

# Rules and Regulations

Federal Register

Vol. 68, No. 76

Monday, April 21, 2003

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## NUCLEAR REGULATORY COMMISSION

### 10 CFR Part 35

RIN 3150-AH08

#### Medical Use of Byproduct Material: Clarifying and Minor Amendments

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Direct final rule.

**SUMMARY:** The Nuclear Regulatory Commission (NRC) is amending its regulations regarding the medical use of byproduct material. The direct final rule will clarify the definitions of authorized users, authorized medical physicists, authorized nuclear pharmacists, and radiation safety officers; clarify the notification requirements if the patient is in a medical emergency or dies; clarify the recordkeeping requirements for calibration of brachytherapy sources; correct the title for the National Institute of Standards and Technology; clarify that prior to October 24, 2004, individuals who meet the training and experience requirements in Subpart J may undertake responsibilities specified in certain sections in Subparts B and D-H; and eliminate a restriction that training for ophthalmic use of strontium-90 can only be conducted in medical institutions. These amendments are necessary to clarify certain inconsistencies within the regulations and to allow training in ophthalmic treatment to be conducted in eye clinics or private practices, in addition to medical institutions.

**DATES:** The final rule is effective on July 7, 2003 unless significant adverse comments are received by May 21, 2003.

**ADDRESSES:** You may submit comments by any one of the following methods. Please include the following number (RIN 3150-AH08) in the subject line of your comments. Comments on rulemakings submitted in writing or in

electronic form will be made available to the public in their entirety on the NRC rulemaking Web site. Personal information will not be removed from your comments.

Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.

E-mail comments to: [SECY@nrc.gov](mailto:SECY@nrc.gov). If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at (301) 415-1966. You may also submit comments via the NRC's rulemaking Web site at <http://ruleforum.llnl.gov>. Address questions about our rulemaking Web site to Carol Gallagher (301) 415-5905; email [cag@nrc.gov](mailto:cag@nrc.gov).

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. Federal workdays. (Telephone (301) 415-1966).

Fax comments to: Secretary, U.S. Nuclear Regulatory Commission at (301) 415-1101.

Publicly available documents related to this rulemaking may be examined and copied for a fee at the NRC's Public Document Room (PDR), Public File Area O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. Selected documents, including comments, can be viewed and downloaded electronically via the NRC rulemaking web site at <http://ruleforum.llnl.gov>.

Publicly available documents created or received at the NRC after November 1, 1999, are available electronically at the NRC's Electronic Reading Room at <http://www.nrc.gov/NRC/ADAMS/index.html>. From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1-800-397-4209, 301-415-4737 or by e-mail to [pdr@nrc.gov](mailto:pdr@nrc.gov).

**FOR FURTHER INFORMATION CONTACT:** Dr. Anthony N. Tse, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6233, e-mail: [ant@nrc.gov](mailto:ant@nrc.gov).

**SUPPLEMENTARY INFORMATION:**

## Procedural Information

Because NRC considers this action to be noncontroversial, the NRC is using the direct final rule process for this rule. The amendments in this rule will become effective on July 7, 2003. However, if the NRC receives significant adverse comments on this direct final rule by May 21, 2003, then the NRC will publish a document that withdraws this action and will subsequently address the comments received in a final rule as a response to the companion proposed rule published elsewhere in this **Federal Register**. Absent significant modifications to the proposed revisions requiring republication, the NRC will not initiate a second comment period on this action.

A significant adverse comment is a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment is adverse and significant if:

(1) The comment opposes the rule and provides a reason sufficient to require a substantive response in a notice-and-comment process. For example, a substantive response is required when—

(A) The comment causes the staff to reevaluate (or reconsider) its position or conduct additional analysis;

(B) The comment raises an issue serious enough to warrant a substantive response to clarify or complete the record; or

(C) The comment raises a relevant issue that was not previously addressed or considered by the staff.

(2) The comment proposes a change or an addition to the rule and it is apparent that the rule would be ineffective or unacceptable without incorporation of the change or addition.

(3) The comment causes the staff to make a change (other than editorial) to the rule.

## Background

The NRC published in the **Federal Register** a final rule amending 10 CFR part 35 regarding medical use of byproduct material on April 24, 2002 (67 FR 20249) (final rule). Subsequently, the NRC staff (staff) identified typographical and editorial errors as well as inconsistencies in the Part 35 final rule. The staff published a document correcting the typographical