

List of Subjects in 16 CFR Part 13**Layaway merchandise, trade practices.**

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45)

The Order Modifying Cease and Desist Order Issued July 23, 1980 is as follows:

Before the Federal Trade Commission

COMMISSIONERS: James C. Miller III,
Chairman, David A. Clanton, Michael
Pertschuk, Patricia P. Bailey

In the matter of Fred Meyer, Inc., Docket
No. C-3028.

**Order Modifying Cease and Desist Order
Issued July 23, 1980**

The Federal Trade Commission having considered the July 19, 1982, petition of Fred Meyer, Inc., a Delaware corporation, successor to Fred Meyer, Inc., an Oregon corporation, to reopen this matter and modify the consent order to cease and desist issued by the Commission on July 23, 1980, and having determined that public interest warrants reopening and modification of the order

It is ordered that order Paragraph A and B of Section 4 be revised as follows:

Mail to each layaway customer:

1. within twenty (20) days after the end of the period designated in the layaway agreement to make full payment for the merchandise,
2. if the payments received by respondent have not been returned to the customer, and
3. if the merchandise has not been delivered to the customer, and
4. before the merchandise is returned to stock and before making any entries in the layaway account which would close out the account, the following disclosure clearly and conspicuously in twelve-point or larger type, entirely on one side of a single piece of paper, separated from any other written matter:

We Owe You Money

(Date of mailing to be inserted here)

You haven't fully paid for your recent layaway purchase at our (name of store) store. You can fully pay for your purchase within 14 days from the above date. Or you can get a refund from us for the amount you have paid (less 35 cents handling charge). If you want a refund, come to the department of the store where you have the layaway not later than (insert date 14 days from notice) and ask for your money. You also have the choice of getting a credit to purchase other merchandise. Please bring this notice with you. If you don't ask for a refund or a credit, we will send you a check automatically within 45 days if the amount we owe you is more than \$1.

Respondent may insert in the above notice a different handling charge that is reasonable in comparison with a 35 cent charge.

B. Defer returning layaway merchandise to stock until 15 days after the mailing of the notice specified in IV. A. and allow completion of the layaway purchase within 14 days after the mailing of the notice.

By direction of the Commission.

Issued: October 14, 1982.

Carol M. Thomas,
Secretary.

[FR Doc. 82-30489 Filed 11-4-82; 8:45 am]

BILLING CODE 6750-01-M

DEPARTMENT OF THE TREASURY**Customs Service****19 CFR Part 18**

[T.D. 82-204]

**Customs Regulations Amendments
Relating to Customs Bonded
Warehouses****Correction**

In FR Doc. 82-29742, beginning at page 49355, in the issue of Monday, November 1, 1982, on page 49368, in the middle column, § 18.4 is corrected in the last line of the authority citation by changing "16461a" to "1646a".

BILLING CODE 1505-01-M

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES****Food and Drug Administration****21 CFR Part 184**

[Docket No. 75G-0117]

GRAS Status of Ozone

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that ozone is generally recognized as safe (GRAS), with specific limitations, for use as a disinfectant in bottled water. This action is based on an industry petition requesting such affirmation.

EFFECTIVE DATE: November 5, 1982.

FOR FURTHER INFORMATION CONTACT: Mary C. Custer, Bureau of Foods (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-9463.

SUPPLEMENTARY INFORMATION: Under procedures described in § 170.35 (21 CFR 170.35), the American Bottled Water Association, 1141 W. Olympic Blvd., Los Angeles, CA 90015, submitted a petition (GRASP 4G0043) requesting affirmation that the use of ozone as a disinfectant in bottled water is GRAS. FDA published a notice of filing of this petition in the *Federal Register* of June 25, 1975 (40 FR 26723), and the agency gave interested persons an opportunity to review the petition and to submit

comments to the Dockets Management Branch, Food and Drug Administration. No comments were received in response to the notice.

Ozone has the chemical formula O_3 ; is an unstable blue gas with a pungent, characteristic odor; and occurs at low levels (about 0.05 part per million (ppm) in air at sea level) in nature. It is generally encountered in dilute form in a mixture with air or oxygen. Ozone is formed photochemically in the Earth's stratosphere by the action of ultraviolet light of short wavelengths on oxygen. It is produced commercially by passing electrical discharges or ionizing radiation through air or oxygen. Ozone is a powerful oxidant having an oxidation potential of 2.07 volts. In aqueous solution, ozone is relatively unstable. The rate of decay of ozone in solution is dependent both on the temperature and the purity of the water.

Along with chlorine, ozone is generally recognized as one of the most potent germicidal agents used in the treatment of water. Chemical disinfectants kill or inactivate microorganisms by physical or chemical disruption of a critical cellular structure or function. In the case of ozone, a chemical reaction takes place that is oxidative in nature. Thus, the oxidative potential of ozone is an important factor with regard to its capabilities as a disinfectant. The chemical state of ozone that is germicidally active is not known, but it may be the $OH\cdot$ (hydroxyl radical) or the $HO_2\cdot$ (hydroperoxyl radical). The presence of other species, such as $O_3\cdot$ (ozonide radical), $O_2\cdot$ (superoxide radical), and $O\cdot$ (oxide radical), have been demonstrated, but their role in germicidal activity is not known. Most experimental data indicate that the efficiency of ozone as a disinfectant varies with pH, and that it is somewhat more efficient at a lower pH (6.0) than at a higher pH (10.0). This result is probably caused by the greater stability of ozone in water at lower pH's.

The petitioner has sought agency affirmation that the use of this ingredient as a disinfectant in bottled water is GRAS. Information supplied by the petitioner indicates that, under normal conditions, the ozone dosage applied is 0.5 to 2.0 ppm. The petitioner's quality control standard is a maximum level of 0.4 ppm at the time of bottling.

The petition provides information from the published literature verifying that ozone is toxic, particularly by inhalation, at relatively low levels. However, the petition also provides data from the published literature on the rate

of dissipation of ozone in water under a wide range of conditions. These data show that ozone dissipates rapidly when used in water, and that the rate of decay of residual ozone in water varies inversely with the amount of oxidizable materials present. The petition also includes unpublished data confirming the disappearance of ozone under the proposed conditions of use and under what must be considered worst case conditions—from distilled water.

The petition also provides published information indicating that ozone has been in continuous use for disinfecting municipal water for nearly 70 years in Europe, originally in France, extending to Germany, Holland, Switzerland, and other European countries. In addition, published reports indicate that a few municipalities in the United States have used it in their drinking water systems. There have been no reports of human toxicity from the use of ozone in municipal water supplies in the United States and Europe. This information corroborates the safety of the use of ozone as a disinfectant in bottled water.

In a 1968 opinion letter, FDA stated that ozone used to disinfect potable water is GRAS if it is used in accordance with current good manufacturing practice and with the recommendations of the United States Public Health Service. The agency reiterated this position in the preamble to the final rule establishing current good manufacturing practice for bottled water (40 FR 11566; March 12, 1975).

Ozone is also regulated in § 129.80 (21 CFR 129.80), at a level of 0.1 part per million in water, for use in sanitizing operations of product water-contact surfaces and any other critical areas.

After a comprehensive review of all data regarding the use of ozone as a disinfectant for bottled water, the agency has determined that:

1. Ozone is not eligible for GRAS status as a disinfectant in bottled water based on common use in the United States before January 1, 1958.

2. Ozone is GRAS for this limited use based on scientific procedures. The agency's conclusion is based upon published data demonstrating that although ozone may be toxic at relatively low levels, it dissipates rapidly in water. These data are supplemented by unpublished data that confirm the rapid dissipation of ozone in water under the intended conditions of use. This conclusion is corroborated by published information that ozone has been used for 70 years in Europe for disinfecting municipal drinking water, and that it has had a limited use for this purpose in the United States. No reports

of safety problems have been associated with this use.

3. Ozone performs the functional effect claimed by the petitioner.

Therefore, the agency concludes that the use and level of use of ozone as set forth in the petition is GRAS. The agency also has considered the potential consumer exposure to oxidation products formed during the reaction of ozone with impurities found in water. To assure that the levels of any oxidation products formed are low and safe, the agency has included in § 184.1563 (21 CFR 184.1563) the requirement that the starting water, before ozonation, meet the microbiological, physical, chemical, and radiological quality standards for bottled water specified in § 103.35 (b) through (e) (21 CFR 103.35 (b) through (e)). The agency thus concludes that this limited approval for use of ozone in bottled water constitutes a specific limitation on its use in accordance with § 184.1(b)(2) (21 CFR 184.1(b)(2)).

FDA is affirming ozone as GRAS even though there are no applicable food-grade specifications. The agency has determined that the method of manufacture of commercial ozone assures a product with purity suitable for the requested use. Therefore, the agency concludes that ozone must be of a purity suitable for its intended use in accordance with 21 CFR 170.30(h)(1), and that further specifications are unnecessary.

The format of the regulation is different from that in previous GRAS affirmation regulations. The agency has modified the form in which the specific limitations on the use of the ingredient is presented. This change has no substantive effect but is made merely for clarity.

The agency has determined under 21 CFR 25.24(d)(6) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

In accordance with Executive Order 12291, FDA has carefully analyzed the economic effects of this rule, and the agency has determined that the rule is not a major rule as defined by the Order.

List of Subjects in 21 CFR Part 184

Direct food ingredients, Food ingredients, Generally recognized as safe (GRAS) food ingredients

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348,

371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 184 is amended by adding new § 184.1563, to read as follows:

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

§ 184.1563 Ozone.

(a) Ozone (O₃, CAS Reg. No. 10028–15–6) is an unstable blue gas with a pungent, characteristic odor, which occurs freely in nature. It is produced commercially by passing electrical discharges or ionizing radiation through air or oxygen.

(b) The ingredient must be of a purity suitable for its intended use in accordance with § 170.30(h)(1) of this chapter.

(c) In accordance with § 184.1(b)(2), the ingredient is used to treat food only within the following specific limitations:

Category of food	Maximum treatment level in food	Functional use
Bottled water that prior to ozonation meets the microbiological, physical, chemical, and radiological quality standards of § 103.35 (b) through (e) of this chapter.	Not to exceed current good manufacturing practice. Current good manufacturing practice results in a maximum residual level at the time of bottling of 0.4 milligram of ozone per liter of bottled water.	Antimicrobial agent, § 170.3 (a)(2) of this chapter.

Effective date. This regulation shall become effective November 5, 1982.

(Secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348, 371(a)))

Dated: October 18, 1982.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 82-30180 Filed 11-4-82; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 601

Licensing; Reclassification Procedures To Determine That Licensed Biological Products Are Safe, Effective, and Not Misbranded Under Prescribed, Recommended or Suggested Conditions of Use

Correction

In FR Doc. 82-27314, beginning at page 44062, in the issue of Tuesday, October 5, 1982, make the following corrections:

1. On page 44062, in the first column under the "DATE" change "November 6, 1982" to "November 4, 1982".

2. On page 44071, in the middle column, the first full paragraph, last line, add "(d)" after "§ 601.26."

3. On page 44071, last column, the first paragraph under "PART 601—LICENSING", change the last line of the amendatory language from "(1), as follows:" to read "(1), as follows:".

4. On page 44071, in the last column, the footnote designated "2 Note", first line, change "November 6, 1982" to read "November 4, 1982".

5. On page 44073, in the middle column, the first full paragraph, second line, change "November 6, 1982." to read "November 4, 1982".

BILLING CODE 1505-01-M

21 CFR Part 1020

[Docket No. 77N-0061]

Diagnostic X-Ray Systems and Their Major Components; X-Ray Beam Limitation Devices for Radiographic and Fluoroscopic X-Ray Systems

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing regulations to (1) clarify the x-ray beam limitation requirements for stationary, general-purpose radiographic systems; (2) incorporate interpretations that have been made about the performance of these systems; (3) relax certain requirements for field size adjustments; and (4) permit a capability for overriding the automatic x-ray field size adjustment on radiographic spot film and fluoroscopic x-ray systems if appropriate labeling is provided.

EFFECTIVE DATE: December 1, 1983.

FOR FURTHER INFORMATION CONTACT: Raymond F. Coakley, Jr., Bureau of Radiological Health (HFX-460), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3426.

SUPPLEMENTARY INFORMATION: Under the Public Health Service Act as amended by the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602, 42 U.S.C. 263b et seq.), FDA is amending the performance standard for diagnostic x-ray systems and their major components (21 CFR 1020.30, 1020.31, and 1020.32). The amendments modify the requirements of § 1020.31(e)(2) concerning the manner in which means to limit the x-ray field are provided for stationary, general-purpose radiographic systems. The amendments also alter

§§ 1020.31(g) and 1020.32(b) by permitting a capability for overriding the automatic x-ray field size adjustment on spot film and fluoroscopic x-ray systems and by requiring appropriate labels for these override controls when such a capability is provided.

The development of these amendments was announced in a notice of intent published in the *Federal Register* of April 1, 1977 (42 FR 17494), and drafts of the proposed amendments were made available for review and comment by interested parties. Under section 358(f) of the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263f(f)), those proposals were reviewed by the Technical Electronic Product Radiation Safety Standards Committee, a permanent statutory advisory committee to the Secretary, Department of Health and Human Services, which must be consulted before establishment or amendment of performance standards for electronic products. The committee concurred with issuing the proposals for public comment.

In the *Federal Register* of May 9, 1978 (43 FR 19879) FDA published the proposed amendments. Interested persons were given 60 days to comment on the proposal. Written comments were received from four manufacturers, two radiologists, and one radiological physics consultant. The substantive comments received and FDA's conclusions are discussed below.

General Comments

1. Several comments lauded FDA's proposal to simplify the requirements concerning positive beam limitation (PBL) but at the same time criticized the agency for the number of regulations and the burden these rules impose. These same comments questioned the need for regulations of this general type.

The agency believes the PBL systems are useful and reliable. The arguments favoring the rule have been previously made a matter of public record. Subsequent data show that PBL can and does achieve its purpose, which is to reduce x-ray beams to the size of the film.

The Bureau of Radiological Health (BRH) conducted a survey of user practices, attitudes, and assessments regarding devices that provide PBL on stationary, general-purpose radiographic systems. The results were compiled, evaluated, and published in a report entitled "Positive Beam Limitation Effectiveness Evaluation" (Ref. 1).

BRH initiated the survey in 1978 after receiving reports that many users of x-ray systems equipped with PBL were overriding the PBL system when the

same or better results would have been obtained with the device in full operation. The reports also indicated that, among those who did use the PBL, general acceptance was poor.

The survey participants were a stratified random sample of one of every nine known PBL users in June 1977. BRH sent to 543 persons a questionnaire and instructions developed by BRH. The questionnaire was accompanied by letters of endorsement from the American College of Radiology and the American Society of Radiologic Technologists. An overall 75-percent response was achieved.

Survey responses indicated that PBL has been generally well received by its users but that there is room for improvement. Reliability of the PBL system appeared to be a key factor in user acceptance of PBL. Sixty percent of the respondents rated the reliability of the PBL system as better than that of other x-ray components, and 76 percent reported downtime (lack of use due to malfunction) of 4 percent or less. Ratings of reliability were associated with whether users liked using PBL (66 percent did), whether the users thought PBL was effective in reducing x-ray exposure (80 percent thought so), whether the users concluded that they saved time by using PBL (78 percent did), and whether they believed the effort required to take radiographs was reduced by PBL (76 percent did).

The agency concludes that PBL requirements are not only justified but widely accepted and that the comments that questioned the need for these regulations do not warrant any change.

Requirements for Field Size Adjustment

2. A comment argued that the proposed rule would force manufacturers to redesign all existing PBL systems to a less restrictive requirement to remain competitive.

The agency recognizes that redesign may be necessary to incorporate the features permitted by the amendment. However, each PBL manufacturer will have the opportunity to compete in this area. Increased cost of meeting competition is not a persuasive argument against greater flexibility in government regulation.

Under the previous provisions of the standard, the presence of the PBL override and the need for undersizing of the x-ray field have allowed conditions where poor use by operators sometimes caused unnecessary patient exposure. The agency believes that unnecessary radiation exposure arising from the frequent and continual use of the override mode in existing systems will

be reduced when undersizing is more easily accomplished. The amended standard eliminates the requirement that the x-ray field always return to the full size of the image receptor whenever a cassette is changed—even when the cassette is the same size. The universality of that requirement was an occasion for operators to leave the equipment in the override mode when making a series of undersized radiographs (where all the cassettes were the same size) because repeated cassette replacement required repeated undersizing of the field.

Historically, the need for undersizing provided the stimulus for the agency to amend the standard. Practicing radiologists and technologists requested systems that could retain an undersized (coned down) field size smaller than the image receptor size while the operator made a series of exposures. Under the former rule, replacing one image receptor with another (whether of the same size or not) while in PBL mode caused the field size to return to the full size of the image receptor. The proposed amendment was intended to permit (not to require) the field size to remain coned down during a change of image receptor, provided the image receptor's size did not change.

The agency has changed the wording of the final rule to clarify this intent. Section 1020.31(e)(2)(i) requires that the field size and the image receptor size match; however, the agency has added new § 1020.31(e)(5) which permits the operator to initiate undersizing of the field, provided the same image receptor size and the same source-to-image-receptor distance (SID) are maintained.

FDA has also made this change to avoid a possible situation in which, to avoid noncompliance declarations, the field size would be permanently adjusted to a size smaller than the inserted image receptor. The agency evaluated compliance with the current requirements for automatic field size adjustment by analyzing field test results for certified, PBL-equipped, general-purpose radiographic systems. The results showed a significant portion of the noncompliances arose from x-ray field dimensions smaller than permitted. Many of these noncompliances would have resulted in unusable radiographs requiring repeat radiographic studies to obtain usable diagnostic images. Thus, systems fully complying with the proposed rule by permanent adjustment to undersize could be producing radiographs containing little or no diagnostic information and thus force the user to use the override. To avoid

this situation the final rule eliminates this provision of the proposal.

3. A comment noted that, before reliable PBL was developed, it was common practice to leave unexposed margins on radiographs. The comment stated that this practice is "a totally unnecessary waste of film and possible loss of diagnostic information." Routine maintenance should control the accuracy of the PBL system and undersizing should not be permitted.

The agency notes that, at some facilities, uncertified beam limitation systems are required to exhibit an unexposed margin as evidence of collimation. For consistency, such evidence of collimation is usually required for radiographs taken with any x-ray equipment, whether certified or uncertified. The former PBL requirement—which applies to certified equipment but not to uncertified—made this consistency somewhat difficult to accomplish routinely. These current radiological practices, along with other information, led to this amendment, which will allow an unexposed margin without the need of an override. Under the amended standard, those facilities having both certified and uncertified equipment can now establish and continue the policy of unexposed margins as part of a uniform quality control program. As mentioned above, the agency never intended that the undersizing provision be used as an excuse by manufacturers or assemblers to set the PBL sensing mechanism to cause undersizing to satisfy the field limitation requirement by means of poor tolerances. In fact, the capability to retain a reduced field configuration is not required by the standard but is only permitted. The agency is confident that manufacturers will produce reliable PBL systems in response to market pressures. Therefore, the final rule retains the undersizing feature that allows the operator the freedom to retain a reduced x-ray field without the need of an override when the cassette size and SID remain unchanged. At the same time, manufacturers may not set the PBL system so that it always produces undersizing.

4. Three comments on proposed § 1020.31(e)(3)(v) suggested that tomography as well as stereoscopic radiography be excepted from PBL requirements.

The agency intended that tomography be excluded from the conditions requiring that PBL be provided and believes that the proposed rule implicitly excepted tomography. Section 1020.31(e)(3)(v) has been revised so as

explicitly to exclude tomographic radiography from the requirements.

5. A comment objected to the provision in proposed § 1020.31(e)(2) that "x-ray production be prevented," arguing that this provision is stricter than the current requirement. The comment interpreted the 5-second compliance requirement of proposed § 1020.31(e)(4) as a design standard that would inhibit the development and use of systems such as capacitor discharge or field emission units where x-rays are produced but absorbed by a safety shutter.

The agency advises that the final standard, as amended, is identical to the current standard in requiring that x-ray production be prevented. FDA intended that the x-ray tube not be energized to the point of x-ray emission unless the PBL requirements were met. The requirement in § 1020.31(e)(4) of this final rule—for PBL to be effective within 5 seconds of cassette insertion—is the same as the previous requirement; 5 seconds are allowed for automatic adjustment. The agency notes further that this is not a design standard because the means to achieve the required PBL performance within 5 seconds is not specified.

The agency also notes that the capacitor discharge and field emission units mentioned are usually not in the stationary, general-purpose radiographic systems subject to the PBL requirement.

Conditions for Positive Beam Limitation

6. A comment objected to the proposed condition in § 1020.31(e)(3)(i) that "the image receptor is inserted into a permanently mounted cassette holder," as being a design standard and also a change from the previous rule. It also pointed out that, for a PBL design that is continuously in operation, the proposal did not account for: (1) Image receptors that do not use cassettes, (2) techniques that do not use a permanently mounted cassette holder or film changer (such as tabletop or stretcher exposures), and (3) certain special cases such as the use of a portable cassette holder. The comment suggested that this type of system, designed to provide operational PBL at all times, must be allowed a bypass or override mode and proposed that the condition read: "The image receptor is in position for an exposure and a technique requiring PBL is selected."

The agency does not agree that this condition is a design standard. Section 1020.31(e)(3) identifies the circumstances under which PBL must be operative; it does not give detailed specifications on materials or manner of

construction to achieve the required performance. The agency also disagrees with the assertion that § 1020.31(e)(3)(i) is a change from the previous requirement. The rule merely states in a more positive way the conditions under which PBL must be operative. For the type of design mentioned in the comment a bypass mode is not prohibited. The override is present because the standard requires PBL operation only when an image receptor has been inserted into a permanently mounted cassette holder and not for the situations mentioned in the comment. The agency has always discouraged the use of the override switch to permit use of a film changer or to perform table top radiography and other routine radiographic procedures. That type of design requires that the override switch be routinely used for these routine procedures.

This amendment seeks to reduce the misuse of the override switch (as discussed here and in paragraph 2), which PBL design has encouraged or required to use for common everyday operation. The comment is rejected.

7. A comment asserted that the seemingly innocuous changes have major implications that result from applications that were not considered. The comment urged further thought to discover all the techniques for which designs would have to be provided. The only example mentioned is arthrography on a radiographic table that uses film changers with variously sized films instead of a cassette.

The agency concludes that the objection is based on the same premise that was addressed in paragraph 6. The technique mentioned does not require PBL because a permanently mounted cassette holder is not used.

8. One comment objected to proposed § 1020.30(e)(3) (iii) and (iv) that require PBL when the x-ray beam axis is within ± 3 degrees. The comment called it a design standard, contended that it was more restrictive than the previous standard, and argued that industry would have to set sensing mechanisms to ± 4 degrees or ± 5 degrees to assure compliance at ± 3 degrees.

As discussed at length in paragraph 2 of the preamble to the proposal the revision relaxes a restriction in the previous rule that required PBL when the beam was within ± 10 degrees of the horizontal or vertical. A manufacturer may provide effective PBL at any beam axis angulation. The previous rule, the proposed rule, and this final rule require PBL only when the beam axis and the image receptor plane are very nearly perpendicular. This less restrictive requirement is retained in the final rule.

9. One comment questioned the use of English measurement units in proposed § 1020.31(e)(3)(iii) establishing conditions for the SID. The comment stated that, because the previous rule permitted the PBL range limit to be 100 centimeters when a metric scale is provided, the use of 36 inches in proposed § 1020.31(e)(3)(iii) would require a redesign. Furthermore, the comment said, the metric system is being encouraged by Federal policy.

The agency agrees that the metric system is more appropriate both for policy and for consistency within the standard. The final rule reflects this agreement. In addition, although image receptor sizes continue to be commonly measured in inches, for consistency, § 1020.31(e)(3)(ii) identifies the image receptor to read, 50 centimeters. This unit change differs so slightly from the proposed dimension of 20 inches that the agency considers it to be insignificant. The agency advises that, for compliance purposes, systems will be measured in the units that are provided by the manufacturer.

10. A comment asked why chest radiography at an SID of 7 or 8 feet no longer would require PBL.

The agency advises that the conditions for PBL are those for which most common radiographic examinations are performed. Chest radiography normally is performed at SID's of 72 inches or less. The radiography performed at SID's of 7 or 8 feet is considered to be a specialized application and not routine radiography. Because the demand for these specialized applications is low, manufacturers are not required to produce PBL systems designed to operate at SID's in excess of 72 inches.

Radiographic Override Capability

11. A comment objected to labeling that proposed § 1020.31(e)(5) would require to be included on the key switch because the text would not express a warning. The comment argued that a longer and more meaningful text is necessary.

As discussed in paragraph 4 of the preamble to the proposal, the purpose of the key switch label is to indicate the function of the switch—not to express a warning. The label is intended to reduce misinformation—not carelessness. The agency rejects the comment.

12. The comment that argued that the proposed key switch labeling was inadequate also suggested that including a longer text on the unit itself would interfere with the physical arrangement, and there would not be enough space on the unit to accommodate the needed information. As an alternative, the

comment suggested that the longer text should be included in the operator's manual. Another comment noted that the required label may need to be printed in very small type so it would not distract from the operating control labels. This comment also suggested that the warning could be printed on a large holder or durable tag permanently affixed to the key itself. In this manner, the message could be made more prominent, and the tag or holder on the key might also serve to discourage users from leaving the key in the key switch when the override switch is not in use.

The agency recognizes that adding a label will require some production changes on units manufactured after the effective date of this amendment. However, as discussed at length in paragraph 4 of the preamble, FDA believes that labeling the override switch will reduce the inappropriate use of the switch. No data showing the contrary were submitted with the comments. Therefore, the agency concludes that these changes are justified by the reasons explained in the preamble to the proposal and retains in the final rule the requirement for a label. However, the location of the labeling might be improved. The agency rejects the suggestion that the information be confined to the operator's manual and maintains that the switch itself must be labeled to show its intended function. In the final rule, the agency has adopted the suggested option for labeling the key. Thus, an alternative will be available where space limitation is a problem.

13. One comment argued that the costs of attaching any label and of reopening, changing, and repackaging units already manufactured for stock "are not justified when one keeps in mind that the same switch was accepted for years without a label." The comment objected to FDA's proposal to make this requirement effective 60 days after publishing the final rule. The comment claimed 18 months are needed to comply with the provision.

The agency advises that these labels will be required only on units manufactured after the effective date. Thus, it will not be necessary to relabel any warehouse stocks manufactured before that date. The date of manufacture is given on the manufacturer's identification label. The alternative of permanently labeling the key should take even less time than labeling the control unit. The agency, however, has reconsidered the 60-day proposed effective date and has concluded that 1 year is a reasonable period of time to make any changes

required by the amendments. To further ease any burden, FDA is making the new requirements effective on the first working day of the thirteenth month after publication of the final rule, which will permit manufacturers to add the override switch label concurrent with their periodic change in date of manufacture given on the manufacturer's identification label.

14. Another comment stated that the requirement of a label indicating that this override switch is for system failure is not facing up to the fact that it will be used for non-bucky techniques (that do not use permanently mounted cassette holders) and special procedures.

The comment misunderstood the requirement. A PBL system that meets either the current or the amended standard does not need an override for "non-bucky techniques" or any known special procedures. Those techniques that do not use a permanently mounted cassette holder do not now nor did they ever require use of an override switch because PBL has not been required under this condition. The standard has been clarified by changing its current requirement (for PBL after insertion of an image receptor—which has previously been interpreted to mean insertion into a permanently mounted cassette holder) to an explicit requirement (for PBL after insertion of an image receptor into a permanently mounted cassette holder—which most special procedures do not use). This change is intended to assure that the x-ray field is limited to and aligned with the boundaries of an image receptor placed in a cassette holder designed as a permanent part of the system. Thus, it applies to the large majority of routine radiographic procedures performed with stationary, general-purpose radiographic systems. By requiring the key switch or key to be labeled, the agency provides for users that might not be trained in the proper use of PBL. Operators previously have been able to "cone down" to small x-ray fields to satisfy their need for an unexposed margin. They now can cone down to satisfy any need for even smaller x-ray fields on an image receptor inserted in a permanently mounted cassette holder. The operator accessible switch is for system failure only—not for special procedures. No change is required in the final rule.

Fluoroscopic Override Capability

15. A comment stated that "spot-film systems with an override switch should not require a visible indicator, because the override mode is recognized immediately by the radiologist as soon as he takes the first spot-film radiograph."

FDA disagrees with the comment. The purpose of the visual indicator required by §§ 1020.31(g)(5) and 1020.32(b)(3) is to alert the radiologist that the unit is in the override mode before the first radiograph is taken. The agency believes that trial and error is not an appropriate way to become informed of this situation. Not requiring a visual indicator would promote unnecessary radiation exposure to the patient as well as waste of film. FDA concludes that, because the override switch is not key-controlled, visible indication of the status is necessary if the operators are to minimize both unnecessary exposure to the patient and the necessity for retakes.

16. A comment questioned the meaning of the phrase "signal visible at the fluoroscopist's position" in proposed §§ 1020.31(g)(5) and 1020.32(b)(3). The comment objected to the use of a light that might distract the attention of the fluoroscopist, and suggested that FDA should restate the provisions to provide only that a "visual indication shall be required * * *".

The agency intends that the signal attract the fluoroscopist's attention before he or she begins to use a system in which the automatic field adjustment has failed. The comment is rejected.

17. With respect to the effective date of the amendments, a comment argued that, because of the design change required, 2 years are needed before the regulation is made effective. Another comment believed that 60 days are sufficient to implement the labeling change and does not mention any design change.

The agency notes that no manufacturer is required to provide an override capability. However, if a manufacturer provides an override, then it must meet the requirements by the effective date of the amendments. As discussed in paragraph 13 above, FDA concludes that 1 year is a reasonable period of time to add an indicator of the override capability, a change that is not major. However, to permit manufacturers to implement the provisions in an orderly and efficient manner, the amendments will become effective on the first working day of the thirteenth month after date of publication in the Federal Register.

Reference

The following information has been placed on file in the Dockets Management Branch, Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

"Positive Beam Limitation Effectiveness Evaluation," prepared by the Division of Compliance and the Data Systems and Mathematics Staff of the Bureau of Radiological Health, Food and Drug Administration, February 1980 (HHS Publication (FDA) 80-8108). (Available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (GPO Stock No. 017-015-0163-6, \$2.00)).

In accordance with Executive Order 12291, the economic effects of this final rule have been carefully analyzed, and it has been determined that this rule is not a major rule under the criteria of the Order. The amendments to the standard can be considered generally to be a relaxation of the rule and the additional requirements for a key switch label and a signal visible at the fluoroscopist's position involve a very small increase in cost of future units, especially compared with the cost savings of the overall effect of this rule. Specifically, the annual cost of the label required on stationary, general-purpose radiographic equipment is estimated to be \$3,000 (\$1.00 per system for approximately 3,000 systems). The annual cost for the label and visible signal required on stationary, general-purpose fluoroscopic equipment is estimated to be \$30,000 (\$15.00 per system for approximately 2,000 systems). The requirement for a regulatory flexibility analysis under the Regulatory Flexibility Act does not apply to this final rule because the proposed rule was issued prior to January 1, 1981, and is therefore exempt. In any event, this rule will not have a significant economic impact on a substantial number of small entities, for the reasons stated above.

List of Subjects in 21 CFR Part 1020

Electronic products, Ionizing radiation, Medical devices, Radiation protection, Standards, Television, X-rays.

Therefore, under the Public Health Service Act as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 358, 82 Stat. 1177-1179 (42 U.S.C. 263f)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 1020 is amended as follows:

PART 1020—PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS

1. In § 1020.30 by revising paragraph (b)(19), to read as follows:

§ 1020.30 Diagnostic x-ray systems and their major components.

* * * * *

(b) * * *

(19) "Image receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations. In those cases where means are provided to preselect portions of the image receptor, the term "image receptor" shall mean the preselected portion of the device.

2. In § 1020.31 by revising paragraph (e)(2), and by adding new paragraphs (e)(3), (4), (5), and (6) and (g)(5), to read as follows:

§ 1020.31 Radiographic equipment.

(e) * * *

(2) *Positive beam limitation (PBL).* The requirements of this paragraph shall apply to stationary, general-purpose radiographic systems which contain a tube housing assembly, an x-ray control, and, for those systems so equipped, a table, all certified in accordance with § 1020.30(c). Means shall be provided for PBL such that x-ray production is prevented when:

(i) Either the length or width of the x-ray field in the plane of the image receptor differs from the corresponding image receptor dimension by more than 3 percent of the SID; or

(ii) The sum of the length and width differences as stated in paragraph (e)(2)(i) of this section without regard to sign exceeds 4 percent of the SID.

(3) *Conditions for positive beam limitation.* PBL shall be provided whenever all the following conditions are met:

(i) The image receptor is inserted into a permanently mounted cassette holder;

(ii) The image receptor length and width are each less than 50 centimeters;

(iii) The x-ray beam axis is within ± 3 degrees of vertical and the SID is 90 centimeters to 130 centimeters inclusive; or the x-ray beam axis is within ± 3 degrees of horizontal and the SID is 90 centimeters to 205 centimeters inclusive;

(iv) The x-ray beam axis is perpendicular to the plane of the image receptor to within ± 3 degrees; and

(v) Neither tomographic nor stereoscopic radiography is being performed.

(4) *Measuring compliance.* Compliance with the requirements of paragraph (e)(2) of this section shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of paragraph (e)(3) of this section are met.

Compliance shall be determined no

sooner than 5 seconds after insertion of the image receptor.

(5) *Operator initiated undersizing.* The PBL system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 by 5 centimeters. Return to PBL function as described in paragraph (e)(2) of this section shall occur automatically upon any change of image receptor size or SID.

(6) *Override of positive beam limitation.* A capability may be provided for overriding PBL in case of system failure and for servicing the system. This override may be for all SID's and image receptor sizes. A key shall be required for any override capability that is accessible to the operator. It may not be possible to remove the key while the PBL is overridden. Each such key switch or key shall be clearly and durably labeled as follows:

For X-Ray Field Limitation System Failure

The override capability is considered accessible to the operator if it is referenced in the operator's manual or in other material intended for the operator or if its location is such that the operator would consider it part of the operational controls.

(g) * * *

(5) A capability may be provided for overriding the automatic x-ray field size adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position shall indicate whenever the automatic x-ray field size adjustment override is engaged. Each such system failure override switch shall be clearly labeled as follows:

For X-Ray Field Limitation System Failure

3. In § 1020.32 by adding paragraph (b)(3), to read as follows:

§ 1020.32 Fluoroscopic equipment.

(b) * * *

(3) If the fluoroscopic X-ray field size is adjusted automatically as the SID or image receptor size is changed, a capability may be provided for overriding the automatic adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position shall indicate whenever the automatic field adjustment is overridden. Each such

system failure override switch shall be clearly labeled as follows:

For X-Ray Field Limitation System Failure

Effective date. This regulation shall become effective on December 1, 1983.

(Sec. 358, 82 Stat. 1177-1179 (42 U.S.C. 263f))

Dated: October 14, 1982.

Mark Nevitch,

Acting Commissioner of Food and Drugs.

[FR Doc. 82-30181 Filed 11-4-82; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of Assistant Secretary for Housing—Federal Housing Commissioner

24 CFR Part 3280

[Docket No. R-82-1017]

Manufactured Home Construction and Safety Standards

Correction

In FR Doc. 82-29865, beginning at page 49383, in the issue of Monday, November 1, 1982, make the following corrections:

1. On page 49386, last column, first paragraph, first line, "(1)(2)(i)" should read "(i)"

2. On page 49387, middle column, third full paragraph, designated as amendment "9.", the second line, "(1)(2)(ii), (1)(2)(iii) and (1)(2)(iv)" should read "(e)(2)(ii), (e)(2)(iii) and (e)(2)(iv)" by changing the "1's" to "e's".

BILLING CODE 1505-01-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 51

[T.D. 7844]

Crude Oil Windfall Profit Tax Act of 1980; Excise Tax Regulations

AGENCY: Internal Revenue Service, Treasury.

ACTION: Final regulations.

SUMMARY: This document provides final excise tax regulations relating to the windfall profit tax on domestic crude oil imposed by title I of the Crude Oil Windfall Profit Tax Act of 1980. It contains most of the final regulations on