

Federal Assistance Program

The title and number of the Federal Assistance Program, as found in the Catalog of Federal Domestic Assistance, to which this rule applies are Commodity Loans and Purchases—10.051.

Regulatory Flexibility Act

It has been determined that the Regulatory Flexibility Act is not applicable because the CCC is not required by 5 U.S.C. 553 or any other provision of law to publish a notice of proposed rulemaking with respect to the subject matter of these determinations.

Environmental Evaluation

It has been determined by an environmental evaluation that this action will have no significant impact on the quality of human environment.

Executive Order 12372

This program is not subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials. See the Notice related to 7 CFR part 3015, subpart V, published at 48 FR 29115 (June 24, 1983).

Executive Order 12778

This final rule has been reviewed pursuant to Executive Order 12788. To the extent State and local laws are in conflict with these regulatory provisions, it is the intent of CCC that the terms of the regulations prevail. The provisions of this final rule are not retroactive. Prior to any judicial action in a court of competent jurisdiction, administrative review under 7 CFR part 780 must be exhausted.

Paperwork Reduction Act

Public reporting burden for the information collections contained in this regulation with respect to price support programs is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collections of information. The information collections have previously been cleared under the current regulations by OMB, and assigned OMB Nos. 0560-0087 and 0560-0129.

Interim Rule

The interim rule published in the **Federal Register** on May 9, 1994, with respect to the Honey Price Support Loan Program amended the price support loan rates for 1994 through 1998; revised the limitation on the total

amount of payments a producer may receive; revised the provisions of the honey marketing assessment; lessened the administrative actions Commodity Credit Corporation (CCC) imposes on producers who violate the loan and loan deficiency payment agreements; provided more authority to State and county CFSA committees in administering the program; eliminated obsolete provisions, and incorporated the provisions of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 1994, and the Omnibus Budget Reconciliation Act of 1993.

Comments

No comments were received during the comment period which ended on June 8, 1994.

Accordingly, the interim rule published at 59 FR 23789 on May 9, 1994, which amended 7 CFR part 1434 is hereby adopted as a final rule without change.

Signed in Washington, DC, on December 27, 1994.

Bruce R. Weber,

Acting Executive Vice President, Commodity Credit Corporation.

[FR Doc. 95-00133 Filed 1-3-95; 8:45 am]

BILLING CODE 3410-05-P-M

NUCLEAR REGULATORY COMMISSION

10 CFR Part 32

RIN: 3150-AD69

Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule; clarification.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending regulatory text and the response to a public comment contained in a final rule published in the **Federal Register** on Friday, December 2, 1994, entitled "Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use." This action is necessary following reconsideration by the NRC regarding the requirements for the information to be included on labels for radioactive drugs to be transferred for commercial distribution. The effect of this action is to reduce regulatory burden and uncertainty for licensees that manufacture and distribute radiopharmaceuticals that

contain byproduct material for medical use.

EFFECTIVE DATE: January 1, 1995.

ADDRESSES: Copies of the public record, including the final regulatory analysis and any public comments received on the proposed rule, may be examined and copied for a fee in the Commission's Public Document Room at 2120 L Street, NW. (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. John L. Telford (301) 415-6229 or Mr. Samuel Z. Jones (301) 415-6198, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

SUPPLEMENTARY INFORMATION:

I. Background

On Friday, December 2, 1994 (59 FR 61767), the NRC published in the **Federal Register** a final rule regarding 10 CFR Parts 30, 32, and 35 (Preparation, Transfer for Commercial Distribution, and the Use of Byproduct Material for Medical Use). On Thursday, November 17, 1994, the NRC staff received comments on the regulatory guides associated with this rulemaking action during a public meeting with the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI). Initially, the NRC staff believed that these comments could be resolved through appropriate regulatory guidance. However, these comments resulted in the NRC staff concluding that the final published requirements in 10 CFR 32.72(a)(4)

(1) Contained an undue burden with regard to the information required to be included on syringe labels; and

(2) Were not clear with regard to what was meant by a "container."

The NRC staff subsequently developed revised regulations to specify the information to be included on each label. In this rulemaking, the NRC is modifying the requirements of 10 CFR 32.72(a)(4) before the published effective date of January 1, 1995. This rulemaking will minimize intrusion into areas related to the practice of medicine in a manner consistent with the Commission's policy as published on February 9, 1979 (44 FR 8242), entitled "Regulation of the Medical Uses of Radioisotopes; Statement of General Policy" and minimize the regulatory burden on licensees. The specific revised requirements and response to the public comment are provided in this document.

II. Discussion

A. Revised NRC Response to the Public Comment

The following comment, in regard to 10 CFR 32.72(a)(4), was published in the **Federal Register** on Friday, December 2, 1994 (59 FR 61771):

“(3) *Comment.* The syringe label should not be limited to the clinical procedure. On the other hand, it is unnecessary to require that the label, or the leaflet or brochure that accompanies the radioactive drug, contain all of the statements specified in the proposed rule.”

The Commission agrees with the comment regarding syringe labels. The revised response is:

On page 61771, in the first column, the second complete paragraph and the first sentence of the third complete paragraph are withdrawn and replaced by the following text:

Response. (a) The revised regulations in § 32.72(a)(4)(ii) require that labels for syringes, vials, or other containers used to hold radioactive drugs to be transferred for commercial distribution must include the radiation symbol and the words “CAUTION, RADIOACTIVE MATERIAL” or “DANGER, RADIOACTIVE MATERIAL” and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label. The radiation symbol has been included for the protection of public health and safety. In the event that a syringe, vial, or other container becomes separated from its transport radiation shield, it would be readily identifiable as radioactive. The radiation symbol is currently required by § 20.1904 to be on containers of radioactive material and that requirement is restated in § 32.72 as a matter of convenience for licensees. This radiation symbol will also need to be the same as described in § 20.1901. The identifier has been included to provide a correlation between a syringe, vial, or other container and the information on the label of its transport radiation shield. The benefits of this correlation are: the transport radiation shield label provides more information than the syringe, vial, or other container label; it allows confirmation that the syringe, vial, or other container is in the correct transport radiation shield; and this additional information facilitates the radioactive drug being administered as directed by a physician authorized user. Thus, this correlation is necessary for both radiation safety and patient safety. By not specifying the identifier, the NRC staff has provided maximum flexibility for licensees to select the

identifier that best suits their operations. Acceptable identifiers may include prescription number, name of the radioactive drug or its abbreviation, the patient's name, or the clinical procedure.

The revised regulations do not require “the clinical procedure to be performed or the patient's or the human research subject's name” to be included on the syringe label since this information may or may not be available to commercial nuclear pharmacies. However, this regulation does not preclude other information from being included on the syringe label, such as the clinical procedure when this information is available and appropriate. Also, the phrase “syringe radiation shield” has been deleted to eliminate any confusion between this shield and the transport radiation shield. The phrases “vial” and “other container” have been added to make clear that the regulatory requirements of § 32.72(a)(4)(ii) are not limited to syringes but apply to any container used to hold a radioactive drug to be transferred for commercial distribution, e.g., generator or ampule.

In addition to these modifications, the revised regulations in § 32.72(a)(4)(i) replace the word “container” with the phrase “transport radiation shield” to make clear the placement of the label containing the specified information. The transport radiation shield could be constructed of lead, glass, plastic, or other material as is appropriate for the isotope to be transferred for commercial distribution. However, the phrase “transport radiation shield” does not refer to the outer suitcase, package, packing, or other carrying device, even though that barrier may provide some radiation shielding. Also, there are two modifications to the information to be included on this label. First, this label must now include the radiation symbol and the words “CAUTION, RADIOACTIVE MATERIAL” or “DANGER, RADIOACTIVE MATERIAL.” The radiation symbol has been included for the protection of public health and safety so that this item can be readily identified as radioactive. Second, the phrase “date and time of assay” has been replaced with “at a specified date and time.” This new phrase recognizes the current licensee practice of providing a date and time on this label that is the specified date and time at which the syringe, vial, or other container will hold the stated quantity of radioactivity rather than the actual date and time of assay. In addition, if a syringe, vial, or other container does not require a “transport radiation shield” because the syringe, vial, or other container itself provides

sufficient radiation shielding, then the information on the label of the syringe, vial, or other container must include the items specified in § 32.72(a)(4)(i). Furthermore, complying with these NRC labeling requirements does not relieve licensees from complying with other applicable requirements (e.g., U.S. Department of Transportation) for labeling the outer suitcase or package.

(b) The Commission agrees with the comment that it is unnecessary to require that the label, or the leaflet or brochure that accompanies the radioactive drug, must contain a statement that the U.S. Nuclear Regulatory Commission has approved distribution of the byproduct material to persons licensed to use byproduct material pursuant to 10 CFR 35.100, 35.200, or 35.300, as appropriate, and to persons who hold an equivalent license issued by an Agreement State.” This sentence was deleted because as revised, the regulations provide greater flexibility and responsibility for licensees. The licensees distributing radioactive drugs must confirm that the recipients are licensed to receive the radioactive drugs and the medical use recipients who can compound radioactive drugs are responsible for ensuring the appropriate uses of those radioactive drugs. Thus, licensees will need to continue to ensure pursuant to § 30.41(c) that radioactive drugs are only distributed to persons authorized to receive such byproduct materials. The Commission is removing from the text of the rule the last sentence of § 32.72(a)(4) reading: “The Commission's labeling requirements are independent of requirements of the U.S. Food and Drug Administration (FDA); one label is acceptable to NRC provided that it contains all of the information which NRC requires.” This sentence is being placed in the preamble because this statement is not a regulatory requirement and simply provides factual information.

B. Justification

These modifications relieve a restriction and result in a relaxation of the labeling requirements and are exempt from the requirements for a 30-day delay in the effective date under 5 U.S.C. 553(d)(1). Therefore, this modification is being made effective on January 1, 1995, to coincide with the effective date for the remainder of the previously published final rule. Further,

as provided in 5 U.S.C. 553(d)(3), good cause exists for making the modification effective on less than 30 days notice. As originally written, the rule would have required that information be included on syringe labels that might not be available to the commercial nuclear pharmacy. This would have made compliance difficult or impossible in some instances. Failure to make this modification effective on the same date as the originally published final rule would run the risk of either disrupting the availability of radiopharmaceuticals, if nuclear pharmacies refused to ship materials without the information needed under the originally published final rule, or shipments being made in violation of the rule because of a medical need for the radioactive drugs but a lack of needed information at the nuclear pharmacy facility. Thus, even if this change did not involve a relaxation of a regulatory requirement, meeting the criteria of 5 U.S.C. 553(d)(1) for exception from the 30-day notice requirement, the Commission finds the January 1, 1995, effective date justified under the "good cause" exception in 5 U.S.C. 553(d)(3).

III. 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 this final amendment is not a major Federal action significantly affecting the quality of the human environment, and therefore an environmental impact statement is not required. This final amendment clarifies the NRC's intent regarding the information to be included on labels for radioactive drugs to be transferred for commercial distribution. It is expected that there will be no increase in radiation exposure to the public or to the environment beyond the exposures currently resulting from transporting radioactive drugs. The NRC prepared an environmental assessment and finding of no significant impact for the final rule published December 2, 1994 (59 FR 61767), and it is available for inspection at the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC. This rulemaking action does not make any substantive changes that would affect the conclusions reached in that assessment. Single copies of the environmental assessment and finding of no significant impact are available from John L. Telford or Samuel Z. Jones

(see **FOR FURTHER INFORMATION CONTACT** heading).

Paperwork Reduction Act Statement

This rulemaking action 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 number 3150-0001 for amendments to 10 CFR Parts 32.

The public burden for this collection of information is estimated to be no change from the current requirements, 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 (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0001, -0010, and -0120), Office of Management and Budget, Washington, DC 20503.

Regulatory Analysis

The Commission prepared a regulatory analysis for the final rule published December 2, 1994 (59 FR 61767). This rulemaking action does not make any substantive changes that would change the conclusions reached in that analysis. The regulatory analysis is available for inspection at the NRC Public Document Room at 2120 L Street, NW. (Lower Level), Washington, DC. Single copies of the regulatory analysis are available from John L. Telford or Samuel Z. Jones (see **FOR FURTHER INFORMATION CONTACT** heading).

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this rule will not have a significant economic impact on a substantial number of small entities. This rule affects manufacturers and commercial nuclear pharmacies. These licensees would not be considered small entities under the NRC's size standards (56 FR 56671; November 6, 1991). This rulemaking action clarifies the NRC's intent regarding the information to be included on labels for radioactive drugs to be transferred for commercial distribution and is expected to result in no change of burden for the affected licensees.

Backfit Analysis

The Commission has determined that the backfit rule, 10 CFR 50.109, does not apply to this amendment because this amendment does not involve any provisions which would impose backfits as defined in 10 CFR 50.109(a)(1). Therefore, a backfit analysis is not required for this amendment.

List of Subjects in 10 CFR Part 32

Byproduct material, Criminal penalties, Labeling, Nuclear materials, 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 Part 32.

PART 32—SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

1. The authority citation for Part 32 continues 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).

2. In § 32.72 paragraph (a)(4) is revised to read as follows:

§ 32.72 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35.

(a) * * *

(4) The applicant satisfies the following labeling requirements:

(i) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half life greater than 100 days, the time may be omitted.

(ii) A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe,

vial, or other container can be correlated with the information on the transport radiation shield label.

* * * * *

Dated at Rockville, Maryland, this 28th day of December, 1994.

For the Nuclear Regulatory Commission.

Hugh L. Thompson, Jr.,

Acting Executive Director for Operations.

[FR Doc. 95-00124 Filed 1-3-95; 8:45 am]

BILLING CODE 7590-01-P

FARM CREDIT ADMINISTRATION

12 CFR Parts 607, 614, 615, and 620

RIN 3052-AB44

Assessment and Apportionment of Administrative Expenses; Loan Policies and Operations; Funding and Fiscal Affairs, Loan Policies and Operations, and Funding Operations; Disclosure to Shareholders; Effective Date

AGENCY: Farm Credit Administration.

ACTION: Notice of effective date.

SUMMARY: The Farm Credit Administration (FCA) published a final regulation under parts 607, 614, 615, and 620 on July 22, 1994 (59 FR 37400). The final regulation amends 12 CFR parts 607, 614, 615, and 620 to establish requirements for the agreement between a Farm Credit Bank (FCB) and its related direct lender associations specifying where the earnings held by the FCB and allocated to associations may be counted as permanent capital, to specify how their earnings would be counted in the absence of an agreement, to provide a date certain for the exclusion from capital of payments by Farm Credit institutions to the Farm Credit System Financial Assistance Corporation made in connection with the repayment of Treasury-paid interest, and to make other conforming changes to implement the statutory amendments. Technical and conforming changes are made throughout the agency's regulations. In accordance with 12 U.S.C. 2252, the effective date of the final rule is 30 days from the date of publication in the **Federal Register** during which either or both Houses of Congress are in session. Based on the records of the sessions of Congress, the effective date of the regulations is December 31, 1994.

EFFECTIVE DATE: The regulation amending 12 CFR parts 607, 614, 615, and 620 published on July 22, 1994 (59 FR 37400) is effective December 31, 1994.

FOR FURTHER INFORMATION CONTACT:

Robert S. Child, Policy Analyst, Regulation Development, Office of Examination, Farm Credit Administration, McLean, Virginia 22102-5090, (703) 883-4498, TDD (703) 883-4444, or

Rebecca S. Orlich, Senior Attorney, Office of General Counsel, Farm Credit Administration, McLean, Virginia 22102-5090, (703) 883-4020, TDD (703) 883-4444.

(12 U.S.C. 2252(a)(9) and (10))

Dated: December 29, 1994.

Floyd Fithian,

Acting Secretary, Farm Credit Administration Board.

[FR Doc. 95-131 Filed 1-3-95; 8:45 am]

BILLING CODE 6705-01-P

12 CFR Part 612

RIN 3052-AB47

Personnel Administration; Effective Date

AGENCY: Farm Credit Administration.

ACTION: Notice of effective date.

SUMMARY: The Farm Credit Administration (FCA) published a final regulation under part 612 on May 13, 1994 (59 FR 24889). The final regulation amends 12 CFR part 612 to reflect statutory changes and the change in focus of the FCA's regulatory oversight of personnel matters. In addition, the final rule enhances and clarifies the regulations to ensure that they fulfill the purposes of section 514 of the Farm Credit Banks and Associations Safety and Soundness Act of 1992 relative to the reporting of financial information and potential conflicts of interest. In accordance with 12 U.S.C. 2252, the effective date of the final rule is 30 days from the date of publication in the **Federal Register** during which either or both Houses of Congress are in session. Based on the records of the sessions of Congress, the effective date of the regulations is December 31, 1994.

EFFECTIVE DATE: The regulation amending 12 CFR part 612 published on May 13, 1994 (59 FR 24889) is effective December 31, 1994.

FOR FURTHER INFORMATION CONTACT:

John J. Hays, Policy Analyst, Policy Development and Planning Division, Office of Examination, Farm Credit Administration, McLean, Virginia 22102-5090, (703) 883-4498, TDD (703) 883-4444, or

Dorothy J. Acosta, Assistant General Counsel, Regulatory Operations Division, Office of General Counsel, Farm Credit Administration, McLean,

Virginia 22102-5090, (703) 883-4020, TDD (703) 883-4444.

(12 U.S.C. 2252(a)(9) and (10))

Dated: December 29, 1994.

Floyd Fithian,

Acting Secretary, Farm Credit Administration Board.

[FR Doc. 95-130 Filed 1-3-95; 8:45 am]

BILLING CODE 6705-01-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. NM-104; Special Conditions No. 25-ANM-93]

Special Conditions: Modified Cessna 550 Series Airplanes, High Intensity Radiated Fields (HIRF)

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final special conditions with request for comments.

SUMMARY: These special conditions are issued for the Cessna 550 series airplanes modified by Modern Avionics, Inc., of Eden Prairie, Minnesota. These airplanes are equipped with digital electronic flight instrument systems (EFIS) that perform critical functions. The applicable type certification regulations do not contain adequate or appropriate safety standards for the protection of these systems from the effects of high intensity radiated fields (HIRF). These special conditions provide the additional safety standards that the Administrator considers necessary to ensure that the critical functions that these systems perform are maintained when the airplane is exposed to HIRF.

DATES: The effective date of these special conditions is December 20, 1994. Comments must be received on or before February 21, 1995.

ADDRESSES: Comments on these special conditions may be mailed in triplicate to: Federal Aviation Administration, Transport Airplane Directorate (ANM-100), Attn: Docket No. NM-104, 1601 Lind Avenue SW, Renton, WA 98055-4056; or delivered in triplicate to the Transport Airplane Directorate at the above address. Comments must be marked; Docket No. NM-104. Comments may be inspected weekdays, except Federal holidays, between 7:30 a.m. and 4:00 p.m.

FOR FURTHER INFORMATION CONTACT:

Michael Zielinski, FAA, Standardization Branch, ANM-113, Transport Airplane Directorate, Aircraft