## 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61771, in the first column, the second complete paragraph and the first sentence of the third complete paragraph are withdrawn and replaced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, contain all of the statements specified in the proposed rule. Therefore, the Commission is deleting the sentence in § 32.72(a)(4) reading: "Furthermore, 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,