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,