadruplicate. The brewer shall list on his return the serial numbers of all Forms 2900 covered by the return.

(d) *Periods.* The periods to be covered by returns on ATF Forms 5110.52, 2927, and 2929, shall be semimonthly; such periods to run from the 1st day through the 15th day of each month and from the 16th day through the last day of each month.

(e) *Filing.* The original and two copies of returns on ATF Forms 5110.52, 2927, and 2929, with remittance covering the full amount of the tax, shall be filed with the Officer-in-Charge not later than the last day for filing as prescribed by paragraph (f) or (g) of this section. Where the return and remittance are delivered by U.S. mail to the office of the Officer-in-Charge, the date of the official postmark of the United States Postal Service stamped on the cover in which the return and remittance were mailed shall be deemed to be the date of delivery. If the last day for filing a return under this paragraph falls on a Saturday, Sunday, or legal holiday in the District of Columbia or in the Commonwealth of Puerto Rico, the filing of such return and remittance shall be considered timely if accomplished on the next succeeding day which is not a Saturday, Sunday, or such legal holiday.

(f) *Last day for filing ATF Form 5110.52.* The last day for filing ATF Form 5110.52, distilled spirits deferred tax return, is as follows:

(1) For return periods in 1980, the return shall be filed not later than the last day of the first succeeding return period plus five days.

(2) For return periods in 1981, the return shall be filed not later than the last day of the first succeeding return period plus ten days.

(3) For return periods in and after 1982, the return shall be filed not later than the last day of the second succeeding return period.

(g) *Last day for filing ATF Forms 2927 or 2929.* The last day for filing ATF Forms 2927 and 2929, deferred tax returns wine and beer, respectively, shall be the last day of the next succeeding return period.

(h) *Default.* Where a taxpayer has defaulted in any payment of tax under this section, during the period of such default and until the Officer-in-Charge finds that the revenue will not be jeopardized by deferred payment of tax under this section, the tax shall be prepaid by such taxpayer in accordance with the provisions of § 250.113. During such period, distilled spirits, wine, or beer shall not be released from bonded premises before the proprietor of the bonded premises has paid the tax thereon. In the event of default, the Officer-in-Charge shall immediately notify the Secretary and the revenue agent at the premises that tax is to be prepaid until further notice, and when he finds that the revenue will not be jeopardized by resumption of deferred payment of tax under this section, he shall notify the Secretary and the revenue agent that deferred payment may be resumed.

§ 250.112a [Revoked]

Paragraph 34. Since all Puerto Rican taxpayers are being required to file a new bond, which will automatically qualify them for the new extended deferral periods, § 250.112a (relating to qualification for extended deferral) is revoked.

Paragraph 35. Section 250.113 is amended to delete a reference to rectification taxes and to replace "withdrawn from bonded storage" with "released for shipment". As amended, paragraph (c) of § 250.113 reads as follows:

§ 250.113 Returns for prepayment of taxes.

* * * * *

(c) *Distilled spirits.* In all cases where taxes equal to the taxes imposed in the United States by 26 U.S.C. 5001(a)(1) are to be paid before distilled spirits may be released for shipment, the proprietor shall pay such taxes pursuant to a return on Form 2925, as prescribed in § 250.81.

* * * * *

§ 250.135 [Amended]

Paragraph 36. The last sentence of § 250.135, which refers to § 250.185, is deleted; since § 250.185 is being

revoked. Furthermore, the prohibition of this sentence against affixing red strip stamps prior to taxpayment is considered unnecessary.

§ 250.137 [Amended]

Paragraph 37. Section 250.137 is amended to delete reference to serial numbers on strip stamps by deleting the words, "serially numbered,".

§ 250.143 [Amended]

Paragraph 38. Section 250.143 is amended to delete reference to serial numbers on strip stamps by replacing, in the first sentence of paragraph (a), the words, "serial numbers of the", with the words, "quantity of".

Subpart I [Revoked]

Paragraph 39. Subpart I, relating to taxpayment in Puerto Rico of liquors withdrawn after rectification or bottling, is no longer necessary; since the repeal of rectification tax removes the necessity of distinguishing between liquors which have, and liquors which have not, been bottled or rectified. All taxpayment will be handled under the revised procedures of Subpart E. Accordingly, Subpart I is revoked.

Paragraph 40. Immediately after Subpart Ia, the following Subpart Ib is added. Sections 170.155, 170.156, 170.157, 170.159, 170.160, 170.161, 170.162, 170.163, 170.164, 170.165 and 170.166 from Subpart G of Part 170 are redesignated as Subpart Ib of Part 250. The requirements of the redesignated regulations are substantially revised (1) to reflect the changes in formula requirements, (2) to eliminate reference to on premises supervision at domestic distilled spirits plants, (3) to eliminate an obsolete requirement for a consent of surety, (4) to delete instructions which are now found on ATF forms and (5) to change the numbers of ATF forms. As added, Subpart Ib reads as follows:

Subpart Ib—Shipment of Bulk Distilled Spirits from Puerto Rico, Without Payment of Tax, for Transfer From Customs Custody to Internal Revenue Bond

Authority: The provisions of this Subpart Ib issued under Sec. 3, Pub. L. 90–630, 82 Stat. 1328, as amended (26 U.S.C. 5232), unless otherwise noted.

§ 250.196 General.

Under the provisions of this subpart and § 250.86, distilled spirits brought into the United States from Puerto Rico in bulk containers may be withdrawn by the proprietor of a distilled spirits plant from customs custody and transferred in such bulk containers or by pipeline to the bonded premises of his plant, without payment of the internal revenue tax, if any, imposed on such spirits by 26 U.S.C. 7652. Such spirits so withdrawn and transferred to a distilled spirits plant (a) may be redistilled or denatured only if of 185 degrees or more of proof; and (b) may be withdrawn from internal revenue bond for any purpose authorized by 26 U.S.C. chapter 51, in the same manner as domestic distilled spirits. Spirits transferred from customs custody to the bonded premises of a distilled spirits plant under the provisions of this subpart shall be received and stored thereat, and withdrawn or transferred therefrom, subject to applicable provisions of Part 19 of this chapter. The person operating the bonded premises of the distilled spirits plant to which spirits are transferred under the provisions of this subpart shall become liable for the tax on distilled spirits withdrawn from customs custody under 26 U.S.C. 5232, upon release of the spirits from customs custody and the person bringing the spirits into the United States shall thereupon be relieved of liability for the tax.

§ 250.197 Furnishing formula to consignee.

Prior to the first shipment, the person shipping the spirits to the United States shall furnish a reproduced copy of the approved formula covering such spirits to the proprietor of the distilled spirits plant to receive the spirits.

§ 250.198 Application to receive spirits in bond.

(a) *Application.* The proprietor of a distilled spirits plant desiring to withdraw Puerto Rican spirits as authorized in § 250.196 of this subpart shall submit an application to the regional regulatory administrator on ATF Form 5100.16 in accordance with the instructions on the form.

(b) *Approval.* The application may be approved if the applicant's operations or unit bond is in the maximum penal sum, or, if in less than the maximum penal sum, is sufficient to cover the internal revenue tax on the spirits to be withdrawn in addition to all other liabilities chargeable against such bond. However, no application may be approved unless the applicant has provided suitable facilities as provided in Part 19 of this chapter.

(c) *Termination.* An applicant may terminate an approved application, by retrieving and returning all outstanding copies, in accordance with the instructions on ATF Form 5100.16.

§ 250.199 Application and permit to ship, ATF Form 5110.31.

Before spirits of Puerto Rican manufacture may be shipped to the United States without payment of tax for withdrawal from customs custody and transfer to internal revenue bond, an application by the consignor on ATF Form 5110.31 for permit to ship must be approved by the Secretary. All copies of the application (original and five copies) shall be delivered to the revenue agent.

§ 250.199a Action by revenue agent.

(a) *Gauge.* Puerto Rican spirits to be withdrawn for shipment to the United States as provided in this subpart shall be gauged by the revenue agent prior to withdrawal from the consignor premises. The revenue agent shall report the gauge on ATF Form 5110.31. If the spirits are in packages, the revenue agent shall report the details of the gauge of each package on ATF Form 5110.45. The revenue agent shall distribute the forms in accordance with the instructions on ATF Form 5110.31.

(b) *Sealing bulk conveyances.* When a shipment is made in a tank, van, or other bulk conveyance (other than barrels, drums, or similar packages that are not containerized), all openings affording access to the spirits shall be sealed by the Puerto Rican revenue agent in such manner as will prevent unauthorized removal of spirits without detection.

(c) *Disposition of ATF Form 5110.31.* The revenue agent shall retain one copy of ATF Form 5110.31 (and any accompanying ATF Form 5110.45) and shall submit the remaining copies to the Secretary.

§ 250.199b Issuance and disposition of permit.

When the Secretary receives an application on ATF Form 5110.31, he shall ascertain that the consignee has on file a currently valid ATF Form 5100.16 for the spirits covered by the ATF Form 5110.31. If the Secretary finds that the applicant is in compliance with law and regulations, he will execute the permit to ship on all copies of ATF Form 5110.31, retain one copy (and any accompanying ATF Form 5110.45) and return the remaining copies to the consignor who shall distribute them in accordance with the instructions on ATF Form 5110.31.

§ 250.199c Action by carrier.

The carrier of the spirits specified on the ATF Form 5110.31 shall, at the time of unlading at the port of arrival in the United States, segregate and arrange the containers of spirits of convenient customs examination and shall assume any expense incurred in connection therewith.

§ 250.199d Customs inspection and release.

On receipt of a properly executed ATF Form 5110.31 and any accompanying ATF Form 5110.45 from the consignor, the customs officer at the port of arrival in the United States shall inspect shipments in bulk conveyances, and if the seals are intact, he shall release the shipment. If such seals are not intact, the customs officer shall, before release of the shipment, affix customs seals. In addition, barrels, drums, or similar packages not shipped in a sealed van or other sealed conveyance shall be inspected, and if it appears that any such package has sustained a loss, it shall be weighed and reported on ATF Form 5110.45. The serial numbers of any seals affixed by the customs officers shall be reported on ATF Form 5110.31 under remarks with an explanation and description of any evidence of loss. After completing his inspection, the customs officer shall execute his certificate on each copy of ATF Form 5110.31 and show thereon any exceptions found at the time of his release for transfer of the spirits to internal revenue bond. Missing packages should be reported separately from packages which have sustained losses. The customs officer shall then release the spirits to the consignee's representative and distribute all forms in accordance with the instructions on ATF Form 5110.31.

§ 250.199e Transfer by pipeline at dock.

If the distilled spirits plant is equipped with suitable dock facilities, the distilled spirits may, subject to all requirements of the customs laws and regulations, be transferred by pipeline from the vessel or barge through weighing tanks or other suitable measuring tanks into tanks on the bonded premises of the distilled spirits plant, or directly into tanks on such premises provided such tanks are equipped with suitable measuring devices for accurately indicating the actual contents therein. In all such cases of pipeline transfers, the distilled spirits shall be released by a customs officer to the proprietor for deposit in the distilled spirits plant.

§ 250.199f Consignee premises.

(a) *General.* When Puerto Rican spirits are received from customs custody under the provisions of this subpart the consignee proprietor shall examine all containers for evidence of loss in transit or of loss due to theft. Spirits after examination shall be immediately deposited in the warehouse. The consignee shall execute the certificate of receipt on ATF Form 5110.31. Losses of spirits shall be determined and reported on ATF Form 5110.31 and losses of spirits in packages shall also be shown on ATF Form 5110.45, with a notation as to the apparent cause thereof.

(b) *Packages.* Packages shall be received on bonded premises by the proprietor on the basis of the most recent official gauge. If any package in a consignment is reported on more than one gauge report, a consolidated gauge report, in duplicate, (on ATF Form 5110.45) reflecting the most recent data shall be prepared, and such consolidated report shall become the active detailed record of deposit for the packages in the consignment. The original of all superseded gauge reports shall be so identified and filed in an inactive file and any remaining copies may be destroyed.

(c) *Bulk conveyances and pipelines.* When spirits are received in bulk conveyances or by pipeline, the consignee shall gauge the spirits and record the receiving gauge on all copies of ATF Form 5110.31.

(d) *Distribution of forms.* The proprietor shall retain the original of ATF Form 5110.31 (and ATF Form 5110.45, if any) and submit the copy of each to the regional regulatory administrator.

§ 250.201 [Amended]

Paragraph 41. Section 250.201b is amended to reflect the addition of Subpart Oa to this part by deleting the last sentence.

Paragraph 42. Immediately after § 250.201b, a new § 250.201c is added to reflect the addition of Subpart Oa to this part. As added, § 250.201c reads as follows:

§ 250.201c Shipments of bulk distilled spirits to the United States without payment of tax.

Bulk distilled spirits may be brought into the United States from the Virgin Islands without payment of tax for transfer from customs custody to the bonded premises of a distilled spirits plant qualified under Part 19 of this chapter. Such shipments are subject to the provisions of Subpart Oa.

§ 250.204 [Revoked]

Paragraph 43. Section 250.204, relating to gauging spirits prior to rectification or bottling, is revoked.

Paragraph 44. Section 250.205 is amended (1) to add a provision for wine, (2) to clarify requirements for distilled spirits, (3) to eliminate references to formulas for liquors and articles, (4) to add a requirement for information relating to liquors and articles containing liquors produced outside of the Virgin Islands, which was previously required on formulas and (5) to delete reference to gauging spirits prior to rectification or bottling. As amended, § 250.205 reads as follows:

§ 250.205 Certificate.

Every person bringing liquors or articles under this part into the United States from the Virgin Islands, except tourists, shall obtain a certificate in the English language from the manufacturer showing, for each shipment, the following information:

(a) The name and address of the consignee;

(b) The kind and brand name;

(c) The quantity thereof as follows:

(1) If distilled spirits, the proof gallons, or liters and degree of proof.

(2) If wine, the taxable grade and wine gallons.

(3) If beer, the gallons, liquid measure, and the percent of alcohol by volume.

(4) If articles, the kind, quantity, and proof of liquors used therein.

(d) The name and address of the producer;

(e) For liquors or articles containing liquors produced outside of the Virgin Islands, the country of origin for each such liquor.

The person bringing the liquors or articles into the United States shall file the certificate with the district director of customs at the port of entry, as provided in § 250.260.

§ 250.207 [Amended]

Paragraph 45. Section 250.207 is amended to replace "Part 201" with "Part 19".

Paragraph 46. Subpart K is revised (1) to make formula requirements for Virgin Islands liquors and articles shipped to the United States conform with formula requirements for domestic manufacturers, (2) to add a requirement for a notice relating to still wines containing carbon dioxide, similar to the notice required for domestic winemakers, and (3) to add a qualification that previously approved formulas are valid. As revised, Subpart K reads as follows:

Subpart K—Formulas for Products from the Virgin Islands

§ 250.220 Formulas for liquors.

(a) *Distilled spirits products.* Persons in the Virgin Islands who ship distilled spirits beverage products to the United States shall comply with the formula requirements of Part 5 of this chapter. If any product contains liquors made outside of Virgin Islands, the country of origin for each such liquor shall be stated on the formula. All formulas

required by this paragraph shall be submitted on ATF Form 5110.38, in accordance with § 250.224.

(b) *Wine.* Persons in the Virgin Islands who ship wine to the United States shall comply with the formula requirements of Part 240 of this chapter. If any wines contains liquors made outside of the Virgin Islands, the country of origin for each such liquor shall be stated on the formula. All formulas required by this paragraph shall be submitted on ATF Form 698–A Supplemental, in accordance with § 250.224.

§ 250.221 Formulas for articles and products manufactured with denatured spirits.

(a) *Formulas for articles.* Formulas for articles made with distilled spirits must show the quantity and proof of the distilled spirits used, or the percentage of alcohol by volume contained in the finished product. Formulas for articles made with beer or wine must show the kind and quantity thereof (liquid measure), and the percent of alcohol by volume of such beer or wine.

(b) *Formulas for products manufactured with denatured spirits.* Formulas for products manufactured with denatured spirits shall be submitted as provided in Part 211 of this chapter for products manufactured in the United States with denatured spirits.

(c) *ATF Form 1479–A.* Formulas required by this section shall be submitted on ATF Form 1479–A, in accordance with § 250.224.

§ 250.222 Still wines containing carbon dioxide.

(a) *General.* Still wines may contain not more than 0.392 gram of carbon dioxide per 100 milliliters of wine; except that a tolerance to this maximum limitation, not to exceed 0.009 gram of carbon dioxide per 100 milliliters of wine, will be allowed where the amount of carbon dioxide in excess of 0.392 gram per 100 milliliters of wine was due to mechanical variations which could not be completely controlled under good commercial practices. Such tolerance will not be allowed where it is found that the limitation of 0.392 gram of carbon dioxide per 100 milliliters of wine is continuously or intentionally exceeded, or where the variation results from the use of methods or equipment not in accord with good commercial practices.

(b) *Notice required.* Proprietors intending to add carbon dioxide to, or retain carbon dioxide in, still wines to be shipped to the United States shall submit a notice to the Chief, Puerto Rican Operations. The notice shall show the name and address of the proprietor and shall identify the method or process, the kinds (class and type) of wine, and the type of equipment to be used. A corrected notice shall be filed if there is any change (except for minor changes) in the information contained in the notice.

(c) *Filing and disposition of notice.* The notice required by paragraph (b) of this section shall be submitted in triplicate to the Chief, Puerto Rican Operations, who shall retain one copy, forward one copy to the Commissioner of Finance of the Virgin Islands, and return one copy to the proprietor. The proprietor shall keep the notice available for examination by insular agents.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1331, as amended (26 U.S.C 5041))

§ 250.223 Changes of formulas.

Any change in the ingredients composing a product covered by an approved formula will necessitate the submission of a new formula.

§ 250.224 Filing and disposition of formulas.

Prior to shipment formulas required by this subpart shall be submitted in triplicate to and approved by the Director. The Director shall retain one copy, forward one copy to the Commissioner of Finance of the Virgin Islands, and return one copy to the applicant. The applicant shall maintain copies of approved formulas available for examination by insular agents.

§ 250.225 Previously approved formulas.

Any formula approved on Form 27–B Supplemental prior to January 1, 1980, shall continue to be valid until revoked or voluntarily surrendered. Any person holding such a formula is not required to submit a new formula. If an approved formula on Form 27–B Supplemental indicates that carbon dioxide will be added to, or retained in, still wine, the notice requirement of § 250.222 shall not apply.

§§ 250.232, 250.240, and 250.240a [Amended]

Paragraph 47. Sections 250.232, 250.240 and 250.240a are amended to delete references to serial numbers on strip stamps (a) in § 250.232 by deleting "serially numbered," (b) in § 250.240, by replacing "serial numbers of the" with "quantity of", and (c) in § 250.240a, by replacing "serial numbers (if any)" with "quantity".

Paragraph 48. Section 250.252 is revised (1) to liberalize requirements on destruction of strip stamps in the Virgin Islands and (2) to delete reference to serial numbers on strip stamps. As revised, § 250.252 reads as follows:

§ 250.252 Destruction or transfer of red strip stamps in the Virgin Islands.

When for any reason a Virgin Islands bottler or exporter has on hand a quantity of red strip stamps which are not to be affixed to containers for shipment to the United States, and it is impractical to return the stamps to the importer from whom they were received or to transfer them to another bottler or exporter conducting operations for the importer, the Virgin Islands bottler or exporter may destroy the stamps upon notice to the regional regulatory administrator of the region in which the importer's place of business is located. The importer shall file the notice identifying the size and quantity of stamps, the name and address of the Virgin Islands bottler or exporter who has possession of the stamps, and the reasons for destruction in the Virgin Islands. The importer shall prepare the applicable items on Form 1627 covering the stamps to be destroyed and forward it to the Virgin Islands bottler or exporter. Upon destruction of the stamps, the Virgin Islands bottler or exporter shall complete the applicable items on Form 1627 and return it to the importer. The importer may then take credit for the stamps on his strip stamp record and on Form 96.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C 5205))

Paragraph 49. Section 250.260 is amended to delete references to a revoked regulation and to clarify the language. As amended, § 250.260 reads as follows:

§ 250.260 Certificate.

Persons (except tourists) bringing liquors or articles from the Virgin Islands into the United States shall file the certificate provided for in § 250.205 with the district director of customs at the port of entry in the United States.

§ 250.261 [Amended]

Paragraph 50. Section 250.261 is amended to replace reference to formulas with reference to a requirement which will enable a customs officer to determine the rate of tax, by replacing "approved formula" with "certificate required by § 250.205".

Paragraph 51. Section 250.262 is amended to reflect the new method for determining the tax on distilled spirits. As amended, § 250.262 reads as follows:

§ 250.262 Determination of tax on distilled spirits.

If the certificate required by § 250.205 covers distilled spirits, the tax on

distilled spirits (and alcoholic ingredients contained in distilled spirits products), equal to the tax imposed by 26 U.S.C. 5001(a)(1), shall be collected on each proof gallon, and fractional part thereof, contained in the shipment.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1314, as amended (26 U.S.C. 5001))

Paragraph 52. Section 250.265 is revised to reflect the new definition of distilled spirits. As revised, § 250.265 reads as follows:

§ 250.265 Determination of tax on articles.

Where articles contain distilled spirits, the tax will be colleted at the rate prescribed by 26 U.S.C. 5001(a)(1) on all alcohol contained therein, regardless of the source. Articles containing only wine and/or beer will be taxed at the rates prescribed by 26 U.S.C. 5041 and/or 5051, respectively. The quantities and kinds of liquors will be shown on the certificate prescribed in § 250.205.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1314, as amended (26 U.S.C. 5001, 5007))

Paragraph 53. Immediately after Subpart O, the following new Subpart Oa is added. Sections 170.124, 170.126, 170.127, 170.128 and 170.129 from Subpart F of Part 170 are redesignated as Subpart Oa of Part 250. The requirements of the redesignated regulations are substantially revised (1) to reflect the new definition of "bulk container", (2) to delete reference to rectification tax, (3) to reflect the new regulatory provisions relating to bottling in bond (which replace repealed sections of law on that subject), (4) to change references to "Part 201" to "Part 19", (5) to delete instructions in the regulations that are now found on ATF forms, (6) to delete reference to gauging by an insular gauger, which is no longer prescribed, and (7) to change the numbers of ATF forms. As added, Subpart Oa reads as follows:

Subpart Oa—Shipment of Bulk Distilled Spirits From the Virgin Islands, Without Payment of Tax, for Transfer From Customs Custody to Internal Revenue Bond

Authority: The provisions of this Subpart Oa issued under Sec. 3, Pub. L. 90–630, 82 Stat. 1328, as amended (26 U.S.C. 5232) unless otherwise noted.

§ 250.300 General.

Distilled spirits brought into the United States from the Virgin Islands in bulk containers may, under the provisions of this subpart, be withdrawn by the proprietor of a distilled spirits plant from customs custody and transferred in such bulk containers or by pipeline to the bonded premises of his plant, without payment of the internal revenue tax imposed on such spirits by 26 U.S.C. 7652. Such spirits so withdrawn and transferred to a distilled spirits plant (a) may be redistilled or denatured only if 185 degrees or more of proof, and (b) may be withdrawn from internal revenue bond for any purpose authorized by 26 U.S.C. Chapter 51, in the same manner as domestic distilled spirits. Spirits transferred from customs custody to the bonded premises of a distilled spirits plant under the provisions of this subpart shall be received and stored thereat, and withdrawn or transferred therefrom, subject to the provisions of Part 19 of this chapter. The person operating the bonded premises of the distilled spirits plant to which spirits are transferred under the provisions of this subpart shall become liable for the tax on distilled spirits withdrawn from customs custody under 26 U.S.C. 5232, upon release of the spirits from customs custody, and the person bringing the spirits into the United States shall thereupon be relieved of his liability for such tax.

§ 250.301 Application, ATF Form 5100.16.

(a) *Application.* The proprietor of a distilled spirits plant desiring to withdraw distilled spirits as authorized in § 250.300 shall submit an application to the regional regulatory administrator on ATF Form 5100.16, in accordance with the instructions on the form.

(b) *Approval.* The application may be approved if the applicant's operations or unit bond is in the maximum penal sum, or, if in less than the maximum penal sum, is sufficient to cover the tax on the spirits to be transferred in addition to all other liabilities chargeable against such bond. However, no application may be approved unless the applicant has provided suitable facilities as provided in Part 19 of this chapter.

(c) *Termination.* An applicant may terminate an approved application, by retrieving and returning all outstanding copies, in accordance with the instructions on ATF Form 5100.16.

§ 250.302 Gauge and certification.

(a) *Gauge.* Virgin Islands spirits to be transferred from customs custody to internal revenue bond as provided in this subpart shall be gauged by the consignor, who shall prepare a report of such gauge, in duplicate, and attach both copies to the certificate required by § 250.205 of this chapter.

(b) *Certification.* The certificate prescribed by § 250.205 shall be prepared in duplicate if the Virgin Islands spirits are to be transferred from customs custody to internal revenue bond. Both copies of the certificate, with the applicable gauge report attached, shall be filed with the district director of customs at the port of entry. The original of the certificate and related report of gauge shall be attached to the original of ATF Form 5110.27 by the customs officer responsible for preparation of the ATF Form 5110.27 in accordance with § 250.303 of this subpart. The remaining copy of the certificate and related report of gauge shall be retained by the customs officer.

§ 250.303 Customs inspection and release.

The customs officer will not release distilled spirits without payment of internal revenue tax until he has determined that he has on file an approved ATF Form 5100.16 as prescribed in § 250.301 of this subpart, from the proprietor of the distilled spirits plant to which the spirits are to be transferred. Prior to release from customs custody, the customs officer shall inspect the spirits, and, if it appears that losses in transit were sustained from any container, he shall gauge the spirits in such container. The customs officer shall then prepare ATF Form 5110.27 in triplicate in accordance with the instructions on the form. When shipments are made in tanks, tank barges, cargo containers, or similar bulk containers (other than barrels, drums, or similar portable containers), the results of the inspection or the details of the gauge of each such bulk container shall be reported separately. In the case of barrels, drums, or similar portable containers, the results of the inspection shall be reported on the ATF Form 5110.27 and the details of the gauge, if any, shall be reported on ATF Form 5110.45. In compliance with the requirements of customs regulations, and on completion of ATF Form 5110.27 (and ATF Form 5110.45, if prepared) the customs officer shall release the spirits for transfer.

§ 250.304 Bulk conveyances to be sealed.

When a shipment of distilled spirits from customs custody to the distilled spirits plant is made in a tank, tank barge, cargo container, tank car, tank truck, or similar bulk conveyance, all openings affording access to the spirits shall be sealed by the customs officer with customs seals in such manner as will prevent unauthorized removal of spirits through such openings without detection.

§ 250.305 Transfer by pipeline at dock.

If the distilled spirits plant is equipped with suitable dock facilities, the distilled

spirits may, subject to all requirements of the customs laws and regulations, be transferred by pipeline from the vessel or barge through weighing tanks or other suitable measuring tanks into storage tanks on the bonded premises of the distilled spirits plant, or directly into storage tanks on such premises provided such storage tanks are equipped with suitable measuring devices for correctly indicating the actual contents therein. In all such cases of pipeline transfers, the distilled spirits shall be transferred under customs supervision, and released for deposit in the distilled spirits plant.

§ 250.312 [Amended]

Paragraph 54. Section 250.312 is amended to replace "§ 201.540b" and "Part 201" with "Part 19". Section Q. Part 251 is amended as follows:

PART 251—IMPORTATION OF DISTILLED SPIRITS, WINE AND BEER

Paragraph 1. The table of sections for Part 251 is amended to change the number of "Form 2609" to "ATF Form 5100.16" where it appears in the title of § 251.172. As amended, the table of sections reads as follows:

* * * * *

251.172 Application, ATF Form 5100.16.

* * * * *

Paragraph 2. The definitions in § 251.11 are amended to conform terminology to changes made by Pub. L. 96–39, and to reflect a substantive change in the definition of "distilled spirits" made by that law. Additionally, the statutory authority is amended to delete irrelevant citations. As amended, § 251.11 reads as follows:

§ 251.11 Meaning of terms.

* * * * *

Bonded premises—distilled spirits plant. The premises of a distilled spirits plant, or part thereof, on which distilled spirits operations defined in 26 U.S.C. 5002 are authorized to be conducted.

Bulk container. Any container having a capacity of more than 1 gallon.

Bulk distilled spirits. The term "bulk distilled spirits" means distilled spirits in a container having a capacity in excess of 1 gallon.

* * * * *

Distilled spirits or spirits. That substance known as ethyl alcohol, ethanol, or spirits of wine, in any form (including all mixtures or dilutions thereof, from whatever source or by whatever process produced).

Distilled spirits plant. An establishment qualified under the provisions of Part 19 of this chapter for the production, storage, or processing of spirits, or for authorized combinations of such operations.

* * * * *

(68A Stat. 917, as amended (26 U.S.C. 7805); 49 Stat. 981, as amended (27 U.S.C. 205))

Paragraph 3. Sections 251.40 and 215.43 are amended to reflect elimination of the wine gallon method for imposing distilled spirits tax, and to reflect the imposition of distilled spirits tax on all alcoholic ingredients added to distilled spirits products. As amended, §§ 251.40 and 251.43 read as follows:

§ 251.40 Distilled spirits.

A tax is imposed by 26 U.S.C. 5001, on all distilled spirits in customs bonded warehouses or imported into the United States at the rate prescribed in such section on each proof gallon and a proportionate tax at a like rate on all fractional parts of such proof gallon. All products of distillation, by whatever name known, which contain spirits, and any alcoholic ingredient added to such products, are considered to be spirits and are taxed as such. The tax shall be determined at the time of importation, or, if entered into bond, at the time of withdrawal therefrom.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1314, as amended (26 U.S.C. 5201); Sec. 3, Pub. L. 90–630, 82 Stat. 1328, as amended (26 U.S.C. 5232))

§ 251.43 Liqueurs, cordials, and similar compounds.

A tax is imposed by 26 U.S.C. 5001 on all liqueurs, cordials, and similar compounds, containing distilled spirits, in a customs bonded warehouse or imported into the United States at the rate prescribed in such section on each proof gallon, and a proportionate tax at a like rate on all fractional parts of such proof gallon. The tax shall be determined at the time of importation, or, if entered into bond, at the time of withdrawal therefrom. Fortified or unfortified wines, containing not over 24 percent alcohol by volume, to which sweetening or flavoring materials, but no distilled spirits, have been added are not classified as liqueurs, cordials, or similar compounds, but are considered to be flavored wines only and are subject to internal revenue tax at the rates applicable to wines.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1314, as amended, 1331, as amended (26 U.S.C. 5001, 5041))

§§ 251.48 and 251.58 [Amended]

Paragraph 4. Sections 251.48 and 251.58 are amended to replace "Part 201" with "Part 19".

Paragraph 5. Sections 251.63, 251.66, and 251.66a are amended to eliminate reference to serial numbers on strip stamps. As amended, §§ 251.63, 251.66, and 251.66a read as follows:

§ 251.63 Size of red strip stamps.

Red strip stamps shall be issued in a standard size for bottles or containers of 200 ml capacity or more, and in a small size for bottles or containers of less than 200 ml capacity.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5205))

§ 251.66 Approval of requisition and issuance of stamps.

The regional regulatory administrator will approve Form 428 and issue the stamps if:

(a) The importer is the holder of an importer's permit issued under the Federal Alcohol Administration Act and the regulations in 27 CFR Part 1;

(b) The quantity requisitioned is reasonable and necessary; and

(c) There is no information on which a denial of a requisition should be made under the provisions of § 251.92

When satisfied that Form 428 may be approved, the regional regulatory administrator shall enter the quantity of stamps issued and the date of issue and approve all copies of the form. The stamps shall be delivered to the applicant, and, if the stamps are mailed, or are delivered to anyone other than the applicant, two copies of the Form 428 shall accompany the stamp. Upon receipt of the stamps, the applicant shall acknowledge receipt on both copies of Form 428 and return one copy to the regional regulatory administrator who issued the stamps and, if an agent, one copy to the importer. In each instance when the regional regulatory administrator approves a requisition which has been submitted by an agent of an importer, the regional regulatory administrator shall immediately forward a copy of Form 428 to the importer, and, if the importer's place of business is located in another region, the regional regulatory administrator shall forward a copy to the regional regulatory administrator of the region in which the importer's place of business is located. If a requisition is disapproved for any reason, the regional regulatory administrator shall return a copy of Form 428 marked "disapproved" to the applicant.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5205))

§ 251.66a Alternative method for issuance of stamps.

(a) *Action by regional regulatory administrator.* When the regional regulatory administrator determines that the interest of the Government will be

best served, strip stamps may be shipped directly to the applicant, as shown on Form 428, from a location other than the office of the regional regulatory administrator. In that case, the regional regulatory administrator shall notify the applicant that strip stamps will be delivered by an alternative method and state the minimum quantity, if any, of each size of stamp which may be requisitioned on any particular Form 428. Upon approval of Form 428, two copies of the form shall be returned to the applicant, and, if the Form 428 was prepared by an agent of an importer, a copy of the form shall be forwarded to the importer and, if applicable, to the regional regulatory administrator of the region in which the importer's place of business is located.

(b) *Action by applicant.* Upon receipt of the stamps, the applicant shall (1) indicate the quantity of stamps received and acknowledge receipt of the stamps on both copies of Form 428, and (2) return one copy to the regional regulatory administrator to whom the Form 428 was submitted for approval and, if an agent, one copy to the importer.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5205))

Paragraph 6. Section 251.89a is amended to liberalize requirements for destruction of red strip stamps abroad, and to delete reference to serial numbers on strip stamps. As amended § 251.89a reads as follows:

§ 251.89a Destruction or transfer of red strip stamps abroad.

When for any reason a foreign bottler or exporter has on hand a quantity of red strip stamps which are not to be affixed to containers for export to the United States, and it is impractical to return the stamps to the importer from whom they were received or to transfer them to another bottler or exporter conducting operations for the importer, the foreign bottler or exporter may destroy the stamps upon notice to the regional regulatory administrator of the region in which the importer's place of business is located. The importer shall file the notice identifying the size and quantity of stamps, the name and address of the foreign bottler or exporter who has possession of the stamps, and the reasons for destruction abroad. The importer shall prepare the applicable items on Form 1627 covering the stamps to be destroyed and forward it to the foreign bottler or exporter. Upon destruction of the stamps, the foreign bottler or exporter shall complete the applicable items on Form 1627 and return it to the importer. The importer may then take credit for the stamps on his strip stamp record and on Form 96.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5205))

Paragraph 7. Section 251.171 is amended (1) to change the minimum size of bulk containers from 5 gallons to more than 1 gallon, (2) to replace reference to a repealed section of law on bottling in bond with a reference to new regulatory requirements on the same subject in 27 CFR Part 5, and (3) to replace "Part 201" with "Part 19". As amended, § 251.171 reads as follows:

§ 251.171 General provisions.

Imported distilled spirits in bulk containers may, under the provisions of this subpart, be withdrawn by the proprietor of a distilled spirits plant from customs custody and transferred in such bulk containers or by pipeline to the bonded premises of his plant, without payment of the internal revenue tax imposed on imported spirits by 26 U.S.C. 5001. Imported spirits so withdrawn and transferred to a distilled spirits plant (a) may be redistilled or denatured only if of 185 degrees or more of proof, and (b) may be withdrawn from internal revenue bond for any purpose authorized by 26 U.S.C. Chapter 51, in the same manner as domestic distilled spirits. Imported distilled spirits transferred from customs custody to the bonded premises of a distilled spirits plant under the provisions of this subpart shall be received and stored thereat, and withdrawn or transferred therefrom, subject to the applicable provisions of Part 19 of this chapter. The person operating the bonded premises of the distilled spirits plant to which imported spirits are transferred shall become liable for the tax on distilled spirits withdrawn from customs custody under 26 U.S.C. 5232, upon release of the spirits from customs custody, and the importer shall thereupon be relieved of his liability for such tax.

(Sec. 3, Pub. L. 90–630, 82 Stat. 1328, as amended (26 U.S.C. 5232))

Paragraph 8. Section 251.172 is amended (1) to change the numbers of ATF forms, (2) to eliminate references to supervision by ATF officers assigned to distilled spirits plants, (3) to replace references to "Part 201" with "Part 19", and (4) to delete requirements that have been incorporated as instructions on ATF Form 5100.16 (formerly Form 2609). As amended, § 251.172 reads as follows:

§ 251.172 Application, ATF Form 5100.16.

(a) *Application.* The proprietor of a distilled spirits plant desiring to withdraw distilled spirits, as authorized in § 251.171, shall submit an application to the regional regulatory administrator on ATF Form 5100.16, in accordance with instructions on the form.

(b) *Approval.* The application may be approved if the applicant's operations or unit bond; required by Part 19 of this chapter, is in the maximum penal sum, or, if in less than the maximum penal sum, is sufficient to cover the tax on the spirits to be transferred in addition to all other liabilities chargeable against such bond. However, no application may be approved unless the applicant has provided suitable facilities as provided in Part 19 of this chapter.

(c) *Termination.* An applicant may terminate an approved application, by retrieving and returning all outstanding copies, in accordance with instructions on ATF Form 5100.16.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1314, as amended 1322, as amended (26 U.S.C. 5001, 5007); Sec. 3, Pub. L. 90–630, 82 Stat. 1328, as amended (26 U.S.C. 5232))

Paragraph 9. Section 251.173 is amended (1) to change the numbers of ATF forms, (2) to eliminate reference to ATF officers assigned to distilled spirits plants, and (3) to delete requirements that have been incorporated as instructions on ATF Form 5110.27 (formerly Form 206). As amended, § 251.173 reads as follows:

§ 251.173 Customs gauge and release.

The customs officer will not release distilled spirits without payment of internal revenue tax until he has determined that he has on file an approved ATF Form 5100.16 from the proprietor of the distilled spirits plant to which the spirits are to be transferred. Prior to release from customs custody, the customs officer shall prepare ATF Form 5110.27, in accordance with the instructions on the form. When shipments are made in tank cars or tank trucks, the details of the gauge of each tank car or tank truck shall be reported separately. In the case of barrels, drums, or similar portable containers, the details of the gauge shall be shown on ATF Form 5110.45, in triplicate. On compliance with the requirements of customs regulations (including determination of duties due), and on completion of ATF Form 5110.27 (and ATF Form 5110.45, if required), the customs officer shall release the spirits for transfer.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1314, as amended 1322, as amended (26 U.S.C. 5001, 5007); Sec. 3, Pub. L. 90–630, 82 Stat. 1328, as amended (26 U.S.C. 5232))

Paragraph 10. Section 251.175 is amended to delete the requirement for locks on tanks on the bonded premises of a distilled spirits plant and to change

the number of an ATF form. Editorial changes in the statutory citation are also made. As amended, § 251.175 reads as follows:

§ 251.175 Transfer by pipeline at dock.

Where the distilled spirits plant is equipped with suitable dock facilities, the distilled spirits may, subject to all requirements of the customs laws and regulations, be transferred by pipeline from the importing vessel or barge through weighing tanks or other suitable measuring tanks into empty storage tanks on the bonded premises of the distilled spirits plant, or directly into storage tanks on such premises provided such storage tanks are equipped with suitable measuring devices for correctly indicating the actual contents. In all such cases of pipeline transfers, the distilled spirits shall be transferred under customs supervision, gauged immediately by a customs officer, and thereupon released for deposit in the distilled spirits plant. The details of the gauge shall be reported on ATF Form 5110.27 and distribution of the form made in accordance with the instructions thereon.

(Sec. 3, Pub. L. 90-630 82 Stat. 1328, as amended (26 U.S.C. 5232))

§ 251.184 [Amended]

Paragraph 11. Section 251.184 is amended to replace "Form 2629", wherever it appears, with "ATF Form 5110.26".

Paragraph 12. Section 251.202 is amended to delete reference to an obsolete regulation and to change references to "Part 201" to references to "Part 19". As amended, § 251.202 reads as follows:

§ 251.202 Standards of fill.

Distilled spirits imported into the United States in containers of 1 gallon (3.785 liters) or less for sale shall be imported only in liquor bottles, including liquor bottles of less than 200 ml capacity, which conform to the applicable standards of fill provided in § 5.47a of this chapter. Empty liquor bottles, including liquor bottles of less than 200 ml capacity, which conform to the provisions of Part 19, or Subpart E of Part 5 of this chapter, may be imported for packaging distilled spirits in the United States as provided in Part 19 of this chapter. Section R. Part 252 is amended as follows:

PART 252—EXPORTATION OF LIQUORS

Paragraph 1. The table of sections for Part 252 is amended to reflect (1) amendments to titles of some sections, (2) revocation of §§ 252.91a, 252.97, 252.173 (and the undesignated center head immediately preceding it), Subpart J, and §252.263, and (3) addition of new § 252.195b. As amended, the table of sections reads as follows:

* * * * *

252.58 Operations or unit bond—distilled spirits.

* * * * *

252.92 Application or notice, ATF Form 5100.11.

* * * * *

252.96 Approval of application.

* * * * *

252.102 Bottles to be stamped or have alternative devices affixed.

* * * * *

252.116 Notice of return of spirits withdrawn without payment of tax.

* * * * *

252.118 Receipt of spirits.

* * * * *

252.122 Application or notice, ATF Form 5100.11.

* * * * *

252.152 Notice, ATF Form 5100.11.

* * * * *

252.161 Notice of return of specially denatured spirits.

* * * * *

252.163 Receipt of specially denatured spirits.

* * * * *

Filing of Notice and Removal

252.190 Notice, ATF Form 5110.30.

* * * * *

252.195 Disposition of ATF Form 5110.30.

252.195a Claims on spirits tax determined before January 1, 1980.

252.195b Claims on spirits tax determined on and after January 1, 1980.

Subpart J—[Revoked]

* * * * *

§ 252.3 [Amended]

Paragraph 2. Section 252.3 is amended (1) to replace "Part 186" with "Part 13" and (2) to replace "Part 201" with "Part 19".

Paragraph 3. Section 252.11 is amended (1) to amend the definitions of *"Bonded premises—distilled spirits plant"*, *"Bulk container"*, *"Distilled spirits or spirits"*, *"Distilled spirits plant"* and *"Tax"*, (2) to delete definitions of *"Export storage facilities"*, *"Rectifier"* and *"Tax gallon"*, and (3) to correct the statutory authority. As amended, § 252.11 reads as follows:

§ 252.11 Meaning of Terms.

* * * * *

Bonded premises—distilled spirits plant. The premises of a distilled spirits plant, or part thereof, on which distilled spirits operations defined in 26 U.S.C. 5002 are authorized to be conducted.

* * * * *

Bulk container. any container having a capacity of more than 1 gallon.

* * * * *

Distilled spirits or spirits. That substance known as ethyl alcohol, ethanol, or spirits of wine, in any form (including all dilutions and mixtures thereof, from whatever source or by whatever process produced) but not denatured spirits.

Distilled spirits plant. An establishment qualified under the provisions of Part 19 of this chapter for the production, warehousing, or processing of spirits, or for authorized combinations of such operations.

* * * * *

Exportation * * *

Foreign-trade zone or zone. * * *

* * * * *

Proprietor. * * *

Region. * * *

* * * * *

Tax. The distilled spirits tax, the beer tax, or the applicable wine tax, as the case may be, imposed by 26 U.S.C. Chapter 51.

U.S.C. * * *

* * * * *

(68A Stat. 917, as amended (26 U.S.C. 7805); 49 Stat. 981, as amended (27 U.S.C. 205))

§ 252.22 [Amended]

Paragraph 4. Section 252.22 is amended to replace "Form 206, 1582,", wherever this phrase appears, with "ATF Form 5100.11, 5110.30,".

Paragraph 5. Section 252.25 is revised to delete reference to provisions which were repealed from Title 26 of the United States Code. As revised, § 252.25 reads as follows:

§ 252.25 General.

The proprietor of a duly constituted manufacturing bonded warehouse, established in accordance with law and the regulations in 19 CFR Chapter I, may withdraw distilled spirits or wines from any distilled spirits plant or bonded wine cellar, as the case may be, without payment of tax, for use in the manufacture of products for export, or shipment in bond to Puerto Rico or in the case of distilled spirits, for transfer to a customs bonded warehouse, as provided for in 26 U.S.C. 5066. The proprietor of the manufacturing bonded warehouse shall furnish bond in accordance with the provisions of § 252.63 or § 252.64.

(Sec. 311, Tariff Act of 1930, 46 Stat. 691, as amended (19 U.S.C. 1311); Sec. 201, Pub. L. 85-859, 72 Stat. 1362, as amended, 1380, as amended (26 U.S.C. 5214, 5362))

Paragraph 6. Section 252.26 is amended (1) to delete references to spirits bottled in bond and to

withdrawals from export storage facilities at distilled spirits plants, and (2) to add a reference to alternative devices affixed in lieu of strip stamps. As amended, § 252.26 reads as follows:

§ 252.26 Entry into customs bonded warehouses.

(a) *Distilled spirits withdrawn without payment of tax.*

(1) Bottled distilled spirits may, subject to this part, be withdrawn from bonded premises for transfer to customs bonded warehouses in which imported distilled spirits are permitted to be stored in bond for entry pending withdrawal as provided in § 252.27. Withdrawals from bonded premises under the provisions of this paragraph shall be treated as withdrawals for exportation under the provisions of 26 U.S.C. 5214(a)(4).

(2) Distilled spirits may, subject to this part, be withdrawn from bonded premises for transfer (for the purpose of storage pending exportation) to any customs bonded warehouse from which distilled spirits may be exported. These withdrawals shall be treated as withdrawals for exportation under the provisions of 26 U.S.C. 5214(a)(9).

(b) *Bottled distilled spirits eligible for export with benefit of drawback.* Bottled distilled spirits stamped, restamped, or affixed with alternative devices, and marked, especially for export with benefit of drawback may, subject to this part, be transferred to customs bonded warehouses in which imported distilled spirits are permitted to be stored, and entered pending withdrawal as provided in § 252.27, as if such spirits were for exportation.

* * * * *

§ 252.27 [Amended]

Paragraph 7. Section 252.27 is amended to replace the first word in the section, "Distilled", with the words "Bottled distilled".

§ 252.36 [Amended]

Paragraph 8. Section 252.36 is amended to replace "Form 206, 1582," with "ATF Form 5100.11, 5110.30,".

Paragraph 9. The statutory authority for § 252.45 is amended to reflect recodification of one section of law. As amended, the statutory authority for § 252.45 reads as follows:

§ 252.45 Retention of records.

* * * * *

(Sec. 201, Pub. L. 85–859, 72 Stat. 1342, as amended, 1381, as amended, 1390, as amended, 1395, as amended (26 U.S.C. 5114, 5367, 5415, 5555); Sec. 807, Pub. L. 96–39, 93 Stat. 283 (26 U.S.C. 5207))

Paragraph 10. Section 252.51 is amended to clarify the language and to replace "Part 201" with "Part 19". As amended, § 252.51 reads as follows:

§ 252.51 General.

Every person required by this part to file a bond or consent of surety shall prepare and execute it on the prescribed form and file it with the regional regulatory administrator of the region in which is located the premises from which the withdrawal or removal of spirits or wines is made without payment of tax, or, in the case of taxpaid or tax-determined spirits or wines on which claim for drawback of tax will be filed, with the regional regulatory administrator for the region in which the claim will be filed, in accordance with the procedures of this part. The procedures in Parts 19, 240, or 245 of this chapter shall govern bonds covering distilled spirits plants, bonded wine cellars and breweries, respectively.

§ 252.56 [Amended]

Paragraph 11. The statutory authority for § 252.56 is amended to delete reference to a repealed section of law by deleting "1393" from the Statutes at Large citation and by deleting "5522" from the United States Code citation.

Paragraph 12. Section 252.58 is amended (1) to replace "bond, Form 2601," with "operations or unit bond,", (2) to change "Part 201" to "Part 19", (3) to delete an obsolete provision, and (4) to correct the statutory authority. As amended, § 252.58 reads as follows:

§ 252.58 Operations or unit bond—distilled spirits.

(a) *Spirits.* Where spirits are withdrawn without payment of tax, as authorized in § 252.91, from the bonded premises of a distilled spirits plant on application of the proprietor thereof, the operations or unit bond, given by the proprietor and approved under the provisions of Part 19 of this chapter, shall cover such withdrawals.

(b) *Wine.* Where, under the provisions of Part 19 of this chapter, an operations or unit bond has been given and approved to cover the operations of a distilled spirits plant and an adjacent bonded wine cellar, such bond shall cover the withdrawal of wine without payment of tax, as authorized in § 252.121, from such bonded wine cellar on application for such withdrawal by the proprietor.

(c) *Specially denatured spirits.* Where specially denatured spirits are withdrawn free of tax, as authorized in § 252.151, from the bonded premises of a distilled spirits plant on application of the proprietor thereof, the proprietor shall file a consent of surety extending the terms of the operations or unit bond, which consent shall be in the following form:

> The obligors agree to extend the terms of said bond to cover all liability that may be incurred on all specially denatured spirits withdrawn by the principal for exportation or transfer to a foreign-trade zone, for which satisfactory evidence of exportation, or of deposit in a foreign-trade zone, as required by law and regulations, is not submitted to the regional regulatory administrator.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1352, as amended, 1362, as amended (26 U.S.C. 5175, 5214); Sec. 3, Pub. L. 91–659, 84 Stat. 1965, as amended (26 U.S.C. 5066); Sec. 805, Pub. L. 96–39, 93 Stat. 276 (26 U.S.C. 5173))

§ 252.61 [Amended]

Paragraph 13. Section 252.61 is amended to delete reference to a revoked paragraph of regulation by deleting "or (b)," where it appears immediately after "(a) (5),".

§ 252.62 [Amended]

Paragraph 14. Section 252.62 is amended (1) to delete reference to a revoked paragraph of regulation by deleting "or (b)," where is appears immediately after "(a) (5),", and (2) to delete paragraph (d), pertaining to on premises supervision.

Paragraph 15. The statutory authority for § 252.63 is corrected. As amended, § 252.63 reads as follows:

§ 252.63 Bond, Form 2736.

* * * * *

(Sec. 201, Pub. L. 85–859, 72 Stat. 1352, as amended, 1380, as amended (26 U.S.C. 5175, 5362))

Paragraph 16. Section 252.64 is amended (1) to clarify requirements for apportioning bonds and (2) to correct the statutory authority. As amended, paragraph (b) of § 252.64 reads as follows:

§ 252.64 Bond, Form 2737.

* * * * *

(b) *Apportioning bonds.* If the bond, Form 2737 is in less than the maximum penal sum, the principal shall apportion the bond, in accordance with the requirements on the bond form. The principal may reapportion the bond coverage, if changing conditions make this necessary, by filing a consent of surety, Form 1533, for approval by the regional regulatory administrator.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1352, as amended, 1380, as amended (26 U.S.C. 5175, 5362))

§ 252.65 [Amended]

Paragraph 17. Section 252.65 is amended to delete reference to an obsolete form by deleting "1629," from

the listing of form numbers used for filing export drawback claims.

§ 252.67 [Amended]

Paragraph 18. The statutory authority for § 252.67 is amended to delete reference to a repealed section of law by deleting "1393" from the Statutes at Large citation and by deleting "5522" from the United States Code citation.

§ 252.70 [Amended]

Paragraph 19. Section 252.70 is amended to replace "Form 206" with "ATF Form 5100.11". The statutory authority for § 252.70 is amended to delete reference to a repealed section of law by deleting "1393" from the Statutes at Large citation and by deleting "5522" from the United States Code citation.

Paragraph 20. Sections 252.71, 252.72 and 252.73 are amended to correct the statutory authorities. As amended, §§ 252.71, 252.72 and 252.73 read as follows:

§ 252.71 Termination of bonds, Forms 2735, 2737 and 2738.

* * * * *

(Sec. 201, Pub. L. 85–859, 72 Stat. 1336, as amended, 1352, as amended, 1353, as amended (26 U.S.C. 5062, 5175, 5176))

§ 252.72 Application of surety for relief from bond.

* * * * *

(68A Stat. 749, as amended (26 U.S.C. 6065); Sec. 201, Pub. L. 85–859, 72 Stat. 1336, as amended, 1352, as amended (26 U.S.C. 5062, 5175))

§ 252.73 Relief of surety from bond.

* * * * *

(Sec. 201, Pub. L. 85–859, 72 Stat. 1336, as amended, 1352, as amended, 1353, as amended (26 U.S.C. 5062, 5175, 5176))

§ 252.91 [Amended]

Paragraph 21. Section 252.91 is amended to delete reference to export storage facilities at a distilled spirits plant by revoking paragraph (b) and redesignating paragraph (c) as paragraph (b). The statutory authority for § 252.91 is amended to delete reference to a repealed section of law by deleting "1393" from the Statutes at Large citation and by deleting "5522" from the United States Code citation.

§ 252.91a [Revoked]

Paragraph 22. Section 252.91a, relating to export storage facilities at a distilled spirits plant, is revoked.

Paragraph 23. Section 252.92 is revised (1) to change an ATF form number, (2) to delete references to on premises supervision and (3) to correct the statutory authority. As revised, § 252.92 reads as follows:

§ 252.92 Application or notice, ATF Form 5100.11.

(a) *Export, use on vessels and aircraft, and transfer to a foreign-trade zone or a customs bonded warehouse.* Application for or notice of the withdrawal of distilled spirits without payment of tax for exportation from the United States, or for use on vessels and aircraft, or for transfer to a customs bonded warehouse or a foreign-trade zone, shall be made by the exporter on ATF Form 5100.11. If the shipment is for use on aircraft, an extra copy, marked "Consignee's Copy", shall be prepared. If the exporter is not the proprietor of the bonded premises of the distilled spirits plant from which the spirits are to be withdrawn, the exporter shall prepare ATF Form 5100.11 as an application, in accordance with the instructions on the form, and shall forward all copies of the form to the regional regulatory administrator of the region in which the distilled spirits plant is located. If the exporter is the proprietor of the bonded premises of the distilled spirits plant from which the spirits are withdrawn, the exporter shall prepare ATF Form 5100.11 as a notice in accordance with the instructions on the form.

(b) *Manufacturing bonded warehouse.* Application for the withdrawal of distilled spirits without payment of tax for transportation to and deposit in a manufacturing bonded warehouse shall be made by the proprietor of such warehouse on ATF Form 5100.11, in quadruplicate. The proprietor shall forward all copies of the application to the regional regulatory administrator of the region in which the distilled spirits plant is located.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1362, as amended (26 U.S.C. 5214); sec. 3, Pub. L. 91–659, 84 Stat. 1965, as amended (26 U.S.C. 5066))

§ 252.93 [Amended]

Paragraph 24. The statutory authority for § 252.93 is amended to delete reference to a repealed section of law by deleting "1393" from the Statutes at Large citation and by deleting "5522" from the U.S. Code citation.

Paragraph 25. Section 252.94 is amended (1) to change "Part 201" to "Part 19", (2) to provide for the use of alternative devices in lieu of strip stamps, and (3) to correct the statutory authority. As amended, § 252.94 reads as follows:

§ 252.94 Containers.

Distilled spirits authorized to be withdrawn without payment of tax from the bonded premises of a distilled spirits plant under the provisions of this subpart may be withdrawn from such establishment in such containers as may be authorized in Part 19 of this chapter. Except as otherwise provided in this part, the gauging, packing, bottling, casing, marking, stamping or affixing of alternative devices, and reporting of distilled spirits prior to withdrawal shall be in accordance with the provisions of Part 19 of this chapter.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended, 1360, as amended, 1374, as amended (26 U.S.C. 5205, 5206, 5301))

Paragraph 26. Section 252.95 is amended (1) to change "Part 201" to "Part 19", (2) to delete language relating to a repealed section of law, (3) to change an ATF form number, and (4) to correct the statutory authority. As amended, § 252.95 reads as follows:

§ 252.95 Change of packages for exportation.

Whenever the exporter desires to transfer distilled spirits from packages filled in internal revenue bond to such other suitable packages as may be desired for exportation, such change of packages shall be made under the procedures of Part 19 of this chapter, prior to the preparation of ATF Form 5100.11 covering the removal of the distilled spirits.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended, 1360, as amended, 1374, as amended (26 U.S.C. 5205, 5206, 5301))

Paragraph 27. Section 252.96 is revised to reflect elimination of on premises supervision. As revised, § 252.96 reads as follows:

§ 252.96 Approval of application.

If ATF Form 5100.11 has been properly executed, and the required bond has been filed in a sufficient amount, the regional regulatory administrator shall approve the application on all copies of the form and send them to the proprietor of the bonded premises from which the spirits will be withdrawn.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1362, as amended (26 U.S.C. 5214))

§ 252.97 [Revoked]

Paragraph 28. Section 252.97, relating to the repealed 20 year bonded storage limitation, is revoked.

Paragraph 29. Section 252.98 is amended (1) to change the numbers of ATF forms, (2) to change "Part 201" to "Part 19", (3) to delete reference to on premises supervision, and (4) to correct the statutory authority. As amended, § 252.98 reads as follows:

§ 252.98 Inspection and regauge.

The proprietor shall inspect all containers to be withdrawn pursuant to ATF Form 5100.11 and shall regauge all

packages. However, if distilled spirits are contained in bottles, or in tin, glass, or similar containers, or in sealed metal drums, or if they are to be withdrawn on the filling or original gauge (as authorized in Part 19 of this chapter), a regauge of such spirits need not be made. When a container bears evidence of tampering, or of unusual loss, the proprietor shall provide satisfactory explanation and file a report in accordance with the applicable provisions of Subpart P of Part 19 of this chapter. If the withdrawal is to be made subject to regauge, the proprietor shall make such regauge and shall make a report of regauge on ATF Form 5110.45, in quadruplicate. He shall attach a copy of ATF Form 5110.45 to each copy of ATF Form 5100.11 and shall enter his report of regauge on all copies of ATF Form 5100.11.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5204))

§ 252.99 [Amended]

Paragraph 30. Section 252.99 is amended to deleted reference to on premises supervision by deleting the last sentence from the section.

Paragraph 31. Section 252.100 is amended (1) to delete reference to on premises supervision, (2) to change the numbers of ATF forms, (3) to change "Part 201" to "Part 19", and (4) to correct the statutory authority. As amended, § 252.100 reads as follows:

§ 252.100 Gauge after reduction.

Where spirits in packages have been reduced in proof under the provisions of § 252.99, the proprietor shall again gauge the packages and report the details thereof on another set of ATF Form 5110.45, in quadruplicate. Any unusual loss ascertained after reduction shall be satisfactorily explained by the proprietor and reported in accordance with the applicable provisions of Part 19 of this chapter. Each such report of gauge shall have noted thereon the statement "Gauge After Reduction", and a copy thereof shall be attached to each copy of ATF Form 5100.11 in addition to the copy of the ATF Form 5110.45 covering the withdrawal gauge. After the spirits have been reduced and gauged, the proprietor shall also enter a report of such gauge on all copies of ATF Form 5100.11.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5204))

§ 252.101 [Amended]

Paragraph 32. Section 252.101 is amended by changing "Part 201" to "Part 19".

Paragraph 33. Section 252.102 is revised to add provisions relating to alternative devices and to delete reference to export strip stamps for spirits bottled in bond. As revised, § 252.102 reads as follows:

§ 252.102 Bottles to be stamped or have alternative devices affixed.

Every bottle containing distilled spirits to be withdrawn under the provisions of this subpart shall have a strip stamp or alternative device procured and affixed in accordance with the provisions of Part 19 of this chapter, and the strip stamp or alternative device shall be legibly and permanently overprinted or stamped with the word "EXPORT".

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5205))

§ 252.103 [Amended]

Paragraph 34. Section 252.103 is amended by changing "Part 201" to "Part 19". The statutory authority for § 252.103 is amended to delete reference to a repealed section of law by deleting "1393" from the Statutes at Large citation and by deleting "5522" from the U.S. Code citation.

§ 252.104 [Amended]

Paragraph 35. Section 252.104 is amended to delete reference to on premises supervision by replacing the words "ATF officers in charge of distilled spirits plants from which such spirits are withdrawn," with the words "the regional regulatory administrator".

§ 252.105 [Amended]

Paragraph 36. Section 252.105 is amended to change "Form 206" to "ATF Form 5100.11".

§ 252.107 [Amended]

Paragraph 37. Section 252.107 is amended to change "Form 206" to "ATF Form 5100.11" and to change "Form(s) 2630" to "ATF Form(s) 5110.45".

Paragraph 38. Sections 252.116, 252.117 and 252.118 are revised to substantially liberalize the requirements for returning spirits to a distilled spirits plant after withdrawal for exportation. As revised, the introductory paragraph and paragraph (e) of § 252.116 are revised, the last two sentences of § 252.116 are deleted and §§ 252.117 and 252.118 are revised to read as follows:

§ 252.116 Notice of return of spirits withdrawn without payment of tax.

If a proprietor of a distilled spirits plant desires to return spirits to his plant as provided in § 252.115, he shall file a notice with the regional regulatory administrator for the region in which the plant is located. A copy of the notice shall be prepared for submission to the customs official, as required by § 252.117. The notice shall be executed under the penalties of perjury and shall show:

* * * * *

(e) Serial number of the ATF Form 5100.11 and the date withdrawn.

* * * * *

(Sec. 201, Pub. L. 85–859, 72 Stat. 1362, as amended, 1365, as amended (26 U.S.C. 5214, 5223))

§ 252.117 Responsibility for return of spirits.

The principal on the bond under which the spirits were withdrawn without payment of tax shall be responsible for arranging the return of the spirits to the distilled spirits plant receiving them. The principal or his agent shall submit a copy of the notice required by § 252.116 to the appropriate customs official. If the spirits are returned before the ATF Form 5100.11 has been filed with the customs official, the principal shall submit the form with the notice. The customs officer shall, if the spirits are eligible for return under § 252.115, accept the notice as authority for the return of the spirits to the distilled spirits plant identified in the notice. The customs officer shall retain the notice and shall mark each copy of ATF Form 5100.11 "Canceled", note the date thereon, return both copies to the principal, and, if the spirits are in customs custody, release them for return. The principal shall retain one copy of the canceled ATF Form 5100.11 and file one copy with the regional regulatory administrator identified on the form.

(Sec. 201, Pub. L. 85–859, 72 Stat 1362, as amended, 1365, as amended (26 U.S.C. 5214, 5223))

§ 252.118 Receipt of spirits.

The receipt, gauge, and disposition of the distilled spirits at the distilled spirits plant shall be in accordance with the applicable provisions of Subpart U of Part 19 of this chapter.

(Sec. 201, Pub. L. 85–859, 72 Stat 1362, as amended, 1365, as amended (26 U.S.C. 5214, 5223))

§ 252.121 [Amended]

Paragraph 39. The statutory authority for § 252.121 is amended to delete reference to a repealed section of law by deleting "1393" from the Statutes at Large citation and by deleting "5522" from the U.S. Code citation.

§ 252.122 [Amended]

Paragraph 40. Section 252.122 is amended to change "Form 206" and "Forms 206,", wherever these phrases appear, to "ATF Form 5100.11" and to "ATF Forms 5100.11", respectively. The

statutory authority for § 252.122 is amended to delete reference to a repealed section of law by deleting "1393" from the Statutes at Large citation and by deleting "5522" from the U.S. Code citation.

§ 252.123 [Amended]

Paragraph 41. The statutory authority for § 252.123 is amended to delete reference to a repealed section of law by deleting "1393" from the Statutes at Large citation and by deleting "5522" from the U.S. Code citation.

§§ 252.125, 252.131, 252.132 and 252.133 [Amended]

Paragraph 42. Sections 252.125, 252.131, 252.132 and 252.133 are amended to change "Form 206" and "Forms 206", wherever these phrases appear, to "ATF Form 5100.11" and to "ATF Forms 5100.11", respectively.

Paragraph 43. Section 252.151 is amended to change a reference to an ATF form number. As amended, § 252.151 reads as follows:

§252.151 General.

* * * * *

(b) * * *

All such withdrawals shall be made under a consent of surety on the proprietor's operations or unit bond, as prescribed in § 252.58(c).

Paragraph 44. Section 252.152 is amended to change an ATF form number and to delete reference to on premises supervision. As amended, § 252.152 reads as follows:

§ 252.152 Notice, ATF Form 5100.11.

Notice of withdrawal of specially denatured spirits, as authorized in § 252.151 shall be made on ATF Form 5100.11, in quadruplicate, by the proprietor of the distilled spirits plant from which the denatured spirits are to be withdrawn. Upon removal from the bonded premises, a copy of the form shall be submitted to the regional regulatory administrator.

§ 252.154 [Amended]

Paragraph 45. Section 252.154 is amended by changing "Part 201", wherever it appears, to "Part 19".

§ 252.160 [Amended]

Paragraph 46. Section 252.160 is amended to replace the words, "bond, Form 2601," with the words, "operations or unit bond".

Paragraph 47. Sections 252.161, 252.162 and 252.163 are revised to substantially liberalize requirements for returning specially denatured spirits to a distilled spirits plant after withdrawal for exportation. As revised, the introductory paragraph and paragraphs (c) and (g) of § 252.161, and §§ 252.162 and 252.163 read as follows:

§ 252.161 Notice of return of specially denatured spirits.

If a proprietor of a distilled spirits plant desires to return specially denatured spirits to his plant as provided in § 252.160, he shall file a notice with the regional regulatory administrator for the region in which his plant is located. A copy of the notice shall be prepared for submission to the customs official, as required by § 252.162. The notice shall be executed under the penalties of perjury and shall show:

* * * * *

(c) Serial number of the ATF Form 5100.11 and the date withdrawn.

* * * * *

(g) Disposition to be made of specially denatured spirits, i.e. redistillation or return to processing on the bonded premises.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1362, as amended, 1365, as amended (26 U.S.C. 5214, 5223))

§ 252.162 Responsibility for return of specially denatured spirits.

The principal on the bond under which the specially denatured spirits were withdrawn free of tax shall be responsible for arranging the return of the spirits to the distilled spirits plant receiving them. The principal or his agent shall submit a copy of the notice required by § 252.161 to the appropriate customs official. If the specially denatured spirits are returned before the ATF Form 5100.11 has been filed with the customs official, the principal shall submit the form with the notice. The customs officer shall, if the specially denatured spirits are eligible for return under § 252.160, accept the notice as authority for the return of the specially denatured spirits to the distilled spirits plant identified in the notice. The customs officer shall retain the notice and shall mark each copy of ATF Form 5100.11 "Canceled", note the date thereon, return both copies to the principal, and, if the spirits are in customs custody, release them for return. The principal shall retain one copy of the canceled ATF Form 5100.11 and file one copy with the regional regulatory administrator identified on the form.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1362, as amended, 1365, as amended (26 U.S.C. 5214, 5223))

§ 252.163 Receipt of specially denatured spirits.

The receipt, gauge, and disposition of the specially denatured spirits at the distilled spirits plant shall be in accordance with the applicable provisions of Subpart U of Part 19 of this chapter.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1362, as amended, 1365, as amended (26 U.S.C. 5214, 5223))

Paragraph 48. Section 252.171 is amended to add provisions relating to alternative devices in lieu of strip stamps and to change "Part 201" to "Part 19". As amended the introductory clause of § 252.171 reads as follows:

§ 252.171 General.

Distilled spirits manufactured, produced, bottled in bottles, packed in containers, or packaged in casks or other bulk containers in the United States on which an internal revenue tax has been paid or determined, and which have been marked (if in packages) or stamped, restamped, or affixed with alternative devices, and marked (if in cases), under the provisions of Part 19 of this chapter and of this part, as applicable, especially for export with benefit of drawback may be:

* * * * *

§ 252.173 [Revoked]

Paragraph 49. Section 252.173 and the undesignated center head immediately preceding it, relating to standard export drawback rates, are revoked.

§ 252.190 [Amended]

Paragraph 50. Section 252.190 is amended to replace "Form 1582" with "ATF Form 5110.30".

Paragraph 51. Section 252.192 is amended to change the numbers of ATF forms and to eliminate on premises supervision. As amended, § 252.192 reads as follows:

§ 252.192 Packages of distilled spirits to be gauged.

Distilled spirits in packages or other bulk containers which are to be removed for export with benefit of drawback, shall be gauged by the distilled spirits plant proprietor prior to preparation of notice on ATF Form 5110.30. However, if an inspection discloses no evidence of loss and removal is made within 30 days from the time of packaging the distilled spirits, the filling gauge shall be considered the gauge at the time of removal. A report of gauge shall be made by the proprietor on ATF Form 5110.45, in quadruplicate (appropriately modified), and a copy of the report of gauge shall be attached to each copy of ATF Form 5110.30 and considered a part of the claim.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1336, as amended (26 U.S.C. 5062))

§ 252.193 [Amended]

Paragraph 52. Section 252.193 is amended to replace "Part 201", wherever it appears, with "Part 19".

§ 252.195 [Amended]

Paragraph 53. Section 252.195 is amended (1) to replace "Form 1582", wherever it appears, with "ATF Form 5110.30," and (2) to add a reference to a new section of regulations by adding "or § 252.195b" after "§ 252.195a".

Paragraph 54. Section 252.195a is completely revised to cover only claims on spirits tax determined before January 1, 1980. As revised, § 252.195a reads as follows:

§ 252.195a Claims on spirits tax determined before January 1, 1980.

The bottler or packager of the spirits shall compute the drawback rate, unless the regional regulatory administrator established a standard drawback rate before January 1, 1980. The bottler or packager shall complete Parts II and III on both copies of ATF Form 5110.30. If a standard drawback rate was established, the date of approval of the formula and the number shall be shown in any available space in Part II of ATF Form 5110.30. The bottler or packager shall file one copy as the claim for drawback of tax with the regional regulatory administrator of the region in which the claimant's premises are located, and retain one copy on file. Each claim on ATF Form 5110.30 shall be supported, as applicable, by a copy of each related dump and batch record, package gauge report and/or bottling report, covering the dumping and bottling or packaging of the spirits; and in the case of spirits bottled in bond on bonded premises, a copy of each Form 179 covering the taxpayment. Where distilled spirits stamped and marked, or restamped and marked (if in cases), or marked (if in packages), especially for export with benefit of drawback were manufactured (rectified) in the United States before January 1, 1980, with the use of imported spirits (other than such spirits withdrawn from internal revenue bond) or imported wines, the proprietor shall furnish evidence of tax payment for the distilled spirits or wines (such as Customs Forms 7505 or 7501 receipted to indicate payment of taxes) as may be requested by the regional regulatory administrator.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1336, as amended (26 U.S.C. 5062))

Paragraph 55. Immediately after § 252.195a, a new § 252.195b is added to cover claims on spirits tax determined on and after January 1, 1980. As added, § 252.195b reads as follows:

§ 252.195b Claims on spirits tax determined on and after January 1, 1980.

(a) *Preparation.* Claims for drawback of tax on spirits tax determined on and after January 1, 1980, and withdrawn for any purpose authorized by § 252.171, shall be prepared in duplicate by the bottler or packager on Parts II and III of ATF Form 5110.30.

(b) *Supporting documents.* Each claim shall be supported by an invoice, bill of lading or other document which identifies the date of tax determination, unless the bill of lading required by § 252.250 identifies this date. Additional supporting documents are required if the claim covers distilled spirits products on which the drawback rate exceeds $10.50 per proof gallon (e.g., a product containing alcoholic flavoring materials on which drawback s claimed under 26 U.S.C. 5131–5134). For each such product, the additional supporting documents shall consist of a copy of each related dump and batch record, package gauge report (ATF Form 5110.45), and/or bottling record. The regional regulatory administrator may also require these or other supporting documents for any distilled spirits product.

(c) *Filing.* One copy of the claim, with supporting documents, if required, shall be filed with the regional regulatory administrator. The bottler or packager shall retain the other copy on file.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1336, as amended (26 U.S.C. 5062))

Subpart J [Revoked]

§§ 252.201, 252.202, 252.203 and 252.204 [Revoked]

Paragraph 56. Subpart J, and §§ 252.201, 252.202, 252.203 and 252.204, relating to export drawback under a repealed section of law, are revoked.

§ 252.216 [Amended]

Paragraph 57. Since wine may no longer be bottled at a distilled spirits plant, reference to distilled spirits plant regulations is deleted from § 252.216 by deleting "201", where it appears after the word "Parts".

§ 252.244 [Amended]

Paragraph 58. The statutory authority for § 252.244 is amended to delete reference to a repealed section of law by deleting "1393" from the Statutes at Large citation and by deleting "5522" from the United States Code citation.

§§ 252.250 and 252.261 [Amended]

Paragraph 59. Sections 252.250 and 252.261 are amended to change "Form 206, 1582," to "ATF Form 5100.11, 5110.30,".

§ 252.263 [Amended]

Paragraph 60. Section 252.263 is amended to delete reference to a repealed section of law by deleting ", 1393, as amended" from the Statutes at Large citation and by deleting ", 5522" from the United States Code citation.

§ 252.264 [Amended]

Paragraph 61. Section 252.264 is amended to change "Form 206, 1582,", wherever these phrases appear, to "ATF Form 5100.11, 5110.30", and to change "Form 696" to "ATF Form 5180.1".

§ 252.265 [Amended]

Paragraph 62. Section 252.265 is amended to change "Form 206" to "ATF Form 5100.11" and to change "Form 206, 1582," to "ATF Form 5100.11, 5110.30,". The statutory authority for § 252.265 is amended to delete reference to a repealed section of law by deleting "1393" from the Statutes at Large citation and by deleting "5522" from the United States Code citation.

Paragraph 63. Section 252.267 is amended to eliminate performance of customs officer duties by ATF officers assigned to distilled spirits plants and to change ATF form numbers. As amended, § 252.267 reads as follows:

§ 252.267 Exportation from interior port.

Where a shipment made under this part is to be exported to a contiguous foreign country through a frontier port, and it is desired to avoid the delay of customs inspection at such port, the shipment may be entered for exportation at an interior customs port. The inspection and supervision of lading, and the affixing of customs seals, shall be done by a customs officer in accordance with the provisions of U.S. Customs regulations (19 CFR Ch. I). However, where, under the provisions of § 252.263 an ATF officer has been authorized to perform such duties, the ATF officer may perform the duties of the customs officer. On completion of the lading, the seals shall be affixed and the designated officer shall execute the certificate of lading on both copies of the application, notice, or claim, ATF Form 5100.11, 5110.30, 1582–A, 1582–B or 1689, as the case may be, and forward them, with attachments (if any), to the district director of customs at the interior port of entry. The collector shall forward both copies of the form, with attachments (if any), to the customs officer at the frontier port. When the customs officer at the frontier port is satisfied that the shipment as described on the appropriate form has been exported, he shall execute his certificate on both copies of the form and return them with attachments (if any), to the

district director of customs at the interior port of entry.

§§ 252.269, 252.275 and 252.281 [Amended]

Paragraph 64. Sections 252.269, 252.275 and 252.281 are amended to change "Form 206, 1582,", wherever these words appear, to "ATF Form 5100.11, 5110.30,".

Paragraph 65. Section 252.285 is revised to change ATF form numbers and to correct the statutory authority. As revised, § 252.285 reads as follows:

§ 252.285 Receipt in manufacturing bonded warehouse.

On receipt of the distilled spirits or wines and the related ATF Form 5100.11 (and ATF Form 5110.45, if any), the customs officer in charge of the manufacturing bonded warehouse shall make such inspection as is necessary to establish that the shipment corresponds with its description on ATF Form 5100.11 (and ATF Form 5110.45, if any) and shall make a report of gauge on ATF Form 5180.1, in duplicate. However, where, under the provisions of § 252.263, an ATF officer has been authorized to perform the duties of the customs officer, the ATF officer may perform such duties. If the inspection and gauge disclose any discrepancy, the designated officer shall make note of such discrepancy on each copy of ATF Form 5100.11. Where the officer is satisfied that the shipment corresponds with the description on ATF Form 5100.11 (and ATF Form 5110.45, if any), he shall execute the certificate of deposit on both copies of ATF Form 5100.11 and forward the original of ATF Forms 5100.11 and 5180.1, and a copy of ATF Form 5110.45 (if any), to the regional regulatory administrator. The remaining copies shall be kept on file.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1362, as amended, 1380, as amended (26 U.S.C. 5214, 5362))

§ 252.286 [Amended]

Paragraph 66. Section 252.286 is amended to change "Form 206 or 1582" to "ATF Form 5100.11 or 5110.30".

§ 252.290 [Amended]

Paragraph 67. Section 252.290 is amended (1) to change to "Form 206, 1582" to "ATF Form 5100.11, 5110.30", (2) to change both instances to "Form 696" to "ATF Form 5180.1", and (3) to change "Form 2630" to "ATF Form 5110.45".

§§ 252.302 and 252.316 [Amended]

Paragraph 68. Sections 252.302 and 252.316 are amended to change "Form 206" to "ATF Form 5100.11".

§ 252.333 [Amended]

Paragraph 69. Section 252.333 is amended to change "Form 1582, Form 1582–A or Form 1629" to "ATF Form 5110.30 or 1582–A". The statutory authority for § 252.333 is amended to delete reference to a repealed section of law by deleting "1327" from the Statutes at Large citation and by deleting "5009" from the United States Code citation.

§ 252.334 [Amended]

Paragraph 70. Section 252.334 is amended to change "Form 2639" to "ATF Form 5620.2" and to change "Part 201" to "Part 19". The statutory authority for § 252.334 is amended to delete reference to a repealed section of law by deleting "1327" from the Statutes at Large citation and by deleting "5009" from the United States Code citation.

§ 252.335 [Amended]

Paragraph 71. The statutory authority for § 252.335 is amended to delete reference to a repealed section of law by deleting "1327" from the Statutes at Large citation and by deleting "5009" from the United States Code citation.

Signed: November 14, 1979.

G. R. Dickerson,

Director.

Approved: November 30, 1979.

Richard J. Davis,

Assistant Secretary (Enforcement and Operations).

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Part III

Department of Health, Education, and Welfare

Food and Drug Administration

Quality Assurance Programs for Diagnostic Radiology Facilities; Final Recommendation

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Part 1000

[Docket No. 76N-0145]

Quality Assurance Programs for Diagnostic Radiology Facilities

AGENCY: Food and Drug Administration.

ACTION: Final recommendation.

SUMMARY: The agency is issuing a recommendation that encourages voluntary establishment of quality assurance programs by all diagnostic radiology facilities. The recommendation suggests some aspects of the programs, but recognizes that the programs will vary with each facility's size, type, and needs. The agency wants to minimize unnecessary public exposure to electronic product radiation.

EFFECTIVE DATE: December 11, 1979.

FOR FURTHER INFORMATION CONTACT: Charles P. Froom, Bureau of Radiological Health (HFX-460), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3426.

SUPPLEMENTARY INFORMATION: In the Federal Register of April 28, 1978 (43 FR 18207), the Food and Drug Administration (FDA) proposed to add new § 1000.55 (21 CFR 1000.55) to Subpart C—Radiation Protection Recommendations, Part 1000 of Chapter I of Title 21 of the Code of Federal Regulations. New § 1000.55 would recommend that health practitioners and others responsible for operating diagnostic radiology facilities establish quality assurance programs. Seven professional organizations, 14 representatives of government agencies (from 9 agencies), 1 processing chemicals manufacturer, 3 medical facilities, and 33 individual dentists, engineers, physicists, radiologists, technologists, and state employees submitted substantive comments. These comments and the agency's response to them follow:

Comments on the Approach Taken

1. Seven comments endorsed the voluntary approach for encouraging the implementation of quality assurance programs; three said the recommendation would eventually have to be made a regulation to be effective. One of these three suggested that, as an intermediate step, the recommendation be tested in Federal hospitals. Several other comments interpreted the publication as a proposed regulation instead of a proposed recommendation (an error that two other comments predicted would occur more generally). These comments indicated that the recommendation would require that all facilities monitor all of the parameters listed, establish all of the levels of responsibility mentioned, keep extensive records to satisfy some agency outside the facility, include in their manual all items suggested, and comply with other requirements. Some apparently also interpreted the recommendation as saying that facilities already consistently producing good quality images with minimum patient exposure would have to add the recommended actions to their existing program. They feared this would add costs to the facility without giving added benefits.

FDA emphasizes that establishing quality assurance programs in accordance with the recommendation is indeed voluntary. In § 1000.55(a) and in the definition of "diagnostic radiology facility" in § 1000.55(b), the agency attempted to make clear its belief that quality assurance programs would be beneficial in all types of diagnostic radiology facilities. In § 1000.55(c), the recommendation suggests 10 elements for this program. Proposed § 1000.55(a) stated, however, that the extent to which each element of a quality assurance program is implemented in a particular facility would be determined by that facility after its analysis of its objectives and resources. Especially for some small facilities, the cost of implementing every suggestion might exceed the need and benefit. However, the agency believes that the savings resulting from implementing an appropriate program would, in most cases, offset the cost of the actions. Each facility is, therefore, encouraged to implement only those recommendations it believes would lead to benefits in improved image quality, reduced radiation exposure, and/or reduced costs sufficient to compensate for the costs of the action.

To highlight the flexibility enjoyed by the facility with this voluntary approach, the following changes were made in the introductory section: (1) The second sentence of § 1000.55(a) was made the second sentence of § 1000.55(c). (2) A third sentence was added to § 1000.55(c) to emphasize further the flexibility given to each facility. Some additional changes were made in the wording of the specific elements of § 1000.55(c) to emphasize that the program is voluntary. These changes are discussed in response to the comments on the specific paragraphs of the recommendations.

Comments on the Data

Several comments addressed the studies cited to support the need for and value of quality assurance programs.

2. One comment supplied information on the changes made in the pneumoconiosis compensation program since it was studied for the Department of Health, Education, and Welfare's National Institute of Occupational Safety and Health (NIOSH) by the late Dr. Dale Trout. Before participating in the current pneumoconiosis program, facilities must submit to NIOSH sample chest radiographs and a radiograph of a test object developed by Trout. These radiographs must be considered of acceptable quality for the proper classification of pneumoconiosis before NIOSH approves a facility for participation. The reader system has also been changed. C readers are no longer used, and the B readers have been expanded from members of the three major medical centers mentioned in the proposed recommendation to all physicians who have passed an examination administered by NIOSH.

As noted in the proposed recommendation, Trout found in his study that 44 percent of the certified facilities examined had 10 percent or more of their radiographs rejected by the B or the C readers, which were then being used. The total rejection rate for all facilities was 3 percent. As a result of NIOSH's efforts, in the second round of examinations only approximately 9 percent of the facilities had a rejection rate of over 10 percent. During the January 1 to September 30, 1976 period, the average rejection rate was only 0.6 percent. For the third round of examinations, NIOSH has stated that all X-ray facilities that have a rejection rate of 5 percent or more will have to be reapproved.

Because the improvement is attributed by NIOSH to their "* * * quality control requirements for equipment and expert reading for radiographic quality by B readers," comparison of the new data with the Trout results gives a "before" and "after" picture for judging the impact of quality assurance. FDA commends NIOSH and the participating facilities for their outstanding efforts in reducing unnecessary patient exposure.

3. Another comment questioned the cost savings that several studies attributed to quality assurance programs, on the ground that facilities that already had successful programs would not be able to achieve additional savings of the magnitude seen in these

studies. Referring to facilities with successful quality assurance programs, this comment argues further that "additional regulations, imposed on an effective quality assurance program would in fact raise cost."

The savings found in all the various studies were determined by comparing conditions before implementation of a quality assurance program with conditions thereafter. The FDA estimate of the cost and exposure reduction impact of nationwide quality assurance programs was likewise based on before and after conditions. Quality assurance actions implemented by facilities, with or without effective quality assurance programs already in place, will indeed involve some cost. The crucial question the facility must ask itself is, whether these actions provide sufficient benefits in terms of money savings, reduced radiation exposure, or improved image quality to compensate for the costs. If the benefits outweigh the costs, then FDA encourages the facility to undertake the quality assurance actions. The facilities involved in the studies referred to by the comment found that the money savings alone more than paid for the costs of the quality assurance program. Thus, the benefits exceeded the costs even without taking into account any benefits from reduced exposure to radiation and from improved image qualtiy.

Facilities that now have little or no quality assurance activity are likely to obtain the largest savings from establishing a quality assurance program. Facilities that have established quality assurance programs are probably doing many of the things suggested by the recommendation. The latter may achieve some additional benefits by incorporating the remaining suggestions into their program, but if additional benefits do not seem likely, then there would be no reason to increase their quality assurance efforts in the ways suggested. At any rate, the agency reemphasizes that implementation of the program is voluntary. Contrary to the comment's suggestion, no rules are being "imposed" and no "regulations" are involved.

4. Another comment criticized the use of the Nationwide Evaluation of X-Ray Trends (NEXT) data. The preamble to the proposed recommendation noted that the results of the NEXT study indicate that a "standard patient" would have received widely different exposures for the same examination in different facilities or even with different machines within the same facility. This range of exposures is as much as a factor of 100 with some of the 12 examinations considered by NEXT and at least a factor of 10 for any of the examinations. FDA suggested in the preamble to the proposal that unnecessary radiation exposure may be caused by exposure variation that could be eliminated by quality assurance. The comment argued, however, that the differences among facilities are "chiefly due to the wide variety of image receptor sensitivities and peak kilovoltages employed."

The original analysis of the NEXT data did not divide the measured exposure data into groups based on the values of the various technical factors. However, the values of certain technique factors, among them peak kilovoltage (kVp), were collected. An analysis of the effect of different techniques has been done (Bunge, et al., 1976, Midyear Symposium of the Health Physics Society), and it has been found that, even with kVp and half-value layer (HVL) limited to a narrow range, there was still a large variation in the output of the machines. For example, with a kVp range of 78 to 82 and HVL range of 2.3 to 2.7 mm of Al, the output in milliroentgens per milliampere-seconds (mR/mAs) at 12 inches varied from less than 5 to 100. Choice of kVp by the practitioner thus does not explain the wide variation in exposures from facility to facility.

FDA has concluded that machine malfunction leading to the actual kVp and mAs values deviating from the machine settings is a major contributor to the large variation in the output values. (In the NEXT system, the kVp and mAs values are recorded from the machine settings, in contrast to the exposure values, which are measured, and the HVL values, which are calculated from exposure measurements.) For example, if a practitioner chooses to set a machine at 80 kVp, this does not mean that this is the kVp actually produced. Machine malfunction would be a problem that could be minimized by an effective quality assurance program.

The other factor mentioned by the comment, "the wide variety of image receptor sensitivities," has been studied in the last 2 years with the use of an image receptor module add-on to the main NEXT system. When a sufficient number of surveys was completed, multiple regression analysis of the P/A chest projection data was carried out using the factors of kVp, HVL, relative speed of the image receptor, grid, type of processing, and mAs. It was found that these factors could account for only 50 percent of the exposure variation (Showalter, et al., *Proceedings of the Society of Photo-Optical Instrumentation Engineers*, 127:136–139). Thus, the exposure variation cannot be explained solely on the basis of the practitioner's choice of technique factor, image receptor, etc. This analysis will be continued with more examinations as sufficient data become available. At present, it supports the conclusion drawn in the preamble of the proposed recommendation, that part of the exposure variation seen by NEXT represents unnecessary patient exposure due to equipment malfunction that might be reduced or eliminated by quality assurance programs.

5. The comment referred to in paragraph 4 argued further that the mR/mAs variation was due to the method used in calculating the HVL from the NEXT measurements, not machine malfunction. The comment said the method resulted in erroneous HVL values, which accounted for the wide variation in mR/mAs found with machines with similar HVL's.

The NEXT method, which is designed to allow a rapid survey to minimize disruption of facility routine, calculates HVL using a linear least-squares fit to three exposure measurements. FDA has evaluated the potential error in HVL's however, and found that for the kVp and HVL range reported, the maximum value would not exceed 12 percent. FDA does not believe that the small potential errors in the NEXT HVL measurements can account for the wide range in output found in machines with similar kVp and HVL values. Thus, the agency still concludes that a significant part of the mR/mAs variation is due to deviation of the actual kVp and mAs values from the machine settings. Again, this is a problem that can be minimized with a quality assurance program. The agency concludes that the comment does not invalidate the use of the NEXT data for this recommendation.

6. The comment discussed in paragraphs 4 and 5 also argued that the practitioner should be free to choose whatever techniques lead to radiographs that meet the practitioner's requirements.

This comment indicates a philosophical difference with FDA. FDA agrees that the practitioner must have the latitude to select equipment and techniques that meet the practitioner's special imaging requirements. There is, however, generally a range of exposures that will produce radiographs with roughly the same quality. FDA believes that practitioners should be encouraged to choose those techniques that give the least radiation exposure. Secondly, even when a set of technique factors is shown to be appropriate for a specific imaging

task, quality assurance programs can ensure that the practitioner's equipment is actually delivering the technique values the practitioner has selected. This helps avoid the possibility that the practitioner or the practitioner's operator may repeatedly have to change the technique factors (usually toward higher exposures) due to the decreasing ability to get a satisfactory image with the old values.

7. Another comment criticized the NIOSH and Pennsylvania Blue Shield studies because, in its view, the "vast majority" of problems revealed by these studies "were due to human error" and, therefore, would be unaffected by an equipment quality assurance program.

In the NIOSH study, Trout simply listed the problems he found, without indicating their relative magnitudes. Some were probably due to human error and some to equipment malfunction, but there was no basis for concluding that either category was responsible for a "vast majority" of the problems. However, the later data from this study indicate that, regardless of the source of the problems, the quality assurance program was effective in solving many of the problems identified.

The Blue Shield study did provide a breakdown of the reasons for judging the submitted radiographs to be unsatisfactory. A little over 30 percent of the submitted radiographs were rejected for reasons that were probably due to human error. However, another approximately 20 percent of the submitted radiographs were rejected for reasons that were probably due to equipment malfunction. Once again, equipment malfunction was proven not to be an insignificant problem.

FDA agrees that "people errors" lead to unsatisfactory radiographs and unnecessary patient exposure. But this does not mean that the equipment problems can be ignored. FDA has launched or is developing several programs in the "people" areas, but the agency is also supporting quality assurance programs to deal with equipment problems. Quality assurance actions may also help solve some of the "people" problems. For example, evaluation measures such as retake analysis can help identify operator performance problems. Identification is, of course, the first step in solving the problem.

8. The comment referred to in paragraph 7 also criticized the NIOSH and Blue Shield studies as not reflecting the general practice of radiology because they are limited only to pneumoconiosis and dental examinations.

FDA did not present the studies as representative of the total field, but only as an indication of problems in certain specialties. A study by a major film company of more than 150 general radiographic facilities was presented as evidence that the problems found with pneumoconiosis and dental examinations might be present in all types of facilities (Reference 3 in the April 28, 1978 proposal). This study found an average retake rate of 9 percent and an average rejection rate of 13 percent in facilities without quality assurance programs. (The difference between the 9 and 13 percent is partly due to blank films and is also probably partly due to radiographs that were not repeated because other views gave adequate information.) When the facilities established quality assurance programs, they were able to reduce their average rejection rate to 7 percent.

9. The same comment criticized the use of the film company study by noting that the retake rate of 9 percent of the radiographs due to unsatisfactory quality was close to twice that found in previous studies. The comment suggested that the lower retake rate was more representative of national experience than the 9 percent rate.

This assertion is not well founded. Comprehensive studies have not been done. However, the film company study, which examined more than 150 facilities, shows that many hospitals have higher rates. In contrast, the studies relied on in the comment in most cases included only 1 or 2 facilities, a slim basis on which to estimate representative conditions for the nation. In addition, the authors of at least two of the studies cited by the comment indicated their retake rates were probably underestimated (perhaps by as much as 100 percent in one case) due to various factors including lack of technologist cooperation.

10. The same comment also criticized the agency's estimate in its environmental impact analysis report (Ref. 11 in the proposal) of the dose savings impact of quality assurance programs in terms of a total national figure (209,000 to 333,000 rems of active bone marrow dose or 195,000 to 330,000 rems of whole body dose). The comment suggested instead that it would be more accurate simply to state it in terms of the percentage of per capita dose saved.

FDA believes this is simply a difference in philosophy. Physicians, such as the one who commented, treat individual patients, and the agency recognizes that per capita dose might have more meaning to them. As an agency with public health responsibilities, however, FDA must look at the impact on the genetic pool and cost of medical care for the entire population. Thus, the total nationwide savings has more meaning to the agency. It should also be noted that other groups concerned with population exposure, such as the Advisory Committee on the Biological Effects of Ionizing Radiations of the National Academy of Sciences and the United Nations Scientific Committee on the Effects of Atomic Radiation also report dose figures in terms of population dose rather than individual dose. Further, although the savings can be calculated on a per capita basis, the actual dose savings to an individual who did not have to undergo a repeated examination is far greater than the per capita savings, which is only an average figure. Thus, in this particular case the use of per capita dose savings is somewhat misleading even if the concern is with the individual rather than the entire population.

11. In another criticism of the supporting references, the same comment questioned the figure, $37,000 per 300,000 radiographs, for the cost savings due to quality assurance at the University of Alabama at Birmingham (Reference 12 in the proposal). The comment noted that the savings reported were $27,000 per 300,000 radiographs.

The $27,000 figure represented the savings using the discount prices for supplies purchased by the University of Alabama. The $37,000 figure was obtained by using the retail prices. Because discounts vary from facility to facility, the agency believes that retail prices should be used for a fair comparison. Using retail prices, the University of Alabama staff reported an average annual savings in supply costs of $67,566 after quality assurance was initiated. From this the FDA staff substracted the reported annual quality assurance labor costs of $27,625, the estimated $1,500 a year for supplies for the quality assurance program, and $1,500 for the prorated cost of the quality assurance equipment to obtain an annual savings of approximately $37,000. Because the annual workload at the University of Alabama is approximately 300,000 radiographs, the savings were expressed as $37,000 per 300,000 radiographs.

12. The comment further criticized the agency's use of the Alabama data because, according to the comment, the authors of the study stated that had their department been better organized at the outset, such large savings as they report would not have been possible.

The comment's concern is apparently based on a narrower definition of

quality assurance than that used by FDA. FDA believes that quality assurance is not limited to taking physical measurements or repairing equipment but is fundamentally a matter of good departmental management. This is one reason why the recommendation is primarily concerned with administration. If implementation of a quality assurance program stimulates or permits an improvement in the general organization of the department (as apparently occurred at the University of Alabama), then the savings from that improvement in organization should be credited to the quality assurance program. This belief is supported by the Alabama authors in their statement that: "The abrupt difference between the 1971–2 and 1972–3 fiscal years is attributed to the implementation of the main aspects of the quality assurance program."

Comments on the Paragraphs of the Recommendation

Many comments focused on one or more of the paragraphs of the proposed recommendation. For each of these paragraphs, the comments are presented, and FDA's reply to them is given.

Applicability

13. The comments addressing § 1000.55(a) chiefly concerned the application of the recommendation to small facilities. Two comments stressed that small facilities should be included. In contrast, one comment said that the major emphasis should be put on the large facilities because their example would stimulate small facilities to join the quality assurance effort. Six comments said that assistance would be needed by small facilities in implementing these programs. Their suggestions as to the nature of the assistance needed ranged from a request to prescribe a program specifically for small facilities to the establishment of regional quality assurance consulting centers. Finally, three comments said it would be impossible for small facilities to implement a quality assurance program as described in the recommendation. This belief seemed to stem in part at least from interpreting the recommendation as having to be implemented verbatim.

FDA recognizes that quality assurance programs for small facilities would be quite different from those for large facilities. For example, a committee such as that described in § 1000.55(c)(9), would obviously be valuable only for larger facilities. All facilities, small or large, are also encouraged to modify FDA's other general suggestions to meet their specific needs where necessary, although the agency believes that the vast majority of its recommendations are applicable to all facilities.

FDA also recognizes that most of the guidance now available on the details of quality control monitoring and maintenance is designed for large facilities. There is a need for guidance directed specifically to small facilities, especially because they do not have their own physicists and quality assurance technologists who could adapt large facility procedures to fit their needs. FDA has begun to collect information on quality assurance programs already available to small facilities. After this information is collected, additional techniques will be developed as needed, and information on both existing and new techniques will be distributed to the facilities. The comments that made suggestions as to appropriate programs for small facilities will be considered in the projects to provide aid to these facilities. FDA believes that these methods of providing assistance to small facilities should be tried before the concept of regional quality assurance consulting centers is considered further because of the expected costs of such centers.

To emphasize that FDA does not expect small facilities to duplicate the programs of large facilities, a sentence has been added at the end of § 1000.55(b)(3), the definition of a quality assurance program, specifically recognizing that any program will vary with the size and type of facility as well as other criteria.

Responsibility

14. A number of comments addressed § 1000.55(c)(1) on the assignment of responsibility for the quality assurance program and of the duties within that program.

Most of the comments addressed the suggested roles for the various segments of the staff, especially the relative roles of the practitioner in charge and of the technologists. Two comments supported the statement that the primary responsibility for the quality assurance program belonged to the medical practitioner in charge of the facility. A third comment implicitly agreed when it criticized the recommendation as not recognizing the importance of the trained radiologist in achieving the goal of reducing unnecessary radiation exposure. In contrast, three other comments argued that the recommendation should give more emphasis to the importance of the staff members involved either with production of images or with maintenance of the equipment. One of these comments specifically criticized § 1000.55(c)(1)(iii) for emphasizing physicists, engineers, and radiologists to the exclusion of staff technologists. A third position was taken by a comment that opposed the entire recommendation because too much emphasis was put on monitoring by technologists rather than on preventive and corrective maintenance by trained personnel. Another comment suggested that the role of the consultants to the facility should be spelled out in more detail. In the proposed § 1000.55(c)(1)(v), it was merely suggested that in some cases it would be of value to assign certain responsibilities to consultants.

In contrast to those comments that argued for increased responsibility for one or another segment of the staff, a response from a professional organization representing a nonradiologist specialty area that makes extensive use of x-ray systems indicated that the practitioners in that area were ready to yield primary if not total responsibility for the quality assurance program to "professionals trained in radiation safety and diagnostic radiology."

Finally, two comments said § 1000.55(c)(1) should be rewritten, though only one included specific suggestions. The latter comment suggested that the responsibilities should be described to fit a program for small facilities, with the roles for specialized personnel as alternatives available to large facilities. This comment voiced concern that small facilities, on viewing the suggestion that responsibilities be assigned to personnel they could not afford, would assume that they could not conduct a quality assurance program.

FDA emphasizes its belief that there are two fundamental areas of quality assurance responsibility in facilities of all sizes, from the individual practitioner's office to the largest medical facility. First, FDA firmly believes that the owner of the equipment, or the practitioner in charge, if different from the owner, must have primary responsibility for the quality assurance program even as that individual has primary responsibility for all other aspects of the facility's activities. This is true whether the owner or practitioner in charge is a radiologist, dentist, cardiologist, or any other specialist. The owner or practitioner in charge may, especially in large facilities, delegate part or all of his or her responsibility to other staff members, but this does not relieve that individual of final responsibility. Furthermore, free and open

communication between the practitioner and his or her staff is essential to the quality assurance program. The owner or practitioner in charge cannot simply set up the program and then forget it if the program is to achieve maximum success.

Second, FDA recognizes that the staff technologists will play a major role in the execution of the program. In a small facility, staff technologists may often be responsible for all the monitoring and maintenance performed by the facility and may also be responsible for recommending when outside help should be called in for more complex monitoring and maintenance. In a larger facility, staff physicists, quality assurance technologists, service engineers, or supervisory technologists may assume much of the quality assurance monitoring and maintenance responsibility, but the staff technologists will always have the important role of bringing possible problems to the attention of the specialized personnel. This alerting of the specialized personnel makes possible the prompt corrective action that is essential to the quality assurance program.

FDA agrees with the comments that noted that § 1000.55(c)(1)(iii) as proposed did not properly recognize the importance of the staff technologists and maintenance personnel. Therefore, this section has been revised to remedy this deficiency. Section § 1000.55(c)(1)(iv) has also been revised to answer the concern of the comment that stated that small facilities would be discouraged by the listing of personnel they could not afford.

Although the suggestions of the comment concerning consultant duties were valuable, FDA has decided not to incorporate them into the recommendation. If more details on consultant duties were included, the duties of other quality assurance personnel should be described in more detail also. In view of the wide variety of diagnostic radiology facilities throughout the country, FDA does not believe that such a detailed description would be appropriate for the recommendation. However, the possibility of providing more detailed suggestions in future technical publications is being considered.

Purchase Specifications

15. One comment noted that one of the greatest problems of a quality assurance program is that manufacturers may simply state that their equipment will not perform within a hospital's specifications.

Section 1000.55(c)(2) recognizes that, in developing purchase specifications, the state-of-the-art should be considered and the need for a specification balanced against the cost of meeting it. If a reasonable set of purchase specifications is developed, then the problem described by the comment should disappear. The facility would deal only with vendors who are willing to meet the specifications and agree to acceptance testing to show that they are meeting the specifications.

16. Another comment on proposed § 1000.55(c)(2) warned that the radiology staff often is not consulted on the purchase of new equipment, or their recommendations are overruled for reasons of finance or convenience.

FDA hopes that the quality assurance program will create channels of communication, such as the suggested quality assurance committee, that will allow the medical and administrative staffs to reach satisfactory compromises on purchase specifications for new equipment.

17. A third comment commended the mention of the alternative of stating the specifications in terms of functional requirements. It also suggested that the availability of experienced service personnel be taken into account in writing purchase specifications.

FDA agrees with this suggestion and has inserted a sentence in § 1000.55(c)(2) to emphasize this point.

18. The same comment also expressed concern about the suggestion that acceptance of the equipment be withheld until the necessary corrections have been made by the vendor. The comment feared that a "self-appointed expert" could break the vendor by being too unreasonable.

The vendor, of course, is entitled to assure himself or herself that the specifications and channels of acceptance are not ambiguous or dependent upon the whim of members of the facility staff. Conversely, if the vendor agrees to meet certain specifications, it is reasonable to require the vendor to meet them. Withholding payment until corrections are made is obviously a powerful weapon, and FDA believes this suggestion should remain in the recommendation. It is, of course, the facility's decision whether to accept this suggestion.

19. Two comments indicated some confusion about the relationship of the purchase specifications and acceptance testing suggested for the quality assurance programs and the requirements of FDA's diagnostic X-ray equipment performance standard (21 CFR 1020.30 through 1020.32). Both comments focused on the report in the preamble to the proposed recommendation from one of the persons commenting on the May 7, 1976 notice of intent to propose the recommendations (41 FR 18863). This individual had tested 50 new rooms of equipment after the vendor had completed installation and adjustment. Not one of the rooms met the purchase specifications. One of the comments on the April 28, 1978 proposal suggested that the vendor be reported for failure to comply with FDA's diagnostic X-ray equipment performance standard, while the other suggested that this was evidence that the performance standard had failed in its mission to remedy problems of improperly performing X-ray equipment.

FDA advises that the purchase specifications suggested as part of a facility's quality assurance program are not synonymous with the requirements of the diagnostic X-ray equipment performance standard. The purchase specifications would be developed by the facility itself based upon its needs. They would most likely address parameters in addition to those minimum requirements covered by the performance standard, which is concerned with radiation safety. Even when the purchase specifications refer to parameters discussed by the performance standard, the facility might decide to put more stringent requirements on the vendor than do the regulations. Thus, the failure of a vendor to meet purchase specifications, as in the case referred to, may have little or no bearing on the question of the value of the performance standard. The incident does underline, however, the importance of not only establishing purchase specifications but of carrying out acceptance testing to see whether they are met.

Monitoring

20. One comment on proposed § 1000.55(c)(3) differed with FDA's approach by arguing that monitoring had been overemphasized greatly. It argued that it is futile to monitor the system if quality radiographs are being produced and that it is also futile to monitor if the system is failing because the failure will be obvious.

FDA disagrees that it is futile to monitor the X-ray system under either of these conditions. If the system is producing satisfactory radiographs, monitoring may still allow detection of problems that exist but have not yet grown to the point where they seriously affect image quality. Thus, if the monitoring is followed by corrective maintenance, problems can be eliminated before they adversely affect patient care. FDA does agree that, if monitoring of a particular parameter

does not reveal any change over a period of time, then it would be appropriate to reevaluate the monitoring program for that parameter.

Similarly, FDA believes that monitoring of parameters after quality control problems appear in the radiograph is of value. The comment suggested that examination of the radiograph in such cases will reveal that a problem exists without the need for monitoring. This is true, but such examination often cannot tell the source of the problem. Monitoring of the parameters and comparing the results with the values from before the problems occurred can be valuable in pinpointing the source of difficulty.

Interestingly, despite its apparent opposition to monitoring tests, the comment stated, "The quality control test can only give information which verifies that a problem does exist or which helps to pinpoint the source of the problem." This statement indicates that the comment recognized these benefits. The comment also correctly noted that testing after a service call can reveal that problems were not resolved because a "manufacturer's service personnel do not always install and maintain X-ray equipment within acceptable standards."

FDA thus has concluded that the importance of monitoring in the quality assurance program should not be deemphasized.

21. The same comment further stated that "testing can only identify a possible problem but will not provide the solution." It also asked, "what good is any test which pinpoints a problem, if there is no one available who is capable of correcting the deficiency?", a question echoed by another comment. The comment also suggested that a major cause of "technologist's apathy" noted in some quality assurance programs was the feeling that quality assurance testing was a waste of time because no one ever did anything when problems were found.

Although FDA does not agree that monitoring should be deemphasized, the agency does agree that maintenance, both preventive and corrective, is important. Preventive maintenance has been shown effective in existing programs (Nelson, et al., *Radiologic Technology*, 49:129–134), and the essential nature of corrective maintenance both to improve equipment performance and to overcome "technologists's apathy" is obvious. Although corrective maintenance has been mentioned in the Evaluation, Records, Manual, and Review elements (§ 1000.55(c) (5), (6), (7), and (10)), further emphasis should be given. Thus, § 1000.55(c)(3) has been retitled "Monitoring and Maintenance", the introduction to this element has been rewritten; and a new subdivision (iv) has been added to provide further comments on maintenance and on the need for trained service personnel.

22. Four comments on the list of possible parameters to be monitored noted that the long list might be discouraging to facilities. The comments suggested various systems for reorganizing the list, such as pointing out the general areas of importance or listing the parameters in their order of importance. Two comments made opposing suggestions: One suggested shortening the list to only key tests; the other suggested general descriptions of the specific quality assurance procedures that should be included.

The agency is concerned that two general problems hamper the reorganization or shortening of the list of parameters. The first is that the field of quality assurance is still rapidly developing, and a consensus on the relative importance of a number of the parameters does not yet exist. In addition, the wide variety of types and sizes of diagnostic radiology facilities and their equipment will probably make it impossible ever to develop a single list of parameters that apply generally to all facilities. Thus, FDA has preferred to develop as comprehensive a list as possible and to encourage the facilities to select the ones to monitor based on what is important to them. FDA has accepted the suggestion of one comment that general areas that probably should be monitored in all programs be listed. This is done in a new § 1000.55(c)(3)(ii). The old § 1000.5(c)(3)(ii) is now § 1000.55(c)(3)(iii). The introduction to § 1000.55(c)(3)(iii) has been rewritten, and the parameter list rearranged to correspond to the areas of new § 1000.55(c)(3)(ii).

23. Two comments referred to the list of parameters to be monitored as reasonable and very important, but other comments made a number of suggestions on adding or deleting parameters.

FDA has added four parameters to the list in response to these suggestions. These are "view box surface conditions", added to § 1000.55(c)(3)(iii)(*d*), "continuity of exposure" and "flatness of cassette" added to § 1000.55(c)(3)(iii)(*f*), and "representative entrance skin exposures" added to § 1000.55(c)(3)(iii) (*b*) and (*f*). In addition, suggestions that mechanical and electrical components undergo visual inspection have been added to new § 1000.55(c)(3)(iv) on maintenance. FDA did not accept suggestions that nominal voltage and latent images in intensifying screens be monitored. The comment did not provide documentation to support the belief that variations in these parameters cause problems, and FDA is unaware of any evidence that they do.

As suggested, FDA has dropped the parameter, "solution compositions" from § 1000.55(c)(3)(iii). It is now generally accepted that pH measurements of the solutions are of little value in quality assurance monitoring and that specific gravity measurements are of value only in determining whether a fresh batch of solution has been correctly mixed (and then only if the proper value is known for comparison). FDA also agrees that other methods of monitoring solution composition require a strong knowledge of chemistry and more effort than is warranted by the results.

The suggestion that focal spot measurement should be dropped until there is a consensus standard for such measurements was not accepted. FDA believes that any of the existing methods are accurate enough for quality assurance purposes as long as the same method is used consistently. FDA also did not agree that "linearity of mA stations" should be dropped. Although this measurement is perhaps covered by the monitoring of the parameters of automatic exposure control devices, it would not be covered with machines lacking these devices.

A suggestion that it was too early to establish quality assurance protocols for computed tomography (CT) systems was not accepted. It is not too early to develop an awareness that quality assurance monitoring is necessary for these devices even though the methods might require more effort. (Most CT manufacturers even provide a test device that can be used to monitor some parameters).

One comment also suggested dropping daily measurement of fixer temperature, while another suggested that with tomographic units, "thickness of cut plane," "flatness of field," and "exposure angle" could be dropped because these parameters would not change very rapidly. It appears that the disagreement is not so much with these parameters as with the frequency of monitoring. It should be noted that the frequency of monitoring of the parameters has been left to the facility to decide. Thus if the tomographic parameters do not change rapidly, semi-annual or annual monitoring of these might be sufficient, while other parameters, such as some of those involved in film processing, might have to be done daily. Similarly, the frequency of fixer temperature

monitoring could be chosen to correspond to facility needs. Facilities are encouraged to consider revision of the monitoring schedules for the different parameters as part of the evaluation and review elements.

24. Comments also suggested that the parameters "response capability" in proposed § 1000.55(c)(3)(ii)(*e*) and "accuracy of SID indictors" in proposed § 1000.55(c)(3)(ii)(*d*) are not clear.

FDA agrees and, in an effort to solve this problem, has changed these parameter names to "minimum response time" and "accuracy of SFD indicators," respectively. (With the reorganization of the parameter list mentioned above, these parameters are now under § 1000.55(c)(3)(iii)(*b*)).

25. With respect to monitoring parameters, several comments pointed out that work remains to be done on the procedures for monitoring many of them.

Fortunately, efforts are under way in both the private and public sectors to fill these gaps, and FDA will continue to encourage progress in these areas.

Standards for Image Quality

26. Three comments addressed § 1000.55(c)(4) on setting standards for image quality. Two comments remarked about the difficulty of setting standards for quality in view of the many different opinions of what constitutes adequate quality and whether that quality should be measured or be determined by "the eye of the beholder." One comment urged that, because of this, the paragraph should either be rewritten or deleted. In contrast, a third comment urged that FDA go further by helping the facilities set standards of quality and by conducting frequent inspections to ensure that the standards are met.

FDA believes that some definition of acceptable standards of image quality is essential if quality control monitoring and maintenance is to be effective. The purpose of the monitoring is to detect parameter variations that may cause or are causing image quality problems. Appropriate standards of image quality would serve as a guide to indicate when these variations have become serious enough to require corrective action.

Ideally, if the values of these parameters are kept within certain defined limits, the image quality will be acceptable. If such limits can be agreed upon, they can serve as the standards for image quality. Such objective standards may be emerging with respect to processor performance. FDA realizes, however, that, for most parameters of the x-ray system, the standards of image quality will remain subjective for some time. This is largely because of a lack of consensus among medical practitioners as to what is "good" quality, and in some cases means for measuring the relationship between parameter variation and quality may be lacking.

FDA believes that it is not now possible or desirable to develop uniform nationwide standards. Instead, the practitioners in each facility are encouraged to determine their own standards of image quality based on their training and experience and to relate these standards to system parameter values. FDA has suggested and will suggest in other publications objective standards of image quality as they become known from research and the experience of medical facilities. In the future these objective standards (or those from other sources) may become the national norm. However, even if this should occur, the implementation of these standards would still be on a voluntary basis.

In conclusion, FDA does not agree that changes in § 1000.55(c)(4) are warranted at present.

Evaluation

27. Three comments on § 1000.55(c)(5) said that the importance of reject analysis in evaluating both the total program and the individual technologist's performance should be further emphasized.

Reject analysis is referred to in § 1000.55(c)(5)(ii) as "ongoing studies of the retake rate and the causes of the repeated radiographs." FDA agrees with the comment that the emphasis should be increased to reflect the fact that reject analysis is probably the most useful evaluation method now available. Several sentences have been added to § 1000.55(c)(5)(ii) to emphasize the value of studies of the reject rate and to suggest study characteristics and frequencies.

Records

28. Many comments were received on the recordkeeping recommendations in proposed § 1000.55(c)(6). Several comments urged that FDA emphasize the importance of maintaining records by conducting inspections of them. Others interpreted the recordkeeping suggestions as regulatory requirements and opposed them as being an added burden. One comment took an intermediate position. It recognized that the proposals on recordkeeping were recommendations, but feared that states might adopt them as regulations. This might make the recordkeeping an end in itself rather than a tool for achieving improved performance.

The importance of recordkeeping cannot be overemphasized. FDA is convinced that accurate and complete records are essential for guaranteeing that necessary monitoring and maintenance have been performed, for making effective use of the equipment warranty provisions and the services of manufacturers' representatives, for aiding in future equipment selection, for planning the replacement schedule for x-ray equipment, and for evaluating the quality assurance program so that it can be modified for maximum effectiveness.

The agency recognizes, however, that the extent of the recordkeeping, just as all other aspects of the quality assurance program, should be determined by the facility itself on the basis of what is necessary for support of its program. Because recordkeeping recommendations, like all others, are voluntary, FDA inspections to enforce them would be unauthorized by law and inappropriate.

FDA shares the concern of the comment that suggested recordkeeping might become an end in itself. Obviously the purpose of keeping quality assurance records is not just to record numbers, but to collect data that can be used. These data should be used in the evaluation (§ 1000.55(c)(5)) and review (§ 1000.55(c)(10)) elements to determine whether either the equipment or the quality assurance program itself requires adjustment to ensure effective performance. Furthermore, some problems occur periodically. Therefore, records of successful past corrective actions will help to solve the problems quickly when they recur. Clear records may also be quite useful to the facility in demonstrating the need to change vendors or improve purchase specifications.

In a further response to the comments on recordkeeping, and to clarify FDA's views, § 1000.55(c)(7) has been rewritten. In response to a question raised by one comment, § 1000.55(c)(7)(vii) has also been changed to make it clear that the facility decides how long records are to be kept.

Manual

29. The several comments on § 1000.55(c)(7) generally agreed upon the importance of a manual. One comment, however, said that for its purposes a series of manuals already in use in its agency would be preferable to that suggested in the recommendation. Two other comments made opposing suggestions. One urged that some details, specifically the suggestion for a loose-leaf format, should be deleted, while the other suggested that more details, even a complete sample manual, should be provided, though not necessarily as part of the recommendation.

Facilities are encouraged to modify the recommendations to meet their own needs. Any facility or agency may use materials of a different type or content to meet the goal of keeping all concerned personnel informed about the quality assurance program and their own quality assurance responsibilities. The introduction to § 1000.55(c)(7) has been rewritten to make this clearer. The "loose-leaf" format suggestion has also been dropped. In response to the request for more detail, other FDA publications, available or planned, will provide details on some of the items suggested for the manual. A sample manual for individual practitioners may result from a project to provide guidance to small facilities, which has recently been initiated by the FDA.

Training

30. Several comments urged that the agency expand proposed § 1000.55(c)(8) both to emphasize the importance of training and to specify further its nature.

FDA does not believe that this recommendation is the place to give detailed descriptions of training requirements because these requirements are likely to change with time. However, the training element has been expanded somewhat to emphasize the need for both initial and continuing education and the value of supervised instruction.

31. Several other comments suggested training programs that FDA might initiate or support.

The agency advises that it will continue its efforts, through the production of training materials and through cooperation with professional organizations and industry, to increase the quality assurance training available.

32. Two comments in reference to § 1000.55(c)(1), asked what is meant by the term "qualified" when referring to personnel who might be assigned quality assurance duties.

Again, FDA does not believe that these recommendations provide the proper forum for a detailed list of qualifications because these might well change with time. However, § 1000.55(c)(1) has been modified by addition of the words "by training or experience" following the word "qualified" wherever it appears.

33. Another comment related to training said the recommendation did not recognize the training in radiation protection received by radiologists.

Section 1000.55(c)(1)(ii) states that the practitioner in charge of the facility has primary responsibility for the quality assurance program. If a radiologist is a staff member at the diagnostic radiology facility, that specialist will almost certainly be in charge of the facility. Thus, the recommendation does give recognition to the training received in that specialty. However, FDA does not believe that it can single out any medical specialty as being especially qualified by its general training for quality assurance duties. Although some radiologists have been very active in the quality assurance area and have pioneered in the development of quality assurance programs, FDA's information on the training of these specialists indicates that quality assurance techniques and procedures are not routinely made a part of their education or certification examinations.

Committee

34. The comments on the suggestion that a quality assurance committee (§ 1000.55(c)(9)) be established at large facilities were mixed. Some comments endorsed the idea and suggested that the membership and duties of the committee be expanded. Other comments, however, expressed fears that such a group might "throttle" or "frustrate" the program.

The recommendation to establish a committee resulted from a comment on the May 7, 1976 notice that described the success of a quality assurance committee in a facility as well as from the agency's knowledge of the value of committees in other areas. FDA still believes that a quality assurance committee can be useful in facilitating open and frequent communication among the various groups in a facility and that such communication is essential for the quality assurance program. FDA does recognize, however, that, depending upon the attitude of its membership, a committee might act to frustrate the quality assurance program. To help forestall this possibility, changes have been made in § 1000.55(c)(9) to clarify the agency's belief that any quality assurance committee should serve communications and policy-making roles rather than an operational role. The proposed recommendation recognized that small facilities would not find a committee useful. Large facilities also do not need to organize such a committee if it is believed to be unneeded or counterproductive. Also, § 1000.55(c)(9) has been reworded slightly to indicate that the facility may not wish to assign all the suggested responsibilities to the committee. Other wording changes are intended to make clear that representatives of all departments with x-ray equipment should be included, if possible, to ensure maximum communication. Also, changes have been made to indicate that the duties of the committee could be given to an already existing committee, as one comment suggested, rather than a newly established committee. All the groups involved with diagnostic radiology should be represented on that committee.

Comments Suggesting Additional Actions

35. One comment urged that an eleventh quality assurance element—on "patient exposure"—be added to the recommendation. The comment suggested that, just as § 1000.55(c)(4) suggests establishing acceptability limits for variations of image quality parameter values, a patient exposure element could contain acceptability criteria for variation in exposure for different examinations.

FDA's quality assurance activities, including the proposed recommendation, are directed at achieving optimal diagnostic x-ray equipment performance. The agency believes that such performance will lead to reduced patient exposure as well as high image quality and reduced medical costs. A separate patient exposure recommendation would significantly expand the proposed recommendations beyond their intended scope, which is limited to equipment performance. Injection of this new consideration would involve the practitioner's choice of technique factors and raise the complex question of striking the proper balance between patient exposure and image quality. For these reasons, FDA believes that the establishment of standards for patient exposure is too important and too complex to be dealt with merely as one of eleven elements in a quality assurance recommendation directed at equipment performance. Instead, FDA published in the **Federal Register** of August 17, 1979 (44 FR 48354) a notice of intent requesting information on a number of aspects of the patient exposure problem. This is a preliminary action to possible future recommendations dealing specifically with patient exposure.

Although FDA is not now prepared to recommend standards for patient exposure, the agency does recognize that exposure measurements may be useful in evaluating equipment performance. Thus, as noted above, the "representative entrance skin exposures" has been added to the list of parameters to be considered for monitoring in § 1000.55(c)(3)(iii).

36. Several comments suggested that FDA publish recommendations or regulations in areas other than quality assurance to reduce radiation exposure. These suggestions included limitations

on the types of equipment that could be used, film-screen standards, new designs of equipment to provide for easy quality assurance testing, specification of techniques to be used, and certification programs to ensure that the owners and operators of x-ray equipment are adequately trained.

FDA appreciates these expressions of concern and will consider them in planning future programs. The agency advises that activities in cooperation with professional groups or other agencies are already being planned or are under way in some of these areas, e.g., film-screen standards and certification programs. However, inclusion of recommendations in these added areas as part of the basic quality assurance recommendation would significantly expand this recommendation beyond its intended scope. The agency believes that it is more appropriate to proceed independently in these other areas.

37. One comment suggested that patient exposure reductions could be achieved if the States were encouraged to make more frequent inspections of radiology facilities.

FDA believes that this suggestion is worthy of consideration, but it falls outside the area of a quality assurance recommendation. FDA notes, however, that the Bureau of Radiological Health has undertaken some activities designed to help solve the problem of limited resources for State inspections. The Bureau's efforts have been designed to enable the States to locate facilities with problems so that their resources may be concentrated on them. Two such efforts, the Dental Exposure Normalization Technique (DENT) and the Breast Exposure Nationwide Trends (BENT) programs, have been under way for some time. Both programs use thermoluminescent dosimeter (TLD) mailers to locate facilities with problems. These facilities are then visited by State personnel, who work with them on a voluntary, nonregulatory basis to help solve the problems. Average exposure reductions of 40 percent in dental facilities and 20 percent in mammography facilities have been achieved. Development of similar programs for other types of examinations as well as a program that could be used with facilities doing a number of types of examinations is currently under way.

38. Two comments suggested that the government establish some means of providing quality assurance services, especially for private offices.

The agency's BENT and DENT programs do provide some such services and, as discussed in paragraph 37, this concept is being expanded to other examinations. The time intervals between the BENT and DENT type of contacts, however, are too long for routine quality assurance actions. The option of setting up regional quality assurance centers, equivalent to the Regional Radiological Physics Centers, or programs through professional organizations or private facilities will be kept open. However, owing to the expense of such centers or programs, action will not be taken until the need is more clearly demonstrated.

39. Some comments suggested that FDA enlist the aid of the Joint Commission on Accreditation of Hospitals (JCAH) to encourage the adoption of quality assurance programs. Others asserted that the FDA efforts were not needed because the JCAH already "mandated" quality assurance programs.

FDA received a comment from the JCAH, which made clear its interest in quality assurance and radiation protection, and which in general endorsed the FDA approach. It does not appear that FDA suggestions for quality asssurance programs for diagnostic radiology facilities either conflict with or duplicate the JCAH efforts to encourage quality assurance in all hospital departments. FDA will continue to coordinate its efforts with those of the JCAH.

40. Three comments mentioned the problem of motivating personnel to initiate and maintain a quality control program.

FDA recognizes that this is perhaps the central problem that must be solved if the quality assurance program is to be successful. The agency believes that the first step in solving this problem is to win the support of the person in charge. Thus, through pilot tests of quality assurance techniques and through its publication program, FDA is attempting to collect and disseminate information on the benefits of quality assurance. FDA believes that this information is essential to convince the practitioner in charge, the facility administrator, and the administrative technologist initially to establish a quality assurance program. FDA is also working to disseminate information (by this recommendation, manuals, etc.) to help the program succeed in the facility once it has been implemented, for such success is the best method of motivation.

41. A conference conducted by the American College of Radiology with FDA support is planned for the fall of 1979. One comment suggested that this conference might be used to write a recommendation to replace the one proposed. The comment suggested further that this could serve as a motivating influence.

In view of the general support for the proposed recommendation, FDA has decided to proceed with publication of this final recommendation. The conference can then be devoted to its original purpose of discussing means to motivate facilities to use the recommendation and other guidance to establish quality assurance programs.

42. One comment suggested that the availability of "sources of information, consultants, and other resources" should be included for the benefit of facilities developing quality assurance programs.

FDA notes that, because such resources would be constantly changing, it would be impractical to include a list in the recommendation. FDA recognizes, however, that it may be difficult for a facility to locate the information, equipment, training, and other items needed for a quality assurance program. To assist in solving this problem, FDA published a Diagnostic Radiology Quality Assurance Catalog in the summer of 1977. The catalog contains information on available quality assurance equipment, services, training materials, and publications. A supplement to the catalog (covering the same types of items) was published in the fall of 1978. More than 12,000 copies of each of these volumes have been distributed, and FDA's Bureau of Radiological Health will continue to provide individual copies free of charge for as long as supplies last.

43. One comment suggested that "any quality control programs should stress conservation of silver and other resources vital to radiology."

FDA notes that quality assurance programs can indirectly conserve resources by reducing retakes and thus by reducing film usage, which in turn would conserve resources such as silver. FDA believes, however, that including direct conservation suggestions would be beyond the scope of this recommendation, which concerns equipment performance. This should not be interpreted as downgrading the value of the important conservation effort.

44. The agency advises that the new references cited in this final recommendation have been added to the administrative record for this matter. These references as well as those cited in the April 28, 1978 proposal are on file in the office of the FDA Hearing Clerk under Docket No. 76N-0145, and are available for public review in Rm. 4-65, 5600 Fishers Lane, Rockville, MD, between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Therefore, under the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 356, 82 Stat. 1174–1175 (42 U.S.C. 263d)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), 21 CFR Part 1000 is amended in Subpart C by adding new § 1000.55, to read as follows:

§ 1000.55 Recommendation for quality assurance programs in diagnostic radiology facilities.

(a) *Applicability.* Quality assurance programs as described in paragraph (c) of this section are recommended for all diagnostic radiology facilities.

(b) *Definitions.* As used in this section, the following definitions apply:

(1) "Diagnostic radiology facility" means any facility in which an x-ray system(s) is used in any procedure that involves irradiation of any part of the human body for the purpose of diagnosis or visualization. Offices of individual physicians, dentists, podiatrists, and chiropractors, as well as mobile laboratories, clinics, and hospitals are all examples of diagnostic radiology facilities.

(2) "Quality assurance" means the planned and systematic actions that provide adequate confidence that a diagnostic x-ray facility will produce consistently high quality images with minimum exposure of the patients and healing arts personnel. The determination of what constitutes high quality will be made by the facility producing the images. Quality assurance actions include both "quality control" techniques and "quality administration" procedures.

(3) "Quality assurance program" means an organized entity designed to provide "quality assurance" for a diagnostic radiology facility. The nature and extent of this program will vary with the size and type of the facility, the type of examinations conducted, and other factors.

(4) "Quality control techniques" are those techniques used in the monitoring (or testing) and maintenance of the components of an x-ray system. The quality control techniques thus are concerned directly with the equipment.

(5) "Quality administration procedures" are those management actions intended to guarantee that monitoring techniques are properly performed and evaluated and that necessary corrective measures are taken in response to monitoring results. These procedures provide the organizational framework for the quality assurance program.

(6) "X-ray system" means an assemblage of components for the controlled production of diagnostic images with x-rays. It includes minimally an x-ray high voltage generator, an x-ray control, a tube-housing assembly, a beam-limiting device, and the necessary supporting structures. Other components that function with the system, such as image receptors, image processors, view boxes, and darkrooms, are also parts of the system.

(c) *Elements.* A quality assurance program should contain the elements listed in subparagraphs (1) through (10) of this paragraph. The extent to which each element of the quality assurance program is implemented should be determined by an analysis of the facility's objectives and resources conducted by its qualified staff or by qualified outside consultants. The extent of implementation should be determined on the basis of whether the expected benefits in radiation exposure reduction, improved image quality, and/or financial savings will compensate for the resources required for the program.

(1) *Responsibility.* (i) Responsibility and authority for the overall quality assurance program as well as for monitoring, evaluation, and corrective measures should be specified and recorded in a quality assurance manual.

(ii) The owner or practitioner in charge of the facility has primary responsibility for implementing and maintaining the quality assurance program.

(iii) Staff technologists will generally be delegated a basic quality assurance role by the practitioner in charge. Responsibility for specific quality control monitoring and maintenance techniques or quality administration procedures may be assigned, provided that the staff technologists are qualified by training or experience for these duties. The staff technologists should also be responsible for identifying problems or potential problems requiring actions beyond the level of their training. They should bring these problems to the attention of the practitioner in charge, or his or her representative, so that assistance in solving the problems may be obtained from inside or outside the facility.

(iv) In facilities where they are available, physicists, supervisory technologists, or quality control technologists should have a major role in the quality assurance program. Such specialized personnel may be assigned responsibility for day-to-day administration of the program, may carry out monitoring duties beyond the level of training of the staff technologist or, if desired by the facility, may relieve the staff technologists of some or all of their basic monitoring duties. Staff service engineers may also be assigned responsibility for certain preventive or corrective maintenance actions.

(v) Responsibility for certain quality control techniques and corrective measures may be assigned to personnel qualified by training or experience, such as consultants or industrial representatives, from outside of the facility, provided there is a written agreement clearly specifying these services.

(vi) In large facilities, responsibility for long-range planning of quality assurance goals and activities should be assigned to a quality assurance committee as described in paragraph (c)(9) of this section.

(2) *Purchase specifications.* Before purchasing new equipment, the staff of the diagnostic radiology facility should determine the desired performance specifications for the equipment. Initially, these specifications may be stated in terms of the desired performance of the equipment, or prospective vendors may be informed solely of the functions the equipment should be able to perform and asked to provide the performance specifications of items from their equipment line that can perform these functions. In either case, the responses of the prospective vendors should serve as the basis for negotiations to establish the final purchase specifications, taking into account the state of the art and balancing the need for the specified performance levels with the cost of the equipment to meet them. The final purchase specifications should be in writing and should include performance specifications. The availability of experienced service personnel should also be taken into consideration in making the final purchase decisions. Any understandings with respect to service personnel should be incorporated into the purchase specifications. After the equipment is installed, the facility should conduct a testing program, as defined in its purchase specifications, to ensure that the equipment meets the agreed upon specifications, including applicable Federal and State regulatory requirements. The equipment should not be formally accepted until any necessary corrections have been made by the vendor. The purchase specifications and the records of the acceptance testing should be retained through out the life of the equipment for comparison with monitoring results in order to assess continued acceptability of performance.

(3) *Monitoring and maintenance.* A routine quality control monitoring and

maintenance system incorporating state-of-the-art procedures should be established and conducted on a regular schedule. The purpose of monitoring is to permit evaluation of the performance of the facility's x-ray system(s) in terms of the standards for image quality established by the facility (as described in paragraph (c)(4) of the section) and compliance with applicable Federal and State regulatory requirements. The maintenance program should include corrective maintenance to eliminate problems revealed by monitoring or other means before they have a serious deleterious impact on patient care. To the extent permitted by the training of the facility staff, the maintenance program should also include preventive maintenance, which could prevent unexpected breakdowns of equipment and disruption of departmental routine.

(i) The parameters to be monitored in a facility should be determined by that facility on the basis of an analysis of expected benefits and cost. Such factors as the size and resources of the facility, the type of examinations conducted, and the quality assurance problems that have accurred in that or similar facilities should be taken into account in establishing the monitoring system. The monitoring frequency should also be based upon need and can be different for different parameters.

(ii) Although the parameters to be monitored will vary somewhat from facility to facility, every diagnostic radiology facility should consider monitoring the following five key components of the x-ray system:

(*a*) Film processing.

(*b*) Basic performance characteristics of the x-ray unit.

(*c*) Cassettes and grids.

(*d*) View boxes.

(*e*) Darkroom.

(iii) Examples of parameters of the above-named components and of more specialized equipment that may be monitored are as follows:

(*a*) For film processing:

An index of speed.
An index of contrast.
Base plus fog.
Solution temperatures.
Film artifact identification.

(*b*) For basic performance characteristics of the x-ray unit:

(*1*) For fluoroscopic x-ray units:

Table-top exposure rates.
Centering alignment.
Collimation.
kVp accuracy and reproducibility.
mA accuracy and reproducibility.
Exposure time accuracy and reproducibility.
Reproducibility of x-ray output.
Focal spot size consistency.
Half-value layer.
Representative entrance skin exposures.

(*2*) For image-intensified systems:

Resolution.
Focusing.
Distortion.
Glare.
Low contrast performance.
Physical alignment of camera and collimating lens.

(*3*) For radiographic x-ray units:

Reproducibility of x-ray output.
Linearity and reproducibility of mA stations.
Reproducibility and accuracy of timer stations.
Reproducibility and accuracy of kVp stations.
Accuracy of source-to-film distance indicators.
Light/x-ray field congruence.
Half-value layer.
Focal spot size consistency.
Representative entrance skin exposures.

(*4*) For automatic exposure control devices:

Reproducibility.
kVp compensation.
Field sensitivity matching.
Minimum response time.
Backup timer verification.

(*c*) For cassettes and grids:

(*1*) For cassettes:

Film/screen contact.
Screen condition.
Light leaks.
Artifact identification.

(*2*) For grids:

Alignment and focal distance.
Artifact identification.

(*d*) For view boxes:

Consistency of light output with time.
Consistency of light output from one box to another.
View box surface conditions.

(*e*) For darkrooms:

Darkroom integrity.
Safe light conditions.

(*f*) For specialized equipment:

(*1*) For tomographic systems:

Accuracy of depth and cut indicator.
Thickness of cut plane.
Exposure angle.
Completeness of tomographic motion.
Flatness of tomographic field.
Resolution.
Continuity of exposure.
Flatness of cassette.
Representative entrance skin exposures.

(*2*) For computerized tomography:

Precision (noise).
Contrast scale.
High and low contrast resolution.
Alignment.
Representative entrance skin exposures.

(iv) The maintenance program should include both preventive and corrective aspects.

(a) Preventive maintenance. Preventive maintenance should be performed on a regularly scheduled basis with the goal of preventing breakdowns due to equipment failing without warning signs detectable by monitoring. Such actions have been found cost effective if responsibility is assigned to facility staff members. Possible preventive maintenance procedures are visual inspection of the mechanical and electrical characteristics of the x-ray system (covering such things as checking conditions of cables, watching the tomographic unit for smoothness of motion, assuring cleanliness with respect to spilling of contaminants in the examination room or the darkroom, and listening for unusual noises in the moving parts of the system), following the manufacturer's recommended procedures for cleaning and maintenance of the equipment, and regular inspection and replacement of switches and parts that routinely wear out or fail. The procedures included would depend upon the background of the staff members available. Obviously, a large facility with its own service engineers can do more than an individual practitioner's office.

(b) Corrective maintenance. For maximum effectiveness, the quality assurance program should make provision, as described in paragraph (c)(5) of this section, for ascertaining whether potential problems are developing. If potential or actual problems are detected, corrective maintenance should be carried out to eliminate them before they cause a major impact on patient care.

(4) *Standards for image quality.* Standards of acceptable image quality should be established. Ideally, these should be objective, e.g., acceptability limits for the variations of parameter values, but they may be subjective, e.g., the opinions of professional personnel, in cases where adequate objective standards cannot be defined. These standards should be routinely reviewed and redefined as needed, as described in paragraph (c)(10) of this section.

(5) *Evaluation.* The facility's quality assurance program should include means for two levels of evaluation.

(i) On the first level, the results of the monitoring procedures should be used to evaluate the performance of the x-ray system(s) to determine whether corrective actions are needed to adjust the equipment so that the image quality consistently meets the standards for image quality. This evaluation should

include analysis of trends in the monitoring data as well as the use of the data to determine the need for corrective actions on a day-by-day basis. Comparison of monitoring data with the purchase specifications and acceptance testing results for the equipment in question is also useful.

(ii) On the second level, the facility quality assurance program should also include means for evaluating the effectiveness of the program itself. Possible means include ongoing studies of the retake rate and the causes of the repeated radiographs, examination of equipment repair and replacement costs, subjective evaluation of the radiographs being produced, occurence and reasons for complaints by radiologists, and analysis of trends in the results of monitoring procedures such as sensitometric studies. Of these, ongoing studies of the retake rate (reject rate) and its causes are often the most useful and may also provide information of value in the first level of evaluation. Such studies can be used to evaluate potential for improvement, to make corrections, and to determine whether the corrective actions were effective. The number of rejects should be recorded daily or weekly, depending on the facility's analysis of its needs. Ideally, the reasons for the rejection should also be determined and recorded. Should determining these reasons be impossible on a regular basis with the available staff, the analysis should be done for a 2-week period after major changes have occurred in diagnostic procedures or the x-ray system and at least semi-annually.

(6) *Records.* The program should include provisions for the keeping of records on the results of the monitoring techniques, any difficulties detected, the corrective measures applied to these difficulties, and the effectiveness of these measures. The extent and form of these records should be determined by the facility on the basis of its needs. The facility should view these records as a tool for maintaining an effective quality assurance program and not view the data in them as an end in itself but rather as a beginning. For example, the records should be made available to vendors to help them provide better service. More importantly, the data should be the basis for the evaluation and the reviews suggested in paragraph (c)(5) and (10) of this section.

(7) *Manual.* A quality assurance manual should be written in a format permitting convenient revision as needed and should be made readily available to all personnel. The content of the manual should be determined by the facility staff, but the following items are suggested as providing essential information:

(i) A list of the individuals responsible for monitoring and maintenance techniques.

(ii) A list of the parameters to be monitored and the frequency of monitoring.

(iii) A description of the standards, criteria of quality, or limits of acceptability that have been established for each of the parameters monitored.

(iv) A brief description of the procedures to be used for monitoring each parameter.

(v) A description of procedures to be followed when difficulties are detected to call these difficulties to the attention of those responsible for correcting them.

(vi) A list of the publications in which detailed instructions for monitoring and maintenance procedures can be found. Copies of these publications should also be readily available to the entire staff, but they should be separate from the manual. (Publications providing these instructions can usually be obtained from FDA or private sources, although the facility may wish to make some modifications to meet its needs more effectively.)

(vii) A list of the records, with sample forms, that the facility staff has decided should be kept. The facility staff should also determine and note in the manual the length of time each type of record should be kept before discarding.

(viii) A copy of each set of purchase specifications developed for new equipment and the results of the acceptance testing for that equipment.

(8) *Training.* The program should include provisions for appropriate training for all personnel with quality assurance responsibilities. This should include both training provided before the quality assurance responsibilities are assumed and continuing education to keep the personnel up-to-date. Practical experience with the techniques conducted under the supervision of experienced instructors, either in the facility or in a special program, is the most desirable type of training. The use of self-teaching materials can be an adequate substitute for supervised instruction, especially in continuing education programs, if supervised instruction is not available.

(9) *Committee.* A facility whose size would make it impractical for all staff members to meet for planning purposes should consider the establishment of a quality assurance committee whose primary function would be to maintain lines of communication among all groups with quality assurance and/or image production or interpretation responsibilities. For maximum communication, all departments of the facility with x-ray equipment should be represented. The committee may also be assigned policy-making duties such as some or all of the following: Assign quality assurance responsibilities; maintain acceptable standards of quality; periodically review program effectiveness, etc. Alternatively, the duties of this committee could be assigned to an already-existing committee such as the Radiation Safety Committee. In smaller facilities, all staff members should participate in the committee's tasks. The Quality Assurance Committee should report directly to the head of the radiology department, or, in facilities where more than one department operates x-ray equipment, to the chief medical officer of the facility. The committee should meet on a regular basis.

(10) *Review.* The facility's quality assurance program should be reviewed by the Quality Assurance Committee and/or the practitioner in charge to determine whether its effectiveness could be improved. Items suggested for inclusion in the review include:

(i) The reports of the monitoring and maintenance techniques to ensure that they are being performed on schedule and effectively. These reports should be reviewed at least quarterly.

(ii) The monitoring and maintenance techniques and their schedules to ensure that they continue to be appropriate and in step with the latest developments in quality assurance. They should be made current at least annually.

(iii) The standards for image quality to ensure that they are consistent with the state-of-the-art and the needs and resources of the facility. These standards should be evaluated at least annually.

(iv) The results of the evaluations of the effectiveness of the quality assurance actions to determine whether changes need to be made. This determination should be made at least annually.

(v) The quality assurance manual should also be reviewed at least annually to determine whether revision is needed.

Effective date: This recommendation shall become effective December 11, 1979. However, interested persons may at any time submit written comments on the recommendation to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857. The comments will be considered in determining whether further amendments to or revisions of the

recommendation are warranted. Comments should be in four copies (except that individuals may submit single copies), identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the Hearing Clerk's office between 9 a.m. and 4 p.m., Monday through Friday.

(Sec. 356, 82 Stat. 1174–1175 (42 U.S.C. 263d))

Dated: December 4, 1979.

Joseph P. Hile,

Acting Commissioner of Food and Drugs.

[FR Doc. 79-37739 Filed 12-10-79; 8:45 am]

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Tuesday
December 11, 1979

Part IV

Department of Health, Education, and Welfare

Food and Drug Administration

National Environmental Policy Act; Proposed Policies and Procedures

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Part 25

[Docket No. 79N-0335]

National Environmental Policy Act; Proposed Policies and Procedures

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The agency proposes policies and supplemental procedures for compliance with the National Environmental Policy Act (NEPA) and the Council on Environmental Quality's (CEQ) National Environmental Policy Act Regulations. This proposal expands the environmental impact consideration regulations to include all programs administered by FDA and adopts in full the CEQ regulations.

DATES: Comments are due on or before February 11, 1980.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Kenneth E. Taylor, Bureau of Veterinary Medicine (HFV-2), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4500.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 15, 1977 (43 FR 19986), the Food and Drug Administration (FDA) revised its rules governing the need and procedures for preparing environmental impact statements under section 102(2)(C) of the National Environmental Policy Act of 1969 (NEPA), and revised guidelines on such procedures issued by the Council on Environmental Quality (CEQ) in the **Federal Register** of August 1, 1973 (38 FR 20550).

This proposal, which was developed in consultation with the CEQ staff, revises the procedures FDA uses for implementing NEPA to comply with CEQ regulations (40 CFR Parts 1500-1508) published November 29, 1978 and effective July 30, 1979. This proposal includes procedures FDA will use for implementing NEPA in all its programs. Several FDA administrative and regulatory programs are categorically excluded from requirements to prepare an EIS (environmental impact statement). The term "EIAR (environmental impact analysis report)," formerly used by FDA to identify a document containing an analysis of proposed actions for potential environmental impacts, is replaced by the term "EA (environmental assessment)" as required by the CEQ regulations (40 CFR 1508.9). The new term refers to a document containing a similar environmental analysis of proposed actions. Other terms have been changed to conform with CEQ terminology.

A detailed explanation of this proposal is not being provided because the proposal responds to mandatory requirements established by the CEQ regulations. The CEQ regulations were subject to public review and comment. The following specific requirements of the CEQ regulations are addressed in this proposal:

1. 40 CFR 1501.2(d) requires that agencies provide guidance and advice sufficient to apply NEPA early in the process of actions planned by private applicants or other non-Federal entities. This proposed regulation, in general, provides necessary guidance to applicants and petitioners. (See, in particular, proposed 21 CFR 25.10(a), 25.22, 25.23, 25.24, 25.30, and 25.31.)

2. 40 CFR 1501.4(a), 1507.3(b), and 1508.4 require that agencies identify actions normally requiring the preparation of EIS's, those normally requiring the preparation of EA's, and those which normally do not require the preparation of either EIS's or EA's. (See proposed 21 CFR 25.20 through 25.24.)

3. 40 CFR 1502.9 requires that agencies adopt procedures for introducing supplemental EIS's into a formal administrative record, if such a record exists. (See proposed 21 CFR 25.42(d).)

4. 40 CFR 1505.1 requires that agencies adopt procedures to ensure that decisions are made in accordance with the policies and purposes of NEPA. (See proposed 21 CFR 25.40.)

5. 40 CFR 1506.6 requires that agencies explain where interested persons can obtain information or status reports on EIS's and other elements of the NEPA process. (See proposed 21 CFR 25.41(b) and 25.42(b).)

6. 40 CFR 1507.3 requires that agencies adopt procedures to implement the CEQ regulations, including procedures required by 40 CFR 1501.2(d), 1502.9(c)(3), 1505.1, 1506.6(e), and 1508.4 of the CEQ regulations.

Other sections of the CEQ regulations are addressed in this proposal to provide additional details on FDA's NEPA procedures and policy. Sections, such as the one on terminology (21 CFR 25.15), are provided to ensure that FDA procedures and requirements are clear. The requirements of FDA's present environmental regulations are treated similarly in the proposal insofar as their being consistent with the CEQ regulations. In an effort to provide guidance for compliance with the regulations, the rationale for a number of requirements has been incorporated into the proposal.

Because the scope of this proposal includes each area now subject to the existing Part 25 and also provides terminology and supplemental procedures consistent with the CEQ regulations, which impose mandatory requirements for Federal agencies, FDA will follow the procedures required by this proposal pending publication of the final rule. The public (e.g., applicants and petitioners) are not obligated to follow this proposal until it is published as a final rule. However, in most cases the public may prefer to comply with the supplemental guidance and procedures provided in this proposal in addition to the binding CEQ regulations.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 701, 52 Stat. 1055-1056 as amended (21 U.S.C. 371); the National Environmental Policy Act of 1969 (sec. 102(2)(C), 83 Stat. 853 (42 U.S.C. 4332)); 40 CFR 1500-1508 (43 FR 55978-56007), EO 11514 as amended by EO 11991; and EO 12114 of January 4, 1979; and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 25 be revised to read as follows:

PART 25—ENVIRONMENTAL IMPACT CONSIDERATIONS

Subpart A—General Provisions

Sec.

25.1 Purpose.
25.5 Policies.
25.10 NEPA planning.
25.15 Terminology.

Subpart B—Agency Actions Requiring Environmental Consideration

25.20 General procedures.
25.21 Actions requiring preparation of an environmental impact statement.
25.22 Actions requiring preparation of an environmental assessment.
25.23 Actions that are exluded from the requirement for the preparation of an environmental assessement.
25.24 Categorical exlusions.
25.25 Retroactive environmental consideration.

Subpart C—Preparation of Environmental Documents

25.30 Content and format.
25.31 Environmental assessment.
25.32 Finding of no significant impact.
25.33 Notice of intent.
25.34 Draft, final, and supplemental environmental impact statements.

Subpart D—Agency Decisionmaking

Sec.

25.40 Procedures for incorporating environmental considerations into agency decisionmaking.
25.41 Actions for which an environmental assessment and finding of no significant impact are prepared.
25.42 Actions for which an environmental impact statement is prepared.

Subpart E—Other Requirments

25.50 Environmental effect abroad of major agency actions.

Authority.—Sec. 701, 52 Stat. 1055–1056 as amended (21 U.S.C. 371); sec. 102(2)(C), 83 Stat. 853 (42 U.S.C. 4332); 40 CFR Parts 1500–1508 (43 FR 55978–56007); Executive Order 11514 of March 4, 1970 (35 FR 4247) as amended by Executive Order 11991 of May 24, 1977; Executive Order 12144 of January 4, 1979.

Subpart A—General Provisions

§ 25.1 Purpose.

(a) The Food and Drug Administration (FDA) recognizes the National Environmental Policy Act of 1969 (NEPA) as the national charter for protection, restoration, and enhancement of the environment. NEPA establishes policy, sets goals (section 101), and provides procedures (section 102) for carrying out the policy. This part supplements the regulations for implementing the procedural provisions of NEPA, which were published by the Council on Environmental Quality (CEQ) in 40 CFR Parts 1500–1508. This part incorporates the CEQ regulations.

(b) These supplemental procedures overlap with the CEQ regulations. The overlap is necessary to highlight items of imporatance for FDA. It is not intended that any overlap supersede the existing body of the CEQ regulations.

(c) These supplemental procedures provide that: (1) Environmental information is to be available to the public and the decisionmaker before decisions are made about actions that may significantly affect the human environment: (2) FDA regulatory actions are to be supported by accurate scientific analyses; (3) FDA-prepared environmental documents are to be available for public scrutiny; and (4) environmental documents are to concentrate on the issues that are timely and significant to the action in question rather than amassing needless detail.

(d) These supplemental procedures for implementing NEPA are intended to ensure that environmental consequences are considered in decisionmaking, as required by NEPA. They allow FDA to assist individuals and non-Federal public entities to take actions that protect and enhance environmental quality.

(e) to avoid delays in decisionmaking, these supplemental procedures made possible the early identification of actions that may have significant efects on the quality of the human environment.

§ 25.5 Policies.

All FDA policies and programs will be planned, developed, and implemented so as to achieve the policies declared by NEPA and to satisfy the requirements of the CEQ regulations to ensure responsible stewardship of the environment for present and future generations.

§ 25.10 NEPA planning.

(a) Environmental impact consideration is an integral part of FDA's regulatory process. The process begins when FDA receives an environmental assessment from an applicant or petitioner or when FDA personnel consult with applicants or petitioners requesting FDA action on the NEPA-related aspects of their request. FDA also may issue a public call for environmental data or otherwise consult with affected individuals or groups when a contemplated action in which it is or may be involved poses potentially significant environmental impacts. Assessment of environmental factors continues throughout planning and is integrated with other program planning at the earliest possible time. FDA's assessment of environmental factors included the identification of the environment that may be affected by the action, the evaluation of pertinent environmental data, and the consideration of alternatives consistent with 40 CFR 1502.14. The level of study committed to environmental factors is to be consistent with planning objectives.

(b) FDA will be the lead agency for actions under programs it administers. If an action affects more than one bureau, the Commissioner of Food and Drugs will designate one bureau to be responsible for the preparation of any environmental documentation that may be required. FDA, as lead agency, will coordinate the participation of all concerned agencies in developing an environmental impact statement according to provisions of 40 CFR 1501.6(a).

(c) FDA and Federal agencies outside HEW will agree which will be the lead agency and which will be the cooperating agencies for actions under programs not administered by FDA. If an agreement cannot be reached, the procedures contained in 40 CFR 1501.5(e) will be followed.

(d) FDA will act as a cooperating agency if requested. FDA may request to be designated a cooperating agency if proposed actions may affect areas of FDA responsibility. FDA, as a cooperating agency, will comply with the requirements of 40 CFR 1501.6(b) to the extent possible, depending on priority and the availablity of funds and personnel.

§ 25.15 Terminology.

(a) Definitions that apply to the terms used in this part are set forth in the CEQ regulations under 40 CFR Part 1508. The terms and the sections of the CEQ regulations in which they appear are as follows:

(1) Categorical Exclusion (40 CFR 1508.4).
(2) Cooperating Agency (40 CFR 1508.5).
(3) Cumulative Impact (40 CFR 1508.7).
(4) Effects (40 CFR 1508.8).
(5) Environmental Assessment (40 CFR 1508.9).
(6) Environmental Document (40 CFR 1508.10).
(7) Environmental Impact Statement (40 CFR 1508.11).
(8) Federal Agency (40 CFR 1508.12).
(9) Finding of No Significant Impact (40 CFR 1508.13).
(10) Human Environment (40 CFR 1508.14).
(11) Lead Agency (40 CFR 1508.16).
(12) Legislation. (40 CFR 1508.17).
(13) Major Federal Action (4 CFR 1508.18).
(14) Mitigation (40 CFR 1508.20).
(15) NEPA Process (40 CFR 1508.21).
(16) Notice of Intent (4 CFR 1508.22).
(17) Proposal (40 CFR 1508.23).
(18) Scope (40 CFR 1508.25).
(19) Significantly (40 CFR 1508.27).

(b) The following terms are defined solely for the purpose of implementing the supplemental procedures provided by this part and are not necessarily applicable to any other statutory or regulatory requirements:

(1) "Agency" means the U.S. Food and Drug Administration (FDA).

(2) "Emissions requirements" specifies the limits on the quantities of pollutants allowed to be released into the work place and the area outside a production site or facility. These requirements or standards are set and enforced by local, State, and Federal (e.g., Environmental Protection Agency, Occupational Safety and Health Administration) government components.

(3) "Frequency of use" means the number of times a product is used in a given period of time as specified by the directions for use or label of the product. "Continuous use" means the product is intended to be used without interruption on a daily basis or for extended periods of time. For example, directions for use for animal drugs and feed additives are often continuous and include those for the "control of" and "prevention of" diseases, "increased rate of weight gain," "growth promotion," "increased

feed efficiency," and "improved pigmentation." "Noncontinuous use" means the product is used only on an infrequent, interrupted, or unscheduled basis. For example, directions for use for animal drugs and feed additives are often noncontinuous and include those "for treatment of" or "for diagnosis of" diseases.

(4) "Mode of administration" means the condition under which the product is used. For animals, when the product is used after a few individuals in a herd or flock have been diagnosed and segregated for receiving the product, then the mode of administration is termed "individual basis." Products administered on an "individual basis" are generally marketed and used in small quantities, and the proportion of the population receiving the product is small. Other products are used, generally without diagnosis of individuals, on whole populations of animals. This mode of administration is termed "whole population." An example of a "whole population" product would be an anthelminthic drug (wormer) for swine, which is generally administered because it is probable that the animals are infected, even though they have not been diagnosed.

(5) "Production" includes manufacture, processing (including reprocessing), and packaging operations for items to be introduced into the marketplace.

(6) "Responsible agency official" means the agency decisionmaker designated in Part 5 of this chapter; the Commissioner of Food and Drugs or the Commissioner's designated representative.

(7) "Toxic substance" means any substance that is harmful to some biological mechanism or system. A substance is considered to be toxic if, based on the data available to the agency, it is harmful to any organism at expected environmental concentration even though it may be relatively harmless to man or other organisms and may even be used by man because of its toxic properties. A substance is considered to be toxic if the maximum concentration of the substance at any point in the environment (i.e., either at any point of entry or any point where higher concentrations are expected as a result of bioaccumulation or other types of concentration processes) exceeds the concentration of the substance that causes any effect in a test organism (minimum effect level) or exceeds $\frac{1}{100}$ of the concentration that causes 50 percent mortality in a test organism, whichever concentration is less.

Subpart B—Agency Actions Requiring Environmental Consideration

§ 25.20 General procedures.

(a) These procedures apply to all FDA actions that are not covered by environmental documents prepared under environmental regulations previously in effect.

(b) All agency actions are subject to environmental consideration. Actions are individually examined for potential environmental impact unless excluded as a class by categorical exclusions under § 25.24.

§ 25.21 Actions requiring preparation of an environmental impact statement.

(a) There are no categories of agency actions that usually have a significant impact upon the quality of the human environment and therefore would normally require the preparation of an environmental impact statement.

(b) Environmental impact statements are prepared for agency actions when:

(1) Evaluation of data in an environmental assessment leads to a finding by the responsible agency official that a proposed action will have a significant impact upon the quality of the human environment.

(2) Initial evaluation by the responsible agency official of any action, including any action for which an environmental assessment would otherwise be required, establishes that significant environmental effects may be associated with one or more of the courses of action being considered for proposal.

§ 25.22 Actions requiring preparation of an environmental assessment.

(a) Proposed actions of the types specified in this paragraph (a)(1) through (18) normally required the preparation of an environmental assessment, unless they qualify for categorical exclusion under §§ 25.23 and 25.24:

(1) Major recommendations or reports made to Congress on proposals for legislation in instances where the agency has primary responsibility for the subject matter involved.

(2) Destruction of articles condemned after seizure or whose distribution or use has been enjoined.

(3) Destruction of articles following detention or recall at agency request.

(4) Disposition of Food and Drug Administration (FDA) laboratory waste materials.

(5) Approval or issuance of licenses for biological products.

(6) Establishment by regulation of labeling or other requirements for marketing articles other than through any of the other types of actions specified in this paragraph.

(7) Establishment by regulation of standards for articles.

(8) Approval of new drug and abbreviated new drug applications.

(9) Approval of new animal drug applications and supplements and amendments to new animal drug applications.

(10) Approval of requests to provide for certification of new antibiotic drugs (antibiotic form 5 or 6).

(11) Approval of food additive petitions.

(12) Approval of color additive petitions.

(13) Withdrawal of approval of drugs, Class III devices, food or color additives, and biological products.

(14) Amendments or exemptions with respect to existing regulations and approval of supplements to existing approvals.

(15) Establishment of tolerances or action levels for unavoidable posionous or deleterious substances in food for human consumption or in packaging materials to be used for food for human consumption.

(16) Approval of premarketing approval applications or declaration that product development protocols have been completed for Class III medical devices.

(17) Actions other than those listed in paragraph (a)(1) through (16) of this section, except those subject to categorical exclusion under §§ 25.23 and 25.24, that could significantly affect the quality of the human environment.

(b) A person who submits an application or petition requesting action by the agency of a type specified in paragraph (a) of this section shall include an environmental assessment of the requested action in the format prescribed in § 25.31, unless the action qualifies for categorical exclusion under §§ 25.23 and 25.24. Failure to submit an adequate environmental assessment in an application or petition if one is required shall be sufficient grounds to refuse to accept or file the application or petition.

(c) A manufacturer, distributor, or dealer who proposes to destroy or otherwise dispose of a food, drug, cosmetic, device, or electronic product that has been condemned, detained, recalled, or whose distribution or use has been enjoined shall submit to the agency an environmental assessment in the format prescribed in § 25.31 analyzing the environmental impact of the proposed disposition of such article, unless the action qualifies for categorical exclusion under §§ 25.23 and 25.24.

(d) The responsible agency official will evaluate the information contained in the environmental assessment to determine whether it is accurate, whether the proposed action will have a significant effect on the quality of the human environment and whether an environmental impact statement (EIS) will be prepared. FDA is responsible for assuring the accuracy of the environmental assessment, as required by 40 CFR 1506.5(b). When significant effects requiring the preparation of an environmental impact statement are identified, a "Notice of Intent" to prepare an EIS will be published in the Federal Register. When significant effects requiring the preparation of an environmental impact statement are not present and the decision is made not to prepare an EIS, the responsible agency official will prepare a "Finding of No Significant Impact."

§ 25.23 Actions that are excluded from the requirement for the preparation of an environmental assessment.

(a) Actions of a type that individually or cumulatively have been determined under § 25.24 not to have a significant impact on the quality of the human environment do not normally require the preparation of an environmental assessment or an environmental impact statement. In extraordinary circumstances the preparation of an environmental assessment may be required under paragraph (b) of this section for specific actions.

(b) An environmental assessment will be required for any specific action, normally excluded, if there is sufficient evidence available to the agency to establish that the proposed action may have significant environmental effects.

(c) An applicant or petitioner requesting action of a type subject to categorical exclusion under § 25.24 is not required to submit an environmental assessment if the applicant or petitioner specifies the provision of this part that exempts the action from the requirement for an environmental assessment and provides information that establishes to the agency's satisfaction that the action requested is included within an excluded category and meets the criteria for the applicable categorical exclusion.

(d) If an applicant or petitioner fails to specify the provision of this part that exempts the action from the requirement for an environmental assessment or fails to provide sufficient information to establish that the requested action is subject to a categorical exclusion under § 25.24, the agency may refuse to accept or file the application or petition.

§ 25.24 Categorical exclusions.

(a) General actions belonging to any of the classes designated in paragraph (b) of this section as categorical exclusions normally do not require the preparation of an environmental assessment because, as a class, they will not result in the production or distribution of any substance and, therefore, will not result in the introduction of any substance into the environment. Actions belonging to any of the classes designated in paragraph (c) of this section as categorical exclusions normally do not require the preparation of an environmental assessment because, as a class, they are routine maintenance or minor construction activities conducted or contracted for by the Food and Drug Administration (FDA). Actions belonging to any of the classes designated in paragraph (d) of this section as categorical exclusions normally do not require the preparation of an environmental assessment because they meet specific criteria that are intended to ensure that they will not cause significant environmental effects.

(b) Actions of any of the folllowing classes are categorically excluded:

(1) Routine administrative and management activities, including action on personnel matters; provision of legal services; conduct of public affairs activities, program evaluations, or inspections; issuance of field compliance programs, program circulars, as investigative field assignments.

(2) Recommendation for enforcement action to be initiated in a Federal court.

(3) Data processing and systems analysis.

(4) Liaison functions with other Federal, State, and local government agencies, foreign governments, the public, and industrial firms or organizations.

(5) Exchange of technical assistance with other Federal, State, and local government agencies, foreign governments, and the public.

(6) Promulgation of an interim food additive regulation.

(7) Extramural contracts, grants or other agreements for statistical and epidemiological studies, surveys and inventories, literature searches, and report and manual preparation, or any other studies meeting the criteria specified in paragraph (a) of this section;

(8) Training grants and contracts.

(9) Publication of notices in the Federal Register.

(10) Agency requests for the initiation of recalls.

(11) Activities of voluntary Federal-State cooperative programs, including issuance of model regulations proposed for state adoption.

(12) Issuance of procedural or administrative regulations.

(13) Issuance, amendment, or repeal of standards for foods, class II devices, and radiological products or variances from standards for radiological products.

(14) Testing and certification of batches of colors, antibiotics, or insulin.

(15) Establishment of action levels for natural or unavoidable defects in food for human use that present no health hazard (pursuant to section 402(a) of the Federal Food, Drug, and Cosmetic Act).

(16) Changes in new drug applications (NDA) and new animal drug applications (NADA) described in §§ 314.8(a)(5) and 514.8(a)(5) of this chapter, respectively.

(17) Promulgation of regulations governing the submission of a "Notice of Claimed Investigational Exemption for New Drug" (IND), "Notice of Claimed Investigational Exemption for New Animal Drug" (INAD), or "Investigational Device Exemption" (IDE).

(18) Approval of an animal feed bearing or containing a drug approved under the provisions of § 514.2 of § 514.9 of this chapter.

(19) Device premarket notifications and submissions.

(20) Reclassification of devices under Subpart C of Part 860 of this chapter.

(21) License applications for transfusable blood and blood products.

(22) Corrections and technical changes to regulations, including those providing for certification of antibiotic and antibiotic-containing drugs.

(c) Actions of any of the following classes are categorically excluded:

(1) Repair to or replacement of equipment or structural components (door, roof, window, etc.) of facilities controlled by FDA.

(2) Lease extensions, renewals, or succeeding leases.

(3) Construction or lease construction of 10,000 square feet or less of occupiable space.

(4) Relocation of employees into existing owned or currently leased office space.

(d) Actions of any of the following classes are categorically excluded:

(1) Approval of an NADA or supplemental NADA for a previously approved animal drug of the following types if the drug product will not be administered at higher dosage levels, for longer duration or for different indications than were previously in effect; and, if data available to the agency do not establish that the substance may be toxic to organisms in

the environment at the expected level of exposure:

(i) An animal drug to be distributed under conditions of approval of a previously approved animal drug;

(ii) A combination of previously approved animal drugs;

(iii) A new premix for a previously approved animal drug;

(iv) Changes specified in § 514.8(d) of this chapter; and

(v) Approval for additional distributors of a previously approved animal drug.

(2) Withdrawal of NDA's and NADA's when the drug is no longer being marketed or at the request of the application holder.

(3) Promulgation of an animal drug monograph if the monograph will not permit the animal drug that is the subject of the monograph to be administered at higher dosage levels, for longer duration, or for significantly different indications that were previously in effect.

(4) Approval of a request for diversion of adulterated or misbranded human food or animal feed to use as animal feed if such disposition of the article, including packaging material, will not result in the release of a toxic substance into the environment.

(5) Approval of a color additive petition to change a provisional listing to permanent listing if the additive is already marketed for the petitioned use and data available to the agency do not establish that is may be toxic to organisms in the environment at the expected levels of exposure.

(6) Affirmation of or approval of a petition for affirmation that a substance is generally recognized as safe (GRAS) for humans and animals under Part 182, 184, or 582 of this chapter if the substance is already marketed for the use for which affirmation is sought and data available to the agency do not establish that the substance may be toxic to organisms in the environment at the expected levels of exposure.

(7) Promulgation of regulations relating to the control of communicable disease and to interstate conveyance sanitation under:

(i) Part 1240 of this chapter if the method of destruction or disposition of any article, including packaging material, does not result in the release of a toxic substance into the environment; or

(ii) Part 1250 of this chapter.

(8) Approval of a supplement or amendment to an NDA for any of the types of changes specified in § 314.8(d) of this chapter if the proposed approval provides that the drug will not be administered at higher dosage levels, for longer duration, or for different indications than were previously in effect.

(9) Promulgation of a monograph for a "not new" drug, antibiotic drug, over-the-counter (OTC) drug, or in vitro diagnostic product if the proposed monograph will not permit the article to be administered at higher dosage levels, for longer duration, or for significantly different indications than were previously in effect.

(10) Promulgation of additional standards for licensed biological products or amendment to licenses for biological products if there is no change in the existing levels of use or intended uses for the product.

(11) Destruction or disposal of articles condemned after seizure or whose distribution or use has been enjoined or following detention or recall at agency request if the method of destruction or disposition of any article, including packaging material, will not result in the release of a toxic substance into the environment.

(12) Promulgation of current good manufacturing practices regulations (CGMPR's), emergency permit control regulations, and permits, exemptions, or variances issued under these regulations if there is no change in the existing uses of the product and if there is no increase in the quantities or toxicity of wastes entering the environment as a direct or indirect result of the action.

(13) Establishment by regulation of labeling requirements for marketing articles if there will be no increase in the existing levels of use or change in the intended uses of the product or its substitutes.

(14) Promulgation of good laboratory practice (GLP) regulations if there is no increase in the quantities or toxicity of wastes entering the environment as a direct or indirect result of the action.

(15) Action on a "Notice of Claimed Investigational Exemption for New Drug" (IND), "Notice of Claimed Investigational Exemption for New Animal Drug" (INAD), or "Investigational Device Exemption" (IDE) if the drug or device shipped under such notices is intended to be used for clinical studies or research in which waste will be controlled or the amount of waste be expected to enter the environment may reasonably expected to be nontoxic.

(16) Extramural contracts, grants, and other agreements for research to develop analytical methods or other test methodologies if the waste from such research will be controlled or the amount of waste expected to enter the environment may reasonably be expected to be nontoxic.

§ 25.25 Retroactive environmental consideration.

(a) The need for preparing an environmental impact statement for existing regulations or approvals of any of the types specified in §§ 25.21 through 25.24 that have not previously received environmental analysis shall be considered when such consideration is necessary to the consideration of the environmental effects of an amendment, supplement, or exemption proposed with respect to such a regulation or approval. Environmental documents prepared on existing regulations under this paragraph may govern classes of existing regulations as well as existing individual regulations. For existing regulations or approvals for which an amendment, supplement, exemption, or any other action based on existing approvals is proposed:

(1) The current applicant or petitioner shall submit an environmental assessment as described by § 25.31 with respect to the existing regulation or approval if notified by the agency in writing that one is required.

(2) Any applicant or petitioner who initiated the existing regulation, if different from the current applicant of petitioner, and other persons governed by such regulations or approvals shall submit an environmental assessment as described by § 25.31 with respect to the existing regulation or approval if notified by the agency in writing that one is required.

(b) The need for preparing an environmental impact statement for existing regulations or approvals of any of the types specified in §§ 25.21 through 25.24, whether or not previously subject to environmental analysis, may be considered by the agency when an amendment, supplement, or exemption is proposed with respect to such regulation or approval or there is new information before the agency with respect to the environmental effects of such regulation or approval.

Subpart C—Preparation of Environmental Documents

§ 25.30 Content and format.

(a) Sections 25.31 through 25.34 describe the environmental documents that may be required in the course of the agency's consideration of the environmental aspects of an action, their purpose, contents and format, and the relationships of these documents to each other. Additional information concerning the nature and scope of information required to be submitted in environmental documents by an applicant or petitioner may be obtained from the bureau or other office of the

agency having responsibility for the action that is the subject of the environmental evaluation.

(b) Data and information that are protected from disclosure by 18 U.S.C. 1905 or 21 U.S.C. 331(j) shall not be included in environmental documents prepared under this Part 25. When pertinent to the environmental review of a proposed action, such information shall be submitted separately as a confidential section of the application or petition. Such information shall be referenced in the environmental document and summarized there to the extent permissible.

§ 25.31 Environmental assessment.

(a) As defined by the Council on Environmental Quality (CEQ) in 40 CFR 1508.9, the environmental assessment is the public document in which the agency evaluates environmental and other pertinent information on a proposed action for the purpose of determining whether to prepare an environmental impact statement or a finding of no significant impact.

(b) An environmental assessment shall be prepared in the following format:

Environmental Assessment

1. Date:
2. Name of applicant/petitioner:
3. Address:
4. Description of the proposed actions: Briefly describe the purpose and need for the action, the locations where the action and activities consequent to the action will occur, and the types of environments present at those locations.
5. Introduction of substances into the environment: Specify to the extent possible the quantities and composition of substances expected to enter the environment at the sites of production, use, and/or disposal of products affected by the action. The physical/chemical characteristics, locations and duration of emissions, the controls exercised, and a citation of and statement of compliance with applicable emissions requirements at the state, local and Federal level should be specified.
6. Fate of emitted substances in the environment: "Worst case" environmental concentrations and exposures to compounds entering the environment as a consequence (direct or indirect) of the action shall be predicted for the following environmental compartments, including when possible the area (e.g., square miles, hectares, etc.) of each compartment affected, and consideration of the major environmental transport and transformation processes involved:

(a) Air—taking into account volatilization, photochemical and chemical degradation, rainout, dispersion, etc., to the extent possible;

(b) Freshwater, estuarine, and marine ecosystems—taking into account chemical and biodegradation; exchange between the water column and sediments via adsorption/desorption processes; accumulation in plantlife, plankton, and fish through bioconcentration, excretion, and decomposition processes; introductions due to rainfall; losses due to volatilization, etc.;

(c) Terrestrial ecosystems—taking into account chemical and biodegradation, adsorption/desorption and leaching in soils, bioaccumulation in animal and plantlife, inputs due to rainfall, losses due to volatilization, etc.

7. Effects on the environment of released substances: Given the information developed on the introduction (item 5) and fate (item 6) of substances which would be released as a consequence of an action, relevant toxicological data, worst case analyses, or other appropriate methods shall be used to predict effects, including chronic and subchronic effects on humans and other organisms and ecosystem-level effects in each of the environmental compartments listed in item 6.
8. Utilization of natural resources and energy: Specify the natural resources, including land use and energy, used to produce a given amount of any products which are the subject of the action, including the resources and energy used to dispose of wastes generated, as a consequence of the production, use, and/or disposal of the product.
9. Disruptions of the physical environment: Describe any noise, odors, construction, or other disruptions associated directly or indirectly with the action.
10. Mitigation measures: Describe measures taken to avoid or mitigate potential adverse environmental effects associated with the proposed action.
11. Alternatives to the proposed action: If potential adverse environmental effects have been identified for the proposed action, describe in detail the environmental impact of all reasonable alternatives (including no action) to the proposed action, particularly those that will enhance the quality of the environment and avoid some or all of the adverse environmental effects of the proposed action. Discuss in detail the environmental benefits and risks of each such alternative.
12. List of preparers: Those persons preparing the assessment and their areas of expertise shall be presented. Persons and agencies consulted and their areas of expertise shall also be listed.
13. Certification: The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of the firm or agency responsible for preparation of the environmental assessment.

_____

(Date)

_____

(Signature of responsible official)

_____

(Title)

14. References: List complete citations for all referenced material. Copies of referenced articles not generally available should be attached.
15. Appendices: (a) Data summary charts (e.g., structural formula, vapor pressure, water solubility, octanol/water partition coefficient, biodegradation LC_{50} half-life for each species tested, etc.)

(b) Test reports (for each experiment: research objective, experimental design and procedure, all data relevant to interpretation of the test result given in item 15(a), sample calculations, and statistical analyses).

(c) Wherever consistent with a reasonable scientific approach, the existing scientific and engineering literature, chemical/physical properties of the substances released, the levels of production (environmental introduction) and any other existing knowledge shall be used, in lieu of conducting additional environmental impact studies. Where such studies are required to predict the potential environemental impacts associated with a proposed action, applicants and petitioners should consult with the agency to determine the most efficient, scientifically sound approach to gather the needed information.

(d) To the extent possible, the environmental impacts associated with the entire production-use-disposal cycle (raw materials to final product to disposal) of the product(s) which is the subject of a requested action should be addressed. When the petitioner or agency responsible for supplying information required in the environmental assessment has no direct control over some aspect of the production-use-disposal cycle, it will often not be possible to directly measure the environmental effects associated with those aspects. In those cases, the scientific and engineering literature may be used to develop a worst case analysis as the basis for predicting potential environmental effects of the proposal under 40 CFR 1502.22.

(e) The agency has determined that, for the following actions, only the factors specified in this paragraph are required to be assessed in items 5, 6, and 7 of the environmental assessment. Agency evaluation of these data may require that additional environmental information applicable to items 5, 6, or 7 of the environmental assessment be gathered and assessed.

(1) For the approval of NADA's and supplements and amendments to NADA's for animal drugs intended for use under prescription or veterinarian's order, for treatment of a disease, for use in nonfood animals, for opthalmic or topical application, for local or general anesthesia, or as in vitro diagnostics, the following factors are required to be assessed:

(i) The expected environmental concentrations of the product, its metabolites and degradation products resulting from the use of the product

based on the frequency of use, mode of administration, and availability of the product; and

(ii) Environmental impacts that are expected to occur at the site of production of the product.

(2) For the approval of food additive petitions for substances to be used as minor constituents of food-packaging material, the following factors are required to be assessed:

(i) Whether the substance, in the quantities that will enter the environment through use and disposal, estimated by a worst case analysis, may reasonably be expected to be a toxic substance;

(ii) Whether the substance will materially change the potential uses or disposal methods of the packaging material to which it is added;

(iii) Whether the substance is for the same use as another additive already in use; and

(iv) The environmental impacts that are expected to occur at the site(s) of production of the food additive and the packaging material.

(3) For approval of food additives to be used as components of food-contact surfaces of permanent or semipermanent equipment or of other food-contact articles intended for repeated use, the following factors are required to be assessed:

(i) Whether the substance, in the quantities that will enter the environment through use and disposal, estimated by a worst case analysis, may reasonably be expected to be a toxic substance; and

(ii) The environmental impacts that are expected to occur at the site of production.

(4) For approval of NDA's for human drugs intended for use for the prevention, treatment, or diagnosis of a rare disease or for a similarly infrequent use; for opthalmic or topical application; or for local or general anesthesia, the following factors are required to be assessed:

(i) The expected environmental concentrations of the product, its metabolites, and degradation products resulting from the use of the product based on the frequency of use, mode of administration, and availability of the product; and

(ii) Environmental impacts that are expected to occur at the site of production of the drug product.

(5) For approval of licenses for biological products intended for the prevention, treatment, or diagnosis of a rare disease or for a similarly infrequent use, the following factors are required to be assessed:

(i) The expected environmental concentrations of the product, its metabolites and degradation products resulting from the use of the product based on the frequency of use, mode of administration, and availability of the product; and

(ii) Environmental impacts that are expected to occur at the site of production of the product.

(6) When the agency approves or issues, for a substance that occurs naturally in the environment, an NDA, abbreviated or supplemental NDA, NADA, supplemental NADA, food or color additive petition, or biological product license, the following factors are required to be assessed:

(i) Whether the substance, its metabolites, degradation products, and its constituent parts may reasonably be considered to be a toxic substance in the amounts used;

(ii) Whether the use of the substance can reasonably be expected on the basis of all available evidence to alter significantly the prevalence and/or distribution of the substance, its metabolites, degradation products, or its constituent parts in the environment; and

(iii) Environmental impacts that are expected to occur at the site of production of the product.

(7) For withdrawal of approval of drugs, class III devices, animal drugs, food or color additives, and biological products, the following factors are required to be assessed:

(i) Whether there are substitute products or components for the restricted article; and

(ii) The environmental impact of increased use of any substitutes for the restricted article which have not been considered for their potential environmental impacts or have been previously considered by the agency and found to cause significant environmental effects.

(8) For approval or issuance by the agency of an NDA, abbreviated and supplemental NDA, NADA, supplemental NADA, food or color additive petition, or biological product license for a regulated product that has received approval from the Environmental Protection Agency (EPA) under section 4 or 5 of the Toxic Substances Control Act (TSCA) or under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) or its amendments for a use similar to that proposed under the Federal Food, Drug, and Cosmetic Act, the following information is required:

(i) A brief description and summary of results of each study submitted to EPA for review under TSCA or FIFRA;

(ii) An adequate explanation of the basis for the environmental review performed by EPA being accepted as sufficient to cover the environmental impact(s) resulting from the production, use, and disposal of the product for its proposed use regulated by FDA; and

(iii) A description of any potential environmental impacts determined to be adverse by EPA and how these are to be mitigated.

(9) For extramural contracts, grants, or other agreements subject to environmental assessment, specific information requirements will be provided in subsequent guidelines made available to prospective contractors and grantees.

§ 25.32 Finding of no significant impact.

(a) As defined by the Council on Environmental Quality regulation (40 CFR 1508.13), this document includes the environmental assessment and a finding that the action is one that "will not have a significant effect on the human environment and for which an environmental impact statement therefore will not be prepared."

(b) The finding of no significant impact will be prepared by the agency as appropriate for all proposed actions, including those for which an applicant or petititoner has prepared the environmental assessment.

(c) The finding of no significant impact will evaluate the information presented in the environmental assessment for potential environmental impacts, for its accuracy, and to identify any unknowns which remain. If the environmental assessment has been prepared by an applicant or petitioner, the agency may choose to include further evidence of its own in the finding of no significant impact.

(d) The agency official responsible for the preparation and approval of the finding of no significant impact will sign the document, thereby establishing that the official approves the conclusion not to prepare an environmental impact statement for the action under consideration.

§ 25.33 Notice of intent.

(a) As defined by the Council on Environmental Quality regulation (40 CFR 1508.22), the "Notice of Intent" notifies the public that the agency has determined that an environmental impact statement (EIS) will be prepared. This determination may occur after evaluation of the information contained in an environmental assessment or if other information available to the agency indicates that potentially significant effects may be associated with a proposed action.

(b) As required by 40 CFR 1508.22, the "Notice of Intent" will describe the proposed action, possible alternatives, the agency's proposed scoping process (which may include a request for information or suggestions regarding the scope of the EIS and notice of public meetings), and the identification of persons within the agency to contact for further information.

§ 25.34 Draft, final, and supplemental impact statements.

(a) The Council on Environmental Quality (CEQ) regulations (40 CFR Part 1502) provide detailed requirements for the preparation of environmental impact statements (EIS).

(b) The format recommended by CEQ for EIS's (40 CFR 1502.10) will be followed unless "the agency determines that there is a compelling reason to do otherwise."

(c) When chemical substances enter the environment as a result of a proposed action or other alternatives, the portion of the EIS format "Environmental Consequences" (40 CFR 1502.10(g)) will include discussions of the routes of environmental fate and effects of those substances similar to that described in § 25.31.

(d) Final EIS's will contain revisions and corrections resulting from comment or additional information gathered by the agency subsequent to the publication of the draft EIS and will contain the comments received on the draft and agency responses as required in 40 CFR Part 1503.

(e) Supplemental EIS's will conform to the EIS format (40 CFR 1502.10) when this is consistent with the concise presentation of changes, revisions, or clarification of issues raised after the publication of a final EIS.

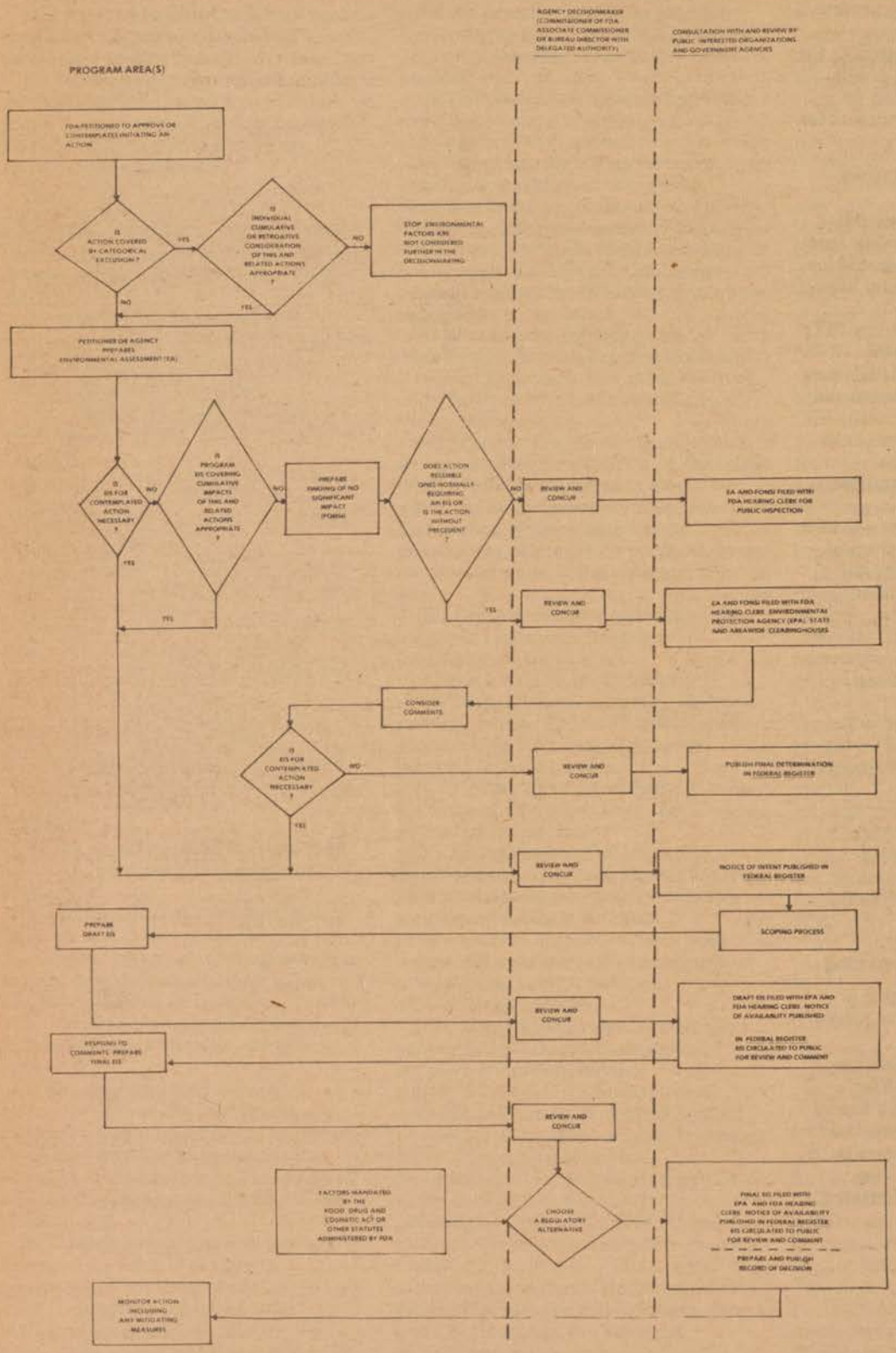
Subpart D—Agency Decisionmaking

§ 25.40 Procedures for incorporating environmental considerations into agency decisionmaking.

(a) These procedures are to ensure that environmental information is provided to decisionmakers in a timely manner. The National Environmental Policy Act of 1969 (NEPA) process is an integral part of the Food and Drug Administration (FDA) decisionmaking (Fig. 1):

BILLING CODE 4110-03-M

ENVIRONMENTAL FACTORS IN FDA DECISIONMAKING



BILLING CODE 4110-03-C

Agency decisionmakers ensure that the policies and purpose of NEPA and CEQ regulations are complied within FDA decisionmaking by:

(1) Completing an environmental assessment and determining whether an environmental impact statement (EIS) is required before deciding to propose an action subject to § 25.22.

(2) Including in decision documents and supporting environmental documents a discussion of all alternatives considered in the decision. Every action memorandum proposing an agency action included under § 25.21 or § 25.22 will contain an evaluation of the environmental impact of the proposed action and will be accompanied by a draft or final EIS if one is required.

(3) Submitting relevant environmental documents, comments, and responses with other decision documents through the review process.

(4) Including in the record of formal rulemaking or adjudicatory proceedings relevant environmental documents, comments, and responses.

(5) Completing and circulating a final environmental impact statement before the decision to implement an action that may significantly affect the quality of the human environment.

(b) There are certain regulatory actions which, because of their immediate importance to the public health, make adherence to the requirements of the CEQ regulations and these regulations concerning minimum periods of public review impractical. Compliance with the requirements for environmental analysis under NEPA is impossible where emergency circumstances require immediate regulatory action to safeguard the public health. For such actions, the responsible agency official may consult with the CEQ about alternative arrangements in the manner prescribed by 40 CFR 1506.11.

(c) Certain FDA actions are subject to statutorily prescribed time limits, which sometimes do not provide sufficient time to complete the required environmental document. Should the responsible agency official be unable to complete environmental consideration of the proposed action before the notice of filing is required to be published and the subsequent environmental analysis leads to the conclusion that no EIS is necessary, the **Federal Register** document publishing the regulation rather than the notice of filing shall state that no EIS is necessary and that the environmental assessment is available upon request and filed in the FDA Hearing Clerk's office.

§ 25.41 Actions for which an environmental assessment and finding of no significant impact are prepared.

(a) An environmental assessment and finding of no significant impact are prepared for an individual action or group of related actions that are not expected to significantly affect the quality of the human environment. If potentially adverse environmental impacts are identified for an action or group of related actions, the assessment will include a consideration of alternative courses of action. In these cases, any reasonable alternative courses of action that offer less environmental risk or that are environmentally preferable to the proposed action are considered under 40 CFR 1502.14(a).

(b) Environmental assessments and findings of no significant impact will be available to the public as follows:

(1) When the proposed action is the subject of a notice of proposed rulemaking or a notice of filing published in the **Federal Register**, the notice shall state that no environmental impact statement is necessary and that the finding of no significant impact, including the environmental assessment, is available for public inspection at the Food and Drug Administration Hearing Clerk's office.

(2) When the proposed action involves destruction of condemned, detained, recalled articles, articles whose distribution or use has been enjoined, or disposition of Food and Drug Administration laboratory waste materials, the agency will observe disposal guidelines consistent with Federal, State, and local regulations applicable on a case-by-case basis. The environmental assessments prepared for such actions shall be available upon request.

(3) For actions for which notice is not published in the **Federal Register**, the finding of no significant impact, including the environmental assessment, shall be made available to the public upon request according to the procedures in 40 CFR 1506.6.

(4) For a limited number of actions, the agency may file the finding of no significant impact and the environmental assessment with the Environmental Protection Agency and State and areawide clearinghouses for public review, under the requirements of 40 CFR 1501.4(e).

(c) Program area officials and environmental staff prepare or ensure that the information contained in environmental assessments is complete and accurate, and they prepare the finding of no significant impact. The responsible agency official designated in Part 5 of this chapter examines the environmental risks of the proposed action and the alternative courses of action, selects a course of action and ensures that any necessary mitigating measures are implemented as a condition for approving a course of action.

§ 25.42 Actions for which an environmental impact statement is prepared.

(a) An individual action or group of related actions requires the preparation of an environmental impact statement (EIS) when at least potentially significant environmental impacts are associated with one or more of the probable courses of action. The responsible agency official weighs the environmental impacts of each alternative course of action, including possible mitigating measures, and selects the course of action that is consistent with the applicable law and the agency's environmental analysis of the action.

(b) For actions for which an EIS is prepared, the public has the opportunity to offer comments and otherwise participate in the National Environmental Policy Act of 1969 (NEPA) process from the time the decision is made to prepare the document as described in this paragraph (b)(1) through (5):

(1) A notice of intent to prepare an EIS is prepared for publication in the **Federal Register** and serves as the first public notification that an EIS will be prepared.

(2) The scoping process, as announced in the Notice of Intent, allows the public and Federal, State, and local government agencies to participate in determining the issues to be considered in the EIS.

(3)(i) Draft EIS's are filed with the Environmental Protection Agency (EPA), sent to parties having an interest in the document, and are available to the public upon request for the purpose of receiving substantive comment, corrections, and additional information on the issues covered.

(ii) Where the subject of a draft EIS is also the subject of a notice of proposed rulemaking, the **Federal Register** notice of proposed rulemaking will state that the draft EIS is available upon request, and will solicit comments from all interested persons.

(iii) Where the subject of a draft EIS is not also the subject of a notice of proposed rulemaking published in the **Federal Register**, a notice will be published in the **Federal Register** describing the proposed action, and possible alternatives, stating that the

draft EIS is available upon request, and soliciting comments by all interested persons.

(iv) Comments will be solicited from Federal agencies having jurisdiction by law or special expertise with respect to the environmental impact of a proposed action by sending them a copy of a draft EIS.

(v) All comments on draft EIS's are required to be submitted in five copies to the Hearing Clerk (HFA–305), Food and Drug Administration, Department of Health, Education, and Welfare, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, where they will be available for public inspection from 9 a.m. to 4 p.m., Monday through Friday.

(vi) Draft EIS's will be prepared, forwarded to EPA, and made available to the public early enough in the consideration of the proposed action to permit meaningful review of the environmental issues involved. Except in emergencies, no final action will be taken on the proposal earlier than 90 days after a draft environmental impact statement has been prepared, forwarded to EPA, and made available to the public.

(4) The final text of an EIS will be prepared by the responsible agency official after comments on the draft statement have been reviewed and will receive full consideration in the agency's decisionmaking process. The responsible agency official will forward 10 copies of the final statement to the Office of the Secretary and 5 copies to EPA, and copies of the final statement will be made available for public inspection in the FDA Hearing Clerk's office. Copies of each final EIS will be forwarded to those persons who requested or submitted comments on the pertinent draft statements and upon request.

(5)(i) The weighing of environmental factors in choosing a final course of action, as described in paragraph (a) of this section, will be reflected in the agency record of formal decisionmaking as required by 40 CFR 1505.2.

(ii) Except in emergencies, no agency action will be effective earlier than 30 days after the final statement has been forwarded to EPA and made available by FDA for public inspection. Where the subject of a final statement is also the subject of a regulation published in the **Federal Register**, this requirement may be met by simultaneous publication of a notice of availability of the final statement and the regulation, provided the regulation becomes effective at least 30 days after the date of publication.

(iii) Where the subject of an EIS is an FDA action governed by specific time requirements under statute or regulation, those time requirements shall be extended, if at all, only as long as necessary to permit the agency to consider or issue an EIS for the action.

(c) As described in 40 CFR 1505.3, the agency may provide for monitoring to ensure that its decisions, any mitigating measures, and other conditions are carried out.

(d) Under the conditions prescribed in 40 CFR 1502.9(c), the agency will prepare a supplement for a draft or final EIS and introduce the supplement into its formal administrative record.

(e)(1) The responsible agency official designated in Part 5 of this chapter ensures that there will be a balancing of environmental impacts with objectives of the agency in choosing an appropriate course of action and that the public is involved and notified of the decision, as described in paragraphs (a) through (d) of this section.

(2) The Office of the Commissioner is responsible for preparing a draft or final EIS on actions not delegated by the Commissioner.

(3) The director of each bureau is responsible for preparing a draft or final EIS on actions delegated to that bureau by the Commissioner under Subpart B of Part 5 of the chapter.

(4) The Executive Director for Regional Operations is responsible for preparing a draft or final EIS on the destruction of articles condemned after seizure, subject to an injunction, under import detention, or under detention or recalled at agency request.

Subpart E—Other Requirements

§ 25.50 Environmental effects abroad of major Federal actions.

(a) In accordance with Executive Order 12114 "Environmental Effects Abroad of Major Federal Actions" of January 4, 1979 (44 FR 1957; January 9, 1979), the responsible agency official shall analyze actions under his/her program delegation authority giving due regard for the environmental effects abroad of such actions. The responsible agency official shall consider whether such actions involve:

(1) Potential environmental effects on the global commons (e.g., oceans and the upper atmosphere).

(2) Potential environmental effects on a foreign nation not participating with or otherwise involved in Food and Drug Administration activity.

(3) The export of products (or emissions) which in the United States are prohibited or strictly regulated because their effects on the environment create a serious public health risk.

(4) Potential environmental effects on natural and ecological resources of global importance.

(b) Before deciding on any action falling into the categories specified in paragraph (a) of this section, the responsible agency official shall determine whether such actions may have a significant environmental effect abroad.

(c) If the responsible agency official determines that an action may have a significant environmental effect abroad, the responsible agency official shall determine whether the subject action requires:

(1) An environmental impact statement; or

(2) Bilateral or multilateral environmental study and review of environmental issues.

Interested persons may, on or before February 11, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administration.

Dated: November 29, 1979.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-37741 Filed 12-10-79; 8:45 am]

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Tuesday
December 11, 1979

Part V

Department of Health, Education, and Welfare

Public Health Service

Health Systems Agency and State Agency Reviews of the Appropriateness of Existing Institutional Health Services; Final Regulations

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Public Health Service

42 CFR Parts 122 and 123

Health Systems Agency and State Agency Reviews of the Appropriateness of Existing Institutional Health Services

AGENCY: Public Health Service, HEW.

ACTION: Final regulations.

SUMMARY: These regulations set forth the requirements for the review of the appropriateness of existing institutional health services by health systems agencies (Part 122, Subpart F) and State health planning and development agencies (Part 123, Subpart G). These reviews are required by sections 1513(g) and 1523(a)(6) of the Public Health Service Act and are intended to result in careful reviews by these agencies of all existing institutional health services, public findings as to the appropriateness of each service, and recommendations for remedial action when a service is found inappropriate.

EFFECTIVE DATE: December 11, 1979.

FOR FURTHER INFORMATION CONTACT: Colin C. Rorrie, Jr., Ph.D., Acting Director, Bureau of Health Planning, Center Building, Room 6–22, 3700 East-West Highway, Hyattsville, Maryland 20782, (301) 436–6850.

SUPPLEMENTARY INFORMATION: On May 16, 1978, a Notice of Proposed Rulemaking (NPRM) was published in the **Federal Register** (43 FR 21274–82), proposing to amend 42 CFR Part 122 and 42 CFR Part 123. That Notice set forth proposed regulations governing health systems agency and State health planning and development agency reviews of the appropriateness of existing institutional health services. These reviews are required by sections 1513(g) and 1523(a)(6) of the Public Health Service Act and are intended to result in careful reviews by these agencies of all existing institutional health services, public findings as to the appropriateness of each service, and recommendations for remedial action when a service is found inappropriate. Interested persons were invited to submit written comments, suggestions, or objections on or before June 30, 1978. Because of the interest raised by the proposed rules and numerous requests to allow more time for review, the comment period was reopened on August 1, 1978, for an additional 30 days. By the August 31 deadline, a total of 216 comments were received. All comments were considered in developing these final regulations.

These regulations include several changes based on the Health Planning and Resources Development Amendments of 1979 (Pub. L. 96–79). There are a number of technical changes regarding reviews of HMO services based on a revised definition of "institutional health services," and changes to the review criteria at § 122.607. Changes to the required review procedures resulting from the amendments are not being made at this time. Planning agencies are to use the procedures prescribed in these regulations, which reflect the Act prior to the amendments. The Secretary will issue proposed regulations for the necessary revisions to procedures in the near future. Furthermore, the Secretary wishes to point out that other changes in appropriateness reviews required by the amendments are effective one year from the enactment of the amendments; proposed regulations or guidance, as required, will be issued before that time.

Because of the similarity in the content and structure of Subpart F, Part 122, and Subpart G, Part 123, many individual comments addressed points included in both subparts or raised questions regarding aspects of one subpart which affect aspects of the other. This Preamble is organized to reflect this parallel structure. The first part of the Preamble includes general comments and those specific comments which are not readily encompassed in the discussion of the particular sections. The second part includes comments specific to particular sections of the proposed regulation. The comments received, the Department's responses, and the changes that have been made in the regulations are discussed below.

Comments of a General Nature

Many commenters objected to the implication that appropriateness reviews may serve a regulatory function. Some maintained that any sanctions imposed as a result of State health planning and development agency ("State Agency") findings would be counter to Congressional intent, and should be prohibited. Others expressed concern that a finding of inappropriateness would amount to an implicit sanction, creating financial hardships for many providers. One commenter felt that since appropriateness reviews are very similar to reviews of new institutional health services, providers might assume that the same sanctions apply.

On the other hand, several commenters felt that without sanctions, appropriateness reviews would have only limited impact, because agencies would not be able to enforce recommendations for remedial action.

To clarify this issue, the Secretary calls attention to the evolution of the concept of appropriateness review as reflected in the legislative history of Pub. L. 93–641 which enacted Title XV of the Act. The function of periodically reviewing existing institutional health services developed from a review combined with recertification authority, to a periodic determination as to the continuing need for a service (with sanctions not required), to the present requirement for periodic reviews of services as to their "appropriateness." While the required application of sanctions was dropped as the legislation evolved, there is no indication that Congress wished to prohibit agencies from considering sanctions. In fact, as stated in the Report of the House Committee on Interstate and Foreign Commerce on this legislation:

> The Committee has not required any sanction related to these reviews which would require that unneeded existing institutional health services be eliminated or closed. However, were a State to decide on its own initiative to create such a sanction the Committee would of course have no objection to this. The Committee did indicate its intent to consider requiring such a sanction at a later date. (H.R. Rep. No. 93–1382, 93d Cong. 2d Sess., Sept. 26, 1974, p. 79.)

Thus, the intent of Congress with respect to sanctions based on these reviews is clear: Sanctions are not required, but neither are they prohibited. Accordingly, the Secretary is not requiring the imposition of sanctions based on State Agency findings from an appropriateness review, nor is he prohibiting sanctions. He expects, however, that planning agencies will be extremely cautious in considering them.

The Secretary is concerned that there has been too much emphasis on the possible negative outcomes of appropriateness reviews. He sees these reviews as an excellent and exciting opportunity for providers and health planners to assess cooperatively the current health system and to make changes that can benefit the community. These reviews should not only address areas of excess and duplication but should also identify areas needing additional or improved services.

Several commenters felt that planning agencies would react in an arbitrary and capricious manner to a finding of inappropriateness. The Secretary points out that criteria developed with public input are used in making appropriateness review recommendations and findings and that these regulations contain procedural

safeguards which should help ensure an open and fair process.

Many commenters endorsed either linking appropriateness reviews to, or having these reviews replace, other project reviews, such as certificate of need reviews. The nature of appropriateness reviews differs from the other project reviews in that it is initiated by the planning agencies and may involve a service as it is provided in a number of facilities. In addition, appropriateness reviews are concerned only with existing institutional health services, whereas certificate of need reviews are concerned with proposed new institutional health services. Consequently, it may be overly burdensome to require the integration or coordination of reviews, and the Secretary has chosen not to require it. Nevertheless, where the regulatory and statutory provisions are satisfied, he would not object to having one review serve more than one purpose. The Secretary agrees with the commenter who suggested that the procedures and criteria developed for the various types of reviews should be largely in agreement, and, to the extent feasible, the same. He has therefore specified, where appropriate, minimal procedural requirements and considerations for criteria which are similar to those required for other types of reviews.

Several commenters objected to or asked for clarification of the phrase in the Preamble of the NPRM which indicated that appropriateness reviews "bridge the gap between planning and regulation." HSAs have no formal regulatory authority. Their responsibilities are limited in reviews of both proposed and existing institutional health services to making recommendations to the appropriate State Agency, which is then authorized to issue a certificate of need or make a finding, depending on the review performed. Because of the Act's emphasis on and the Secretary's endorsement of locally based health planning, it is expected that State Agency determinations will conform in most cases to the HSA's recommendations. These regulations therefore require the State Agency to justify any finding which is inconsistent with an HSA's recommendation, and enable the HSA to appeal any such State Agency finding.

Appropriateness reviews can be a valuable and logical extension of the health planning process. Through the process of using health plans as the basis for regulatory decisions, and using the results of reviews to aid in the development of better plans, planning agencies will have two effective tools, each complementing the other, for having a positive influence on the health care system. This process of adjustment and modification can be as effective in reviews of existing services, even without explicit sanctions, as are reviews of new services with sanctions.

The Secretary noted in the Preamble to the proposed rules that he was concerned that the appropriateness review workload was "potentially enormous" and that therefore he was proposing regulations which would "permit the gradual assumption of this function in accordance with agency capabilities." Commenters suggested that this be accomplished in the following ways: (1) To allow HSAs more than three years after full designation to complete their reviews; (2) not require *all* existing institutional health services to be reviewed in three years; and (3) exclude some HSAs, e.g., minimally funded agencies, from the three year requirement. The Secretary is unable to accept any of these recommendations because the Act requires that HSAs complete appropriateness reviews of all existing institutional health services within three years of their initial full designation.

To assist agencies, the Department has issued technical assistance documents on conducting appropriateness reviews, including recommended criteria and procedures for these reviews. These documents are available from the National Health Planning Information Center, 3700 East-West Highway, Hyattsville, Maryland 20782. In addition, the Department will issue further guidance on the development of these reviews, including recommendations on how appropriateness reviews of some institutional services may be conducted in more detail than those of other services. The Secretary understands the need to emphasize appropriateness reviews of acute care services, given the general excess of hospital beds in this country and the proliferation of expensive medical equipment. This approach is consistent with the resource standards of the National Guidelines for Health Planning issued on March 28, 1978. (See 43 FR 13040–13050).

One commenter noted that HSAs are being asked to assume other new responsibilities, such as the review of proposed uses of certain Federal funds, at the same time as appropriateness reviews and was concerned that the possibility of funding cutbacks might further lessen the capability of HSAs to perform reviews. HSAs have known for some time that both of these functions must be performed, and many HSAs have begun preparations for them. In addition, the conduct of appropriateness reviews is a statutory requirement; thus, the Secretary has no authority to delete it. The Secretary also notes that appropriation levels for the HSAs have risen in the last few years and he does not expect them to be reduced.

Several commenters noted the problems the HSAs have experienced in completing acceptable Health Systems Plans ("HSPs") and wondered how it is reasonable to expect such agencies to succeed in accomplishing quality appropriateness reviews. The Report of the House Committee on Interstate and Foreign Commerce (H.R. Rep. No. 93–1382, cited above, at p. 65) that accompanied the National Health Planning and Resources Development Act of 1974 noted that, "Good planning cannot be accomplished without an analysis of community needs, and how what it has already compares with those needs * * * either excesses or deficiencies * * *" The Secretary sees the appropriateness review function as integrally tied to the plan development function of each HSA. As the HSPs and Annual Implementation Plans ("AIPs") described more specifically resource needs and deficiencies, appropriateness reviews will become less burdensome. Departmental staff have noted that a number of initial HSPs have incorporated appropriateness reviews of some institutional health services.

One commenter recommended that the work program require specific information on the budget and staff resources to be used for appropriateness reviews. While the Secretary intends to monitor carefully the use of resources for this function, he feels that such a requirement would constitute overregulation of HSAs.

Some commenters were concerned about the apparent lack of experience of health planners in the delivery of health services, and the lack of information available to make reasoned judgments in areas such as pediatric services. The Secretary believes that judgments can be made by those who have not directly participated in the delivery of a service. In addition, providers of services and consumers are on project review and plan development committees of most HSAs. The Secretary believes that the professional expertise present in these committees will benefit the appropriateness review process. Additionally, appropriateness reviews, as well as other HSA activities, are conducted through a process in which the public, including health providers, is invited to participate. The Department

has issued detailed guidelines on the acquisition, analysis, use and development of data for health planning. The Secretary believes, therefore, that with consumer and provider involvement and with technical assistance from the Department, planning agencies can make fair and technically accurate findings on the appropriateness of services.

Many comments addressed the impact of appropriateness review on the providers of institutional health services. One commenter was concerned about the impact of reviews on the ability of providers to plan long term capital investments which might be judged inappropriate over the short range. This concern had been brought to the attention of Congress during hearings on the bills which were to become Pub. L. 93–641, and to the attention of the Department during the initial phases of developing these regulations. While the Secretary understands this concern, there is a statutory mandate for the conduct of these reviews. The Secretary encourages State Agencies, HSAs, and providers of institutional health services to work together in planning new services and the expansion of existing institutional health services to assure that they are needed by the residents of the health service area and the State and that they will be appropriate over the short range or immediate planning horizon. This does not guarantee that the emergence of new technology or unforeseen changes in demographics will not cause the service to be inappropriate at some future date.

Several commenters expressed concern that findings of inappropriateness would deter institutions from expanding. Appropriateness reviews are not intended to duplicate the activities of existing licensing and accreditation organizations. If a determination is made that the provision of that service is inappropriate for a particular institution, it might be inconsistent to grant a certificate of need or approve reimbursement under section 1122 of the Social Security Act, so as to permit the expansion of the inappropriate service. Other services could, of course, be expanded in accordance with the State's certificate of need program and section 1122 agreement with the Secretary.

Another commenter expressed concern that rate setters and third party reimbursers may use appropriateness review findings in making reimbursement decisions. Realizing the impact of these sanctions on providers, she urges providers, planners, and third party payors to work together to correct any situation found inappropriate.

One commenter expressed concern that appropriateness review would have a negative impact on the long-term care industry. The Secretary does not anticipate that appropriateness review will have a negative impact on any particular segment of the health care industry.

Numerous comments addressed the impact on providers of submitting data to State Agencies and HSAs for appropriateness reviews. To avoid duplication, these suggestions, while of general applicability, are discussed below in the specific section dealing with data (§ 123.603(c)).

Comments on Specific Portions of the Regulations

Sections 122.501 and 123.601 Definitions

These sections include definitions of appropriateness, areawide reviews and the services which are to be covered by appropriateness reviews. The comments on these sections were quite extensive and tended to fall into three categories: those which (1) requested further clarification of "appropriateness review"; (2) asked for clarification of the term "areawide"; and (3) questioned the definition of "existing institutional health services."

With respect to the proposed definition of "appropriateness," a few commenters believed that HSAs should be allowed to define appropriateness, although the vast majority felt that the regulations should define appropriateness more completely and specifically to prevent arbitrary and capricious decisions by local planning agencies. A few commenters suggested that "appropriateness" could be clarified by describing in greater detail the six characteristics agencies are to consider in developing criteria, i.e., availability, accessibility, acceptability, continuity, cost, and quality. Another commenter felt the need for elaboration on how planning agencies should weigh each of these six characteristics in making the "appropriateness" determinations. Finally, one commenter asked whether the certificate of need criteria (42 CFR 123.409) should be applied in the appropriateness review process.

The Secretary believes that it is of paramount importance to retain considerable flexibility in the way HSAs and State Agencies are able to conduct reviews and to relate these reviews to their other health planning responsibilities. Therefore, the proposed rules set forth only those minimal requirements which the Secretary considers necessary to achieve compliance with the statute and to insure an adequate level of coordination between HSAs and State Agencies. Appropriateness review is not only a logical outgrowth of the plan development process, but also it clearly has a regulatory aspect to it in that in all likelihood appropriateness review findings will influence other project review decisions.

Thus, the Secretary feels that further clarification of the term "appropriateness" is not desirable. The Guidelines for the Development of HSPs and AIPs, as well as other technical assistance materials, provide additional guidance on what agencies should consider within the six categories.

With respect to the definition of the term "areawide review," one commenter suggested that the definition be expanded to include contiguous areas, particularly in large metropolitan centers. The Secretary believes that while expanded areawide reviews may be desirable, they should not be required by regulation, since they would require local planning agencies to conduct reviews in areas outside of their jurisdiction. The Secretary strongly recommends, however, that HSAs governing contiguous areas with overlapping institutional service areas develop mechanisms for sharing information about institutions and services as part of an appropriateness review. He also calls attention to § 123.607(a)(7), which requires that consideration be given to the special needs and circumstances of those entities which provide a substantial portion of their services to individuals who do not reside in the health service area.

A second respondent requested that it be made clear that the planning agencies in conducting areawide reviews are not precluded from reviewing services on the basis of areas which are smaller or larger than an HSA's health service area. The Secretary notes that there may be circumstances where larger or smaller areas are proper, depending on institutional service areas, service areas for types of services (especially tertiary care services), and available data. Because of the wide local variations in these matters, the Secretary does not prescribe any one approach in regulation, believing they can best be addressed by specification of service and planning areas in HSPs and AIPs and by agency adoption of review criteria which address service area differences.

Finally, several commenters asked for clarification of the relationship between

areawide reviews and institution-specific reviews. One commenter suggested that the term "institution-service-specific reviews" be used to emphasize that the review is directed toward the service, and not the institution. The Secretary wishes to emphasize that the distinction between areawide reviews and institution-specific reviews was to be the nature of the findings, and not necessarily the techniques of analysis or data requirements for performing the reviews. For that reason, the term "institution-specific reviews" has been deleted as misleading, and the description of the two types of findings which may result are dealt with in the definition of "areawide reviews." Comments on required levels of review are discussed in this Preamble under § 122.503 and § 123.603, *"Appropriateness review work program."*

Other comments questioned the definition of the phrase "existing institutional health services" or asked that the definition be expanded to include services provided through community mental health centers, home health agencies, and alcohol and drug abuse treatment centers. The NPRM incorporated by reference the definition of institutional health services as it appears in the regulations governing reviews of new institutional health services (42 CFR 122.301). This definition includes services provided by HMOs and other health care facilities. The Amendments to the Health Planning Act contain a new definition of institutional health services which was effective on enactment and is included in these regulations. The statute now specifies that the services required to be reviewed include, at a minimum, those provided through private and public hospitals, rehabilitation facilities, and nursing homes, but that the Secretary may, by regulation, include other facilities. The Secretary has chosen not to expand the regulatory definition at this time. Rather, he will explore issues related to coverage in the proposed revisions to the certificate of need regulations which will be issued in the near future. At that time, the Department will entertain comments on whether "institutional health services" should be limited to facilities identified in the statute or whether coverage should be broader. In the interim, the Secretary encourages agencies to review all health services regardless of their setting and expects that any health services not reviewed will be addressed in the agencies' plan development activities, since they are part of the community's health system.

Sections 122.501 and 123.601 have been revised to include among the "existing institutional health services" which are subject to review, those services which will be offered during the 12 months following an appropriateness review. This will result in more complete appropriateness reviews.

Numerous commenters questioned whether the term "all existing health services" includes services provided through Federal health institutions. Many argued that the exclusion from review of Federal facilities (Veterans Administration, the Public Health Service, Department of Defense, and Indian Health Service hospitals) would present a less accurate view of the health care system's characteristics. The Secretary feels that a thorough review of the health care delivery system requires a review of the availability of Federal services to any population group which also is served by non-Federal services, and consideration of the impact of Federal services on the non-Federal system. Accordingly, the Secretary has chosen to submit services provided through the nine Public Health Service Hospitals to appropriateness reviews as well as other reviews. Departmental staff are working with other Federal agencies to encourage them to share data and plans with HSAs and SHPDAs. The Secretary notes, however, that States may not regulate Federal facilities, and that any regulation which States might choose to attach to appropriateness reviews would not apply to Federal facilities, and that any findings of inappropriateness would have the effect only of recommendations. Nonetheless, the Department will be encouraging the Federal facilities to cooperate with HSAs and State Agencies in supplying necessary operating data and statistics which are relevant in the review of the appropriateness of services.

Several commenters suggested that the review for appropriateness should include high cost services which are provided outside of institutions subject to review but which are made available to patients of these institutions (e.g., CT scanners located in physicians' offices). The Secretary agrees that agencies should attempt to review all existing institutional health services regardless of the settings in which they are located. He points out that the definition of "institutional health services" at Section 1531(5) of the Act includes health services provided *through* covered facilities, and that this provides a basis for review of some of these services.

A number of commenters suggested that in order to avoid confusion between planning agencies and providers, the terms "affected persons," and "directly affected persons," should be defined by the Secretary. The Secretary notes that the proposed rules defined these terms by reference to Subpart D of 42 CFR Part 122 and Subpart E of 42 CFR Part 123. However, because these terms as referenced are not entirely applicable to appropriateness reviews, (i.e., references are to "proposals"), they have been modified and placed in these regulations at § 122.505(a)(1) and § 123.605(a)(1). Furthermore, since the distinction between "affected persons" and "directly affected persons" is a small one and has little substantive impact on the conduct of appropriateness reviews, the term "affected persons" has been used for both categories.

Sections 122.503 and 122.603 Appropriateness Review Work Program

Sections 122.503 and 122.603 require HSAs and State Agencies to submit annual work programs to the Secretary which describe their plans for assuming the appropriateness review function and for performing appropriateness reviews on a continuing basis.

In order to address fully the issues raised, the comments received on these sections have been divided into six separate categories, as follows: (1) The coordination of the reviews between State Agencies and HSAs; (2) the timing and criteria for Departmental review; (3) the role of the State Agencies as to definitions, priorities and schedules; (4) the collection, transfer, and use of data; (5) the initiation of reviews; and (6) the level of reviews.

Coordination

Some commenters felt that the amount of coordination required by this regulation is excessive and will tend to hamper the expeditious development of a satisfactory program for performing appropriateness reviews. However, others suggested that additional coordination is necessary, including coordination with contiguous HSAs and with HSAs sharing common standard metropolitan statistical areas. And finally, a number of commenters suggested that a greater degree of coordination ought to be specified with provider groups in the health service areas involved.

The Secretary concurs that the additional coordination suggested would be of value in many instances. However, he believes that it is unnecessary to require this by regulation inasmuch as coordination between contiguous HSAs and HSAs sharing standard metropolitan statistical areas has been

dealt with in other regulations (at 42 CFR 122.107(c)(10), (11), and (12)) and Health Systems Agency Application Guidelines previously issued by the Department (November 1978) which apply to appropriateness review as well as to other agency functions.

One respondent asked how the State Agency should handle appropriateness review until all of the HSAs in the State are conducting appropriateness reviews. The Secretary recognizes that agencies will be developing their capabilities to conduct appropriateness reviews at different rates, and the local circumstances will require different strategies on the part of State Agencies which intend to proceed in the absence of recommendations from all HSAs in the State. There is no single answer to this question, and the actual response of State agencies to their situations rests with them; however, the Secretary does suggest that State Agencies review carefully their proposed strategies with members of the public, with their Statewide Health Coordinating Councils (SHCCs), and with all HSAs in the State regardless of whether those HSAs are able to assist them in appropriateness review at the time. Once a newly capable HSA is prepared to make its recommendations, the State agency should be willing to reevaluate any of its own previous findings and conclusions. Since appropriateness reviews are meant to be repeated every five years at the State level, and appropriateness review findings must be reconsidered when good cause is shown, both State Agencies and providers should be prepared to respond more than once to the same issue. The ability to reevaluate the appropriateness of any existing institutional health service in response to system changes should become an integral part of HSA and State Agency programs.

A commenter was concerned about the duplication of HSA and State Agency staff and volunteer time and suggested that whenever possible, one agency should take primary responsibility. The Secretary agrees that wherever feasible the planning agencies ought to assist one another in performing their respective functions, and that if arrangements can be made which satisfy the agencies involved, staff and volunteer time can be applied to reviews in a fashion which reflects State and local circumstances. He notes, however, that each agency must always retain its prerogative to reach its own conclusion.

Departmental Review—Timing and Criteria

One respondent questioned how the Department would judge the capability of agencies to carry out appropriateness review solely on the basis of their work programs. The Department's judgment will be made on the basis of many factors, such as their performance in other activities, in addition to the quality of agency work programs. Agencies which have shown that they are capable of carrying out an approved work program will find the Department willing to accept that past performance in combination with a satisfactory appropriateness review work program as sufficient evidence of their ability to do these reviews. Agencies whose past performance indicates that they frequently miss deadlines or fail to achieve adequate quality in essential actions will find that the Department requires evidence more convincing then a minimially satisfactory work program.

It was suggested that the regulations specify when agencies will be required to submit their work programs to the Department and that the agencies should be required to publish their appropriateness review work program in advance to obtain public comment. The Secretary agrees in general that greater public involvement at this point is warranted. In the NPRM neither HSA amendments to their work programs (for the performance of appropriateness reviews) nor State Agency changes to the State Administrative program were required to be subjected to public scrutiny prior to their adoption. The lack of a requirement for advance public comment on work program amendments at the HSA level is less of a problem than at the State Agency level because: (1) The requirements for adoption of procedures and criteria assure public participation for this element of reviews, (2) all meetings held by an HSA for whatever purpose are open to the public, and (3) it is not the HSA but the State Agency which prescribes the definitions of services to be reviewed, the priorities for reviews, and the schedule for reviews. Accordingly, no requirement for public comment on the HSA work program has been added. The State Agency lead role in coordinating appropriateness reviews poses a more difficult situation because there is no opportunity for public review of the State Agency's decision regarding the administrative framework for reviews. Accordingly, the regulations now require that the State Agency submit to the Secretary, with the work program, evidence that the public was afforded an opportunity to comment on it, and a summary of the comments.

One respondent suggested that the work program should allow for the development of review criteria over a number of years rather than a single deadline for the development of all criteria. The Department agrees, and § 123.503(a) has been amended to indicate that the work program developed by the health systems agency must "specify the steps to be taken to develop" procedures and criteria. This revision is intended to permit agencies to develop applicable procedures and criteria over time, rather than a one-time effort. The Secretary points out, however, that applicable procedures and criteria must be adopted prior to a review.

Sections 122.503(b) and 123.603(b) Lead Role of State Agency With Respect to Definitions, Priorities and Schedules

These regulations give the State Agency a lead role in defining the services to be reviewed and in establishing the review priorities and schedules. In addition, they establish that it is the State Agency's responsibility to collect and transfer data used in appropriateness reviews. However, in the event that a State Agency does not assume leadership, a provision has been added which would still enable HSAs to proceed with their reviews. The proposed regulations placed the lead role in the State Agency, which, after consultation with HSAs and the SHCC, would: (1) Define services to be reviewed, (2) establish review priorities, and (3) establish review schedules. The Secretary solicited public comment using the SHCC as a mediator when HSAs and the State Agency could not agree on these matters.

Although a number of those who commented on this issue, including many HSAs, endorsed this State Agency lead role provision, a greater number expressed concern because: (1) It preempts HSA prerogatives, and (2) in practice, it puts some HSAs in a difficult position because of review timing conflicts. It was also felt to be inconsistent with the intent of the Act, which the commenters felt emphasizes a more balanced HSA and State Agency approach. The Secretary believes, however, that the effectiveness of appropriateness review is largely dependent on coordination, and that designation of a leadership role is necessary. He has chosen the State Agency to provide this leadership, but notes that the responsibility for

developing procedures and criteria remains with each reviewing agency.

A great number of comments dealt with the proposed role of the SHCC as a mediator in the resolution of differences between HSAs and State Agencies. Some commenters felt that the SHCC ought to have a much stronger role, while others indicated that it would be overwhelmed with the volume of coordination required in States where there are many HSAs. Others thought the staff of the SHCC would have a conflict of interest, since as a rule it is also the State Agency staff. Additionally, some commenters suggested that the representatives of the HSAs on the SHCC would be in a position of conflict.

Since various strategies to health planning are being pursued, no single approach could be expected to work equally well in all of the States. Therefore, the Secretary has chosen to retain the flexible provisions of the proposed rules with respect to the SHCC's role in this process, recognizing that there will be differences in the effectiveness of the SHCC in mediating State Agency and HSA differences. The Secretary is confident that both agencies will realize the need to work closely with the SHCC to assure that it will have a positive role in resolving issues which may arise. The Department intends to develop technical assistance materials which will describe the roles that agencies are to play in the various States.

A number of commenters expressed concern that the review timing provisions of the proposed rules would allow a State Agency which is reluctant or not ready to proceed with appropriateness reviews to retard an HSA's ability to do so or to delay inordinately reviews of controversial services. Others pointed out that the statutory requirement for HSAs to complete their first reviews within three years of full designation, along with the fact that very few State Agencies have been fully designated, present potentially serious timing problems.

This timing problem stems primarily from some unavoidable overlapping of responsibilities among reviewing agencies during their early years of development, and from differences in the receipt of full designation status by the HSAs and State Agencies. The Secretary believes that this situation will improve over time.

In addition, the regulations now permit HSAs to develop their own definitions, priorities, and schedules if the State Agency has failed to do so within six months of the publication of these regulations. See § 122.503(b)(2). In this event, coordination will be achieved through requirements for common service definitions and schedules for reviews among HSAs in a given State and for giving priority to reviews of the services specified in the National Guidelines.

Review schedule may be established so that health systems agencies can complete their reviews prior to the deadlines established in the State schedule, rather than exactly on the dates set forth. This flexibility will enable different HSAs in a State to concentrate on different issues. Any schedule developed, whether by the State Agency or by the HSAs collectively, should be flexible enough to allow HSAs to proceed with certain appropriateness reviews as long as they complete them prior to the date set forth in the agreed schedule. A few comments suggested that the regulations define services which are subject to review in order to avoid unnecessary debate at the State level. The Secretary intends to assist agencies in their definitions of services and will provide technical assistance for that purpose. However, it would be inappropriate for her to define specifically the services covered, since there are many and varied State laws which provide long established definitions of services. Therefore, the Secretary has chosen not to specify and define the services which will be covered. She does, however, expect that agencies will (at a minimum) specify definitions for those services which are identified in the National Guidelines for Health Planning.

Another respondent suggested that the priorities among services should be tied in to those identified in the HSA's annual implementation plan (AIP). The relationship of the objectives of the AIP to the priorities of services which need to be reviewed for appropriateness is one which will vary from HSA to HSA. Further, the priorities will then be negotiated with the State Agency and other HSAs in the State. However, the Secretary believes that the HSP and AIP provide the analytical bases for this function and as a result that services which have been analyzed in the HSP form the basis for services selected for appropriateness review. The Secretary also agrees that in establishing the AIP and the appropriateness review work program, agencies should carefully examine the linkages between these two functions, including an assessment of staff time involved and a review of program priorities as they relate to the effectiveness of overall implementation of agency goals and objectives. It is possible, for example, that on the basis of an areawide appropriateness review the agency might determine that some aspect of the service is inappropriate, and subsequently and immediately decide that the issue is important enough to merit inclusion in the agency's AIP.

Section 123.603(c) Data

The largest number of public comments received respecting coordination matters concerned data issues. Discussed below are the most important and most frequently cited issues.

Commenters questioned the authority of State Agencies and HSAs to require data from appropriateness review purposes, citing both practical and legal problems. For example, alluding to lack of authority for sanctions, several commenters asked what would happen if providers simply refused to supply the required data. A commenter from one State noted that there is no existing State legislation which would "permit the State Agency to require institutions to submit such data." Another suggested that the State Agency be required to document its State legislative authority for requiring data submission for appropriateness review purposes on grounds that "State Agencies can perform only such functions as they are by State statute authorized to perform." Another stated that providers should be able to challenge the need for required data. Others said that the reviewing agency should justify its need for certain data and that an institution should not be required to submit certain information to the reviewing agencies if it could show that it must report that or similar information to other Federal or State Agencies. While one commenter stated that HSAs in particular do not have authority under terms of the Act to collect data, and that that task should be left to the State Agency, others suggested that HSAs should be able to collect data independently. Another recommended making a provision for submitting proprietary data in summary form as a protection against public revelation of competitive information. Finally, an opinion was offered that data would be required in such specificity that the effect of the appropriateness review function would be harrassment of institutions and public revelation of management prerogatives.

The Secretary is aware of the practical and legal problems associated with performance of appropriateness reviews, including problems of data collection, transfer, and use. Nevertheless, the function must be performed under the terms of the Act, which establishes data responsibilities

in the State Administrative Program in section 1522(b)(7) and in mandated review procedures, 1532(b)(3) of the Act. The former section requires that as a prerequisite for designation and funding renewal a State Agency must make certain operational provisions respecting data acquisition and use, including a requirement that "providers of health doing business in the State make statistical and other reports of such information (related to health and health care) to the State Agency." Also, while the Secretary agrees that State enabling legislation for securing data is desirable, she realizes that the advent of such authority is not imminent in every State, and urges States to use whatever means are available to obtain the data required for their functions.

While the State Agency must require certain data for use in these and other reviews, which data will be shared with the HSAs in the State, HSAs can go beyond the State requirements and request additional data from providers. However, they may lack the authority to require that it be submitted. The Act and these regulations require HSAs and State Agencies to use exisiting data sources before collecting new data and to coordinate data collection with the Cooperative Health Statistics System. Secretarial approval must also be obtained before any new data systems can be established. To avoid any duplicative data collection requirements, the Department will coordinate the implementation of these data provisions with that of the Medicare-Medicaid Anti-Fraud and Abuse Amendments (Pub. L. 95–142) data requirements. The Department has issued data guidelines which provide technical assistance to agencies in developing a cost-effective empirical base for planning and regulation. In addition, to prevent numerous requests during the course of a review, the Secretary has added language to § 122.505(a)(3) and § 123.605(a)(3) to require that agencies may not demand information of a person subject to review unless it is prescribed and published as being required. She also wishes to call attention to the Department's policy (at 42 CFR 122.107(c)(1), and "Guidelines for the Acquisition and Use of Data Under Pub. L. 93–641," June, 1978, p. 2.4) that new data systems are not be established without Secretarial approval and that all reasonable efforts be made to avoid duplicative data requirements.

Other commenters registered the following compliants as to the data provisions: (1) The lack of availability and/or existence of the kind of data necessary for determining the appropriateness of services; (2) the inability of reviewing agencies to effectively analyze and use data, because of limited agency staff expertise and experience, heavy staff workload, etc. and (3) the significant adverse cost implications for both providers and patients with little or no increased benefit in improved health care. The Secretary is aware of such problems but does not believe them to be so overwhelming as to negate the mandate to perform the reviews. She agrees that some additional costs may be incurred by providers and passed on to consumers, but she believes that the potential benefits to be derived from appropriateness review as discussed above reasonably outweigh the costs incurred. The Secretary does not wish to impose additional requirements on the agencies relating to the costs of providing data.

A number of commenters were concerned about the interpretation of data in the course of a review. One suggested starting with pilot reviews which would identify data used problems. Another suggested that agencies should develop and test sample data in limited situations to gain experience about the usefulness of those data, time required to conduct reviews, etc. Several commenters repeated or endorsed the requirement that notices of the kinds of data to be required be published in advance. There was considerable concern that data requirements not be duplicative. Several commenters advocated a more prominent role for the SHCC in data collection activities including approval of the reviewing agencies' data requirements. The Secretary has not adopted these suggestions, believing that to do so would be to overregulate in the absence of experience. She does, however, offer them to the planning agencies for their consideration.

Several commenters advocated strong coordination between State Agencies and HSAs respecting data. The Secretary concurs and calls attention to similar requirements respecting other key elements of reviews. Some commenters stated that in establishing data requirements State Agencies must take into account different review criteria which precipitate various data needs, and that limitations of data would necessarily affect review outcomes. The Secretary concurs with both statements, but she believes that like many of the problems cited above, these difficulties will be ameliorated with the passage of time and the expansion of data resources.

Other commenters raised the problem of the time required to obtain and forward data to the reviewing agency. Some advocated that such time not be included in the review period. The Secretary notes that data may be gathered well before reviews begin, and that agencies may wish to begin collecting it as soon as schedules are established for reviews. A few commenters indicated that data requirements should be allowed to vary according to the type of service reviewed and purpose of the review. The Secretary believes this approach is consistent with the regulations and the general philosphy of the appropriateness review program.

One commenter suggested that State Agencies and HSAs submit their data requests to providers simultaneously. The Secretary does not believe such requirements should be established in regulations but encourages that approach, see § 122.505(c) and § 123.605(c). While the suggestion that agencies requesting data be interviewed as to its intended use is probably not time and cost effective, the Secretary agrees that intended uses of data should be made clear by requesting agencies. Details of doing so are left to agency discretion and forthcoming guidances.

Many commenters expressed concern about the inability of agencies to collect data in the absence of sanctions for providers who refuse to meet the agencies' requests. The Department has been aware of this concern during the process of formulating these regulations; however, it has chosen not to go beyond the statute and specifically require sanctions for noncompliance with data requests. Rather, it relies on the individual States to decide whether or not sanctions are necessary and to develop them in their State Administrative Program if needed. The Secretary, however, urges both providers and planning agencies to cooperate in determining data requirements and the provision of required data so that these sanctions are not necessary.

Finally, several comments were received which indicated concern over the confidentiality of certain financial and medical data. Any data collected by a State Agency or HSA must be made available to the public under section 1532(b)(10) of the Act. The Secretary understands this concern, however, and has asked HSAs and State Agencies not to request data that have confidentiality or privacy requirements associated with them.

Section 123.603(d) Initiation of Appropriateness Reviews

One commenter asked the meaning of "initiating appropriateness reviews." The Secretary intends for State Agencies to develop work plans which call for areawide appropriateness reviews for some services to begin no later than the dates indicated in the regulations (§ 123.603(d)). If the process were allowed to be postponed any further, it would be very unlikely that all of the required appropriateness reviews could be completed within the total time available. This means, therefore, that definitions of at least some services to be reviewed and a schedule for their review will have to be worked out rapidly. The Secretary recommends that agencies give immediate consideration to early scheduling and definition of services which are dealt with in the National Guidelines for Health Planning.

Some commenters suggested that the initiation of appropriateness reviews be delayed until State Agencies and HSAs are fully designated in a State. Others suggested that the work program of the State should be developed first, and then the HSAs could develop their programs. Another commenter recommended that a common timeframe be developed for all agencies in the State which would be mandatory and which might be specified by regulation. Because of the statutory requirements, the Secretary has retained the time requirements specified in the proposed rules.

Sections 122.503(d) and 123.603(e) Levels of Review

When the NPRM was drafted, there was much discussion within the Department concerning whether HSAs and State Agencies should be performing institution-specific appropriateness reviews. While there were many in favor of requiring these reviews, others felt just as strongly that such reviews would alienate providers, require more sophisticated and detailed data, and make significant demands on planning agencies' manpower and time resources.

Numerous comments have been received on this issue. Some commenters objected to institution-specific reviews. Some questioned the ability of planning agencies to do the reviews, arguing that current staffing and funding levels of planning agencies are not sufficient to undertake the potentially enormous work load associated with these reviews. Some also suggested that agencies gain more experience before performing institution-specific reviews or that areawide reviews be done first in order to ensure an adequate aggregate data base before embarking on more specific reviews. Additional commenters expressed the view that the statute does not authorize institution-specific reviews and therefore, the Department has no authority to require them.

Some of the commenters pointed out that the distinction between areawide review and institution-specific review would become meaningless in some instances, particularly in the review of services which are provided by institutions in rural areas. Since all of the HSA's data and records must be made available to the public, there is no way to preclude public knowledge of the locations (hence, in a sparsely populated area, the institutions themselves). Moreover, one commenter suggested that the service area being considered for areawide review should be tailored to the type of service being reviewed. That is, if the services are highly sophisticated and provided by only a small number of institutions within the entire health service area, then it may be appropriate for purposes of that review to use the entire health service area as the "area" for conducting areawide review. On the other hand, at the secondary and primary care level, smaller service areas should be used in order to make the results of the review useful in the conduct of all the agencies' functions. Finally, one respondent indicated that a finding of inappropriateness on an areawide basis might be construed as a comment against all providers of that service within the area.

The Secretary wishes to reiterate that the principal distinction between areawide reviews and institution-specific reviews as defined in the proposed regulations was intended to be in their respective findings rather than the techniques of analysis. Areawide reviews require much of the same data and analysis as institution-specific reviews but were not to involve institution-specific recommendations or findings. In any event, the final regulations clarify that it is in the findings and recommendations that agencies may address specific institutions.

A large number of commenters supported reviews which would result in institution-specific findings. Reasons cited included: (1) Possible links to rate setting agencies, (2) areawide reviews already duplicate plan development activities, (3) institution-specific findings would be much more effective in eliminating excess capacity, and (4) areawide findings of inappropriateness could penalize all providers in the aggregate rather than those for which difficulties actually exist. The Secretary agrees that appropriateness reviews which result in institution-specific findings may be quite helpful. However, he has chosen not to require these findings at this time but to allow agencies to make institution-specific findings at their option as their capabilities and resources permit.

Many comments were received from provider organizations recommending that HSAs and State Agencies be precluded from conducting institution-specific reviews. Many of these commenters expressed the view that such a review is not authorized by the statute. Nearly all, including some planning agencies, indicated that they believed that HSAs and State Agencies would be unable to handle these reviews.

The Secretary emphasizes that under the statute, agencies are to review all services although the nature and depth of each review is best left to the judgment of the agencies. The Secretary agrees that in States where rate setting activities are carried out, HSAs and State Agencies should be sensitive to the need for a fairly high degree of specificity in their findings. Although he has not chosen to require institution-specific findings, he expects that planning agencies and rate setting agencies will work together to support one another's activities toward that end. Whether or not rate setting agencies are present, the Secretary strongly recommends that agencies convey any findings of inappropriateness in a fashion which indicates that the findings do not necessarily apply to all providers of that service. The Secretary feels that agencies must be aware of the problems associated with using vague criteria and standards to render decisions that may be viewed as regulatory in nature.

One correspondent raised the question as to whether the 180-day review period was mandatory for both areawide reviews and institution-specific reviews. The commenter felt that institution-specific reviews would probably take longer than areawide reviews. The Secretary points out that since the regulations now require all appropriateness reviews to take place within the 180-day review period, regardless of the nature of the findings (i.e., areawide or institution-specific), the specification of two time periods is not necessary.

Numerous commenters suggested that HSAs and State Agencies would be unable to complete their reviews of *all* existing institutional health services within the required time. The Secretary

agrees that this provision will be difficult to implement, but points out that the time limits for completing reviews of all services are statutory and cannot be waived. He notes, however, that the definition of services rests with the State Agencies, in consultation with the HSAs, and that this mechanism should allow agencies to collapse subcategories of services so that resources may be devoted to those specific services which merit the most attention. Agencies should concentrate initially on the services for which the National Guidelines for Health Planning have been issued.

Several commenters recommended additions to the list of requirements for HSA and State Agency work programs for appropriateness review. These include suggestions that: (a) Work programs specify the new data which must be obtained from providers as well as those which can be obtained from secondary sources, (b) work programs include a description of how agencies intend to coordinate their appropriateness reviews with their plan development and project reviews, (c) a section be added to encourage the participation of task forces in appropriateness review and to advise agencies on the development of procedures and criteria, (d) work programs describe the agency budget and staff resources that will be applied to the appropriateness reviews, and (e) the State Agency document its authority for conducting appropriateness review. The Secretary will consider these suggestions if and when requirements for work programs are revised, but finds it unnecessary to do so at this time.

Finally, several editorial improvements have been made to this section of the regulations as a result of comments received. These include the following:

Section 123.603 (a) has been revised to clarify that the review procedures and criteria which a State Agency is required to develop and apply are those which that State Agency will be applying; thus these do not govern HSAs in that State. Sections 123.603(a) and (c) have been amended to indicate the need for coordination with agencies in *all* of the States (as opposed to *both* States) where health service areas are shared by more than one State.

Sections 122.504 and 123.604 Adoption and Public Notice of Review Procedures and Criteria

One commenter emphasized that all review procedures should be made known to providers subject to appropriateness review prior to the initiation of a review. Sections 122.305 and 123.406 of 42 CFR provide ample opportunity for providers (as well as consumers) to becomes aware of appropriateness review procedures prior to their initiation.

Another commenter suggested that State Agency appropriateness review procedures should be approved by the SHCC so that consumers and providers would have direct input into decisions affecting the health care delivery system. While the intent of Title XV of the Act is to involve consumers and providers in these decisions at the local level, there is no statutory authority for the SHCC to approve or disapprove the State Agency's appropriateness review procedures. However, residents of a State may comment on the State Agency's proposed procedures under 42 CFR 123.406, as may the SHCC. Furthermore, SHCCs are required to advise the State Agencies generally on the performance of their functions.

Sections 122.505 and 123.605 Health Systems Agency and State Agency Procedures; General Comments

One commenter suggested that these procedures be expanded to enable use of a screening process in setting the priorities of services to be reviewed or in defining the services subject to review. While the Secretary realizes that the HSAs and State Agencies may elect to perform a screening process for this purpose, it is not expected that a screening process would result in recommendations and finding as to the appropriateness or inappropriateness of a specific service. If a recommendation or findings were to be made as a result of a screening process, these procedures would be applicable. It should be pointed out that there are two ways in which State Agencies and HSAs have an opportunity to perform "non-substantive" or "non-intensive" reviews. The provisions found in § 122.505(b) and § 123.605(b) permit health planning agencies to adopt review procedures which, while meeting all the requirements of § 122.505 and § 123.605, may vary according to the type of health service being reviewed. In addition, § 122.506 and § 123.606 permit the agencies to seek an exception to the requirements of § 122.505 and § 123.605. One possible use of this latter provision is for an HSA or a State Agency to propose alternative procedures which it will utilize in the case of services defined by the HSA to require a less intensive or expedited review.

Sections 122.505(a)(1) and 123.605(a)(1) Notification of the Beginning of a Review by Health Systems Agencies and State Agencies

A number of commenters suggested that the written notification should include what service is to be reviewed, the review authority of the agency (including citations to the statute and regulations), review procedures and criteria, the work program, and the review timetable. While the Secretary agrees that this information should be made available to providers and persons subject to appropriateness review, in the interest of allowing agencies flexibility in establishing procedures beyond the minimum statutory requirements, he has not chosen to require this of the agencies at this time. Furthermore, review procedures and criteria are available to the community through the agencies' process for adoption and public notice of procedures and criteria as required by §§ 122.504 and 123.604.

One commenter asked clarification on when notification was required and suggested that it be required 30 days before the initiation of a review. Another writer asked for a specific definition of the term "initiate," as a review could be judged to have been initiated at any time from its initial planning until its implementation. The Secretary agrees that providers need ample advance notice of the beginning of a review, but he wishes to allow planning agencies flexibility to establish procedures to suit local circumstances.

Another commenter suggested that a newsletter or a legal notice in a newspaper of general circulation could serve to notify affected persons of the beginning of a review. In view of the demands that appropriateness review will place on HSAs' and State Agencies' resources, the Secretary has added language to §§ 122.505(a)(1) and 123.605(a)(1) to permit agencies to provide written notification to members of the public through newspapers of general circulation in the area and other public information channels. However, notification to all other affected persons shall be by mail (which may be as part of a newsletter).

Sections 122.505(a)(2) and 123.605(a)(2) Health Systems Agency and State Agency Schedules for Reviews

In addition to the previously cited comments on schedules for and the timing of reviews, a number of commenters questioned the Secretary's authority to establish procedures not specified in the statute. When the proposed regulations were drafted, careful consideration was given to the

problem of the amount of time for conducting an appropriateness review. The Secretary decided that the statutory time limit was insufficient because of the complexity of these reviews and extended the time limit under section 1532(a) of the Act. The Secretary also views this matter as falling within his general rulemaking authority under the Act.

One commenter urged that there be a provision for deferring a scheduled review under extenuating circumstances. The procedures in these regulations are minimal requirements, and agencies may adopt procedures beyond those required in this subpart. The Secretary encourages agencies to consider concerns such as this one when developing and adopting their review procedures, and points out that agencies may wish to define "to the extent practicable" to cover just such circumstances.

Another commenter urged that there be a mechanism for extending the review period, upon request and for good reason. Sections 122.506 and 123.606 permit HSAs and State Agencies to request an exception to the requirement that they use review procedures which meet the requirements of §§ 122.505 and 123.605; a mechanism of this sort may be proposed in such a request.

On the other hand, one commenter suggested deletion of the phrase, "to the extent practicable," as some agencies would routinely extend the review period. The Secretary notes that this phrase is derived from the statute and has determined in any event that an absolute limit on the time period for conducting these reviews is too rigid and would generate an excessive number of requests for exceptions under §§ 122.506 and 123.606.

Another commenter requested clarification on what activities take place in the 180-day review period. One commenter requested that the regulations specifically define and restrict the activities to be performed by the agencies in conducting these reviews. The Secretary believes that the regulations should allow sufficient flexibility for State Agencies and HSAs to implement this function consistent with other review and planning activities within the State or health service area. Therefore, he has chosen not to define further or restrict the agencies' activities in this regard.

Another commenter suggested that persons and institutions subject to review be given 30 days to submit data and that the 180 days should be counted from the date the materials are submitted. The Secretary believes that the review periods specified in the regulations provide adequate time for submission of data and performance of the review and has rejected this suggestion.

Another commenter suggested that the regulations should stipulate that more than one service may be reviewed simultaneously. While the Secretary does not choose to add language to the regulations as suggested, he does wish to indicate here that agencies may need to conduct simultaneous reviews of more than one service.

Several commenters recommended that State Agency reviews be sequential to those of the HSAs so that determinations regarding a specific service will be made within a reasonable time frame. In this regard, there is no language in the statute which mandates either a sequential or concurrent review by the State Agency. Although the Secretary believes that sequential reviews best permit State Agencies to consider HSA's recommendations, he has chosen not to require this result by regulation, leaving this to the State Agencies' discretion.

Sections 122.505(a)(3) and 123.605(a)(3) Submission of Information by Persons Subject To Review to Health Systems Agencies and State Agencies

The issues raised by commenters concerning the procedures for submitting data for appropriateness review have already been addressed in the section on data, above, at § 123.603(c).

Sections 122.505(a)(4) and 123.605(a)(4) Provision for Written Findings

One commenter recommended that the regulations should specify which parties should receive written notification of an HSA recommendation or State Agency finding, including the institutions offering the service under review, the State Agency, contiguous HSA's, and others upon request. Another commenter asked how the public will be informed about the HSA's and State Agency's recommendations and findings. Sections 122.505(a)(5) and 123.605(a)(5) require the HSA's and State Agencies to notify providers of health services and other persons subject to review of the status of reviews, findings made in the course of the reviews, and other appropriate information respecting the reviews. Section 122.5503(c) also requires the establishment of procedures for transmittal of the HSA's recommendations to the State Agency. Finally, §§ 122.505(a)(8) and 123.605(a)(8) require that the planning agencies give the general public access to all written materials pertinent to their reviews. Accordingly, the Secretary has concluded that no further notification requirements are necessary.

One commenter recommended that § 123.605(a)(4) be revised to require that a finding of inappropriateness made by a State Agency should be accompanied by (1) a detailed statement of the reasons for the finding, (2) the data and evidence upon which the finding was based, and (3) identification of which published criteria were not used in the review and the reasons why. Section 123.608(b) requires the State Agency to state in a finding of inappropriateness that the service has not met one or more of its established criteria and the ways in which the service failed to meet the criteria, including any that are beyond the control of the persons providing that service. The Secretary believes that this requirement will provide sufficient detail to the providers and the public as to the inappropriateness of a particular service. This does not preclude State Agencies from providing additional information to support their findings, and the Secretary encourages the agencies to do so to the extent practicable.

Sections 122.505(a)(5) and 123.605(a)(5) Notification of providers and other Persons Subject To Review of the Status of the Review

A number of comments was received requesting that this requirement be further clarified as to who should receive this notification, how frequently this notification is to be made, the substance of the notification, and the process for providing the notification. The Secretary does not wish to elaborate on this subparagraph through regulation. While planning agencies are required to notify only the providers of health services and other persons subject to review, they may and are encouraged to inform other providers and persons at their discretion. Furthermore, since §§ 122.505(a)(8) and 123.605(a)(8) require that the general public be given access to all written materials concerning reviews, the concerns expressed by the commenter are satisfied.

Several commenters suggested that State Agencies and HSAs notify providers of the service being reviewed of their interim recommendations and findings. Similarly, several commenters suggested that persons subject to review be provided an opportunity to respond to the HSA's recommendations and that this response be forwarded to the State Agency with the HSA recommendations. Again, the Secretary does not wish to restrict planning agencies in developing

their procedures through regulation. Rather, he chooses to allow these agencies flexibility in developing their procedures, to receive comments from providers and consumers through the public notice and adoption process and to modify these procedures to reflect local and State concerns.

Sections 122.505(a)(6) and 123.605(a)(6) Provision by Health Systems Agencies and State Agencies of Public Hearings in the Course of Agency Review and Hearings for Good Cause Shown

Several commenters suggested that public hearings should not be required during the course of the review while many others suggested that a public hearing be required for all appropriateness reviews. The Secretary notes that the statute requires that persons directly affected by a review be given the opportunity to request a public hearing in the course of a review. The Secretary believes that the present requirement is fair and equitable to all parties concerned.

One commenter requested that the regulations provide the procedures for conducting a public hearing. Planning agencies have already established procedures for conducting public hearings during certificate of need and new institutional health service reviews. These proceduree may be applicable to appropriateness reviews and should be adopted by the agencies with any necessary changes.

One commenter suggested that health systems agencies be required to post notices of hearings in public locations at the institutions providing the service under review. While the Secretary believes that the planning agencies have generally established effective mechanisms for notifying affected persons of a public hearing, he does urge the agencies to evaluate the adequacy of their procedures and to modify them as appropriate.

A large number of commenters urged that the procedures provide an opportunity for providers to appeal or ask for a reconsideration of an HSA recommendation or State Agency finding of inappropriateness. These commenters pointed out that even though there are no official sanctions attached to this function, there may be some impact on providers, and therefore, as a matter of due process, the provider should have an opportunity to appeal the finding. In addition, since the State Agency has a year to make findings after the HSA recommendations, providers are concerned that adverse recommendations will be public for a full year and they will have no formal channel through which to refute the findings. The proposed regulations called for hearings during the course of a review for persons directly affected at both the HSA and State Agency level. They also included a requirement that a State Agency provide the opportunity for a public hearing at which it would reconsider its findings if a person can show good cause for reconsideration. For purposes of this subparagraph, "good cause" has the same meaning as that in § 123.407(a)(8) of the regulations for review of new institutional health services.

This provision states that a request for a public hearing will be deemed by the HSA or State Agency to have shown good cause if it (1) presents significant, relevant information not previously considered by the agency, (2) demonstrates that there have been significant changes in factors or circumstances relied upon by the agency in reaching its decision, (3) demonstrates that the HSA or State Agency has materially failed to follow its adopted procedures in reaching its decision, or (4) provides such other basis for a public hearing as the planning agency determines constitutes good cause.

The Secretary has given careful consideration to these arguments. Accordingly, the regulations now provide for "good cause" hearings at the HSA level after a recommendation derived from a review which results in an institution-specific finding (§ 122.505(a)(6)) and also add a requirement for an administrative appeal after the State Agency finding at the request of any provider whose services have been found inappropriate in such a review (§ 123.605(a)(10)). Because these procedures tend to be expensive and time-consuming, he has decided to require that they be available only with respect to institution-specific findings.

Sections 122.505(a)(7) and 123.605(a)(7) Preparation and Publication by Health Systems Agencies and State Agencies of Regular Reports of the Reviews Being Conducted

Several commenters requested clarification of the term "regular." One commenter questioned the statutory basis for this requirement, while others suggested that agencies be permitted to use existing mechanisms to comply with this requirement or that only the State Agency be required to prepare and publish these reports. Section 1532(b)(9) of the Act mandates that both HSAs and State Agencies prepare and publish reports of this nature. The Secretary has chosen not to elaborate on the statutory language in these regulations and believes that the details of meeting this requirement should be determined by State Agencies and HSAs.

Sections 122.505(a)(8) and 123.605(a)(8) Access by the General Public to all Written Materials Pertinent to Reviews

Numerous comments were received expressing concern about the confidentiality of data submitted by providers to health planning agencies. These concerns have been addressed in the Preamble under section 123.603(c).

Section 123.605(a)(9) Health Systems Agency Appeal of a State Agency Finding

One commenter expressed concern that allowing HSAs to appeal State Agency decisions would weaken the leadership role of the State Agency. While the Secretary is sensitive to this concern, the HSA's right to appeal is required by section 1522(a)(13)(A) of the Act.

Numerous comments were received which urged that the regulations permit providers to appeal a State Agency finding of inappropriateness particularly when specific institutions are cited. The Secretary agrees with the suggestion and has amended this section, providing that if a State Agency makes a finding regarding the appropriateness of an existing institutional health service on an institution-specific basis, the providers of that service may appeal the State Agency's finding under an appeals mechanism consistent with State law governing the practices and procedures of administrative agencies, by an agency of the State (other than the State health planning and development agency) designated by the Governor and that the finding of the reviewing agency shall be considered the final finding of the State Agency. This requirement does not preclude providers from appealing a finding of inappropriateness on an areawide basis: however, the States are not required to provide a mechanism for such an appeal.

Section 123.605(a)(11) State Agency Decisions Inconsistent with Health Systems Agency Plans

Note.—This subparagraph was numbered § 123.605(a)(10) in the NPRM.

Several comments were received which indicated confusion as to the intent of this requirement. This provision clearly provides that the emphasis of this procedure is to be on the inconsistency of the State Agency's findings with the goals of the HSP or the priorities of the AIP, not the inconsistency of the service with the goals of HSP or the priorities of the AIP.

Sections 122.505(c) and 123.605(c) Provision for Corresponding Procedures

The Secretary has concluded that because of the length of time (up to one year) between the HSA's and the State Agency's reviews of an existing institutional health service, both agencies should provide procedures for written notification to affected persons of the beginning of their reviews and procedures for the provisions of public hearings in the course of the review if requested by persons directly affected by the review. The provisions permitting one agency to satisfy these requirements for both agencies have therefore been deleted. However, since the State Agency has been given the responsibility to establish requirements for submission of data after consultation with the SHCC and the HSAs of the State (§ 123.604(c)), the Secretary has maintained the provision that § 122.505(a)(3) is deemed satisfied for the HSA if the State Agency has provided for a corresponding procedure.

Sections 122.506 and 123.606 Exceptions To Use of Procedures

One commenter urged that no exceptions be allowed to the procedures required in § 122.505 and 123.605. The statute does not require that the procedures adopted by the planning agencies be the same for every HSA or State Agency, and permits every agency to develop and publish its own set of procedures. Agencies may find it necessary, with respect to any type or group of reviews, to deviate from the minimal requirements set forth in section 1532(b) of the Act. The Secretary has the authority, under section 1532(a) of the Act, to permit exceptions to use of these procedures, although he anticipates doing so only in unusual circumstances.

Sections 122.507 and 123.607 Criteria for Health Systems Agency and State Agency Reviews; General Comments

A number of comments revealed that there is a great deal of confusion concerning the respective roles of the State Agencies and the HSAs in developing the criteria to be used in appropriateness reviews. Unlike the role accorded to the State Agency in coordinating and establishing definitions, schedules, and priorities for reviews, no comparable role has been assigned for the development of review procedures or criteria. The agencies must, under § 122.503(b)(1) and 123.603(a), consult with each other and the SHCC before they decide on the criteria they will use, but neither agency is bound by the decisions of the other.

Several commenters were concerned over how the criteria would be used in determining appropriateness. Specific concerns were expressed over how the criteria will be balanced by the State Agency and whether or not all criteria will be used in making a finding of appropriateness. The Secretary intends that the State Agency and the HSAs use judgment in developing specific criteria to be applied in the review of each type of existing service which they undertake. The regulations allow considerable latitude in § 123.607(a) and (b) and § 123.608(b) in the selection and application of criteria. A minimum of one negative finding must be made in order to support a finding of inappropriateness. The Secretary believes mechanistic formulas for the weighing of criteria would overly simplify a complex set of local judgments.

Several respondents sought either additional considerations for criteria or more detail in those listed in § 123.607(a). The Secretary believes that the considerations as presently enumerated enable the agencies to develop all the criteria relevant and necessary to make a recommendation or a finding concerning appropriateness. He prefers that the regulations allow flexibility so that the agencies can develop and apply criteria suitable to local situations rather than to regulate fixed and rigid considerations aimed at meeting all possible needs.

A number of respondents felt strongly that providers should be involved in the development of review criteria. Since providers are represented on the governing bodies of each HSA, they should be directly involved in the development of criteria at the local agency level. The State Agency, however, might not have direct provider participation. The Secretary, therefore, strongly urges that the State Agencies give proper consideration to both provider and consumer concerns which are conveyed in the consultation meetings that take place between the State Agency, the HSA, and the SHCC. In addition, the Secretary reminds all interested parties that under § 122.504 and § 123.604 the HSAs and the State Agencies must give the public an opportunity to comment on criteria as well as procedures prior to their adoption. The Secretary feels that through these means, participation by government officials, providers, consumers, and planners in the formulation of review criteria is assured.

One commenter thought that since quality of care is monitored by Professional Standards Review Organizations (PSROs), it should not be included as a consideration. The Secretary does not agree with this suggestion, but rather believes that the quality of health care is important and that to remove it from consideration in appropriateness reviews would be contrary to the best interests of the public. It should be noted that section 1513(d)(1) of the Act requires each HSA to coordinate its activities with those of the PSRO in its area. It is through this mechanism that PSROs are expected to have a significant role in identifying quality considerations for use as review criteria.

The Secretary notes that Pub. L. 95–619, the National Energy Conservation Policy Act, which became law on November 9, 1978, amends section 1532(c)(9) of the Act to provide that in the case of a construction project, the "costs and methods of the proposed construction" to be considered must include the "costs and methods of energy provision." Because appropriateness reviews do not include reviews of proposed construction projects, the original provisions of section 1532(c)(9) of the Act were not included in the proposed regulation; for the same reason the amended provisions are not included in these regulations. Reviews of proposed construction projects are already required to employ this criterion when they are conducted as reviews of new institutional health services (including certificate of need) by 42 CFR 123.409(a)(12)(i).

Pub. L. 95–619 also added paragraph (c)(10) to section 1532(c) of the Act, providing for an additional criterion. This requires consideration of the special circumstances of health care facilities and HMOs with respect to the need for conserving energy. This provision has been incorporated into the regulations as § 123.607(a)(11).

Section 123.607(a)(1) Relationship of Services Reviewed to Plans

Several respondents stated that review criteria should not be required to include the relationship of the health services to the State health plan (SHP). The major reason given for this assertion is that these plans may not have been completed in time to allow the HSAs to complete their reviews in the required time. Since the new health planning amendments now require that reviews consider the relationship to the State health plan, these regulations continue to contain this provision.

The Secretary has revised this paragraph to describe more fully the "population" served as including low income persons, racial and ethnic minorities, women, handicapped

persons, and other underserved groups. Further discussion of these population groups is set forth below in regard to § 123.607(a)(10).

Section 123.607(a)(3) Need for the Services

Several commenters requested that the regulation make provision for the special needs and circumstances of osteopaths, including their facilities and patients. The Secretary has considered these comments and concludes (as noted in the Preamble to the final regulations governing the reviews of new institutional health services (42 FR 4018) January 21, 1977) that to include such a provision in Federal regulations would interfere with the local planning process which the statute was designed to foster. As the distribution of osteopathic services varies greatly from State to State, and as the governing bodies of the HSAs must include consumers, public officials, and representatives of provider groups, the Secretary feels that osteopathic concerns can be adequately voiced on the boards of the HSAs. Furthermore, he notes that the statute provides for public hearings by a planning agency and that there is opportunity for community input in the development of both the HSP and the SHP, as well as in the adoption of other review criteria. Thus, osteopathic concerns, in areas where they are a factor, may be addressed in the applicable health plans and criteria.

The Secretary reiterates his intent that there be no discrimination against populations which wish to have osteopathic services and facilities available. He therefore encourages State Agencies and HSAs to incorporate consideration of the needs of those being served by such services into the health plans. However, he is not advocating the development of duplicative systems of health care and of expensive facilities and equipment.

Other requests for special consideration were received from rural providers, the developmentally disabled, and clinical health manpower training facilities. The Secretary feels that the rationale regarding opportunity to participate in HSA and State Agency decisions in areas of the country where a particular need exists, as discussed above, is applicable to a number of the other requests for special consideration.

One writer asked whether a service ought to be considered inappropriate if it is insufficient to meet the needs of the community. The Secretary believes that an insufficiency might be a basis for a finding of inappropriateness, but should be weighed against the availability of the service outside the immediate community, the alternative services to meet the same health needs, and other adopted criteria. The Secretary encourages the use of appropriateness reviews to identify areas in need of additional services, as well as to identify excess capacity and he calls attention to § 123.608(d), which requires that a finding of inappropriateness lead to a recommendation for remedial action.

Section 123.607(a)(4) Availability of Alternatives

One commenter suggested that consideration be given to making comparisons of the costs of services by institutions in a health service area. Another suggested that the alternate form of care also be judged as to whether it is less restrictive, citing court decisions which state that disabled persons have the right to treatment in the least restrictive environment appropriate to their needs. The Secretary declines to accept this suggestion. He feels that the revised language for § 123.607(a)(3) and (10) provides adequate assurance that the needs of handicapped persons will be considered in reviewing existing services, and although he is not prescribing language for the handicapped (nor for that matter any other group), he expects planning agencies to develop criteria consistent with these considerations as local circumstances require.

Section 123.607(a)(5) The Relationship of Services Reviewed to Existing System

One commenter pointed out the relativity of the term "inappropriate," suggesting the decision depended on determining which services were least appropriate. Clarification was also requested as to whether the term relates to oversupply. While the Secretary is concerned with excess capacity, he maintains that appropriateness review must address, to the extent practicable, all of the characteristics of health service delivery systems in the State. As discussed above, the insufficiency of a service should also be identified during appropriateness reviews, and the agencies have a responsibility for recommending remedial action.

Section 123.607(a)(6) Availability of Resources

A number of providers requested deletion of this section, which addresses the availability of resources for the provision of the service being reviewed and the possible alternate use of these resources for the provision of other health care services. They asserted that this provision is an unwarranted intrusion into the way providers conduct their day to day business and that such a provision would lead to the destruction of free enterprise in the health care system. The Secretary believes that health care resources are not infinitely expandable, that decisions need to be made concerning their allocation, and that he would be undermining the planning process if he complied with this request.

Section 123.607 (a)(8) and (c) Reviews of Health Maintenance Organizations

The Secretary notes (see the Preamble to the NPRM for appropriateness review, 43 FR 21277, May 16, 1977) his expectation that *areawide* appropriateness reviews will not impact adversely on HMOs. It was with this expectation that the special HMO related provisions of the regulations (specifying and limiting criteria and providing for required findings) apply only with regard to institution-specific findings. He notes, however, that the Act clearly requires that institutional health services provided by or through an HMO be subject to appropriateness reviews, even if the findings are stated only on an areawide basis. Accordingly, planning agencies are now required to review only those services of HMOs which are provided through public and private hospitals, rehabilitation facilities and nursing homes. Other services provided by HMOs, such as outpatient services, are no longer required by statute to be reviewed.

A few respondents felt that if the Federal government wants to foster the development and growth of HMOs, the Secretary should exclude them from all planning and regulatory activities. The Secretary has no authority to exempt HMOs from all planning and regulatory activities, and he does not agree that the special criteria place HMOs outside the regulatory process. The purpose of these regulations is to ensure that reviews of HMOs are performed in a manner consistent with the Federal initiative to aid in their development, as mandated by section 117(a) of the HMO Amendments of 1976 (Pub. L. 94–460) and the National Health Priorities in section 1501 of the Act. He submits further that the history of the development of the HMO system of health delivery shows that they have been the object of discrimination by some in the medical community. He feels that these regulations will establish a process which may help protect them from this discrimination and will place them on an equal footing with other providers.

Other commenters asserted that HMOs should not be given special privileges or be judged by special criteria, since this approach is discriminatory against other health care providers and sets a precedent for other exceptions. The Secretary does not agree that this regulation discriminates against other providers. It simply implements the Congressional intent, as set forth in Pub. L. 93–641, 93–222, 96–79 and 94–460, that the development of HMOs be encouraged and that HMOs be given special consideration in the health planning process.

One commenter suggested that HMO members be subtracted from the population base which is used to justify new non-HMO services. The Secretary notes that it is the responsibility of health planning agencies to plan for health services for the total population of their planning areas for all types of services. Nothing in these regulations lessens the responsibility of health planning agencies to plan for the segment of the population who are HMO enrollees, or to implement their plans within the requirements of the regulations. However, the Secretary does feel that population based planning must take into consideration that certain populations obtain service from separate providers, such as Federal health care facilities or HMOs.

The Secretary has reviewed these sections and agrees with the commenters who questioned the applicability of § 122.508(d) and § 123.608(d) (as well as § 123.607(a)(8)(ii)) to appropriateness reviews. He notes that while it is necessary to consider the relationship of HMO services to the health system services as a whole, it is not advisable to evaluate the HMO services in such a way as to encourage their being deemed inappropriate simply because the service may be, or may become, available from non-HMO providers. He feels that these proposed provisions, although helpful in certificate of need reviews, would create unintended hardships for HMO's in appropriateness reviews. Therefore, the Secretary has: (1) Deleted two of these paragraphs (§ 122.508(d) and § 123.608(d)) from the regulations, and (2) clarified the other provision (§ 123.607(a)(8)(ii)) to state that the agencies shall consider whether the services could be obtained from non-HMO, or other HMO, providers in a reasonable and cost-effective way, consistent with the HMO mode of operation. He does not, however, agree with the commenter who also advised deleting § 123.607(a)(8)(iii). He urges health planning agencies to submit, under the provisions of § 123.607(a)(8)(iii), any other factors which they propose to use to determine the appropriateness of these HMOs within the health delivery system, including the relationship of one HMO to other HMOs or to non-HMO providers.

Section 123.607(a)(9) Special Needs and Circumstances of Biomedical and Behavioral Research Projects

One commenter asked whether specific criteria should be used by the State Agency for review of research projects of national importance and whether, in fact, findings regarding such projects would have the effect of recommendations to the Secretary. The Secretary points out that this subparagraph requires the HSAs and State Agencies to take into consideration needs of projects which may extend beyond their boundaries. Appropriateness reviews, based in part on this consideration, result in findings, not in recommendations to the Secretary. He points out that these findings may provide the basis for HSA's reviews of proposed uses of Federal funds within their areas under section 1513(e) of the Act. Nevertheless, the Secretary encourages the State Agencies to notify the appropriate Federal funding agency when it determines that a Federally funded research project is inappropriate, although he is not requiring by regulation that they do so.

Section 123.607(a)(10) Needs of medically underserved groups and groups with problems of equal access to health care.

Commenters both praised and criticized the proposal that consideration be given the contribution of the institutional health service in meeting the health related needs of women, minorities and the handicapped. Some suggested that the regulations be expanded to include additional groups such as the elderly, children, pregnant women and the medically underserved generally, whose health care problems merit special consideration.

Others thought that there is no evidence that women and minorities have special unmet health care needs and that requiring their consideration places HSAs in the role of civil rights investigators. Another commenter questioned the legal basis for the section and said that § 123.607(a)(3), (the "need that the population served * * * has for such services") logically includes consideration of any special needs. One commenter suggested that such consideration prevented giving equal consideration to needs of *all* individuals in the health service area. And finally, a State Agency stated that this provision was unnecessary because consideration of the needs of these and other groups would already be part of an agency's planning process.

After thoughtful consideration of the comments, the Secretary is revising § 123.607(a)(10) by stating that special consideration shall be given to the needs of "members of medically underserved groups and members of groups which have traditionally experienced difficulties in obtaining equal access to health services."

The regulation then cites low income persons, racial and ethnic minorities, women, and handicapped persons as examples of these groups. The Secretary points out that these are only illustrative and that there may be other groups whose needs merit special attention in particular health service areas or States. The regulation also calls attention to those health related needs identified in the applicable health systems plan and annual implementation plan as deserving of priority.

The Secretary believes the revision serves several purposes. First, while highlighting several of the more prominent groups which are underserved or have problems of access, it does not limit consideration exclusively to them. Second, it enables agencies to identify the groups in their area which have traditionally experienced access problems and to provide special consideration as to how the health related needs of these groups can be met. Third, the section is designed to remind the agencies that the Secretary is vitally interested in the health care that is accorded to these example groups and will be monitoring their situations closely.

While the Secretary agrees that consideration of the "need the population served * * * has for such (proposed) services" can be read broadly to include the needs of these groups, he has concluded that this more explicit statement is necessary because it is the most appropriate way to call attention to problems of equal access and medical underservice, given the Department's strong commitment to resolving these problems.

The Secretary views the promulgation of paragraph (a)(10) as clearly being authorized because: (1) Section 1532(c) of the Act refers to criteria which include consideration of "at least" the factors specified in the Act, (2) the Secretary views paragraph (a)(10) as being a more explicit statement of paragraph (a)(3) (which is derived from Section 1532(c)(3) of the Act), and (3)

issues of equal access and medical underservice were so explicitly referred to by the Congress in enacting Title XV (see, for example, Sections 2(a)(2) and (3) of Pub. L. 93–641, Sections 1502 and 1532(c) of the Act).

Section 123.607(b) Criteria for different types of reviews.

The individual character of each State and health service area will dictate the criteria to be used in reviewing the services offered in that area. Different factors will assume different degrees of importance, depending on such considerations as the nature of the service under review and the characteristics of the area where the review is being conducted. The recommendation or finding that results from an appropriateness review should be based on the integrated application of all criteria, rather than absolute compliance with each set. The Secretary agrees that additional clarity is needed and therefore, is revising § 123.607(b), by adding that "should an agency fail to use criteria addressing all six of the characteristics of appropriateness in a review, it must explain this in the finding." Technical assistance, in the form of suggestions of possible measures of the six characteristics of appropriateness, will be made available to the agencies. Definitions of these six characteristics are in the *Guidelines for the Development of Health Systems Plans and Annual Implementation Plans*, distributed with the Bureau of Health Planning's Program Policy Notice 79–05.

Sections 122.508 and 123.608 Required recommendations/findings.

One commenter questioned the negative impact on an institution of making public a finding of inappropriateness. In the absence of regulatory sanctions, planning agencies can rely only on voluntary actions which may be stimulated (in part) by the public finding. While this may have a negative impact upon a given institution, it should result in better overall health care by stimulating the institutions affected, the community, and the planning agency to seek solutions through suggested remedial action to the causes of the finding.

Several commenters objected to paragraphs (e) of these sections, regarding inpatient facilities of HMOs. Some advised deleting the provisions entirely because it was not suitable for use in appropriateness reviews. The Secretary has reexamined the proposed required findings and has deleted proposed § 122.508(e) and § 123.608(e) as superfluous. He has also deleted § 122.508(d) and § 123.608(d) because he has concluded that the limited review criteria which may be applied to HMOs are sufficient to prevent discrimination against HMOs in the review process.

Sections 122.508(f) and 123.608(f) (Renumbered as § 122.508(d) and § 123.608(d) Plan for remedial action.

A number of commenters were concerned about the requirement that HSAs and State Agencies suggest remedial actions whenever they find a service inappropriate. Some commenters felt it should be clear that the remedial actions would be voluntary, and one felt that development of remedial action plans should not be a function of HSAs or State Agencies; rather it should be performed by the governing body of the institutions in question.

Another commenter was concerned that the kinds of findings and recommendations which might be developed would need to provide an adequate basis for administrative or judicial review which might occur in the event of an appeal. Several other commenters believed that the language in the proposed rule did not adequately emphasize that HSAs and State Agencies should actively work with all affected groups to change or eliminate inappropriate services.

The Secretary believes that a finding of inappropriateness carries with it an obligation for suggesting remedial action which is consistent with the planning functions of Sections 1513 and 1523 of the Act. This requirement to develop remedial action suggestions is intended to encourage HSAs and State Agencies to refine their analyses of the appropriateness of services to the point where specific actions can be suggested. The Secretary intends that it will serve as a check on health planning agencies, preventing them from arbitrarily finding services provided in the area to be inappropriate.

Although some States may wish to develop regulatory programs around the appropriateness review function, the Secretary expects that most States and agencies will rely, at least initially, on the voluntary efforts of institutions to implement the remedial actions suggested to them. Moreover, the Secretary feels strongly that planning agencies should work closely with institutions which provide services that have been deemed inappropriate in order to obtain agreement on reasonable remedial actions.

With regard to the need for findings and recommendations to constitute an adequate basis for further administrative or judicial review, the Secretary concurs that such findings and recommendations need to go beyond the mere statement of whether a service is deemed appropriate or inappropriate. Any finding or recommendation should be supported by a summary of major comments and information received. It should also explain how any concerns or problems raised were resolved by the agency and what led the agency to its ultimate finding or recommendation. Moreover, although findings and recommendations need not address all six characteristics in detail, the record should show that the agency gave consideration during the course of its review to all six of those characteristics (availability, accessibility, acceptability, continuity, cost, and quality) as well as all other criteria which apply to the service being reviewed, or explain in its findings why it has chosen not to do so.

Remedial action plans should be developed by the HSA and the State Agency after due consideration of the suggestions received from the institutions involved, major creditors, third party insurers, consumers, and providers of health services which would be affected by the proposed remedial action. Examples of potential remedial action would include the possibility of conversion of some services to other health care uses, use of facilities that are nearby, or the elimination of the service together with some plan for providing patient access to other convenient facilities.

One commenter felt that the remedial plans could not be effective unless they dealt with specific institutions. As indicated previously, the Secretary agrees that remedial plans which address changes in individual institutions will ultimately have a greater impact on the health care system than those which deal generally with services being provided in the area. However, remedial plans which are applicable to services provided over an entire health service area will still have value which will vary as a function of the services being reviewed. For example, if there is a widespread problem of access to primary care in a health service area, such a finding and the formulation of a remedial action plan could be used to assist in the development of additional primary care resources. A second example is a finding that the delivery of a particular service is inappropriate because of the setting in which it is offered or most frequently offered in the area (e.g., end stage renal disease services provided primarily at clinics, as opposed to a home setting). Another example might be psychiatric services provided primarily on an inpatient basis instead

of community alternatives such as outpatient services or partial hospitalization services.

As agencies gain experience with appropriateness reviews, the nature of remedial actions which they suggest will provide a basis to evaluate the need for further action. The Secretary will be carefully monitoring the effectiveness of remedial action plans. If it becomes evident that remedial action plans lack adequate specificity, the Secretary will consider changing the requirements for these plans. For the time being, however, he feels that the lack of experience with appropriateness review does not justify any greater degree of specificity than was set forth in the NPRM.

One change, however, has been adopted to make § 122.508(f) and § 123.608(f) of the NPRM, now numbered § 122.508(d) and § 123.608(d) more consistent. That is, both sections now require agency plans for remedial action only to the extent practicable.

Accordingly, 42 CFR Parts 122 and 123 are amended in the manner set forth below.

Dated: February 6, 1979.

Julius B. Richmond,

Assistant Secretary for Health.

Approved: November 26, 1979.

Patricia Roberts Harris,

Secretary.

PART 122—HEALTH SYSTEMS AGENCIES

1. Part 122 of Title 42, CFR, is amended by adding thereto a new Subpart F, to read as follows:

Subpart F—Health Systems Agency Reviews of Existing

Institutional Health Services for Appropriateness

Sec.

122.501 Definitions.
122.502 Purpose and applicability.
122.503 Appropriateness review work program.
122.504 Adoption and public notice of review procedures and criteria.
122.505 Procedures for health systems agency review.
122.506 Exceptions to use of procedures.
122.507 Criteria for health systems agency review.
122.508 Required recommendations.

Authority: Sec. 215 of the Public Health Service Act, 58 Stat. 690 (42 U.S.C. 216); sections 1513 and 1532 of the Public Health Service Act, as amended, 93 Stat. 592–630 (42 U.S.C. 300l–2, 300n–1)

Subpart F—Health Systems Agency Reviews of Existing Institutional Health Services for Appropriateness

§ 122.501 Definitions.

Except for the term "institutional health services," terms used in this subpart shall have the meaning given them in Subparts A (Definitions) and D (Procedures and Criteria for Review of New Institutional Health Services) of this part. In addition, as used in this subpart:

The term "institutional health services" means health services which (a) are provided through private or public hospitals, rehabilitation facilities, and nursing homes, and (b) entail annual operating costs of at least the expenditure minimum. For purposes of this paragraph, the term "expenditure minimum" means $75,000 for the twelve month period beginning with October 1979, and for each twelve month period thereafter, $75,000 or, at the discretion of the State, the figure in effect for the preceding twelve month period, adjusted to reflect the change in the preceding twelve month period in an index to be specified by the Secretary.

The term "existing institutional health services" or "services" means institutional health services:

(a) Being offered in the health service area at the time of review for appropriateness, or

(b) Offered at any time in the 12 months prior to the review and also planned to be offered at any time in the 12 months following the review, or

(c) which will be offered during the 12 months following the review.

A finding of "appropriateness" means a finding that a service meets the needs of a population, in accordance with the criteria development and published under § 122.507.

The term "areawide review" means the review of a specific institutional health service as delivered by all the institutions providing the service in the health service area (a) which shall culminate in recommendations regarding the appropriateness of that service over the entire health service area, and (b) which may result in recommendations regarding the appropriateness of that service in a particular institution.

§ 122.502 Purpose and applicability.

Section 1513(g) of the Act requires each health systems agency to review on a periodic basis, but at least every 5 years, all institutional health services offered in its health service area and to make recommendations to the State Agency for each State in which any part of the health systems agency's health service area is located respecting the appropriateness in the area of such services (hereinafter referred to as an appropriateness review). Section 1532(a) of the Act requires that in performing its review functions under section 1513(g) of the Act or in conducting any other reviews of existing health services, each health systems agency shall follow procedures and apply criteria developed and published by the health systems agency in accordance with regulations of the Secretary. This subpart sets forth minimum procedures and criteria to be used by health systems agencies in conducting these reviews and the requirements respecting the assumption, conduct, and timing of the appropriateness review function by health systems agencies; requirements respecting the coordination with the State Agency and the Statewide Health Coordinating Council; and the administrative steps which are necessary for the effective performance of the appropriateness reviews.

Note.—Under 42 CFR 122.106(c), a health systems agency may not perform the appropriateness review function during its first year of conditional designation, and may not in any event perform this function during its period of conditional designation until it has established a health systems plan and annual implementation plan in accordance with sections 1513(b)(2) and (3) of the Act, and the Secretary has in writing authorized the agency to perform this function.

§ 122.503 Appropriateness review work program.

(a) Each appropriateness review shall be performed on an areawide basis and shall result in a finding as to the appropriateness of the service being reviewed as it is delivered in the health service area. The health systems agency may, at the same time, make findings as to the appropriateness of that service in particular institutions.

(b) The work program submitted by each health systems agency in accordance with 42 CFR 122.104(a)(3) or (b)(9), whichever is applicable, shall with respect to the assumption and continuing performance of the appropriateness review function:

(1) Specify the steps to be taken to develop procedures and criteria to be applied in performance of appropriateness reviews, in consultation with the Statewide Health Coordinating Council and State Agency of each State in which any part of the health systems agency's health service area is located;

(2) Include an assurance (i) that the health systems agency will abide by the decision of the State Agency with respect to the definitions of services, priorities among services, and the schedule for areawide reviews of such

services if the State Agency written decision is communicated to the health systems agency within 6 months following publication of these regulations; or after such time (ii) that the health systems agency will abide by the definitions of services and schedules for reviews agreed to by the majority of the health systems agencies in the State, and will give priority in its reviews to services for which National Guidelines for Health Planning have been issued.

(3) Provide for the establishment of administrative procedures governing the transmittal of appropriateness review recommendations to the State Agency in accordance with procedural requirements established by the State Agency; and

(4) Specify the steps necessary to complete areawide appropriateness reviews of all existing institutional health services within 3 years of the date of the health systems agency's initial full designation and during each succeeding 5-year period. Review schedule priorities may be established, but such review priority setting shall not result in the exclusion from review of any existing institutional health service during any applicable time period.

(c) Each health systems agency shall, within three months after the effective date of these regulations, submit to the Secretary a revised work program under § 122.104(a)(3) or (b)(9) of this title, whichever is applicable, which conforms to the requirements of this section.

§ 122.504 Adoption and public notice of review procedures and criteria.

The provisions of 42 CFR 122.305 apply to the adoption and public notice of review procedures and criteria under this subpart.

§ 122.505 Procedures for health systems agency review.

(a) The procedures adopted and used by a health systems agency conducting the reviews covered by this subpart shall include at least the following:

(1) Written notification to affected persons of the beginning of a review. Written notification to members of the public may be provided through newspapers of general circulation in the area and public information channels; notification to all other affected persons shall be by mail (which may be as part of a newsletter). "Affected persons" include at a minimum, the person whose service is being reviewed, the State Agency for each State in which all or any part of the agency's health service area is located, health systems agencies serving contiguous health service areas, health care facilities and HMOs located in the health service area which provide institutional health services, entities with which the health systems agency must coordinate its activities pursuant to section 1513(d) of the Act, any agency which establishes rates for health care facilities or HMOs in its health service area, and those members of the public who are to be served by the service subject to review.

(2) Schedules for areawide reviews which provide that no review shall, to the extent praticable, take longer than 180 days from the date of notification to affected persons made in accordance with paragraph (a)(1) of this section to the date of submission of the health systems agency's recommendations to the State Agency.

(3) Provision for persons subject to a review to submit to the health systems agency such information as the health systems agency may require concerning the subject of such review, in the form and manner and containing the information which the health systems agency shall prescribe and publish. Such information requirements may vary according to the purpose for which a particular review is being conducted or the type of health service being reviewed; however, the health systems agency may require no information of a person subject to review which is not prescribed and published as being required in accordance with § 122.504.

(4) Provision for written findings which state the basis for any recommendations made by the health systems agency.

(5) Notification of providers of health services and other persons subject to the health systems agency review of the status of the health systems agency's review of the institutional health services, findings made in the course of the review, and other appropriate information respecting the review.

(6) Provision for (i) public hearings in the course of the health systems agency review if requested by persons affected by the review, and (ii) that any person may, for good cause shown, request in writing a public hearing for purposes of reconsideration of a health systems agency recommendation derived from an institution-specific finding.

(7) Preparation and publication of regular reports by the health systems agency of the reviews being conducted (including a statement concerning the status of each such review), and of the reviews completed by the health systems agency (including a general statement of the findings made in the course of these reviews and the recommendations made to the State Agency) since the publication of the last report.

(8) Access by the general public to all written materials pertinent to any health systems agency review.

(b) Procedures adopted for reviews in accordance with paragraph (a) of this section may vary according to the type of health service being reviewed.

(c) The procedures adopted for reviews may provide that the requirements of paragraph (a)(3) of this section shall be deemed satisfied for any health service area within the State if the State Agency has provided for a corresponding procedure.

§ 122.506 Exceptions to use of procedures.

A health systems agency may, with respect to any type or group of reviews, request from the Secretary an exception to the requirement that it use review procedures which meet the requirements of § 122.506. The requirements of 42 CFR 122.307 apply to such a request for an exception.

§ 122.507 Criteria for health systems agency review.

The provisions of 42 CFR 123.607 apply to the adoption and use of review criteria under this subpart.

§ 122.508 Required recommendations.

(a) After completing its review of an existing institutional health service a health systems agency shall make recommendations respecting the appropriateness of the service in its health service area to the State Agency of each State in which all or any part of the health systems agency's health service area is located.

(b) A health systems agency may not recommend that a State Agency find an existing institutional health service to be inappropriate unless the health systems agency has stated in writing that the service has not met one or more of the established criteria of the health systems agency and the ways in which the service failed to meet the criteria, including any that are beyond the control of the person(s) providing that service.

(c) A health systems agency, in conducting an areawide review which results in institution-specific findings may not recommend that an existing institutional health service provided by or through an HMO be found inappropriate solely because there is an HMO of the same type, as specified in section 1310(b) of the Act, in the same health service area, or solely because the services being reviewed are not discussed in the applicable health systems plan, annual implementation plan, or State health plan.

(d) When a health systems agency recommends to a State Agency that a service be found inappropriate, the health systems agency shall, to the extent practicable, suggest to the State Agency a plan for remedial action.

PART 123—STATE HEALTH PLANNING AND DEVELOPMENT AGENCIES

2. Part 123 of Title 42, is amended by adding thereto a new Subpart G, to read as follows:

Subpart G—State Agency Reviews of Existing Institutional Health Services for Appropriateness

Sec.

123.601 Definitions.
123.602 Purpose and applicability.
123.603 Appropriateness review work program.
123.604 Adoption and public notice of review procedures and criteria.
123.605 Procedures for State Agency review.
123.606 Exceptions to use of procedures.
123.607 Criteria for State Agency review.
123.608 Required findings.

Authority: Sec. 215 of the Public Health Service Act, 58 Stat. 690 (42 U.S.C. 216); secs. 1523 and 1532 of the Public Health Service Act, as amended, 93 Stat. 592–630 (42 U.S.C. 300m–2, 300n–1).

Subpart G—State Agency Reviews of Existing Institutional Health Services for Appropriateness

§ 123.601 Definitions.

Except for the term "institutional health services," terms used in this subpart shall have the meaing given them in Subparts A (definitions) and E (certificate of need and review of new institutional health services) of this part. In addition, as used in this subpart:

The term "institutional health services," means health services which (a) are provided through private or public hospitals, rehabilitation facilities, and nursing homes, and (b) entail annual operating costs of at least the expenditure minimum. For purposes of this paragraph, the term "expenditure minimum" means $75,000 for the twelve month period beginning with October 1979, and for each twelve month period thereafter, $75,000 or, at the discretion of the State, the figure in effect for the preceding twelve month period, adjusted to reflect the change in the preceding twelve month period in an index to be specified by the Secretary.

The term "existing institutional health services" or "services" means institutional health services:

(a) Being offered in the State at the time of review for appropriateness, or

(b) Offered at any time in the 12 months prior to the review and also planned to be offered at any time in the 12 months following the review, or

(c) Which will be offered during the 12 months following the review.

A finding of "appropriateness" means a finding that the service meets the needs of a population in accordance with the criteria developed and published under § 123.607.

The term "areawide review" means the review of a specific institutional health service as delivered by all the institutions providing the service in a health service area or State (a) which shall culminate in findings regarding the appropriateness of that service over the entire health service area or State, and (b) which may result in recommendations regarding the appropriateness of that service in a particular institution.

§123.602 Purpose and applicability.

Section 1523(a)(6) of the Act requires each State health planning and development agency to review on a periodic basis (but not less often than every 5 years) all institutional health services being offered in the State (hereinafter referred to as an appropriateness review) and, after consideration of the recommendations submitted by health systems agencies under Section 1513(g) of the Act and 42 CFR Part 122, Subpart F, to make public its findings as to the appropriateness of such services. Section 1523(b)(3) of the Act requires the State Agency to complete its findings as to the appropriateness of any existing institutional health service within one year after the date a health systems agency has made its recommendation with respect to the appropriateness of the service under Section 1513(g) of the Act and 42 CFR Part 122, Subpart F. Section 1532(a) of the Act requires that in performing its review functions under Section 1523 of the Act (which includes reviews conducted under Section 1523(a)(6)), each State Agency shall (except to the extent approved by the Secretary) follow procedures and apply criteria developed and published by the State Agency in accordance with regulations of the Secretary. This subpart sets forth minimum procedures and criteria to be used by State Agencies in conducting these reviews; requirements respecting the assumption, conduct, and timing of the appropriateness review function; requirements respecting the coordination with health systems agencies and statewide health coordinating councils and the administrative steps which are necessary for the effective performance of appropriateness reviews.

§123.603 Appropriateness review work program.

(a) Each appropriateness review shall be performed on an areawide basis and shall result in a finding as to the appropriateness of the service being reviewed as it is delivered in the State or health service area. The State Agency, may, at the same time, make findings as to the appropriateness of that service in particular institutions.

(b) Each State Agency must, within three months after the effective date of these regulations, develop and submit to the Secretary a work program for the orderly assumption and/or continued performance of appropriateness reviews. This work program will be used in the Secretary's determination of the State Agency's capability of assuming and performing the appropriateness review function in a satisfactory manner as required by Sections 1521(b)(1)(B), (b)(2)(A), and (b)(4) of the Act. The State Agency must submit to the Secretary, with the work program, evidence that prior to its adoption, the public was afforded an opportunity to comment in writing or at a public hearing. It shall also submit a summary of the comments received. The work program shall provide for:

(1) The development of the review procedures and criteria to be applied by the State Agency in the performance of appropriateness reviews, in consultation with the statewide health coordinating council and all the health systems agencies in the State, and the State Agency(s) and statewide health coordinating council(s) of any contiguous State(s) where a health service area is shared by more than one State.

(2) The establishment of the definitions of services to be reviewed, priorities among services, and the schedule for reviews of such services, after consultation with the statewide health coordinating council and all the health systems agencies in the State, and the State Agency(s) and statewide health coordinating council(s) of any contiguous States where a health service area is shared by both States. In establishment of these definitions, priorities, and schedules, the State Agency must take into account the statutory time limits applicable to appropriateness reviews by health systems agencies, and the need within the State for priority reviews of the services for which National Guidelines for Health Planning have been issued.

(3) The establishment of requirements for submission by providers of data to be used in performance of appropriateness reviews to the State Agency and to the health systems

agencies, after consultation with the statewide health coordinating council and all the health systems agencies in the State, and the State Agency(s) and statewide health coordinating council(s) of any contiguous States where a health service area is shared by more than one State. At a minimum, the State Agency shall establish such data requirements for services provided by hospitals and nursing homes during the first and second years, respectively, of its reviews of appropriateness. Data requirements shall be limited to data reasonably needed for appropriateness reviews and the State Agencies shall use existing data sources to the maximum extent feasible.

(4) Plans for initiating appropriateness reviews:

(i) No later than 6 months after the effective date of these regulations if: (A) The State Agency is fully designated prior to the date of publication of these regulations, or (B) the State Agency is conditionally designated and the Secretary has determined that the State Agency is capable of performing appropriateness reviews (see 42 CFR 123.105) prior to the effective date of these regulations; or

(ii) In the case of a State Agency not covered by paragraph (b)(4)(i) of this section, no later than 6 months after: (A) The date of full designation, or (B) the date the Secretary determines that the State Agency, although conditionally designated, is capable of performing appropriateness reviews, whichever is earlier.

(5) Plans for completing areawide reviews of all existing institutional health services within 5 years of the date of the State Agency's initial full designation and during each succeeding 5-year period, but in any event within 1 year of receipt of an appropriate health system agency recommendation. Review schedule priorities may be established, but such review priority setting shall not result in the exclusion from review of any existing institutional health service during any applicable time period.

§ 123.604 Adoption and public notice of review procedures and criteria.

The provisions of 42 CFR 123.406 apply to the adoption and public notice of review procedures and criteria under this subpart.

§ 123.605 Procedures for State Agency review.

(a) The procedures adopted and used by a State Agency for conducting the reviews covered by this subpart shall include at least the following:

(1) Written notification to affected persons of the beginning of a review. Written notification to members of the public may be provided through newspapers of general circulation in the area and public information channels; notifications to all other affected persons shall be by mail (which may be part of a newsletter). "Affected persons" include at a minimum, the person(s) whose service is being reviewed, the State Agency for each State in which all or any part of the agency's health service area is located, health systems agencies serving contiguous health service areas, health care facilities and HMOs located in the health service area which provide institutional health services, any agency which establishes rates for health care facilities or HMOs in its health service area, and those members of the public who are to be served by the service subject to review.

(2) Schedules for review which provide that no areawide review shall, to the extent practicable, take longer than 180 days from the date of notification to affected persons made in accordance with paragraph (a)(1) of this section to the date of the written findings made in accordance with paragraph (a)(4) of this section.

(3) Provisions for persons subject to a review to submit to the State Agency any information which the State Agency may require in accordance with its work program under § 123.603(c) concerning the subject of the review in the form and manner and containing the information which the State Agency shall prescribe and publish. These information requirements may vary according to the purpose for which the particular review is being conducted or the type of health service being reviewed; however, the State Agency may require no information of a person subject to review which is not prescribed and published as being required in accordance with § 123.604

(4) Provision for written findings which state the basis for any findings made by the State Agency.

(5) Notification of providers of health services and other persons subject to the State Agency review of the status of the State Agency's review of the institutional health services, findings made in the course of the review, and other appropriate information respecting the review.

(6) Provision for (i) public hearings in the course of the State Agency review if requested by persons affected by the review; and for (ii) public hearings, for good cause shown, respecting the State Agency finding.

(7) Preparation and publication of regular reports by the State Agency of the reviews being conducted (including a statement concerning the status of each review), and of the reviews completed by the State Agency (including a general statement of the findings made in the course of these reviews) since the publication of the last report.

(8) Access by the general public to all written materials pertinent to any State Agency review.

(9) Provision that if the State Agency makes a finding regarding the appropriateness of an existing institutional health service which is inconsistent with a recommendation made with respect thereto by the health systems agency making such recommendation pursuant to 42 CFR 122.508: (i) the finding (and the record upon which it was made) shall, upon request of the health systems agency, be reviewed, under an appeals mechanism consistent with State law governing the practices and procedures of administrative agencies, by an agency of the State (other than the State health planning and development agency) designated by the Governor, and (ii) the finding of the reviewing agency shall be considered the final finding of the State Agency.

(10) Provision that a decision of the State Agency resulting in an institution-specific finding of inappropriateness shall, upon request of the person(s) providing that service, be reviewed, under an appeals mechanism consistent with State law governing the practices and procedures of administrative agencies, by an agency of the State (other than the State Agency) designated by the Governor. The decision of the reviewing agency shall be considered the final decision of the State Agency.

(11) Provision that if a State Agency (or a reviewing agency, under paragraph (a)(9) of this section) makes a finding regarding an existing institutional health service which the State Agency determines is not consistent with the goals of the applicable health systems plan (established under Section 1513(b)(2) of the Act) or the priorities of the applicable annual implementation plan (established under Section 1513(b)(3) of the Act, the State Agency (or the reviewing agency, as appropriate) shall submit to the appropriate health systems agency a detailed statement of the reasons for the inconsistency.

(b) Procedures adopted for reviews in accordance with paragraph (a) of this section may vary according to the type of health service being reviewed.

(c) The procedures adopted for reviews may provide that the requirements of paragraph (a)(3) of this section shall be deemed satisfied for

any health service area within the State if the health systems agency has provided for a corresponding procedure.

§ 123.606 Exceptions to use of procedures.

A State Agency may, with respect to any type or group of reviews, request from the Secretary an exception to the requirement that it use review procedures which meet the requirements of § 123.605. The requirements of 42 CFR 123.408 apply to such a request for an exception.

§ 123.607 Criteria for State Agency review.

(a) The State Agency shall adopt, and use as appropriate, specific criteria for conducting the reviews covered by this subpart. These criteria shall relate to availability, accessibility, acceptability, continuity, cost, and quality and shall include at least the general considerations listed below, but in the case of areawide reviews which result in institution-specific findings of services provided by or through HMOs, the considerations shall be limited to those set forth in paragraph (a)(8) of this section.

(1) The relationship of the health services being reviewed to the applicable health systems plans, annual implementation plans, and State health plan.

(2) The relationship of the services reviewed to the long-range development plan (if any) of the person providing the services.

(3) The need that the population served has for the services, and the extent to which low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups have access to those services.

(4) The availability of less costly or more effective alternative methods of providing the services.

(5) The relationship of the services reviewed to the existing health care system of the area in which the services are provided.

(6) The availability of resources (including health manpower, management personnel, and funds for capital and operating needs) for the provision of the services reviewed and the availability of alternative uses of these resources for the provision of other health services.

(7) The special needs and circumstances of those entities which provide a substantial portion of their services or resources or both, to individuals not residing in the health service areas in which the entities are located or in adjacent health services areas. These entities may include medical and other health professions schools, multidisciplinary clinics, and specialty centers.

(8) The special needs and circumstances of HMOs. In the case of areawide reviews which result in institution-specific findings regarding services provided by or through an HMO, the needs and circumstances shall be limited to:

(i) The needs of enrolled members and reasonably anticipated new members of the HMO for the existing institutional health services provided by the organization.

(ii) Whether the services could be obtained from non-HMO, or other HMO, providers in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO.

(iii) Any other factors which the State Agency may propose and the Secretary may, in accordance with paragraph (c) of this section, find to be consistent with the purpose of Title XIII of the Act.

(9) The special needs and circumstances of biomedical and behavorial research projects which are designed to meet a national need and for which local conditions offer special advantages.

(10) The contribution of the existing institutional health services in meeting the health related needs of members of medically underserved groups and groups which have traditionally experienced difficulties in obtaining equal access to health services (for example, low income persons, racial and ethnic minorities, women, and handicapped persons) particularly those needs identified in the applicable health systems plan and annual implementation plan as deserving of priority.

(11) The special circumstances of health service institutions with respect to the need for conserving energy.

(12) In accordance with Section 1502(b) of the Act, the effect of competition on the supply of the health services being reviewed.

(13) Improvements or innovations in the financing and delivery of health services which foster competition, in accordance with Section 1502(b) of the Act, and serve to promote quality assurance and cost effectiveness.

(14) The quality of care provided by the services or facilities in the past.

(b) Criteria adopted for reviews in accordance with paragraph (a) of this section may vary according to the type of health service being reviewed and the purpose of the review. Furthermore, the criteria used in the review of a particular service need not address all six of the characteristics of appropriateness (availability, accessibility, acceptability, continuity, cost, and quality). Should an agency fail to use criteria addressing all six of the characteristics of appropriateness in a review, it must explain this in the finding.

(c) Where a State Agency proposes under paragraph (a)(8)(iii) of this section that it be permitted to base areawide reviews resulting in institution-specific findings of services provided by or through HMOs on criteria which consider factors not set forth in paragraph (a)(8) of this section, it shall do so in a written request to the Secretary, specifying the reasons for the proposal. The Secretary will approve the request if he finds the additional factors to be consistent with the purpose of Title XIII of the Act. Unless the Secretary has approved the additional factors, the State Agency shall base its review solely on the factors set forth in paragraph (a)(8) of this section.

§ 123.608 Required findings.

(a) A State Agency shall, in accordance with the requirements of this subpart, make public its findings with respect to the appropriateness of existing institutional health services.

(b) A State Agency may not make a finding that an existing institutional health service is inappropriate unless it has stated in writing that the service has not met one or more of the established criteria of the State Agency and the ways in which the service failed to meet the criteria, including any that are beyond the control of the person(s) providing that service.

(c) A State Agency, in conducting an areawide review resulting in institution-specific findings, may not make a finding that an existing institutional health service provided by or through an HMO is inappropriate solely because there is an HMO of the same type, as specified in section 1310(b) of the Act, in the same health service area, or solely because the services being reviewed are not discussed in the applicable health systems plan, annual implementation plan, or State health plan.

(d) Where a State Agency has made a finding that a service is inappropriate, the State Agency shall, to the extent practicable, at the same time, make recommendations for remedial action.

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