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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 998

[Docket No. FV-90-169FR]

Marketing Agreement No. 146 Regulating the Quality of Domestically Produced Peanuts

Changes in Incoming and Outgoing Quality Regulations and Terms and Conditions of Indemnification for 1990 Crop Peanuts

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule changes the incoming and outgoing quality regulations and the current terms and conditions of indemnification for 1990 crop peanuts. The incoming regulation is changed by inserting a paragraph that was inadvertently deleted from that regulation. The outgoing regulation is changed to provide that a larger portion of the costs of aflatoxin sampling and testing be paid by peanut buyers. Changes in the sales contract provisions of the terms and conditions of indemnification section of the regulations are made to provide that handlers include in their sales contracts a provision that peanut buyers pay such additional costs. Another change in the provisions provides that handlers include a provision that buyers shall agree, in certain situations, to accept lots of peanuts which have been reconditioned and meet the requirements of the outgoing quality regulation. The terms and conditions of indemnification are also changed to increase the indemnification payment rate on quota peanuts and to increase the allowance paid by the Peanut Administrative Committee (Committee) to handlers for remilling qualified peanuts under the indemnification program. These changes, which were unanimously recommended by the Committee, are implemented in conjunction with a reduction in the level of aflatoxin allowed in raw peanuts for human consumption. The changes are intended to help handlers provide peanut buyers, manufacturers, and ultimately consumers with a more wholesome product.

EFFECTIVE DATE: August 23, 1990.

FOR FURTHER INFORMATION CONTACT: Patrick Packnett, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, Room 2525–S, Washington, DC 20090–6456, telephone 202–475–3862.

SUPPLEMENTARY INFORMATION: This final rule is effective under Marketing Agreement No. 146 (7 CFR part 998), regulating the quality of domestically produced peanuts, hereinafter referred to as the Agreement. This Agreement is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the Act.

This final rule has been reviewed by the U.S. Department of Agriculture (Department) in accordance with Departmental Regulation 1512–1 and the criteria contained in Executive Order 12291 and has been determined to be a "non-major" rule under criteria contained therein.

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Administrator of the Agricultural Marketing Service (AMS) has considered the economic impact of this final rule on small entities.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened.

There are approximately 50 handlers of peanuts subject to regulation under the agreement, and there are about 46,950 peanut growers in the 16 states covered under the program. Small agricultural producers have been defined by the Small Business Administration (13 CFR 121.2) as those having annual receipts of less than $500,000, and small agricultural service firms are defined as those whose annual receipts are less than $3,500,000. Some of the handlers signatory to the agreement are small entities, and a majority of the growers may be classified as small entities.

There are three major peanut production areas in the United States covered under the agreement: (1) Virginia-Carolina, (2) Southeast, and (3) Southwest. These areas encompass 16 states. The Virginia-Carolina area (primarily Virginia and North Carolina) usually produces about 18 percent of the total U.S. crop. The Southeast area (primarily Georgia, Florida and Alabama) usually produces about two-thirds of the crop. The Southwest area (primarily Texas, Oklahoma, and New Mexico) produces about 15 percent of the crop. Based upon the most current information, U.S. peanut production in 1989 totalled 4.03 billion pounds, a one percent increase from 1988, and ten percent more than in 1987. The 1989 crop value is $1.12 billion and the 1988 crop was of approximately the same value.

The objective of the Agreement is to insure that only wholesome peanuts enter edible market channels. Since aflatoxin was found in peanuts in the mid-1960's, the domestic peanut industry has sought to minimize aflatoxin contamination in peanuts and peanut products.

The agreement play a very important role in the industry's quality control efforts. It has been in place since 1965 and participating shellers (handlers) annually handle about 95 percent of the U.S. crop. Requirements established pursuant to the agreement require farmers' stock peanuts with visible *Aspergillus Flavus* mold (the principal producer of aflatoxin) to be diverted to non-edible uses. Each lot of shelled peanuts for edible use must be officially sampled and chemically tested for aflatoxin by the Department or in laboratories approved by the Committee. The Committee works with the Department in administering the marketing agreement program. The inspection and chemical analysis programs are monitored by the Department. Provision is made under the Agreement for indemnification of sheller losses if the peanuts are deemed unsuitable for consumption because of aflatoxin. All indemnification and administration costs are paid by assessments levied on shellers signatory to the Agreement.

The incoming quality regulation specifies the quality of farmers' stock peanuts which handlers may purchase

from producers. Handlers are required to purchase only good quality, wholesome peanuts for edible products. The outgoing quality regulation requires shellers to mill peanuts to meet certain quality specifications and have them inspected before such peanuts can be sold to edible outlets. Foreign material and damaged and immature peanuts are removed in the milling operation. Each lot of shelled peanuts also must be sampled and chemically analyzed for aflatoxin. If the chemical assay shows the lot to be positive as to aflatoxin, the lot is not allowed to go to edible channels. Such lots may be remilled or blanched in order to remove aflatoxin contamination. Lower quality peanuts are crushed for oil and meal. The end result is that only good quality peanuts end up in human consumption outlets.

On May 17, 1990, the Committee, by a unanimous mail vote, made the following five-part recommendation, which includes changes in the outgoing quality regulation and terms and conditions of indemnification for 1990 crop peanuts (7 CFR 998.200 and 998.300; 55 FR 30902, July 30, 1990).

A proposed rule on the recommended changes was published in the **Federal Register** on July 17, 1990 (55 FR 29028). The comment period ended on August 1, 1990. Eleven comments were received on the proposed rule. The comments, which were from the shelling and manufacturing segments of the peanut industry, were in support of the action, but only if the entire set of changes recommended by the Committee is implemented.

The first change amends paragraph (c)(3) of § 998.200 *Outgoing quality regulation*, to provide that a larger portion of the costs of aflatoxin sampling and testing be paid by peanut buyers than has previously been paid by such buyers. The testing procedure specified in paragraph (c) requires the drawing of three 48-pound samples (designated as samples #1, #2, and #3). These samples are ground and subsamples (1–AB, 2–AB and 3–AB) are extracted and chemically analyzed for aflatoxin by Department laboratories or laboratories approved by the Committee. Under the previous provisions of paragraph (c), buyers paid for the cost of the chemical assay on subsample 1–AB, and for a portion of the cost of drawing the three 48-pound samples, grinding sample #1 and preparation and delivery of the initial subsample to the laboratory (for 1989, the cost of the chemical assay on subsample 1–AB was $28.00–$33.00 and the other costs were $10.00). This change provides that a larger portion of the costs of sampling and testing be paid for by buyers. These costs include: (1) Drawing, handling and dividing samples; (2) grinding sample #1; (3) analysis of subsample 1–AB; (4) sample bags; (5) estimated average value of the peanuts in the samples; (6) grinding, handling and testing samples 2–AB and 3–AB; and (7) indirect or irregular costs (overtime, mileage, delivery of samples, etc.). The Committee computed an industry-wide average cost per pound for aflatoxin sampling and testing. This average cost per pound will be multiplied by the total poundage the buyer purchases. The resulting figure is the cost for which the buyer will be invoiced by the handler for aflatoxin sampling and testing. Therefore, the additional costs are based on the amount of peanuts purchased.

Data on the cost of aflatoxin sampling and testing was collected by the Committee from the Federal-State Inspection Service, Department laboratories and Committee approved laboratories in all the states within the production area that are currently conducting aflatoxin testing. The costs vary from state to state. The Committee believes that the fees charged to buyers should be the same throughout the production area to avoid confusion between handlers and buyers and to facilitate the orderly flow of peanuts in the marketplace. Because of the state-to-state variation in fees, calculations were done to derive an industry-wide weighted average for each fee category based upon the volume of peanuts tested in each state. The industry's average total cost per lot for the sampling and testing program was divided by the average peanut lot size (49,698 pounds—based upon Committee records for the 1989 crop year) to derive a cost per pound for the aflatoxin sampling and testing program. The average fees in each category are shown in the table below.

Average Aflatoxin Sampling and Testing Costs [1]

1. Drawing, handling & dividing samples	$15.77
2. Grinding sample #1	10.00
3. Lab fee for 1–AB	28.56
4. Sample bags	0.96
5. Estimated average value of peanuts in the sample	82.08
6. Five-year average cost per lot testing and related costs subsamples 2–AB and 3–AB [2]	3.70
7. Indirect or irregular costs	6.90
Average cost per lot	147.97

Avg. Cost/Lot $147.97/Avg. Lot Size 49,698 lbs. = $0.0030 per pound or $0.30 per hundredweight.

[1] Figures represent averages and may vary slightly for individual handler operations.

[2] Cost currently paid by the Committee under the indemnification program funded by handler assessments.

The Committee recommended that the rate per pound charged to buyers on 1990 crop peanuts be established at $0.0027 per pound or $0.27 per hundredweight. Based upon available data and the variability in sampling and testing fees throughout the production area and individual handler operations, the Committee believes that this rate is equitable and will accomplish its objectives. If the computed average cost shown above were used, the total cost charged to buyers would approach or slightly exceed the total cost for aflatoxin sampling and testing. Accordingly, the Committee's recommendation that only $0.0027 per pound or $0.27 per hundredweight be charged is implemented.

Previously, the provisions of paragraph (m)(3) of § 998.300 *Terms and conditions of indemnification* applied only to costs associated with sampling and testing subsample 1–AB. Accordingly, a related conforming change in paragraph (m)(3) is made to reflect the changes in § 998.200(c)(3).

The second change amends paragraphs (m)(1), (m)(2) and (m)(3) of § 998.300 to include provisions that handlers' sales contracts include a provision that on any lot of peanuts rejected by buyers under the appeal procedure and on any lot that is rejected on the basis of the test results of the pre-shipment sample made in the name of the buyer, whose name is shown on the covering certificate, the buyer shall agree to accept the lot of peanuts once it has been successfully remilled or blanched (reconditioned). Specific reasons for these changes are discussed later in this document.

The third change amends paragraphs (e), (h), (j) and (x) of § 998.300 to increase the base rate of indemnification payment paid to handlers for rejects on quota peanuts from 43 cents to 45 cents per pound. The 43 cents per pound rate was established in 1987 and was based on the support price for sound mature kernels under the peanut price support program. The support price for sound mature kernels for Runner type peanuts, which are handled in the greatest volumes, has increased from 43 cents in 1987 to 45 cents in 1990. Thus, the Committee recommended that the indemification rate be adjusted to reflect this increase.

The fourth change also amends paragraph (e) of § 998.300 to increase the allowance paid to handlers by the

Committee for remilling qualified peanuts under the indemnification program from two and one-half cents to three and one-half cents per pound. The terms and conditions of indemnification require handlers to remill and/or blanch lots of peanuts on which indemnification claims are made in an effort to make such peanuts suitable for human consumption and to minimize indemnification costs. On lots of peanuts covered by indemnification claims, handlers pay the difference between the actual cost for remilling and the allowance given by the Committee. This change reflects an increase in remilling costs over the past few years. The one cent increase will further protect handlers from losses due to aflatoxin. The change will also encourage remilling lots of peanuts to remove contaminated kernels as opposed to blanching which requires removal of the skins and thus, shortens the storage life of the peanuts.

The four changes discussed above are implemented in conjunction with a recommendation made by the Committee to reduce the level of aflatoxin allowed in raw peanuts for human consumption under the Agreement from 20 parts per billion (ppb) to 15 ppb. This voluntary 25 percent reduction brings the level of aflatoxin allowed in raw peanuts for human consumption under the Agreement below that allowed in finished products by the U.S. Food and Drug Administration. Moreover, because good manufacturing practices remove significant quantities of unfit peanuts and levels of aflatoxin are reduced by heating and sorting, this action will help the industry provide even higher quality peanuts and peanut products to consumers. The reduction is in response to the peanut industry's desire to provide consumers with the best product possible and is in line with the primary objective of the Agreement to insure that only wholesome peanuts enter edible market channels. Section 998.200(a) is amended to reflect this change.

The reduction in the aflatoxin level is expected to cause an increase in costs related to the processing (milling) of edible quality peanuts and could also cause a larger portion of such peanuts to be disposed of for uses other than for human consumpton. In addition, sampling and testing costs are expected to increase. By requiring handler contracts to provide that peanut buyers (mostly manufacturers of peanut products) assume a larger portion of the costs of the aflatoxin sampling and testing program, the industry can share the additional costs of providing better quality peanuts and peanut products to consumers. The peanut industry has, since the mid 1960's, worked cooperatively under the Agreement to maintain consumer satisfaction and product safety. Peanut product manufacturers, like handlers under the Agreement, have a strong interest in providing wholesome, high quality products. The Committee believes that the cost and burden of providing a higher quality product should be distributed throughout the industry and should not rest on handlers alone.

The reduction in the aflatoxin level is also expected to cause an increase in the quantity of blanched peanuts available for human consumption. Requiring that handlers include in their contracts provisions that buyers agree to accept successfully remilled and/or blanched lots of peanuts which were rejected under the appeal procedure or on the basis of the test results of the pre-shipment sample made in the name of the buyer whose name is shown on the applicable inspection certificate, as indicated in the second change, will help to facilitate the orderly marketing of remilled and/or blanched peanuts. It should be noted that peanuts rejected by buyers under the appeal procedure have previously met all quality requirements under the marketing agreement and are in the buyer's possession. Previously, handlers incurred additional expenses in reconditioning such peanuts with no guarantee that the contracted buyer would accept the successfully reconditioned lots. Handlers are not fully reimbursed for these expenses under the indemnification program. Successfully reconditioned lots of peanuts are sound, wholesome and meet all quality requirements under the Agreement. This recommendation assures handlers that such peanuts will be accepted by buyers. However, to allow handlers to meet the specific needs of their buyers, handlers will have the option to replace any rejected lot of peanuts with another lot.

One change is made in the incoming quality regulation (7 CFR 998.100; 55 FR 30902, July 30, 1990) to insert a paragraph that was inadvertently omitted from that section. Due to an error in the amendatory language when the 1988 crop regulations were published in the **Federal Register** (July 15, 1988, 53 FR 26757), paragraph (d)(2) of § 998.100 was omitted.

A conforming change is made in § 998.300(r) which refers to 1987 quality regulations. Paragraph (r) should reference current crop year regulations. To alleviate the need to specifically amend this paragraph each year, the wording of paragraph (r) is changed so that no reference to a particular crop year regulation is made.

The information collection requirements that are contained in the sections of these regulations which are hereby amended have been previously approved by the Office of Management and Budget (OMB) and have been assigned OMB No. 0581–0067.

Based on available information, the Administrator of the AMS has determined that this final rule will not have a significant economic impact on a substantial number of small entities.

After consideration of all relevant information presented, the committee's recommendation, the comments received, and other information, it is found that the changes in incoming and outgoing quality regulations and terms and conditions of indemnification, as set forth in this final rule, will tend to effectuate the declared policy of the Act.

Pursuant to 5 U.S.C. 553, it is also found and determined, that good cause exists for not postponing the effective date of this action until 30 days after publication in the **Federal Register** because the harvest and shipment of 1990 crop peanuts has already begun and the changes should be implemented as soon as possible.

List of Subjects in 7 CFR Part 998

Marketing agreements, Peanuts, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 998 is amended as follows:

PART 998—MARKETING AGREEMENT REGULATING THE QUALITY OF DOMESTICALLY PRODUCED PEANUTS

1. The authority citation for 7 CFR part 998 continues to read as follows:

Authority: Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674.

2. Section 998.100 is amended by redesignating paragraph (d) as (d)(1) and adding a new (d)(2) to read as follows:

§ 998.100 Incoming quality regulation—1990 crop peanuts.

* * * * *

(d) * * *

(2) Each handler shall be required to submit to the Committee a flow chart for each plant operation diagramming the procedures and equipment used in the removal of loose shelled kernels and in the processing of splits. Upon any subsequent changes in flow, procedures, or equipment, the handler shall submit

to the Committee a revised flow chart reflecting those changes.

* * * * *

3. Section 998.200 is amended by revising paragraph (c)(3) and adding a new paragraph (c)(4) to read as follows:

§ 998.200 Outgoing quality regulation—1990 crop peanuts.

* * * * *

(c) * * *

(3) All costs involved in sampling and testing Subsample 1–CD shall be for the account of the buyer of the lot and at the buyer's expense. However, if the handler elects to pay any portion of these cost the handler shall charge the buyer accordingly. Aflatoxin sampling and testing cost for the AB Subsamples shall be included as a separate item in the handler's invoice to the buyer at the rate of $0.0027 per pound or $0.27 per hundredweight of the peanuts covered by the invoice. When any of the samples or subsamples have been lost, misplaced, or spoiled and replacement samples are needed, the entire cost of drawing the replacement samples shall be for the account of the handler. The results of each assay shall be reported to the buyer listed on the notice of sampling and, if the handler desires, to the handler. If a buyer is not listed on the notice of sampling, the results of the assay shall be reported to the handler, who shall promptly cause notice to be given to the buyer of the contents thereof, and such handler shall not be required to furnish additional samples for assay.

(4) For the current crop year, "Negative" aflatoxin content means 15 parts per billion (ppb) or less for peanuts which have been certified as meeting edible quality grade requirements and 25 ppb or less for non-edible quality categories, as determined by the Committee's sampling plan applicable to the respective grade categories.

* * * * *

4. Section 998.300 is amended by revising the second sentence of paragraph (e), revising the first, the second and the fourth sentence of paragraph (h), revising the second sentence of paragraph (j), revising the fifth sentence of paragraph (m)(1), revising paragraph (m)(2), revising the second sentence of paragraph (m)(3), revising paragraph (r), and revising paragraph (x) to read as follows:

§ 998.300 Terms and conditions of indemnification—1990 crop peanuts.

* * * * *

(e) * * * The indemnification payment for "quota peanuts" so disposed of shall be 45 cents per pound, or the indemnification value of the lot of peanuts as hereinafter provided for "quota peanuts" less five cents per pound, whichever is lower. * * *

* * * * *

(h) The indemnification payment on peanuts declared for remilling, and which contain not more than 1.00 percent damaged kernels other than minor defects, shall include an allowance for remilling of three and one-half cents per pound on the original weight. The indemnification payment on the pounds of peanuts removed in the process and not cleared for human consumption shall be: for "quota peanuts," 45 cents per pound, or the indemnification value as hereinafter provided for "quota peanuts", whichever is lower; and for "additional peanuts", the indemnification value as hereinafter provided for "additional peanuts". * * * On lots on which the remilling is not successful in making the lot wholesome as to aflatoxin and such lots of peanuts are declared for custom blanching after remilling, the indemnification payment shall be the blanching cost, plus the transportation costs from origin (whether handler or buyer premises) to point of blanching and on unsold lots from point of blanching to handler's premises and 45 cents per pound or the applicable indemnification value, whichever is lower, of the weight of reject peanuts removed from the lot. * * *

* * * * *

(j) * * * If a suitable reduction in the aflatoxin content is not achieved on any lot which is remilled or custom blanched, or both, the Committee shall declare the entire lot for indemnification, and the indemnification payment rate on "quota peanuts" shall be 45 cents per pound, or the indemnification value as hereinafter provided for "quota peanuts," less five cents per pound, whichever is lower, plus other applicable costs authorized heretofore, and the indemnification payment for "additional peanuts" shall be the indemnification value for "additional peanuts" as hereinafter provided for "additional peanuts," less three cents per pound, plus other applicable costs authorized heretofore. * * *

* * * * *

(m) * * *

(1) * * * Upon a determination of the Committee, confirmed by the Agricultural Marketing Service, authorizing rejection, such peanuts, and title thereto, if passed to the buyer, shall be returned to the seller, and such peanuts, after successful remilling and/or blanching, shall be delivered to the buyer to satisfy the applicable contract.

* * *

(2) If the buyer's or receiver's name is shown on the grade certificate prior to the time of the aflatoxin analysis results, covering a lot which, upon the protesting sampling procedure prescribed in paragraph (c) of the Outgoing Quality Regulation (§ 998.200), exceeds Committee requirements for wholesomeness as to aflatoxin, such peanuts shall be offered to the buyer to satisfy the existing applicable contract, and the buyer shall agree to accept the peanuts resulting from successful remilling and/or blanching of the rejected lot. Alternatively, the seller may replace any rejected lot of peanuts with another lot, if the seller elects to do so.

(3) * * * A portion of the costs of aflatoxin sampling and testing, as provided in § 998.200(c)(3), shall be for the account of the buyer and the buyer agrees to pay such costs.

* * * * *

(r) Any handler who fails to remove, hold, or dispose of loose shelled kernels pursuant to paragraph (d)(1) of the Incoming Quality Regulation (§ 998.100) or paragraph (g) of the Outgoing Quality Regulation (§ 998.200) shall be ineligible for any indemnification payments until such condition or conditions are corrected to the satisfaction of the Committee and/or any complaints of violations made by the Committee to the Secretary are resolved.

* * * * *

(x) The indemnification value for "additional peanuts" shall be equal to 45 percent of either 45 cents per pound or the established indemnification value, per category, of "quota peanuts," whichever is lower.

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Dated: August 21, 1990.

Robert C. Keeney,

Deputy Director, Fruit and Vegetable Division.

[FR Doc. 90–20009 Filed 8–22–90; 8:45 am]

BILLING CODE 3410–02–M

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30 and 35

RIN 3150-AD43

Authorization To Prepare Radiopharmaceutical Reagent Kits and Elute Radiopharmaceutical Generators; Use of Radiopharmaceuticals for Therapy

AGENCY: Nuclear Regulatory Commission.

ACTION: Interim final rule with request for comment.

SUMMARY: The Nuclear Regulatory Commission (NRC) is issuing an interim final rule amending its regulations related to the preparation and the therapeutic uses of radiopharmaceuticals. This interim rule allows licensees who elute generators and prepare reagent kits to depart from the manufacturer's instructions for elution and preparation in the package insert (a part of the Food and Drug Administration (FDA) approved labeling) provided the licensees meet certain conditions and limitations. The interim rule also permits NRC licensees using byproduct material in a radiopharmaceutical for a therapeutic use to depart from the package insert regarding indications and method of administration if certain requirements are met. This amendment is necessary to allow health professionals to provide diagnostic or therapeutic medical results not otherwise attainable or to reduce medical risks to particular patients because of their medical condition while continuing to protect public health and safety adequately. The interim rule applies only to radiopharmaceuticals for which the FDA has approved a "New Drug Application" (NDA).

DATES: *Effective date:* From August 23, 1990, to August 23, 1993.

Comment closing date: In view of the interim nature of this rulemaking, comments will be welcome at any time during the three-year period.

ADDRESSES: Submit written comments and suggestions to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch. Hand deliver comments to 11555 Rockville Pike, Rockville, Maryland, between 7:45 a.m. and 4:15 p.m. on Federal workdays.

Copies of the regulatory analysis, environmental assessment, and the comments received on this rule may be examined at the Commission's Public Document Room at 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the Regulatory Analysis are available from Dr. Anthony Tse, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

FOR FURTHER INFORMATION CONTACT: Dr. Tse, see **ADDRESSES** heading, Telephone (301) 492-3797.

SUPPLEMENTARY INFORMATION:

I. Background

A. Nuclear Medicine

Radioactive materials are used in drugs in the field of nuclear medicine. Drugs labeled with radioisotopes are known as radiopharmaceuticals. In diagnostic nuclear medicine, patients receive these materials by injection, inhalation, or oral administration. Physicians use radiation detection equipment to visualize the distribution of a radioactive drug within the patient. Using this technology, it is possible to locate tumors, assess organ function, or monitor the effectiveness of a treatment. An estimated 7 million diagnostic nuclear medicine procedures are performed in this country annually. In therapeutic nuclear medicine, radiopharmaceuticals are administered to treat various medical conditions (e.g., hyperactive thyroid). An estimated 30,000 therapeutic procedures are performed each year.

B. Regulatory Program and Policy Regarding Medical Use of Byproduct Materials

In a policy statement, "Regulation of the Medical Uses of Radioisotopes," published on February 9, 1979 (44 FR 8242), the NRC stated:

(1) The NRC will continue to regulate the medical uses [1] of radioisotopes as necessary to provide for the radiation safety of workers and the general public.

(2) The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.

(3) The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.

The NRC has the authority to regulate medical use to protect the health and safety of patients, but also recognizes that physicians have the primary responsibility for the protection of their patients. NRC regulations are predicated on the assumption that properly trained and adequately informed physicians will make decisions in the best interest of their patients.

Under the Federal Food, Drug, and Cosmetic Act, as amended, the Food and Drug Administration (FDA) regulates drug research and the manufacturer and sale of drugs, including radiopharmaceuticals. FDA has regulated the safety and effectiveness of investigational radioactive drugs since 1975, when FDA revoked its 1963 exemption of radioactive drugs from the "Investigational New Drug" (IND) regulation. The NRC withdrew from regulating radioactive drug safety and efficacy to avoid dual Federal regulation, but continues to regulate the radiation safety of workers, patients, and the public.

Each new drug approved for human use by the FDA, including radiopharmaceuticals, has labeling approved by FDA that includes a description of the drug, its pharmacology, indications for use, contraindications, warnings, adverse reactions, dosage and administration, and other information. The labeling of certain drugs, including some radiopharmaceuticals, includes manufacturer's instructions that specify the method of preparation. FDA reviews and approves the information in the labeling to ensure that it accurately reflects the data on safety and effectiveness on which the drug approval is based. NRC has, in the past, relied primarily on FDA's determination of a drug's safety and effectiveness when it is prepared and used according to the approved labeling, which some NRC regulations refer to as the package insert, as one means of ensuring protection of the public health and safety.

NRC regulations in 10 CFR 35.200(b) require medical use licensees to prepare radiopharmaceuticals in accordance with the manufacturer's instructions in the package insert (a part of the FDA-approved labeling). Similar requirements are placed on commercial nuclear pharmacies through NRC license conditions. Regulations in 10 CFR 35.300, "Use of Radiopharmaceuticals for Therapy," require, among other things, that the licensees comply with the package insert instructions regarding indications and method of administration for the therapeutic use of radiopharmaceuticals.

[1] "Medical use," as defined in 10 CFR 35.2, means the "intentional internal or external administration of byproduct material, or the radiation therefrom, to human beings in the practice of medicine in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico." "Medical use" includes the diagnostic and therapeutic use of radiopharmaceuticals in the practice of nuclear medicine, but does not include *in vitro* diagnostic tests.

II. Petition for Rulemaking Filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine

On June 8, 1989, the NRC docketed as PRM-35-9 a petition for rulemaking dated June 5, 1989, which was filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine (ACNP-SNM). The ACNP-SNM are composed of over 12,000 individuals who participate in the medical use of byproduct materials. Members include physicians, technologists, and nuclear pharmacists. As characterized by the petitioners, the physicians supervise the preparation and administration of radiopharmaceuticals to diagnose and treat patients. Also, technologists administer radiopharmaceuticals to diagnose and perform clinical procedures under the direction and supervision of an authorized user physician.[2] Nuclear pharmacists reconstitute radiopharmaceutical kits, compound radiopharmaceuticals, and dispense radiopharmaceuticals for medical purposes.

Among other things,[3] the petitioners requested that the NRC amend its regulations at 10 CFR part 35, "Medical Use of Byproduct Material," to recognize their appropriate practice of medicine and to allow (1) departures from the manufacturer's instructions for preparing diagnostic radiopharmaceuticals and (2) the use of radiopharmaceuticals for therapeutic indications and methods of administration not included in the package insert approved by the FDA.

The petitioners stated that, under current NRC regulations, members of the petitioning organizations believe they cannot appropriately practice their professions. The petitioners also stated that authorized user physicians cannot prescribe certain radiopharmaceuticals or routes of administration for proper patient care, even though they believe they are permitted to do so by the FDA and by their State medical licenses. According to the petitioners, nuclear pharmacists have been disenfranchised as a professional entity because activities that they believe are permitted by the FDA and by the States are not allowed under NRC regulations. The petitioners stated that, although a nuclear pharmacist is authorized by State license to prepare radiopharmaceuticals upon receipt of a prescription by an authorized user physician, current NRC regulations severely restrict their activity. The petitioners believe that their professional activities are curtailed by the limitations imposed by the NRC on nuclear physicians and pharmacists.

A notice of receipt of the petition with a public comment period of 90 days was published in the **Federal Register** on September 15, 1989 (54 FR 38239). The Federal Register notice set forth the petitioners' proposed amendments to 10 CFR parts 30, 33, and 35, including the deletion of the restriction regarding the preparation of radiopharmaceuticals in § 35.200(b) and the deletion of the restriction in § 35.300, with respect to following the package insert instructions regarding indications and method of administration (54 FR 38240). The comment period closed on December 14, 1989, and 466 comment letters have been received.

Comments were received from many different sources such as hospitals, pharmacies, and medical associates. About 60 percent of the letters were similar to a form letter written for members of ACNP-SNM. These letters indicated agreement with the petition on all essential points. Fifteen percent of the comment letters were similar to a form letter written for the staff of Syncor International Corporation, also agreeing with the assertions in the petition. Twenty-five percent of the responses were letters from other individuals.

Most letters (99 percent) supported the petition and stated that the NRC should amend its regulations to relax its current restrictions on the practice of nuclear medicine and nuclear pharmacy. The majority of these letters did not provide specific supporting rationale. Some commenters provided rationale and examples of clinical cases that the commenters believe demonstrate how the relevant NRC regulations prevent physicians from providing proper care for their patients. The commenters stated that, although a licensee may request an exemption from specific requirements in the regulations on a case-by-case basis, this exemption process is time consuming and cumbersome. The commenters believe that a delay in order to obtain NRC approval for a particular departure from the package insert may, in some cases, jeopardize the patient's health. Some examples of clinical cases the commenters provided are described below:

(1) Licensees are not able to use Tc-99m macroaggregated albumin with high specific activity and low particle concentration to safely perform lung scans for patients who have pulmonary hypertension because the ranges of specific activity and particle concentration given in the package insert would be exceeded.

(2) Licensees are not able to add ascorbic acid as an antioxidant to Tc-99m-DTPA, which would increase stability and enhance image quality, because NRC regulations do not permit departure from the manufacturer's instructions for reconstituting reagent kits.

(3) When evaluating potential blood transfusions, licensees are not able to perform *in vivo* crossmatching using potential donar red cells radiolabeled with Tc-99m because this is not provided for in the package insert.

(4) Licensees are not able to use P-32 sodium phosphate to treat primary *Thrombocythemia* because this use is not specified in the package insert.

III. Need for a Rule

Information submitted by the ACNP-SNM in the petition for rulemaking and obtained during subsequent discussions with licensees indicates that the requirements in § 35.200(b) regarding preparation of radiopharmaceuticals and in § 35.300 regarding indications and method of administration for therapy procedures are preventing authorized user physicians from providing certain nuclear medicine clinical procedures. License conditions similar to § 35.200(b) currently placed on commercial nuclear pharmacies have the same effect. For some uncommon disease states or patient conditions, in order to provide proper patient care, it may be necessary to depart from the FDA-approved instructions to obtain diagnostic or therapeutic medical results not otherwise attainable or to reduce medical risks to particular patients because of their medical condition.

The NRC believes that continued application of these restrictions governing the preparation of radiopharmaceuticals and the indications and the method of administration for therapeutic use of radiopharmaceuticals would not permit proper patient care to be provided to some patients.

Under its 1979 Medical Use Policy Statement (44 FR 8242, February 9, 1979), the NRC stated that it would regulate the medical use of byproduct material in order to protect the health and safety of workers, patients, and the public. In general, NRC regulatory requirements are oriented to ensure that the properly prepared radiopharmaceutical is administered to the correct patient as prescribed by an authorized user

[2] Whenever the term "authorized user physician" is used, it means the "authorized user" or the physician working under the supervision of the authorized user.

[3] The NRC is working to resolve the remaining issues identified in the petition.

physician. Aside from the requirements in § 35.200(b) and § 35.300, other requirements in part 35, such as the use of dose calibrators, are intended to ensure that the patient receives the prescribed dose. NRC's regulations need to provide a balance between adequate controls and avoidance of undue interference in medical judgments. The high level of public health and safety protection that accrues from following the FDA-approved instructions must be balanced with the need to depart from those instructions to obtain diagnostic or therapeutic results not otherwise attainable or to reduce patient risk in some uncommon disease states or patient conditions in order to provide proper patient care.

The diagnostic use of radiopharmaceuticals is, in most cases, an area of inherently low radiation risk to patients (Policy Statement, 44 FR 8242; February 9, 1979). Although there are greater risks inherent in the use of therapeutic levels of radioactive drugs, in light of the information provided with and gathered subsequent to the petition, the NRC does not believe that limiting the therapeutic use of radiopharmaceuticals in all cases to only the indications and methods of administration specified in the package insert is justified. Moreover, as stated in its 1979 Policy Statement, the NRC recognizes that physicians have the primary responsibility for the protection of their patients. The Commission believes that basic decisions concerning the diagnosis and treatment of disease are a part of the physician-patient relationship and are traditionally considered to be part of the practice of medicine.

The NRC has made a determination that continued application of the subject requirements, without exceptions, may adversely affect the public health and safety because the delivery of proper patient care may require, in certain instances, that some radiopharmaceuticals be prepared and administered in a manner different from that stated in the FDA-approved instructions. The NRC has reviewed the information on nuclear medicine clinical procedures and believes that adequate protection of the public health and safety can be maintained while, at the same time, providing proper patient care. Hence, the NRC is issuing an interim final rule that permits, on the direction of an authorized user physician, departures from the manufacturer's instructions in preparaing radiopharmaceuticals and departures from package inserts for indication and method of administration for therapeutic use, provided a proper record of the departure is made. These records will be examined by the NRC to determine whether to extend the interim period for the rule, make the rule permanent, or revise it based on the nature of, reasons for, and frequency of departures. The NRC will provide FDA the opportunity to review this information.

Because these amendments involve relief from restrictions which if left in place could have an adverse impact on public health and safety, and because the NRC has received and considered public comments on the petition for rulemaking, good cause exists for omitting the notice of proposed rulemaking and the public procedures thereon as unnecessary and contrary to the public interest, and for making these amendments effective upon publication in the **Federal Register** without the customary thirty-day notice. This interim rule will terminate 3 years after the date of publication in the **Federal Register**.

IV. Future Agency Action

This interim rule amending 10 CFR parts 30 and 35 represents only one phase of NRC's resolution of the ACNP–SNM petition for rulemaking. During the 3-year period, the NRC may modify the interim rule or take other regulatory action it determines necessary to protect the public health and safety. Based on continued NRC analysis of the ACNP–SNM petition, the comments on petition and on this interim rule, experience with the implementation of this interim rule, and other information, the NRC may propose amendments to this rule or to other provisions of 10 CFR parts 30 and 35 as part of its resolution of all the issues raised in PRM–35–9.

V. Discussion

Section 35.200 Use of Radiopharmaceuticals, Generators, and Reagent Kits for Imaging and Localization Studies

The NRC believes that persons licensed by the NRC to elute generators and prepare reagent kits should not always be bound by the requirement specified in 10 CFR 35.200(b) to follow the manufacturer's instructions for radiophmaceuticals for which the FDA has approved an NDA. They should not be bound if they have a written directive (*e.g.*, prescription) made by an authorized user physician directing a specific departure for a particular patient, or patients, or for a radiopharmaceutical, and which includes (1) the specific nature of the departure, (2) a precise description of the departure, and (3) a brief statement of the reasons why the departure from the manufacturer's instructions would obtain medical results not otherwise attainable or would reduce medical risks to particular patients because of their medical condition. The NRC recognizes that the physician may face severe time constraints during an emergency; therefore, an exception has been provided in § 35.200(c). Under the exception, a written directive is not required before preparing the radiopharmaceutical if an authorized user physician determines that the delay in obtaining a written directive would jeopardize the patient's health. The written directive together with a statement of the emergency determination must be prepared with 3 working days of the emergency administration. The written directive and a record of the number of patient administrations under each departure must be retained by the licensee for a period of 5 years and made available for NRC inspection.

This interim rule does not address departures from "Investigational New Drug" (IND) generator elution instructions or IND protocol directions for reagent kit preparation because the departures may compromise the scientific integrity of the clinical investigation. Therefore, licensees must continue to follow the IND generator elution instructions and IND protocol directions for reagent kit preparation.

Section 35.300 Use of Radiopharmaceuticals for Therapy

For a radiopharmaceutical for which the FDA has approved an NDA, the amendments to § 35.300 would permit a licensee, under certain circumstances, to use therapeutic radiopharmaceuticals for indications or a method of administration not specified in the package insert. Specifically, these uses would be permitted if an authorized user physician makes a record of the departure which includes the specific nature of the departure and a brief statement of the reasons why the departure would obtain medical results not otherwise attainable or would reduce medical risks to particular patients because of their medical condition. A record of the departures from indications and method of administration and a record of the number of patient administrations under each departure must be retained in an auditable form and be available for inspection for 5 years. If a kit or generator for a radiopharmaceutical for therapy were approved by FDA (through an NDA), this interim rule does not

authorize departures from the manufacturer's instructions for eluting the generator or preparing the therapy kit.

Section 30.34 Terms and Conditions of Licenses

Commercial nuclear pharmacies are licensed pursuant to 10 CFR part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material." These licensees are required by a license condition similar to § 35.200(b) to elute generators and prepare reagent kits in accordance with the manufacturer's instructions. The NRC believes that authorized users obtaining radiopharmaceuticals from commercial nuclear pharmacy licensees should not be bound by this restriction in the commercial nuclear pharmacy license. Therefore, the NRC is amending 10 CFR 30.34, "Terms and Conditions of Licenses," to permit actions within the scope of those permitted by the new § 35.200(c). For situations not within the scope of the amended § 30.34, a commercial nuclear pharmacy licensee may file an application to have its license amended to permit specific departures from the manufacturer's instructions for identified products.

Under the interim rule, commercial nuclear pharmacy licensees would no longer be bound by the requirement in their licenses to follow the manufacturer's instructions for a radiopharmaceutical for which the FDA has approved an NDA if they have a written directive made by an authorized user physician directing a specific departure for a particular patient, or patients, or for a radiopharmaceutical, and which includes the specific nature of the departure, a precise description of the departure, and why the departure from the manufacturer's instructions would obtain medical results not otherwise attainable or would reduce medical risks to particular patients because of their medical condition. As in § 35.200(c), there is an exception to the requirement for a written directive before preparing the radiopharmaceutical in an emergency situation if an authorized user physician determines that a delay in obtaining the written directive would jeopardize the patient's health. In this case, the commercial nuclear pharmacy licensee shall obtain the written directive from the authorized user physician within 3 working days of the prescribed departure. The directive must contain information regarding the emergency and all other required information. Licensees shall keep those records in an auditable form and available for inspection for 5 years.

These amendments to § 30.34 take precedence over the restrictive conditions (*i.e.*, on eluting generators and preparing reagent kits for NDA radiopharmaceuticals) in the licenses of commercial nuclear pharmacies. Therefore, those parts of the license conditions no longer apply during the 3-year period when the interim rule is in effect. This interim rule does not address departures from IND generator elution instructions or IND protocol directions for reagent kit preparation, thus licensees shall continue to follow the IND instructions.

Continuing Applicability of Regulatory Requirements

The NRC notes that this interim rule does not relieve licensees from the requirements to comply with other applicable NRC, FDA, and other Federal or State regulations or NRC orders or license conditions concerning possession or use of byproduct material for medical use or other purposes as specified in 10 CFR parts 30, 32, 33, and 35. Moreover, if a radioactive biologic receives a product license approval (PLA), this interim rule does not authorize departures from the manufacturer's instructions for preparing the biologic. In addition, if a kit or generator for a radiopharmaceutical for therapy receives an approved NDA, this interim rule does not authorize departures from the manufacturer's instructions for eluting the generator or preparing the therapy kit. Neither of these approvals exists at this time and neither is authorized by current regulations.

Radiation Safety Responsibilities of Medical Use Licensees

NRC medical use licensees are required by § 35.21 to appoint a Radiation Safety Officer (RSO) responsible for implementing the licensee's radiation safety program. The licensee is required, through the RSO, to ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program. Nothing in this rulemaking relieves the licensee from complying with the requirements of § 35.21.

In accordance with 10 CFR 35.22, NRC medical institution licensees are required to establish a Radiation Safety Committee (RSC) to oversee the use of byproduct material. The duties of the RSC are specified in § 35.22(b) and include reviews, on the basis of safety, of numerous aspects of a licensee's use of byproduct material. Nothing in this rulemaking relieves the licensee from complying with the requirements of § 35.22.

VI. Administrative Statements

Finding of No Significant Environmental Impact: Availability

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in subpart A of 10 CFR part 51 that these amendments are not a major Federal action significantly affecting the quality of the human environment and therefore an environmental impact statement is not required. This interim rule amends NRC regulations to permit licensees who elute generators and prepare reagent kits to depart from the manufacturer's instructions if those persons have a written directive made by an authorized user physician that requests a specific departure for a particular patient, or patients, or for a radiopharmaceutical. This directive must provide the specific nature of the departure, a precise description of the departure, and the reasons why the departure from the manufacturer's instructions would obtain medical results, diagnostic or therapeutic, not otherwise attainable or would reduce medical risks to particular patients because of their medical condition. The amendment does not address departures from IND generator elution instructions or IND protocol directions for reagent kit preparation. The NRC is also modifying its regulations to permit, if certain requirements are met, the therapeutic use of radiopharmaceuticals without following the package instructions regarding indications and method of administration. The interim rule does not affect the exemption in 10 CFR part 20 for the intentional exposure of patients to radiation for the purpose of medical diagnosis and therapy.

Although the rule may cause some patients to be exposed to higher or lower levels of radiation than otherwise expected, those exposures would be given to obtain medical results not otherwise attainable or to reduce other risks to the patient. It should be noted that current requirements do not limit the radiation dose prescribed by the authorized user physician for either diagnosis or therapy. The amendments would not relieve licensees from meeting the requirements in 10 CFR parts 20 and 35 that restrict radiation exposure to medical care personnel in the restricted area or to the general public in the unrestricted area, or radioactive effluent releases. It is expected that there would be no

significant change, either increase or decrease, in radiation exposure to the public or to the environment beyond the exposures currently resulting from deliver the dose to the patient.

The Environmental Assessment and Finding of No Significant Impact is available for inspection at the NRC Public Document Room at 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the Assessment are available from Dr. Tse (see **ADDRESSES** heading).

Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). These requirements were approved by the Office of Management and Budget approval numbers 3150–0010 and 3150–0017.

Public reporting burden for this collection of information is estimated to average .05 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Information and Records Management Branch (MNBB–7714), U.S. Nuclear Regulatory Commission, Washington, DC 20555; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB–3019 (3150–0017 and 3150–0010), Office of Management and Budget, Washington, DC 20503.

Regulatory Analysis

The Commission has prepared a regulatory analysis for these amendments. The analysis examines the benefits and impacts considered by the NRC. The regulatory analysis is available for inspection at the NRC Public Document Room at 2120 L Street NW. (Lower Level), Washington, DC. Single copies are available from Dr. Tse (see **ADDRESSES** heading).

The Commission requests public comments on the regulatory analysis. Comments are welcome at any time during the three-year period that the interim final rule is in effect. Comments on the analysis may be submitted to the NRC as indicated under the **ADDRESSES** heading.

Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to these amendments because they do not involve any provisions that would impose backfits as defined in 10 CFR 50.109(a)(1).

List of Subjects

10 CFR Part 30

Byproduct material, Criminal penalty, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 35

Byproduct material, Criminal penalty, Drugs, Health facilities, Health professions, Incorporation by reference, Medical devices, Nuclear materials, Occupational safety and health, Radiation protection, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR parts 30 and 35.

PART 30—RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

1. The authority citation for part 30 is revised to read as follows:

Authority: Secs. 81, 82, 161, 182, 183, 186, 68 Stat. 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2111, 2112, 2201, 2232, 2233, 2236, 2282); secs. 201, as amended, 202, 206, 68 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Section 30.7 also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 30.34(b) also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 30.61 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 30.3, 30.34(b), (c), (f), (g), and (i), 30.41(a) and (c), and 30.53 are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 30.6, 30.9, 30.34(g), 30.36, 30.51, 30.52, 30.55, and 30.56(b) and (c) are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

2. In § 30.34, paragraph (i) is added to read as follows:

§ 30.34 Terms and conditions of licenses.

* * * * *

(i)(1) From August 23, 1990, to August 23, 1993, each licensee eluting generators and processing radioactive material with diagnostic reagent kits for which the Food and Drug Administration (FDA) has approved a "New Drug Application" (NDA) may depart from the manufacturer's elution and preparation instructions (for radiopharmaceuticals authorized for use pursuant to § 35.200) provided that:

(i) The licensee has a written directive made by an authorized user physician that directs a specific departure for a particular patient, or patients, or for a radiopharmaceutical, and which includes the specific nature of the departure, a precise description of the departure, and a brief statement of the reasons why the departure from the manufacturer's instructions for preparing the radiopharmaceutical would obtain medical results not otherwise attainable or would reduce medical risks to particular patients because of their medical condition. The licensee shall keep the written directive and record of the number of prescriptions dispensed under the departure in an auditable form and available for inspection for 5 years; or

(ii) An authorized user physician determines, in accordance with § 35.200(c), that a delay in preparing the radiopharmaceutical in order to make a written directive would jeopardize the patient's health because of the emergent nature of the patient's medical condition. In this case, the licensee shall obtain the written directive made by the authorized user physician which contains the notation regarding the emergency and all the information specified in paragraph (i)(1)(i) of this section within 3 working days after the prescribed departure. The licensee shall keep these records in an auditable form and available for inspection for 5 years.

(2) The actions authorized in paragraph (i)(1) of this section are permitted notwithstanding more restrictive language in license conditions unless those license conditions specifically reference § 30.34(i).

(3) Nothing in this section relieves the licensee from complying with other applicable NRC, FDA, and other Federal or State regulations governing the elution of generators and preparation of reagent kits.

PART 35—MEDICAL USE OF BYPRODUCT MATERIAL

3. The authority citation for part 35 is revised to read as follows:

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 35.11, 35.13, 35.20 (a) and (b), 35.21 (a) and (b), 35.22, 35.23, 35.25, 35.27 (a), (c) and (d), 35.31 (a), 35.49, 35.50 (a)–(d), 35.51 (a)–(c), 35.53 (a)–(b), 35.59 (a)–(c), (e)(1), (g) and (h), 35.60, 35.61, 35.70 (a)–(f), 35.75, 35.80 (a)–(e), 35.90, 35.92(a),

35.120, 35.200 (b) and (c), 35.204 (a) and (b), 35.205, 35.220, 35.300, 35.310(a), 35.315, 35.320, 35.400, 35.404(a), 35.406 (a) and (c), 35.410(a), 35.415, 35.420, 35.500, 35.520, 35.605, 35.606, 35.610 (a) and (b), 35.615, 35.620, 35.630 (a) and (b), 35.632 (a)–(f), 35.634 (a)–(e), 35.636 (a) and (b), 35.641 (a) and (b), 35.643 (a) and (b), 35.645 (a) and (b), 35.900, 35.910, 35.920, 35.930, 35.932, 35.934, 35.940, 35.941, 35.950, 35.960, 35.961, 35.970, and 35.971, are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 35.14, 35.21(b), 35.22(b), 35.23(b), 35.27 (a) and(c), 35.29(b), 35.33 (a)–(e), 35.36(b), 35.50(e), 35.51(d), 35.53(c), 35.59 (d) and (e)(2), 35.59 (g) and (i), 35.70(g), 35.80(f), 35.92(b), 35.200(c), 35.204(c), 35.300(b), 35.310(b), 35.315(b), 35.404(b), 35.406 (b) and (d), 35.410(b), 35.415(b), 35.610(c), 35.615(d)(4), 35.630(c), 35.632(g), 35.634(f), 35.636(c), 35.641(c), 35.643(c), 35.645, and 35.647(c) are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

4. In § 35.8, paragraph (b) is revised to read as follows:

§ 35.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 35.12, 35.13, 35.14, 35.21, 35.22, 35.23, 35.27, 35.29, 35.31, 35.33, 35.50, 35.51, 35.53, 35.59, 35.60, 35.61, 35.70, 35.80, 35.92, 35.200, 35.204, 35.205, 35.300, 35.310, 35.315, 35.404, 35.406, 35.410, 35.415, 35.606, 35.610, 35.615, 35.630, 35.632, 35.634, 35.636, 35.641, 35.643, 35.645, and 35.647.

* * * * *

5. In § 35.200, paragraph (c) is added to read as follows:

§ 35.200 Use of radiopharmaceuticals, generators, and reagent kits for imaging and localization studies.

* * * * *

(c)(1) From August 23, 1990, to August 23, 1993, a licensee may depart from the manufacturer's instructions for eluting generators and preparing reagent kits for which FDA has approved an NDA, provided that the licensee has a written directive made by an authorized user physician that directs a specific departure for a particular patient, or patients, or for a radiopharmaceutical, and which includes the specific nature of the departure, a precise description of the departure, and a brief statement of the reasons why the departure from the manufacturer's instructions for preparing the radiopharmaceutical would obtain medical results not otherwise attainable or would reduce medical risks to particular patients because of their medical condition. If the authorized user physician determines that a delay in preparing the radiopharmaceutical in order to make a written directive would jeopardize the patient's health because of the emergency nature of the patient's medical condition, the radiopharmaceutical may be prepared without first making a written directive. The authorized user physician shall make notation of this determination in the written directive within 3 working days after the prescribed departure.

(2) The licensee shall keep the written directive and a record of the number of patient administrations under the departure in an auditable form and available for inspection for a period of 5 years.

(3) Nothing in this section relieves the licensee from complying with other applicable NRC, FDA, and other Federal or State regulations governing the elution of generators and preparation of reagent kits.

6. In § 35.300, the existing text is designated as paragraph (a) and a new paragraph (b) is added to read as follows:

§ 35.300 Use of radiopharmaceuticals for therapy.

* * * * *

(b)(1) From August 23, 1990, to August 23, 1993, a licensee may depart from the package insert instructions regarding indications or method of administration for a radiopharmaceutical for which FDA has approved an NDA, provided that the authorized user physician makes a record of the departure which includes the specific nature of the departure and a brief statement of the reasons why the departure would obtain medical results not otherwise attainable or would reduce medical risks to particular patients because of their medical condition. Licensees are not authorized to depart from the manufacturer's instructions for eluting a generator or preparing any kit for a radiopharmaceutical for therapy.

(2) The licensee shall obtain this record within 3 working days of the administration and keep this record and a record of the number of patient administrations under the departure in an auditable form and available for inspection for 5 years.

(3) Nothing in this section relieves the licensee from complying with other applicable NRC, FDA (including requirements governing the submission of an IND), and other Federal or State regulations governing the use of radiopharmaceuticals for therapy.

Dated at Rockville, Maryland, this 17th day of August 1990.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 90–19901 Filed 8–22–90; 8:45 am]

BILLING CODE 7590–01–M

10 CFR PART 110

RIN 3150–AD59

Export of Components for Use in Gaseous Diffusion Enrichment Plants: Correction

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule: Correction.

SUMMARY: In the **Federal Register** on July 26, 1990 (55 FR 30449), the Nuclear Regulatory Commission issued a final rule which clarifies the coverage of specially designed or prepared nuclear assemblies and components for use in a gaseous diffusion enrichment plant. As part of the final rule, portions of NRC's export regulations were restructured. However, the amendments necessary to change the references to these restructured provisions were inadvertently omitted. As a result, parts of the export licensing regulations now contain erroneous references. This action is necessary to correct the inconsistent references and reflect the restructured portions of the export regulations.

EFFECTIVE DATE: July 26, 1990.

FOR FURTHER INFORMATION CONTACT: Elaine O. Hemby, Office of Governmental and Public Affairs, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone 301–492–0341, or Joanna M. Becker, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone 301–492–1740.

List of Subjects in 10 CFR Part 110

Administrative practice and procedures, Classified information, Criminal penalty, Export, Import, Incorporation by reference, Intergovernmental relations, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements, Scientific equipment.

For the reasons set out in the summary and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR part 110.

PART 110—EXPORT AND IMPORT OF NUCLEAR EQUIPMENT AND MATERIAL

1. The authority citation for part 110 continues to read:

Authority: Secs. 51, 53, 54, 57, 63, 64, 65, 81, 82, 103, 104, 109, 111, 126, 127, 128, 129, 161, 181, 182, 183, 187, 189, 68 Stat. 929, 930, 931, 932, 933, 936, 937, 946, 953, 954, 955, 956, as amended (42 U.S.C. 2071, 2073, 2074, 2077, 2092–2095, 2111, 2112, 2133, 2134, 2139, 2139a, 2141, 2154–2158, 2201, 2231–2233, 2237, 2239); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

Section 110.1(b)(2) also issued under Pub. L. 96–92, 93 Stat. 710 (22 U.S.C. 2403). Section 110.11 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152) and secs. 54c and 57d., 88 Stat. 473, 475, (42 U.S.C. 2074). Section 110.27 also issued under sec. 309(a), Pub. L. 99–440. Section 110.50(b)(3) also issued under sec. 123, 92 Stat. 142 (42 U.S.C. 2153). Section 110.51 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234); Section 110.52 also issued under sec. 186, 68 Stat. 955 (42 U.S.C. 2236). Sections 110.80–110.113 also issued under 5 U.S.C. 552, 554. Sections 110.30–110.35 also issued under 5 U.S.C. 553.

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); secs. 110.20–110.29, 110.50, and 110.120–110.129 also issued under secs. 161 b and i, 68 Stat. 948, 949, as amended (42 U.S.C. 2201 (b) and (i)); and secs. 110.7a and 110.53 are also issued under sec. 161(o), 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

1a. In § 110.1, paragraph (a) is revised to read as follows:

§ 110.1 Purpose and scope.

(a) The regulations in this part prescribe licensing, enforcement, and rulemaking procedures and criteria, under the Atomic Energy Act, for the export of nuclear equipment and material, as set out in § 110.8 and § 110.9, and the import of nuclear equipment and material, as set out in § 110.9a.

* * * * *

2. Section 110.5 is revised to read as follows:

§ 110.5 License requirements.

Except as provided under subpart B, of this part no person may export any nuclear equipment or material listed in § 110.8 and § 110.9, or import any nuclear equipment or material listed in § 110.9a, unless authorized by a general or specific license issued under this part.

3. In § 110.6, paragraph (a) is revised to read as follows:

§ 110.6 Retransfers.

(a) Retransfer of any nuclear equipment or material listed in § 110.8 and § 110.9, including special nuclear material produced through the use of U.S.-origin source material or special nuclear material, requires authorization by the Department of Energy, unless, the export to the new destination is authorized under a special or general license or an exemption from licensing requirements. Under certain agreements for cooperation, Department of Energy authorization also is required for the retransfer of special nuclear material produced through the use of non-U.S.-supplied nuclear material in U.S.-supplied utilization facilities.

* * * * *

4. In § 110.26, paragraphs (a) and (c)(1) are revised to read as follows:

§ 110.26 Export of nuclear reactor components.

(a) A general license is issued to any person to export any nuclear reactor component listed in appendix A (5) through (9) to this part for use in any light or heavy water-moderated power or research reactor in any of the following countries:

Canada	Philippines
EURATOM [2]	Spain
Indonesia	Sweden
Japan	Switzerland
South Korea	Taiwan

[2] Belgium, Denmark, France, Greece, Ireland, Italy, Luxembourg, the Netherlands, the United Kingdom and West Germany

* * * * *

(c) * * *

(1) A description of the components keyed to the categories listed in appendix A to this part.

* * * * *

5. In § 110.42, Footnote 4 is redesignated as Footnote 3 and the text of Footnote 3 is revised to read as follows:

§ 110.42 Export licensing criteria.

* * * * *

[3] Exports of complete nuclear reactors, complete reactor pressure vessels, primary coolant pumps, control rods, and reactor fuel charging and discharging machines are subject to the comprehensive export criteria in § 110.42(a). A complete nuclear reactor includes those parts and components, as specified in appendix A to this part, which are within or attached directly to the reactor vessel, which control the level of power in the reactor core or which normally contain or come in direct contact with or control the primary coolant of the reactor. Nuclear reactor parts and components (other than complete pressure vessels, primary coolant pumps, control rods, or fuel charging and discharging machines) when exported separately are subject to the export criteria in § 110.42(b).

6. In § 110.43, the introductory text of paragraph (a) and paragraphs (b) and (c) are revised to read as follows:

§ 110.43 Physical security standards.

(a) Commission determinations on the adequacy of physical security programs in recipient countries for Category 1 quantities of nuclear material (see appendix E to this part) are based upon the following:

* * * * *

(b) Commission determinations on the adequacy of physical security programs in recipient countries for Categories II and III quantities of material (see appendix E to this part) are based on available relevant information and written assurances from the recipient country or group of countries that physical security measures providing, as a minimum, protection comparable to that set forth in INFCIRC/225 will be maintained.

(c) Commission determinations on the adequacy of physical security programs in recipient countries for exported facilities are made in accordance with the categories of material (see appendix E to this part) in use or in storage at the exported facilities and are based on available relevant information and written assurances from the recipient country or group of countries that physical security measures providing, as a minimum, protection comparable to that set forth in INFCIRC/225 will be maintained.

* * * * *

7. In appendix A, a new paragraph (9) is added to read as follows:

Appendix A—Illustrative List of Nuclear Reactor Equipment Under NRC Export Licensing Authority

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(9) Any other components specially designed or prepared for use in a nuclear reactor or in any of the components described in this appendix.

* * * * *

Dated at Rockville, Maryland, this 13th day of August 1990.

For the Nuclear Regulatory Commission.

James M. Taylor,

Executive Director for Operations.

[FR Doc. 90–19768 Filed 8–22–90; 8:45 am]

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DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

12 CFR Parts 502 and 563d

[No. 90–1345]

RIN 1550–AA16

Assessments

AGENCY: Office of Thrift Supervision, Treasury.

ACTION: Final rule.

SUMMARY: The Director of the Office of Thrift Supervision ("OTS" of "Office") is

publishing a final assessment regulation to fund the expenses of the agency, to recover the costs of examinations of institutions under the jurisdiction of OTS, to recover the costs of processing various types of applications, filings (including securities filings), notices and requests with the Office, and to recover the costs of providing other optional services such as seminars and publications.

DATES: Effective date: August 23, 1990. Application and securities filing fees will be charged for applications and filings submitted on or after September 4, 1990.

FOR FURTHER INFORMATION CONTACT: For general information, contact Kymberly K. Copa, Attorney, 202/906–6636, or Deborah Dakin, Regulatory Counsel, 202/906–6445, Regulations and Legislative Division; with respect to corporate application fees, contact Cynthia A. Miller, Financial Analyst, 202/906–7492, or Patrick G. Berbokos, Director, Corporate Activities Division, Supervision 202/906-6720; with respect to securities filing fees, contact Jacqueline Lussier, Attorney, Corporate and Securities Division 202/906–6575, or Julie L. Williams, Deputy Chief Counsel, 202/906–6459, Office of the Thrift Supervision, 1700 G St., NW., Washington, DC 20552.

SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority

Pursuant to the authority granted to the Director of the Office of Thrift Supervision by the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 ("FIRREA"), Pub. L. 101–73, 103 Stat. 183, the OTS is today adopting a final regulation setting forth a system for funding its operations that replaces and rescinds the interim funding rule adopted by the Office on September 8, 1989. *See* 54 FR 39983 (Sept. 29, 1989). The final regulation, as explained in greater detail in section IV below, creates a bifurcated sliding scale assessment formula as the Office's primary funding mechanism. Troubled savings associations will be assessed at a rate 50% higher than non-troubled savings associations at the same level of assets. For purposes of this regulation, "troubled savings associations" are defined generally as those operating under the jurisdiction of the Resolution Trust Corporation ("RTC") as the result of a conservatorship or with a MACRO (Management, Asset Quality, Capital Adequacy, Risk Management, and Operating Results) rating of 4 or 5.[1] This higher rate reflects the Office's increased costs in examining and supervising those institutions, because of the increased, in-depth scrutiny their assets, management, capital adequacy, operations, and levels of risk require. The final regulation also provides for a daily examination fee for examinations of savings association affiliates and holding companies. Finally, it includes fees for applications, securities filings, and miscellaneous optional services such as publications, certifications, and seminars.

The Office's predecessor agency, the Federal Home Loan Bank Board ("FHLBB" or "Board"), funded its supervisory and regulatory functions from two primary sources. The first was from contributions by the Federal Home Loan Banks ("FHLBankss"), which in turn are funded by their member associations. Because the Board undertook many of its functions not only in its own right but also as operating head of the Federal Savings and Loan Insurance Corporation ("FSLIC"), it was also funded from premiums paid to the FSLIC. In addition, savings associations paid fees to the FHLBanks to cover the cost of examinations by Federal Home Loan Bank System employees. Several FHLBanks also charge fees based on the asset size of savings associations. The funding of OTS' statutory responsibilities,[2] like the prior FHLBB funding methods, depends on funding provided, through one avenue or another, by the industry.

Several sections of the HOLA, as amended by FIRREA, authorize this permanent funding regulation. Paragraph (h) of section 3 provides that all OTS expenses may be paid from assessments levied under the terms of the HOLA. Section 9 specifically provides for fees that may be levied by the Director. These include assessments that may be levied on savings associations and affiliates of savings associations, fees to recover the cost of certain examinations of savings associations, and fees to recover the cost of processing applications, filings, notices and other requests which are submitted to the OTS. Paragraph (e) of that section provides that the Director may, by regulation, "establish formulas to determine a fee or schedule of fees to cover the costs of examinations and also to cover the cost of processing applications, filings, notices, and requests for approvals by the Director or the Director's designee." Paragraph (b)(4) of section 10 of the HOLA provides for fees to recover the costs of examinations of holding companies and their subsidiaries. The Office also has general rulemaking authority under sections 3 and 4 of the HOLA.

II. Description of Proposal

On February 22, 1990, the OTS published its proposed funding mechanism for public notice and comment. *See* 55 FR 6274 (Feb. 22, 1990). The OTS proposed to recover a substantial portion of its funding through an asset-based assessment on savings associations, patterned after the model used by the Office of the Comptroller of the Currency ("OCC").[3] The proposed asset-based assessment would incorporate declining marginal assessment rates as asset size increases ("sliding scale assessment"). Thus, under the proposal, all savings associations would pay the same on assets up to a prescribed level, but larger institutions with a larger asset base would pay a lower rate on assets above the prescribed amount. As proposed, the Office would levy assessments quarterly, based on the total consolidated assets of a savings association as shown on its most recent quarterly Thrift Financial Report preceding the payment date.

To supplement the asset-based assessment, the proposal included daily examination fees to recover the Office's costs of a broad range of examinations and investigations of savings associations and their subsidiaries, affiliates, and holding companies.

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[1] As explained more fully in Section IV.C., below, the OTS uses a scale of numerical ratings from one (1) to five (5) to establish an overall composite rating of a thrift's health by assessing five key performance areas of a thrift's operations. These performance areas are commonly identified as Management, Asset Quality, Capital Adequacy, Risk Management, and Operating Results ("MACRO"). A one (1) rating indicates the best rating and the least degree of supervisory concern while a five (5) indicates the worst rating and highest degree of supervisory concern.

[2] The Director of OTS is to provide for the organization, incorporation, examination, operation and regulations of federal savings associations and issue charters for such savings associations. In addition, the Director serves as the primary federal regulator for state-chartered savings associations and is charged with the responsibility of providing for the examination, safe and sound operation, and regulation of such savings associations. Finally, the Director is the primary federal regulator for savings and loan holding companies and is charged with the responsibility for their examination, safe and sound operation, and regulation. *See* sections 5(a), 4(a)(1) and 10 of the Home Owners' Loan Act, 103 Stat. 183, 282, 280, and 310 ("HOLA") (to be codified at 12 U.S.C. 1464(a), 1463, and 1467a, respectively) (hereinafter cited only to sections of the HOLA); section 3(q) of the Federal Deposit Insurance Act, 103 Stat. 183, 192 (to be codified at 12 U.S.C. 1813(q)).

[3] The OCC levies an asset-based assessment upon national banks to recover the direct and indrect costs of supervision of entities under its jurisdiction. The OCC's assessment authority comes from 12 U.S.C. 481, 482 (1982). Its assessment regulations appear at 12 CFR part 8 (1990).

Institutions which required greater amounts of examination time and resources or more frequent examinations would thus pay more in examination fees than would institutions requiring less frequent or intensive examinations. This provision was designed to reflect the Office's experience that troubled institutions are more expensive to examine and supervise than healthy ones due to the more extensive and intensive examination required.

The proposed daily examination fee of $485 was calculated from two components: (1) The projected costs of examination and investigation function for the year (including both direct costs, such as salary, benefits, and travel time, and indirect costs, such as expenses for administration, training, supplies, rent and equipment) and (2) the projected number of staff days to be devoted to examinations and investigations of savings associations, and their holding companies, subsidiaries, and affiliates.

The Office specifically requested comment on the advisability of adopting any of the following funding alternatives or other alternatives not specifically addressed: (1) An assest-based assessment with a fixed rate schedule, supplemented by examination fees; (2) an asset-based assessment with a sliding rate schedule, but without additional examination fees; and (3) a fixed rate asset-based assessment without examination fees.

Pursuant to HOLA section 9(j), the OTS also proposed to establish a formula to determine the cost of processing certain types of applications, filings, notices and other requests (hereinafter collectively referred to as "applications"). The OTS would then calculate, at least annually, its processing costs and would adjust the cost-based fees to reflect changes in Office expenses or procedures. The Office would publish the fees in an application fee schedule to be published at least annually in a "Schedule of Fees" Thrift Bulletin.

The proposal also explained procedures for developing fees for new types of applications, for transactions involving several types of applications, and for forms covering several related transactions. It provided that fees must be paid when an application is submitted and would be nonrefundable. If the full amount of the fee did not accompany the application, the application would not be processed. In addition, for applications that are so substantially incomplete or materially deficient that the Office could not complete its review, a new fee would be required upon the submission of any revised application. Likewise, a new filing fee must be paid upon resubmission of an application voluntarily withdrawn by the applicant.

For securities filings, the Office proposed to adopt basically the same fees imposed by the Securities and Exchange Commission ("SEC") for registration statements under the Securities Act of 1933 ("Securities Act") and for reports and forms required under the Securities Exchange Act of 1934 ("Exchange Act"). The proposal would require that, except as otherwise specifically provided in the Office's application fee schedule, the filing fees specified by the SEC's rules shall apply to filings with the Office. The Office also proposed to impose additional filing fees beyond those specified by the SEC for certain deficient filings of Forms 10–K and 10–Q and Schedules 13D and 13G. The list of fees imposed pursuant to the Exchange Act would be included in the Office's application fee schedule to published as a Thrift Bulletin. The Office also offered an alternative whereby securities filing fees would be calculated in the same manner and pursuant to the same formula as applicable to corporate application fees. The proposal also would impose a percentage-based filing fee for the filing of offering circulars on Form OC relating to the offer and sale of securities by savings associations, similar to that imposed by the SEC.

The Office also proposed to assess fees to recover the cost of various optional services that it provides, such as the cost of publications, seminars, and other services that it may make available to the industry and the public. These would be announced at the time of offering the particular publication, seminar, or service.

The Director proposed a collection process that had been used by the Board and the FSLIC to collect insurance assessments and examination fees and utilized by the OTS under its interim assessment regulation. *See* 54 FR 39983, 39985 (Sept. 29, 1989). Member institutions of FHLBanks that are subject to asset-based assessments and examination fees under this regulation would be required to establish demand deposit accounts at their respective FHLBanks and to authorize the FHLBanks to allow the Director to collect amounts due the Office from the institutions by direct debit of those accounts. Institutions not members of a FHLBank would pay their fees and assessments to the Office upon receipt of a notice. Following the example of the OCC, *see* 12 CFR 8.7, the Director proposed to charge interest on overdue assessments and examination and investigation fees.

With respect to any holding company, affiliate, or subsidiary of a savings association that fails to pay any examination or investigation fee or assessment levied against it before the end of the 60-day period beginning on the date of such assessment, the Office would assess such fee or assessment (including interest) against, and collect it from, such savings association. If any such entity is a holding company, subsidiary, or affiliate of more than one savings association, the Office proposed that the assessment may be levied against each such savings association, in such proportion as the Director may prescribe.

III. Summary of Comments and Office Response

The Office received a total of 38 comment letters in response to the proposal. Commenters include 8 trade associations, 27 savings associations and savings banks, and 3 law firms, 1 on behalf of a provider of services to savings associations, and 1 on behalf of a savings bank. Six commenters opposed the proposal without further substantive comment. Most commenters, while recognizing the Office's need to fund its statutory examination and supervision functions, suggested modifications to the proposed structure or levels of assessments, examination, applications, or filing fees. Two commenters agreed with the proposed structure and levels of charges. A number of commenters expressed their views with respect to two general themes: the cumulative effect of fees, increased insurance premiums, and other regulations on the health of the thrift industry and the need for the OTS to "downsize" its operations and expenses in response to the shrinking industry.

A. Funding of Examination and Supervision Functions

Fourteen commenters addressed the proposed structure of an asset-based assessment combined with examination fees as the primary sources of OTS funding. Of these fourteen commenters, seven supported an asset-based assessment with a fixed rate; six supported the proposed sliding scale approach; [4] one opposed any assessments. One of the commenters supporting the fixed rate approach questioned the Office's authority to

[4] One commenter otherwise supporting a sliding scale mistakenly thought that the proposed scale would not require an assessment to be paid by thrifts with less than $67 million in assets.

adopt a sliding scale method for assessments.

Those who supported a sliding scale approach believed it fairly represented the economies of supervising larger institutions. They argued that the sliding scale would more accurately allocate actual supervision costs among thrift institutions than would a fixed rate approach. Several commenters noted, as had the Office in its proposal, that the OCC uses a similar sliding scale in setting assessment rates for national banks. Two of these commenters favored the Office relying entirely on assessment income, rather than the proposed combination of assessment and examination fee income.

Commenters favoring a fixed assessment rate for all savings associations argued that a sliding scale approach would unfairly affect smaller institutions. These commenters claimed that small savings associations do not require as extensive supervision as do larger institutions. Two commenters asserted that larger thrifts can cost more to supervise because they often engage in nontraditional thrift activities that pose greater risks and their operations are often more complex, requiring more supervision. Some commenters believed that the sliding scale assessment would have the effect of accelerating thrift consolidation.

The proposal included a fixed daily examination rate per examiner in addition to the asset-based assessment. Twenty-five commenters specifically addressed one or more aspects of this component. Two commenters specifically opposed the use of examination fees and preferred that the OTS rely solely on the asset-based assessment. One commenter suggested that OTS only charge examination fees where the OCC would charge such fees. In contrast, one commenter specifically endorsed the proposed examination fee approach as an appropriate method to force troubled institutions to pay the extra costs of their supervision. Most commenters addressing this issue commented only on the amount of the daily fee and related issues such as the frequency and length of examinations. No commenters addressed examination fee charges for examination of affiliates of savings associations, including savings and loan holding companies.

A number of commenters considered the proposed estimated fee amount of $485 a day too high. Some objected that the rate was higher than what they had paid before FIRREA. Some commenters compared the proposed fees unfavorably to those they paid to independent auditors and state examiners. Some commenters urged that OTS not charge a uniform fee for all examiners, because of examiners' varying levels of experience and expertise. One commenter criticized OTS for conducting separate examinations to determine compliance with various non-discrimination and consumer-oriented statutes. Several commenters believed that the proposal did not adequately differentiate between healthy and nonhealthy institutions and suggested that the former pay a lower daily rate. One commenter asserted that, under the proposed rule, the Office had an incentive to increase the duration and staffing levels of examinations in order to maximize examination fees. Another expressed concern that the Office would have no incentive to reduce examination costs.

As discussed more fully in section IV, the Office has decided to adopt a final funding structure that contains a modified version of the proposed sliding scale assessment. Overall, the sliding-scale asset-based assessment best recognizes the economies of scale that the Office experiences in examining and supervising larger institutions. The Office does not believe it appropriate for large savings associations to underwrite the proportionately higher costs incurred in supervising smaller savings associations, which would result from the imposition of a fixed assessment rate. Based upon its examination and supervisory experience as well as the concerns raised by a number of commenters, the Office believes it appropriate to differentiate between troubled and nontroubled thrifts in assessing the industry. This will be accomplished by imposing different assessment rates tied to the assets and condition of the savings association (including any subsidiaries) rather than daily examination fees.[5] Troubled savings associations will be assessed at a higher rate to recover the higher costs of examination and supervision they cause the Office to incur. Nontroubled institutions will pay a lower rate intended to recover the Office's generally lower costs associated with supervising those associations.

The agency believes that this bifurcated scale closely approximates the actual costs incurred in examining and supervising thrifts of varying sizes and conditions and ensures that those which require more extensive examination and supervision at greater expenses to the Office pay their share of that expense.[6] The asset-based assessment approach also offers institutions a measure of predictability as to the amount due at the time of each assessment, whcih would aid both the institutions and the agency in the budgeting process. Finally, this approach is simpler and less costly for the agency to administer. The approach adopted today is also intended in part to address concerns expressed by some commenters that the OTS has no incentive to economize with a daily examination rate, although the Office believes those concerns to be unfounded.

The Office believes the HOLA authorizes a sliding scale approach for assessments, including either the asset-based assessment/daily examination fee approach embodied in the proposal or the bifurcated asset-based assessment with higher rates for troubled thrifts approach set forth herein. Section 9 of the HOLA provides authority for OTS to levy an asset-based assessment but does not dictate the formula it should use, giving the Director the discretion to determine the exact structure of such an assessment. In this regard, the Office notes that the OCC's sliding scale assessment method, adopted pursuant to similar authority in 12 U.S.C. 482, has been upheld against a similar legal challenge. *See First National Bank of Milaca* v. *Heimann*, 572 F.2d 1244 (8th Cir. 1978).

Although the OCC's assessment regulation does not differentiate in assessment rates between healthy and troubled institutions, the Office believes that a bifurcated sliding scale asset-based assessment regulation is appropriate and consistent with the requirements of section 9 of the HOLA. It is conducive to a more accurate recovery of the actual costs incurred by the Office in carrying out its examination and supervision responsibilities. Section 9(e) explicitly contemplates the use of more than one formula in setting fees in order to cover the Office's costs.[7]

The Office has reviewed the actual examination expenses incurred by the FHLBanks in examining and supervising savings associations pursuant to authority delegated to them by the

[5] The Office will, as explained more fully in Section IV.D., follow the proposal in charging daily examination fees for examinations of non-consolidated affiliates of savings associations, including holding companies.

[6] The Office is considering the increased use of advance requests for information as one commenter suggested, and the use of offsite monitoring, where appropriate, in order to reduce actual examination costs.

[7] The Office notes that the National Bank Act does not currently contain parallel explicit authorization for the OCC to use different formulas tied to costs of the agency.

Board during the period from 1985–1989. Although the fees charged by the FHLBanks varied, resulting in a range of examination charges, troubled institutions required significantly more in-depth examination and supervision than other thrifts and consequently paid higher examination fees. Just as the Office believes it would be inappropriate for large savings associations to underwrite the proportionately higher supervision costs of smaller savings associations, it believes that it would be inappropriate for nontroubled institutions to underwrite the higher costs involved in supervising troubled thrifts. This would result from the imposition of a uniform sliding scale assessment rate absent either examination fees or higher rates for troubled institutions.

B. Application Fees

Fourteen commenters addressed the proposed application and securities filing fees.

1. *Size of the Proposed Fees.* Six of the commenters acknowledged that charging application fees is an appropriate method for the Office to recover its costs in processing applications. However, six commenters stated that generally the amounts proposed for application fees were too high and would discourage the filing of applications. Three of the commenters suggested that the application process and fees charged should distinguish between healthy and troubled institutions. It was suggested that for an institution that, for example, is in compliance with its regulatory capital requirements and that has a 1 or 2 MACRO rating, the fee for "certain" applications should be set at a lower amount because applications submitted by such institutions "should not require the same scrutiny and hence the same amount of time and staff resources to process as an identical application filed by an institution not meeting that standard." One commenter indicated that the fees proposed for securities filings were fair and reasonable.

One commenter suggested that fees should be based on the actual cost of processing each individual application. Another commenter stated that calculating application fees based on the average cost of processing all applications of a particular type is unreasonable, arguing that this method effectively requires all applicants to pay the costs for applications which involve significant issues of law or policy.

The Office continues to believe that the application fee method it proposed is the best approach. It was modeled on the approach taken by the OCC for processing corporate applications filed with that agency. *See* 12 CFR 5.5. The proposed approach should be the least burdensome for the industry as a whole. First, it is based on the view that the cost incurred by the Office when processing corporate applications should be borne by the savings associations and others making the filings. Second, this approach, as opposed to a fee based on the actual cost of processing each individual application submitted to the Office, avoids significant administrative costs for the Office, costs which ultimately would have to be passed on to those making the filings. It also enables applicants to know in advance precisely what their costs will be upon submitting an application.

The Office has determined not to distinguish between troubled and non-troubled institutions in setting application fees because the Office's costs in processing applications do not differ significantly on this basis. Similarly, the Office has determined not to distinguish between those applications that can be processed on a delegated basis by the District Offices and those that must be processed by Washington staff because they involve significant issues of law or policy or for other reasons cannot be processed solely by the District Offices. The administrative burdens of this approach would be significant. Basing fees on the projected average cost of processing each type of filing is the least burdensome for those actually submitting applications, especially given that fees may be reduced if it is determined that the amount of the projected fee for a particular type of application would unduly or unjustifiably discourage applications of that type. As explained in the proposal, the Director or his or her designee will evaluate the fees determined by application of the formula proposed and, in his or her discretion, make downward adjustments to take into account any inequities as a result of application of the formula, as well as any projected efficiencies or changes in procedures which would result in lower fees for the coming year not otherwise reflected as a result of the application of the formula. The Office continues to believe that this is the most equitable approach to determining fees.

2. *Retroactive Fees.* Eight commenters opposed the proposed charging of application fees for applications submitted after January 1, 1990. Upon review, the Office has determined to require application fees for applications, filings, notices and other requests received by the Office beginning ten days following the publication of the application fee schedule which appears as Appendix A to this Final Rule.

3. *Additional Filing Fee for Resubmitted Application.* The proposal stated that when an application is substantially incomplete or materially deficient and thus the Office cannot complete its review, a new fee must be paid upon submission of a revised application. This provision confused several commenters. The commenters were under the mistaken impression that the Office was proposing the charge an additional fee to be paid upon the filing of an amendment to an application that is submitted in response to a request for additional information needed to complete the application under the Office's Application Processing Guidelines, 12 CFR 571.12.

As the commenters pointed out, the Office frequently sends requests for additional information to applicants. The Office will not charge an extra fee when an application is amended by the filing of a response to a request for additional information. Under the Guidelines, upon receipt of a properly submitted application, the Office must either (1) deem the application to be complete, (2) request additional information to complete it, or (3) return the application if it is deemed to be materially deficient. If the Office fails to act as described in the preceding sentence within a prescribed period of time, the application will be deemed complete automatically. 12 CFR 571.12(c)(1). The proposal to impose an additional fee would not apply to the second option described above for responses to additional information requests in connection with the normal processing of a properly submitted application under the Guidelines.

However, the additional fees would apply if the Office acts under the third option described above. The Office will require an applicant to pay an additional fee upon filing a new application only in the limited circumstances where the original application was so deficient that it was impossible for the Office to even begin the regular application review process. In the event the applicant chooses to file a new revised application, a new fee must be paid. The amount of the new filing fee will be calculated on the same basis as the original filing fee imposed for that type of application. As explained more fully in the proposal at 55 FR 6277, by charging the applicant an additional fee upon the submission of a new application, the additional costs incurred and staff resources expended by the Office in handling such original

deficient submissions will be properly borne by those savings associations, individuals, and entities directly responsible for causing such additional costs.

4. *Other Comments.* Two commenters urged that the Office charge a fee for capital plans submitted by savings associations that fail their capital standards. The Office is not charging a fee for the submission of capital plans at this time, although it may reconsider this decision in the future.

Two commenters objected to the requirement in the proposal that if a transaction requires the filing of several types of applications, the filing fee associated with all applications must be paid. However, the proposal also stated that certain of the Office's application forms combine different types of applications. In those cases, the fee listed in the application fee schedule will reflect the fee for the combined applications. Applicants should review carefully the application fee schedule and footnotes to determine whether the fee listed for a particular application also includes related applications.

In addition, the Office welcomes specific suggestions on ways to streamline the application process and improve application forms. The Office is working currently on a number of projects to improve its holding company forms, merger applications, and mutual to stock conversion applications, among other initiatives.

Five commenters offered their observation on the specific fees for five different types of applications. One commenter questioned the amount of the fees for a simple holding company reorganization that involves the filing of an Application H-(e)1-S and a proxy statement with the OTS and a registration statement containing a prospectus with the SEC. The commenter mistakenly believed that the fee for the Application H-(e)1-S would be the same as the fee for the Application H-(e)1, which is currently $18,100. That is not the case. The proposed application fee schedule did not list a fee for an Application H-(e)1-S because the Office has not yet determined the fee for this relatively new type of filing. Consequently, there is currently no fee for the filing of a Form H-(e)1-S, but applicants must pay a fee for the related proxy statement filed with the Office.

The commenter also stated that the Office's work in reviewing the Application H-(e)1-S is duplicative of the review of the proxy statement/prospectus that is also generally filed with the OTS for a holding company reorganization transaction. The Office does not agree with this view. The two procedures involve different review standards, one pursuant to Section 10(e) of the HOLA, and the Acquisition of Control Regulations, 12 CFR part 574, and the other pursuant to the proxy rules under the Exchange Act, 17 CFR 240.14a-1—240.14a-101.

In addition, the SEC generally reviews the holding company's prospectus included in the registration statement filed pursuant to the Securities Act to register the securities of the holding company that will be offered to the former shareholders of the savings association proposing to reorganize into a holding company structure. The SEC imposes a filing fee for the registration statement. However, the OTS will impose a fee for the OTS's review of the proxy statement used in connection with the meeting of shareholders of the savings association where they will be asked to vote to approve or disapprove the proposed holding company reorganization. As stated above, this review is different from the review of the Application H-(e)1-S, and from the SEC's review of the holding company's registration statement.

With respect to the four other types of applications commented upon, as the application fee schedule for 1990 shows, the Office has taken these comments into consideration in modifying some of the application fees it will charge for the remainder of 1990.

C. Miscellaneous

Four commenters stressed the need for the OTS to downsize its operations in proportion to the shrinking thrift industry. Commenters urged such shrinkage to relieve the burden assessments and fees would place on the thrift industry and to avoid placing savings associations at a competitive disadvantage with commercial banks. Some commenters suggested that the OTS review its fees more frequently than annually and reduce such fees where appropriate.

The OTS is bound by several statutory restrictions that make major amendments to its budget impossible at the present time. These include the requirement that all banking regulatory agencies provide comparable pay benefits to their employees and the one-year job guarantees given to all former Federal Home Loan Bank Board and System personnel transferring to the OTS.

As discussed in the proposal, the OTS will re-evaluate its schedule of fees at year-end when it has more experience with its funding mechanism. Since fees will be reviewed annually and new fee schedules published annually, there will be ample opportunity to adjust fees as more data is collected on the size of the industry and OTS's costs in supervising the industry.

Finally, the Office agrees that keeping costs down is an important goal, but one which must be balanced by its need to meet its supervisory responsibilities. The recently announced study of consolidating the 12 OTS District offices is one example of the efforts the OTS is making to cut costs where appropriate. However, any cost savings from consolidation and downsizing will take some time to realize. Moreover, effects of operating under the changes mandated by FIRREA cannot be fully known until sometime in early 1991 at best. The OTS has given its best effort to formulating a funding mechanism under variables of this new milieu. By the end of this year, the OTS will be better able to evaluate its first year of experience and make adjustments accordingly for next year's assessment schedule.

Several commenters believed that the OTS should have prepared a Regulatory Impact Analysis under Executive Order 12291. That Executive Order requires such an analysis for "major rules" and defines such rules as those that are likely to result in an annual effect on the economy of $100 million or more, a major increase in costs or prices for consumers or individual industries, among others, or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of domestic enterprises to compete with foreign-based enterprises. The Office continues to believe that this regulation does not meet any of those criteria. First, the commenters raising this issue most often did so in the context of noting the increased costs to the savings association industry from a number of effects of FIRREA, notably the increased insurance premiums, the creation of the OTS, and the costs attendant upon such OTS examination and supervision, and the reduction in FHLBank dividends due to their increased financial obligations under FIRREA. While indeed all of these resulting costs combined might meet one or more of the criteria listed for a major rule under Executive Order 12291, the effects and costs of this particular OTS regulation standing alone do not meet any of these criteria. The OTS budget for 1990 is currently $298 million. The Office expects that this amount will decrease in succeeding years. The portion of the Federal Home Loan Bank Board budget and Federal Home Loan Banks' budget combined attributable to functions now performed by the OTS was $246 million. Thus, this regulation

will not have an effect on the economy greater than $100 million, nor will it, standing alone, result in a major increase in costs or result in the other listed effects which might require a Regulatory Impact Analysis.

IV. Discussion of Regulation

After careful consideration of comments filed in response to the proposed regulation, and based on further analysis and updating of relevant internal data, the OTS has decided to adopt a bifurcated sliding scale asset-based assessment rather than a combination of the asset-based assessment and daily examination fee. Because examination fees will not be charged for examinations of savings associations and their consolidated subsidiaries, the amount of funds to be obtained through asset-based assessments has risen. As a result, the assessment rate needed to fund the Office is higher than the rate set forth in the proposal.

A. Structure of Funding Mechanism

The Office is adopting a bifurcated sliding-scale assessment approach, differentiating between troubled and non-troubled savings associations, in response to a number of factors. These include objections raised by commenters regarding the daily examination fee, the ease of administration inherent in the asset-based assessment approach, and study of additional data on prior examination practices in the 12 OTS Districts. The funding approach adopted today does not differ substantially from the various options set forth in the proposal. It combines concepts inherent in the proposal and raised by a number of commenters: recognition of economies of scale and recognition that unhealthy institutions are more expensive to examine and supervise. *See* 55 FR at 6275–6276 and comments discussed in Section III.A. above. The higher rates charged to troubled institutions (generally defined as those operating under the jurisdiction of the RTC as conservator or with a MACRO 4 or 5 rating as of their last examination) is designed to achieve the same purpose as the daily examination fee concept: ensuring that those institutions which cost the Office more to examine pick up the bill for their extra costs. Absent this feature, healthy institutions would be unfairly subsidizing unhealthy, troubled institutions. The Office is aware of the potential uncertainty in Office revenues that may result from this approach, as these institutions either improve their conditions and ratings or are resolved by the RTC. On the whole, however, as discussed more fully in Section IV.C. below, it believes the advantages of this approach in the allocation of costs outweigh this disadvantage.

B. Computation of Asset-Based Sliding Scale Assessments

New § 502.1 sets forth the two asset-based assessments: the first for non-troubled thrifts; and the second for those defined as troubled thrifts (generally those operating in conservatorship or with a MACRO 4 or 5 rating as discussed in Section IV.C.). Section 502.1(c) sets forth the chart for non-troubled thrifts to determine their assessment and is called the "general assessment". A separate chart is set forth in paragraph (d) for troubled thrifts, known as the "premium assessment." The only difference is that the premium assessment chart rates are 50% higher than the general assessment. The rate set forth in the regulation will provide a cap above which rates will not go without further rulemaking. The Director retains the flexibility to prescribe uniformly lower rates for periods when he or she deems it appropriate. The method for computing either assessment is set forth in section 502.1(b) and is the same as the proposed version. All institutions would pay the same rate on assets up to a prescribed amount. Institutions with a larger asset base would pay a lower rate on assets above the prescribed amount.

In this regard, the Office is adding a new paragraph to § 502.1 that provides the Director with the flexibility to charge lower assessment rates than those set forth in paragraphs (c) and (d) of that section, if it is determined that the Office's funding needs for a period determined by the Director will not require collection of assessments at the higher rate set forth in the regulation. This provision has been added (1) because of the uncertainty of revenues that will be generated from the premium assessment and (2) because the Office wishes to retain the flexibility to lower its rates and reduce the burden on the industry where possible, consistent with its supervisory responsibilities. The actual assessment rates to be charged will be published in the "Schedule of Fees" Thrift Bulletin. Those fees will remain in effect until superseded by any later Thrift Bulletins.

While the final regulation provides for a quarterly assessment for the remainder of 1990, due October 31, it also provides the Director with the flexibility to change to a semiannual assessment in the future. Any change in the frequency of the assessment pursuant to this provision will be announced in a Thrift Bulletin.

The amount owed for each assessment will be calculated as set forth in § 502.1. While the Office had proposed offsetting quarterly assessments under the permanent funding mechanism against interim assessments so that no institution would pay more on an annual basis than it would have paid had the final mechanism been in place for the entire year, the final regulation does not contain this provision. Because of the change in structure and the higher assessment rate which must be charged to replace the proposed examination fees, the assessment rate for the fourth quarter of 1990 will exceed the assessment rates imposed in the first and second quarters under the authority of the interim regulation. When those amounts were assessed, the Office had expected to supplement them with examination fees for examinations of savings associations conducted on or after April 1, 1990. When it became apparent that savings associations would not be charged examination fees, the assessment rate had to be raised to offset the absence of examination revenues.

C. Assessment Charges for Troubled Savings Associations

The higher assessment rates to be paid by troubled thrift institutions are designed to recover costs in a manner similar to the daily examination fee proposed by the Office. The Office has decided to define a troubled savings association in terms that it believes concretely reflect the increased supervisory attention that such an institution necessitates which in turn increases the cost of regulating and examining it. The placement of a savings association into conservatorship is a clear indication of an institution's troubled status and is normally accompanied by a low MACRO rating. After an association has been in conservatorship for a prolonged period of time (generally one year), it is expected that its operations will have stabilized, and the OTS will have recovered any increased examination expenses incurred prior to placing the institutions in conservatorship. At that time the Office will generally adjust its rating and charge the association the general assessment rate. The supervision of stabilized conservatorships is expected not to require the additional time and depth involved in the supervision of more recent conservatorships. Nevertheless, should conditions again deteriorate, the Office reserves the authority to again charge the premium assessment rate

necessary to recoup the costs of more intense scrutiny.

The MACRO rating system, with its correlation to increased supervisory attention, is well suited to differentiating between troubled and non-troubled savings associations. The Regulatory Handbook on Thrift Activities ("Handbook") published and used by the Office states that "the principal purpose of the MACRO rating is to identify, via the composite rating, those institutions which pose an inordinate risk of failure and as such, merit special supervisory attention and/or warrant a higher than normal degree of supervisory concern." *See* Handbook section 071, 071.4 (December, 1989). Moreover, it notes specifically that "[t]he ratings can be used to focus appropriate supervisory attention toward an institution, determine examination frequency and scope, and assist decision making on branch, merger, and other applications." *Id.* at 071.1. Hence, the connection between the MACRO rating and increased supervisory and examination attention is quite direct: it is the primary means of identifying those institutions that need close attention and will take up more of the Office's resources. It is appropriate and reasonable then, that to the extent those institutions can be identified, they should bear the cost of their increased burden to the Office. Otherwise, healthy institutions would unfairly subsidize the unhealthy which demonstrably cost the OTS more to supervise and examine.

As explained previously, the overall rating is expressed through a numerical scale of one (1) to five (5) with five (5) representing the worst rating and highest degree of supervisory concern and a one (1) rating representing the best rating and lowest degree of supervisory concern.[8] Office examination data has demonstrated that institutions rated 4 or 5 cost more to examine and supervise than those rated 1, 2, or 3.[9] The reason is obvious in the definition of each rating. A composite 4 rating indicates major or serious problems or unsafe and unsound conditions that are not being satisfactorily resolved by the institution which, without prompt attention, could impair the future viability of the institution. Handbook at 071.3. The effect on supervision and examination resources is that "[a] potential for failure is present but is not imminent * * *. Institutions in this category require close supervisory attention and financial surveillance." *Id.* The need for increased supervisory resources is also evident in the definition of a composite "5" rating. This cateogry indicates "an extremely high immediate or near-term probability of failure" and institutions so rated "require immediate corrective action and constant supervisory attention." *Id.* at 071.4.

The Office's examinations of less than healthy thrifts must be more frequent, wider-ranging, longer, and more intensive in order to learn of the existence and extent of problems as early as possible and to craft appropriate supervisory responses. In addition, examination data show that the OTS devotes at least 50% more of its resources to examine and supervise a troubled thrift than a non-troubled thrift. Depending upon the type or severity of the problems involved in a particular troubled savings association, the Office's costs may be as high as 200% more than its costs in supervising a comparably sized non-troubled thrift. At this time, however, the asset-based assessments of those thrifts with a MACRO rating of 4 or 5 will be only 50% higher than those charged other savings associations. The MACRO rating to be used for purposes of determining whether an institution pays the premium assessment is the most recent rating conveyed to the savings association through a supervisory letter as a result of an examination. Those savings associations without a current MACRO rating at the time of an assessment will be charged the general rate.

While all institutions will pay the same assessment rate on the same amount of assets subject to their troubled or non-troubled status, because of the sliding scale approach used, the average assessment rate paid by small savings associations on their assets is higher than that for larger savings associations. However, as explained in the proposal, the OTS believes this differential is warranted based on the experience accumulated by the former FHLBB and the OCC. For the past ten years, the OCC has used the sliding scale approach because it has found that supervision costs did not increase in proportion to the asset size of the institution and, thus, a fixed rate assessment would unfairly allocate the bulk of examination costs to the largest banks.

D. Examination Fees for Affiliates

Pursuant to sections 9(b) and 10(b)(4) of the HOLA the agency has determined that it will charge separate examination fees only for examinations of those savings association affiliates which are not consolidated with a savings association in the most recent monthly Thrift Financial Report. The proposal included such entities among those that would be charged examination fees. The term "affiliates" includes, but is not limited to, savings and loan holding companies. It also includes, for example, subsidiaries of a savings association that would not be consolidated with the savings association for purposes of the Thrift Financial Report. Examination fees will be charged at the rate of $480 per day per examiner. The Office believes that daily examination fees in this limited area will best recover the Office's costs of such examinations.

At this time, the Office has chosen not to charge examination fees in the limited circumstances, i.e., fiduciary examinations, where the OCC has chosen to charge examination fees. The Office will monitor this area to determine if a more expansive examination regulation would be appropriate.

E. Application Fees

This final rule sets forth the Office's procedures for determining fees for processing various types of applications, filings (including securities filings), notices and requests.

1. *Corporate Application Fees.* Pursuant to HOLA section 9(j), the OTS is adopting the formula set forth in its proposal to determine the cost of processing applications. As proposed, it will calculate, at least annually, its costs of processing the various types of applications. This will enable it to adjust such costs and the resulting fees over time to reflect changes in Office expenses or procedures and to recover as nearly as possible, its actual costs. The steps the Office will utilize in calculating the cost of processing types of applications other than securities filings are set forth at new § 502.3(b) and explained in the proposal at 55 FR 6276–6277.

If in the interval between publications of the annual Thrift Bulletins announcing the schedule of fees for the ensuing year, the Office develops new

[8] The MACRO rating scale is first used to measure each of the key performance areas (management, asset quality, capital adequacy, risk management, and operating results) of a thrift's operations. An overall composite rating is then assigned to the institution, not by computing an arithmetic average but by appropriately weighting the individual ratings according to how strongly they affect the viability of the institution. For purposes of this regulation, the MACRO rating means the composite rating.

[9] While savings associations with a composite rating of 3 have certain characteristics and weaknesses that require increased supervisory attention, *see* Handbook at 071.3, the Office is not, at this time, for purposes of this regulation, including these institutions within the definition of "troubled savings associations."

types of applications for which a fee will be imposed, it will announce the fees to be imposed for those applications at least thirty days before such fees are effective through publication of a Thrift Bulletin. Initially, these fees will be set in an amount commensurate with fees for processing similar types of applications or applications involving analysis of similar information, policies and legal concerns.

If a transaction requires the filing of several types of applications, the filing fees associated with all applications involved must be paid. However, certain application forms combine different types of applications. In those cases, the fee listed in the application fee schedule will reflect the fee for the combined applications. In addition, the filing fees listed in the fee schedule for certain types of applications reflect the cost of processing certain related applications. Applicants should review carefully the footnotes to the fee schedule to determine whether the fee listed for a particular type of application includes the fee for related applications. All applications should contain a statement of how the fee being paid was determined.

All fees are nonrefundable. When an application is materially deficient and thus the Office cannot begin the regular application review process, a new fee must be paid upon the submission of a new, revised application. The amount of the new filing fee will be calculated on the same basis as the original filing fee imposed for such applications. The Office intends that the additional fees will cover the extra costs associated with initially reviewing and/or commenting on materially deficient submissions. Likewise, if an applicant voluntarily withdraws an application and subsequently refiles it, a new filing fee must be paid upon resubmission.

The Office has made certain revisions to the application fee schedule that was published as appendix A to the proposal. The proposal stated that it would be possible that the amounts of the fees listed could change based on data available at the time the fees were calculated for the year 1990, and that additional types of applications and securities filings could be added to the list at the time the proposal was adopted as a final rule. These revisions are reflected in the final application fee schedule for 1990.

2. *Fees for Securities Filings Under the Exchange Act.* The Office is today adopting the approach for imposing fees associated with securities filings that was set forth in the proposal at 55 FR 6278. It is amending § 563d.1 to require that, except as otherwise specifically provided in the application fee schedule published by the Office, the filing fees specified by the SEC's rules shall be paid to the Office. The Office believes that it will recover its total actual costs of reviewing filings under this approach, though any particular fee may be higher or lower than the cost of processing the particular type of filing for which it is being charged.

The Office is also amending § 563d.1 to impose additional filing fees beyond those specified by the SEC in limited areas. As discussed more fully in the proposal at 55 FR 6278, if after the Office reviews a Form 10–K or a Form 10–Q and determines that the filing is deficient, and the Office requires that an amendment be filed to correct the deficiency, then, upon the filing of the amendment to the Form 10–K or the amendment to the Form 10–Q, the association will be required to pay an additional fee in the same amount as the original fee imposed for the filing of a Form 10–K. Filings on Schedules 13D and 13G will be treated in a similar manner. If, after the Office reviews the Schedule 13D or 13G and determines that the filing is deficient, and the Office requires that an amendment be filed to correct the deficiency, then, upon the filing of the amendment to the Schedule 13D or Schedule 13G, the beneficial owner will be required to pay an additional fee in the same amount as the original filing fee imposed for such Schedules.

The fees imposed pursuant to the Exchange Act are included in the Office's application fee schedule. Associations and other filers should refer also to the Exchange Act and the SEC's rules and forms thereunder for detailed instructions on the amount of the fees and, in certain cases, their method of computation. All filings should contain a statement of how the fee being paid was calculated.

The Office has made certain changes in the application fee schedule that was published as appendix A to the proposal with regard to Exchange Act filings in response to comments received. The revisions are reflected in the final application schedule for 1990.

3. *Fees for Securities Offerings.* The Office also today is imposing a percentage-based filing fee for the filing of offering circulars on Form OC relating to the offer and sale of securities by savings associations as more fully described in the proposal at 50 FR 6278–6279. The SEC imposes a filing fee calculated on a percentage basis of the securities offering's value pursuant to section 6(b) of the Securities Act. The Office is imposing a similar filing fee upon the filing of Form OC by a savings association of 1/40 of one percent of the maximum aggregate price at which the securities are proposed to be offered. This will apply to offering circulars for public offerings filed pursuant to the Office's securities offering regulations under 12 CFR part 563g and the Office's mutual to stock conversion regulations under 12 CFR part 563b, including public offerings of securities in standard conversions, merger conversions, and modified conversion (and to the extent they involve public offering of securities, voluntary supervisory conversions), and pursuant to 12 U.S.C. 1467a(o) for mutual holding company reorganization transactions. Associations should refer to the SEC's Rule 457 under Regulations C, 17 CFR 230.457, for guidance in computing the filing fee for a variety of special circumstances.

The Office's Thrift Bulletin publishing the application fee schedule will set forth the percentage-based fee for securities offerings. Applicants filing conversion applications for standard, merger and modified conversions should note that this filing fee will cover only the securities offering materials submitted with the conversion application. Conversion applications also involve the filing of a Form AC and may involve other types of applications. The filing fees associated with such other types of corporate applications must also be paid. Applicants should refer to the application fee schedule and footnotes to determine those fees. In addition, applicants should submit an explanation showing the total amount of the fees being paid and how the fees were calculated.

The Office has made cetrain changes in the application fee schedule that was published as appendix A to the proposal with regard to fees for securities offerings. The revisions are reflected in the final application fee schedule for 1990.

F. Other Fees and Charges

Pursuant to § 502.7, the Office will also impose a fee for Certification of True Copies provided by the Information Services Division in response to requests for official copies of agency documents and records. The OCC, the SEC, and the Federal Reserve Board charge such fees although the amounts vary greatly by agency. The Office will also charge other agencies for expenses it incurs at their request and on their behalf for services performed that fall beyond its usual examination and supervision responsibilities. As indicated in the proposal, the Office will also charge for

optional services such as publications and seminars.

G. Collection and Notice of Fees

At least thirty days before the beginning of the next calendar year the OTS will issue a notice in a Thrift Bulletin setting forth all fees to be charged for the coming year. Such fees would not be effective until 30 days after publication of the notice. This Thrift Bulletin would include any adjusted assessment rate schedules if the Director determines to exercise his or her authority under new § 502.1(g).

The final revision of § 502.4 regarding collections contains two changes from the proposed version. First, the requirement that each institution provide written authorization to its Federal Home Loan Bank to debit its account is deleted as unnecessary and overly burdensome. Second, a new paragraph (d) is added, clarifying the Office's authority to debit any outstanding fees or assessments from the FHLBank account of such institution before it enters conservatorship or receivership. As provided in paragraph (f) of section 9 of the HOLA, the Office will continue to reimburse the Federal Home Loan Banks for any actual costs the Banks may incur in collecting fees and assessments under this regulation.

In addition, as indicated in the proposal, pursuant to § 502.5, the Office will charge interest on overdue fees. The final version of § 502.5 specifies that fees will be considered overdue 30 days after the invoice date.

V. Administrative Procedure Act

The Director hereby adopts these regulations as final rules effective upon publication in the **Federal Register**, without the usual 30-day delay of effectiveness provided for in the Administrative Procedure Act ("APA"), 5 U.S.C. 553. That requirement may be waived upon a showing of "good cause" by the promulgating agency. 5 U.S.C. 553(d)(3). The Director finds that good cause exists for the immediate implementation of the instant regulations, providing for the full funding of the agency, in view of the public interest in furthering the Office's ability to function maximally and to discharge effectively all of its statutory responsibilities during this period of continued uncertainty and reorganization in the thrift industry. Savings associations have already been paying assessments to fund the OTS pursuant to the interim regulation published in 1989. The Office believes that further assessments should be done pursuant to the final regulation, which follows notice and comment rulemaking, rather than its interim regulation.

The Notice of proposed rulemaking appeared in the **Federal Register** on February 22, 1990, and all interested parties were given the opportunity to comment on the proposal, including the various alternative funding mechanisms, through March 26, 1990, in compliance with the APA. 5 U.S.C. 553(g). The Agency is now adopting one of the alternatives offered, with some adjustments to address one of the primary concerns set forth in the proposal and raised by a number of commenters (the increased costs associated with unhealthy savings associations) in a way more consistent with its overall approach. Finally, implementation of a permanent funding mechanism upon publication offers both the agency and the industry the additional advantages of greater stability and certainty as to the timing and amounts of assessment than the temporary funding provided for under the Interim Final Rule. Thus, the Director has concluded that immediate effectiveness of the rule, contemporaneous with publication in the **Federal Register**, is in the best interests of the industry, the agency, and the public. Application and securities filing fees will be charged for applications and filings submitted on or after 10 days after publication of these regulations as final in the **Federal Register**.

VI. Executive Order 12291

The Director of the OTS has determined that this final regulation does not meet any of the conditions set forth in Executive Order 12291 for designation as a major rule. Consequently, a final Regulatory Impact Analysis has not been prepared.

As required by the FIRREA, the functions of the OTS that have been transferred from the former FHLBB are required to be funded through various types of assessments on the industry. Consequently, the OTS will be charging assessments and fees authorized by FIRREA to cover the costs of examinations and investigations; fees to cover the costs of processing various types of applications, notices, filings, and requests; and fees to recover the costs of providing specific services such as publications and seminars. This method of funding the activities transferred to the OTS from the Federal Home Loan Bank Board replaces the prior method of funding such activities. Because this prior method was also dependent wholly on fees and assessments paid directly or indirectly by the industry, the OTS does not believe that this new method would result in any of the effects that would render this proposed rule a major rule. While the method of funding the transferred activities is being changed, the general nature of the activities being funded and the ultimate source of the funds—the industry regulated by the OTS—are unchanged. The amount to be charged by the OTS pursuant to this regulation will not exceed by $100 million the amounts changed by the FHLBB or the FHLBank System for the same functions. *See also* the discussion in Section III.C., above.

VII. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act, it is certified, for the reasons set forth below, that these changes will not have a significant economic impact on a substantial number of small entities. Accordingly, a Regulatory Flexibility Analysis is not required.

As discussed in the Summary of Comments, a number of commenters were concerned that the regulation might adversely affect small savings associations. Some commenters favored a flat assessment rate as an alternative to minimize this effect, others did not offer a specific alternative other than the OTS reducing its costs. The Office has considered those comments, but does not believe that the bifurcated sliding scale asset-based assessment mechanism poses an undue burden on smaller institutions but rather represents a fair and reasonable approach to balancing the various elements of an assessment mechanism: the true cost to the Office of regulating small institutions, the true costs to the Office of regulating large institutions, and the true costs of regulating troubled institutions both large and small.

The rule will have no impact on small savings associations beyond requiring, pursuant to the HOLA as amended by FIRREA, that they pay fees and assessments approximating the costs of their supervision, examination, regulation, and the processing costs associated with applications and filings that they submit. Such institutions, prior to the enactment of FIRREA, had an obligation to pay for the cost of supervision directly through examination fees and FSLIC insurance premiums and indirectly as a result of contributions by the Federal Home Loan Banks. This regulation, as required by statute, shifts the method of payment of such expenses. It provides only that small institutions, as well as all institutions, pay for the cost of their supervision, examination, and regulation

by OTS, and that they pay for the cost of processing applications that they submit. To the extent that the effective asset-based assessment rate on small institutions is higher than that imposed on large institutions, this difference reflects economies of scale realized by the OTS in supervising large institutions.

The rule would not impose any unnecessary financial, recordkeeping or administrative burdens on small savings associations.

VIII. Paperwork Reduction Act

The collection of information required by this final rule has been submitted to and approved by the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3504(h)). The OMB has assigned this collection of information Control Number 1550–0053. Comments on the collection of information should reference the aforementioned control number and should be sent to the Office of Management and Budget, Paperwork Reduction Project (1550), Washington, DC 20503, with copies to the Office of Thrift Supervision at the address previously specified.

The collection of information referenced in this final rule may be found at 12 CFR 502.3(h). The Office of Thrift Supervision requires the submission of this information in order to ensure that persons submitting applications and filings to the Office have properly calculated the fee or fees which are owed and have remitted the appropriate amount.

List of Subjects in 12 CFR Part 502

Assessments, Reporting and recordkeeping requirements, Savings associations.

12 CFR Part 563d

Authority delegations (Government agencies), Reporting and recordkeeping requirements, Savings associations, Securities.

Accordingly, the Office hereby amends parts 502 and 563d, chapter V, title 12, *Code of Federal Regulations*, as set forth below.

SUBCHAPTER A—ORGANIZATION AND PROCEDURES

1. Part 502 is revised to read as follows:

PART 502—ASSESSMENTS

Sec.

Authority: Sec. 3, 4, 9, 10 as added by sec. 301, 103 Stat. 278, 280, 316, 318 (12 U.S.C. 1462a, 1463, 1467, 1467a).

§ 502.1 Asset-based assessments.

(a) *Assessment overview.* Each savings association shall pay to the Director of the Office of Thrift Supervision an asset-based assessment on all of its assets as reported on its most recent consolidated Thrift Financial Report available at the time of the billing notice sent in accordance with § 502.6(a) of this part, except as provided in paragraph (h) of this section. A troubled savings association as defined in paragraph (f) of this section shall pay a premium assessment at a rate no higher than that specified in paragraph (d) of this section; all other institutions shall pay a general assessment at a rate no higher than that specified in paragraph (c) of this section.

(b) *Computation of assessment.* Assessments due pursuant to this section shall be computed in the following manner: Each savings association falls into one of the seven asset-size brackets denoted by columns A and B. A savings association's assessment is composed of two parts. The first portion is an assessment on assets up to the lower endpoint (column A) of the bracket in which it falls; this portion of the assessment is shown in column C. The second portion is an assessment on the remaining assets, which are assessed at the rate shown in column D. This rate is applied only to the amount in excess of the lower endpoint of the bracket. The total assessment is the sum of the assests in column C plus the product of the assets in excess of column E times the rate in column D. Each assessment is based upon the total consolidated assets shown in the savings association's most recent Thrift Financial Report preceding the payment date. Each savings association subject to the supervision of the Office on the date of the applicable Thrift Financial Report is subject to the full assessment for the next three-month period without proration for any reason.

(c) *General assessment.* The amount of the assessment paid by savings associations subject to this assessment schedule pursuant to paragraph (a) of this section is computed as follows:

If the saving association total assets (including consolidated subsidiaries) are:		The quarterly assessment is:		
Over—column A (million)	But not over—column B (million)	The amount—column C	Plus column D (percent)	Of excess over—column E (million)
0	$67	0	0.01164	0
$67	215	$7,799	.00902	67
215	1000	21,148	.00611	215
1000	6030	69,112	.00430	1000
6030	18000	285,402	.00398	6030
18000	35000	761,808	.00363	18000
35000		1,378,908	.00308	35000

(d) *Premium assessment.* The amount of the assessment paid by troubled savings associations subject to this assessment schedule pursuant to paragraph (a) of this section is computed as follows:

If the savings association's total assets (including consolidated subsidiaries) are:		The quarterly assessment is:		
Over—column A (million)	But not over—column B (million)	The amount—column C	Plus column D (percent)	Of excess over—column E (million)
0	$67	0	0.01746	0
$67	215	$11,699	01353	67
215	1000	31,722	.00917	215
1000	6030	103,668	.00645	1000
6030	18000	428,103	.00597	6030
18000	35000	1,142,712	.00545	18000
35000		2,068,362	.00462	35000

(e) *Frequency.* Assessments under this section shall be assessed either quarterly or semiannually as determined on an annual basis by the Director. Notice of any change in the frequency of the assessment shall be published in a Thrift Bulletin at least thirty days before the beginning of the next calendar year. If assessments for a particular year are on a quarterly basis, such assessments shall be due on January 31, April 30, July 31, and October 31, representing the three month period beginning 30 days before such payment date. If assessments for a particular year are semiannual, such assessments shall be due on January 31 and July 31, representing the six month period beginning 30 days before such payment date. For calendar year 1990, assessments shall be paid quarterly, beginning with the October 31 assessment. If assessments for a later period are semiannual, those assessments shall be at rates published in the Thrift Bulletin announcing the change in the frequency of the assessment.

(f) *Definition.* For purposes of this section only, a troubled savings association shall be defined as a savings association with a MACRO rating of 4 or 5 as of the most recent off-site MACRO rating update (as determined either on-site or off-site by the most recent examination) of which the savings association has been notified by report of examination via supervisory letter. This definition also includes savings associations in conservatorship so long as those associations require increased supervision and examination by the Office.

(g) *Director's authority to adjust rates.* The Director or his or her designee, may, in his or her sole discretion, reduce the assessment rates charged under paragraphs (c) and (d) of this section if he or she determines that the income generated by assessing savings associations at the rate set forth in those sections would generate revenues in excess of the Office's needs, including both its direct and indirect costs and the maintenance of an adequate working capital fund. If the Director so determines, he or she shall set uniformly lower rates for all savings associations at a level he determines appropriate. Those lower rates, and the period for which they shall be in effect, will be published as set forth in § 502.6 of this part at least thirty days before such lower assessment rates will be charged, except that for 1990 any lower rates shall be effective upon publication in the Thrift Bulletin as set forth in § 502.6 of this part.

(h) *Exception to use of consolidated report for October 31, 1990 assessment.* For the October 31, 1990 assessment only, each savings association shall pay to the Director an asset-based assessment on all of its assets as reported on its most recent quarterly Thrift Financial Report.

§ 502.2 Examination fees for affiliates.

(a) The Office shall assess a fee to recover the costs of examinations of affiliates of savings associations, as defined in paragraph (d) of this section completed on or after this rule goes into effect.

(b) For calendar year 1990, a daily fee of $480 shall be charged. The fee assessed under paragraph (a) of this section shall be determined by multiplying the daily fee by the number of days or portions thereof that employees of the Office devote to the examination or investigation of affiliates of savings associations as defined in paragraph (d) of this section including on-site and off-site examinations and related supervisory activities covering time spent after the examination in preparing the examination report among other items.

(c) The daily fee established in paragraph (b) of this section will be reviewed not less frequently than annually and published in a Thrift Bulletin as set forth in § 502.6 of this part. It shall be no higher than the amount determined by dividing the total budget for the expense of conducting examinations and investigations of affiliates of savings associations by the total number of days projected to be spent conducting such examinations and investigations as set forth in paragraph (b) of this section.

(d) The term "affiliate" means an affiliate as defined in 12 U.S.C. 1462(9) (1989), except that for purposes of this part only, the term "affiliate" does not include any entity that is consolidated with a savings association for purposes of the Consolidated Statement of Condition of the Thrift Financial Report.

§ 502.3 Applications processing fees.

(a) Fees must accompany certain applications, filings, notices, and requests (hereafter collectively referred to as "applications") before such applications will be accepted for processing by the Office. Except as provided in paragraph (d) of this section, such fees will be determined by the Office according to the method set forth in paragraph (b) of this section, will be announced at least annually, and will be established at rates calculated to recover the Office's total direct and indirect costs of processing such applications during the ensuing calendar year after such fees are announced.

(b) The Office will determine fees for processing applications by:

(1) Calculating, based on historical data, the average time necessary to process each type of application;

(2) Identifying for the upcoming year the amount to be budgeted for processing applications;

(3) Dividing the amount identified in paragraph (b)(2) of this section by the total number of hours available for applications processing in the ensuing year to yield the average hourly cost for processing applications; and

(4) Multiplying the average hourly cost identified in paragraph (b)(3) of this section by the number of hours spent processing each type of application identified in paragraph (b)(1) of this section and rounding the result to the nearest increment of $100, with a minimum fee of $100. This will yield the amount of the application fee required to recover the cost of processing each type of application;

(5)(i) The Director, or his or her designee, may reduce any fees calculated as set forth above to adjust for any inequities or any efficiencies or changes in procedure which are projected to result in reduced processing costs and which have not been taken into account as a result of application of the formula set forth in paragraphs (b)(1) through (b)(4) of this section. The Director, or his or her disignee, also may adjust downward any fees calculated pursuant to paragraphs (b)(1) through (b)(4) of this section if, in the Director's discretion, he or she determines that the amount of such fee will unduly or unjustifiably discourage applications of a particular type or applications for particular categories of transactions.

(ii) In the event the Office develops a new type of application, and thus has no historical basis on which to establish an application fee, the Director may establish such fee based on a comparison with fees charged for processing similar types of applications or applications involving analysis of similar information, policies, and legal issues.

(c) The fees determined pursuant to paragraph (b) of this section will be published as set forth in § 502.6 of this part at least thirty days before such fees are effective, except that in 1990, such fees shall be effective ten days after publication in the Thrift Bulletin as set forth in § 502.6 of this part.

(d) The Director shall also charge fees to recover the Office's costs of processing filings with the Office made pursuant to 12 CFR parts 563b, 563d, and 563g. These fees will be published as set forth in § 502.6 of this part at least thirty days before such fees are effective, except that in 1990, such fees shall be effective ten days after publication in the Thrift Bulletin as set forth in § 502.6 of this part.

(e) In the event that the Office cannot complete its review of an application because it is found to be materially deficient and the Office accordingly refuses to accept the application for processing, the applicant must pay a new application fee at the time of filing any revised application.

(f) All application fees must be paid at the time of filing by check payable to the Office of Thrift Supervision. No part of a filing fee is refundable.

(g) When a transaction involves the filing of a number of different applications, the appropriate filing fees must be paid for each type of application filed, except as otherwise specifically provided in the Thrift Bulletin published pursuant to § 502.6 of this part.

(h) Each submission must be accompanied by a statement of the

amount of the fee for each application and filing submitted and how the fee was calculated.

§ 502.4 Collection of fees and assessments.

(a) *Debit at Federal Home Loan Banks.* Each institution that is subject to fees and assessments under §§ 502.1 and 502.2 of this part and a member of a Federal Home Loan Bank, shall establish at its Federal Home Loan Bank a demand deposit account for the purpose of paying such fees and assessments. Each institution shall maintain funds in such account in sufficient amount to pay its obligations to the Office. Each Federal Home Loan Bank shall debit such account directly to effectuate payment of assessments and fees to the Office. The Director shall mail a payment notice to each such institution at least seven days prior to the date that any such account is to be debited to pay the member institution's obligations to the Office, which notice shall specify the date on which the debit is to occur. The Director shall also notify each Federal Home Loan Bank that such accounts are to be debited.

(b) *Direct billing of institutions.* As an alternative to the payment mechanism described in paragraph (a) of this section, the Director may collect assessments and fees by sending notice and demand for direct payment thereof to an assessed institution. In such case, the institution shall pay the assessment or fee not later than the date specified in the notice which shall be at least seven days after the date of such notice. This payment procedure shall be used to collect assessments and fees from assessed institutions that are not members of a Federal Home Loan Bank or are affiliates that are not savings associations.

(c) *Failure to Pay.* If any holding company, affiliate, or subsidiary of a savings association fails to pay any fee before the end of the 60-day period beginning on the date such fee is imposed, following the end of the 60-day period, the Director may assess such fee, including interest, against and collect it from such savings association. If any such entity is a holding company, subsidiary, or affiliate of more than one savings association, the fee may be levied against each such savings association in such proportion as the Director may prescribe.

(d) In the case of any savings association for which the Office has determined to appoint the Resolution Trust Corporation as conservator or receiver, the Office may obtain payment from such savings association for fees or assessments due and outstanding under § 502.1, 502.2 or 502.3 of this part by debiting its account at its local Federal Home Loan Bank or by direct billing pursuant to paragraph (b) of this section.

§ 502.5 Interest.

For all institutions, overdue examination fees and asset-based assessments shall bear interest. Such interest shall be calculated at a rate (to be determined quarterly) equal to 150 percent of the average of the bond-equivalent rates of 13-week Treasury bills auctioned during the preceding calendar quarter. Asset-based assessment payments shall be considered delinquent if received after the time for payment specified in § 502.1 of this part as updated by the most recent applicable Thrift Bulletin issues pursuant to § 502.6 of this part. Examination and investigation fees will be considered delinquent if not received within 30 days of the invoice date.

§ 502.6 Notice of fees.

(a) A Thrift Bulletin shall be published in the last quarter of each year setting forth all fees to be charged by the Office for the next calendar year. Thrift Bulletins, providing updated fee schedules, in the Director's discretion, may be published from time to time throughout the year as necessary. Such Thrift Bulletins may set forth application fees to be charged by the Office for new types of applications developed by the Office in the period between publication of the annual Thrift Bulletins setting forth the fee schedule for the ensuing year.

(b) Notwithstanding paragraph (a) of this section, fees to cover the costs of processing applications received by this Office beginning ten days following the publication of the first Thrift Bulletin in 1990 pursuant to paragraph (a) of this section shall be payable immediately.

§ 502.7 Other charges.

The Director, or his or her designee, may impose additional charges to cover the cost of providing various services, including, but not necessarily limited to, publications, seminars, certifications for official copies of agency documents and records and services performed at the request of other agencies.

SUBCHAPTER D—REGULATIONS APPLICABLE TO ALL SAVINGS ASSOCIATIONS

PART 563d—SECURITIES OF SAVINGS ASSOCIATIONS

Subpart A—Regulations

2. The authority citation for part 563d continues to read as follows:

Authority: Sec. 3, as added by sec. 301, 103 Stat. 278 (12 U.S.C. 1462a); sec. 4, as added by sec. 301, 103 Stat. 280 (12 U.S.C. 1463); sec. 5, 48 Stat. 132, as amended (12 U.S.C. 1464); secs. 3(b), 12–14, 23, 48 Stat. 882, 892, 894–895, 901, as amended (15 U.S.C. 78c(b), 78*l*, m, n, w, 78d–1).

3. Amend § 563d.1 by revising the last sentence thereof and by adding a new sentence at the end thereof, so that the last two sentences of § 563d.1 shall read as follows:

§ 563d.1 Requirements under certain sections of the Securities Exchange Act of 1934.

* * * Except to the extent otherwise specifically provided by the Office in the application fee schedule published in the Thrift Bulletin pursuant to 12 CFR part 502, all filing fees specified by the Commission's rules shall be paid to the Office. If, after the Office reviews a Form 10–K, Form 10–Q, Schedule 13D or Schedule 13G and determines that the filing is materially deficient such that the Office requires that an amendment be filed to correct the deficiency, then, upon the filing of the amendment to the Form 10–K, Form 10–Q, Schedule 13D or Schedule 13G, as the case may be, the filer shall pay an additional filing fee to the Office, in the amount specified by the Office in the application fee schedule published in the Thrift Bulletin pursuant to 12 CFR part 502.

Dated: July 2, 1990.

By the Office of Thirft Supervision.

Timothy Ryan,

Director.

Appendix A—Application Fee Schedule

Note: Appendix A will not be codified in the Code of Federal Regulations.

APPLICATION FEE SCHEDULE FOR 1990

Major application categories	
Branch:	
Interstate	$2,400.
Intrastate	$1,900.
Change of control	$12,400(P).
Mutual to stock conversion-part 563b.	(P).
Standard conversion:	
Form AC	$6,400.
Forms OC/PS	(A) below.
Merger conversion: (section 563b.10(c)).	
Form AC	$17,400(B).
Forms OC/PS	(A).
Modified conversion:	
Form AC	$15,700(E).
Forms OC/PS	(A).
Holding company conversion	$18,700(C).
Holding company merger conversion.	$18,700(C).
Holding company modified conversion.	$18,700(C).
Charter conversion	
State mutual to federal mutual.	$1,400.

APPLICATION FEE SCHEDULE FOR 1990—Continued

Major application categories	
State stock to federal stock	$1,400.
Thrift to bank	$5,700.
Mutual holding company reorganization (12 U.S.C. 1467a(o)).	
Form MHC-1	$10,000(D).
Form MHC-2, private placement.	$6,400.
Form MHC-2, public offering	(A).
Holding Company	(P).
Form H-(e)1	$18,100(E).
Form H-(e)2	$18,100(E).
Form H-(e)3	$18,100(E).
Form H-(e)4	$1,000.
Merger, consolidation, transfer of assets, assumption of liabilities.	(P).
Voluntary	$10,400.
Cross industry	$11,400.
Purchase or sale of office	$5,000.
Permission to organize	(P).
Original submission	$16,400.
Compliance	$4,300.
Interim	$2,400.
Supervisory acquisition	(P).
Holding company	$18,100(F)(O).
Change of control	$12,400(F)(O).
Merger or purchase and assumption.	$11,400(O)
Voluntary supervisory conversion.	$18,700(G)(H).
Interim used in transaction	$2,400(O)
Other application categories:	
Affiliated transaction	$3,500.
Agency office	$1,400.
Approval of directors and officers.	$600(P).
Bylaw amendment	$1,400.
Capital	
Dividend notification (form H-(f)).	$250.
Mandatorily redeemable preferred stock.	$4,000.
Capital distribution (section 563.134).	$250.
Repurchase of stock (Section 563b.3(g)(4))	$1,000.
Subordinated debt	$5,300.
Charter amendment	$1,400.
Change of location	$900.
Direct sales of securities at an office (section 563g.17).	$800.
Extension of time	$700.
Extension of forbearance	$2,800.
Equity risk investment	$3,900.
Finance subsidiary	$6,650.
Investment in office building	$2,600.
Liability growth	$3,200.
Management interlock	$2,600.
Modification of condition of approval.	$2,700.
Notice of new activity (section 545.74(b)(7) & 563.37(c)).	$100.
Permissible bank holding company activities of savings and loan holding companies (section 584.2-2).	$150.
Form H-(c)1 (Section 584.2-1)	$150.
Rebuttal of concerted action	$5,600.
Rebuttal of control	$5,700.
Replacement of charter certificate.	$100.
Service corporation (section 545.74(c)).	$6,700.
Securities brokerage services notice (Section 545.74(c)(4)).	$5,000.
Section 563b.3(j)	$4,700.
Securities offerings-part 563g	$(A)(I).

APPLICATION FEE SCHEDULE FOR 1990—Continued

Major application categories	
Trust powers	$4,200.
Waiver	$2,500.
Liquidity penalty	
Regulatory requirements	
Loans to one borrower	
Non-residential lending	
Securities Exchange Act of 1934 Filings	
Proxy statement	(J).
Proxy statement/contest	(K).
Merger proxy statement	(L).
Form 3	No fee
Form 4	No fee
Form 8	No fee, but see below
Form 8-A	$250.
Form 8-B	$250.
Form 8-K	No fee
Securities Exchange Act of 1934 Filings	
Form 10	$250.
Form 10-C	No fee.
Form 10-K	$250.
Form 10-Q	No fee, but see below
Form 12b-25	No fee.
Form 15	No fee.
Schedule 13D	$100.
Schedule 13G	$100.
Schedule 13E-3	(M).
Schedule 13E-4	(M).
Schedule 14D-1	(N).
Schedule 14D-9	No fee.
Schedule 14B	No fee.
Securities Exchange Act of 1934 Filings	
Amendments to the following forms and schedules when required by the Office of Thrift Supervision:	
Form 10-K (amend on form 8).	$250.
Form 10-Q (amend on form 8).	$250.
Schedule 13D	$100.
Schedule 13G	$100.

Footnotes

(A) A fee of 1/40th of one percent of the maximum aggregate price at which the securities are proposed to be offered. See also Rule 457 under the Securities Act of 1933.

(B) The fee includes related merger application.

(C) The fee includes related holding company and merger applications (or change of control notice where applicable with respect to a modified conversion).

(D) If the reorganization application is being filed by more than one savings association, add $7,000 for each additional association. This fee includes related holding company and merger applications.

(E) The fee includes related merger application (where applicable).

(F) The fee includes related merger application (where applicable).

(G) The fee includes the related holding company application, change of control notice, and merger application (where applicable). If the conversion transaction involves the public offering of securities, pay an additional fee of 1/40th of one percent of the maximum aggregate price at which the securities are proposed to be offered.

(H) The acquiror(s) must pay all fees; fees cannot be paid by the savings association.

(I) There is no fee for securities sales reports filed pursuant to Section 563g.12 for offerings under Sections 563g.2 and 563g.4.

(J) Proxy Statements:

1. For definitive proxy material relating to a solicitation for which the savings association does not file preliminary proxy material, a fee of $125. See Rule 14a-6(j) under the Securities Exchange Act of 1934 ("Exchange Act").

2. For preliminary proxy material that solicits proxies for business for which a stockholder vote is necessary, but apparently no controversy is involved, a fee of $125. See Rule 14a-6(j) under the Exchange Act.

(K) For preliminary proxy material where a contest as set forth in Rule 14a-11 under the Exchange Act is involved, a fee of $4,100 from each party to the controversy.

(L) For preliminary proxy material involving acquisitions, mergers, consolidations, and reorganizations, a fee of 1/50th of one percent of the proposed cash payment or of the value of the securities and other property to be transferred to securities holders in the transaction. See Rule 14a-6(j) and Rule 0-11 under the Exchange Act. If the transaction involves the filing of a registration statement with the Securities and Exchange Commission for the registration under the Securities Act of 1933 of securities to be issued by a holding company in the transaction, the fee for the preliminary proxy material filed with the Office of Thrift Supervision shall be $800.

(M) A fee of 1/50th of one percent of the value of the securities proposed to be acquired by the acquiring person. See Rule 0-11 under the Exchange Act.

(N) A fee of 1/50th of one percent of the aggregate of the cash or of the value of the securities or other property offered by the bidder. See Rule 0-11 under the Exchange Act.

(O) The fee for Supervisory Acquisitions will only be charged to the winning bidder as a condition of approval of the transaction.

(P) Any application that requires an FBI fingerprint request must submit an additional $20 per FBI fingerprint request to cover the FBI processing fee.

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12 CFR Parts 506, 545, 563, 564, and 571

[No. 90-1495]

RIN 1550-AA24

Real Estate Appraisals

AGENCY: Office of Thrift Supervision, Treasury.

ACTION: Final rule.

SUMMARY: The Office of Thrift Supervision ("OTS") is adopting a final rule to amend its appraisal regulations in order to implement revised standards to enhance the performance of real estate appraisals. This regulation implements title XI of the Financial Institutions Reform, Recovery and Enforcement Act of 1989 ("FIRREA"), Public Law 101-73, 103 Stat. 183, 511 (1989). Title XI and the final regulation are intended to protect federal financial and public policy interests in real estate-related financial transactions requiring the services of an appraiser. The final regulation provides the OTS with added assurance that real estate appraisals used in connection with federal responsibilities and requirements are performed in accordance with uniform standards by individuals whose competency has been demonstrated and whose professional conduct will be subject to effective supervision. Toward this end, the final regulation identifies which transactions require an appraiser, sets forth minimum standards for