

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30, 32 and 35

[NRC-2008-0175]

RIN 3150-AI63

**Medical Use of Byproduct Material - Medical Event Definitions, Training and Experience,
and Clarifying Amendments; Correction**

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule; correction.

SUMMARY: The U. S. Nuclear Regulatory Commission (NRC) published a proposed rule appearing in the *Federal Register (FR)* on July 21, 2014, to amend the NRC's regulations related to the medical use of byproduct material. The public comment period for the information collection aspects of the proposed rule was to have ended on August 20, 2014. However, the proposed rule inadvertently omitted the one-time implementation costs from the information collection burden estimate. This action sets out the corrected information collection burden estimate in its entirety and allows the public 30 days to comment from the date of publication of this action.

DATES: This correction is effective on **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Submit comments on the information collection aspects of the proposed rule by **[INSERT DATE THAT IS 30 DAYS AFTER THE DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Please refer to Docket ID NRC-2008-0175 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov> and search for Docket ID NRC-2008-0175. Address questions about NRC dockets to Carol Gallagher; telephone: 301-287-3422; e-mail: Carol.Gallagher@nrc.gov. For technical questions, contact the individuals listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The proposed rule is available electronically in ADAMS under Accession No. ML14183B493. The draft proposed guidance document may be found in ADAMS under Accession No. ML13172A189.

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Neelam Bhalla, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone: 301-415-0978, e-mail: Neelam.Bhalla@nrc.gov.

SUPPLEMENTARY INFORMATION: In *FR* Doc. 2014-16753 appearing on page 42409 in the *Federal Register* of Monday, July 21, 2014, beginning on page 42435, in the middle column, Section XV, "Paperwork Reduction Act Statement," is corrected to read as follows:

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). The rule would reduce the burden for existing information collection requirements associated with NRC Form 313, but would increase burden for 10 CFR parts 30 and 35. This rule has been submitted to the Office of Management and Budget for review and approval of the paperwork requirements.

Type of submission, new or revision: Revision.

The title of the information collection: 10 CFR parts 30, 32, and 35, Medical Use of Byproduct Material - Medical Event Definitions, Training and Experience, and Clarifying Amendments, Proposed Rule.

The form number if applicable: NRC Form 313A Series, "Authorized User Training and Experience and Preceptor Attestation."

How often the collection is required: The information is collected as needed. Reports required under the proposed rule are based on events that exceed limits stipulated by various sections of the proposed rule. The NRC Form 313A Series or equivalent is required when an applicant or licensee applies to have a new individual identified as an Authorized User (AU), Radiation Safety Officer (RSO), Alternate Radiation Safety Officer (ARSO), Authorized Nuclear Pharmacists, or an Authorized Medical Physicist on a medical use license during a new license,

a renewal, or an amendment request.

Who will be required or asked to report: Persons licensed under 10 CFR parts 30, 32, and 35 who possess and use certain byproduct material for medical use.

An estimate of the number of annual responses: 12,392 (10 CFR Part 30: 366 responses, 10 CFR Part 35: 8,301 responses, NRC Form 313: 3,725 responses).

The estimated number of annual respondents: 7,845 (1,085 NRC / 6,401 Agreement State medical use licensees and 52 NRC / 307 Agreement State radiopharmacy licensees).

An estimate of the total number of hours needed annually to complete the requirement or request: 33,038.33 hours (10 CFR Part 30: 4,670.5 hours, 10 CFR Part 35: 33,551.58 hours, NRC Form 313: -5,183.75 hours). Of the 33,038.33 hours of total burden, an estimated 6,671 hours are associated with recurring requirements and 26,367.33 hours are one-time implementation burdens.

Abstract: The NRC is proposing to amend its regulations related to the medical use of byproduct material. In this action the NRC addresses three ongoing rulemaking projects and several other related topics. First, this rule proposes amendments to the reporting and notification requirements for a Medical Event for permanent implant brachytherapy. Second, the rule proposes changes to the Training and Experience requirements for AUs, medical physicists, RSOs, and nuclear pharmacists; changes to the requirements for measuring Mo contaminations and reporting of failed technetium and rubidium generators; and changes that would allow ARSOs to be named on a medical license, as well as other clarifying and conforming amendments. Third, the NRC is considering a request filed in a petition for

rulemaking (PRM-35-20) to “grandfather” certain board-certified individuals.

The NRC is seeking public comment on the potential impact of the information collections contained in the proposed rule and on the following issues:

1. *Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?*
2. *Is the estimate of burden accurate?*
3. *Is there a way to enhance the quality, utility, and clarity of the information to be collected?*
4. *How can the burden of the information collection be minimized, including the use of automated collection techniques?*

The public may examine and have copied, for a fee, publicly-available documents, including the draft supporting statement, at the NRC’s PDR, One White Flint North, 11555 Rockville Pike, Room O-1 F21, Rockville, Maryland 20852. The OMB clearance package and rule are available at the NRC’s Web site:

<http://www.nrc.gov/public-involve/doc-comment/omb/index.html> for 60 days after the signature date of this notice.

Send comments on any aspect of these proposed information collections, including suggestions for reducing the burden and on the above issues, by **[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]** to the FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail to INFOCOLLECTS.RESOURCE@NRC.GOV and to the Desk Officer, Danielle Y. Jones, Office of Information and Regulatory Affairs, NEOB-10202, (3150-AI63), Office of Management and Budget, Washington, DC 20503.

Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date. You may also e-mail comments to [Danielle Y. Jones@omb.eop.gov](mailto:Danielle.Y.Jones@omb.eop.gov) or comment by telephone at 202-395-1741.

Dated at Rockville, Maryland, this 15th day of September, 2014.

For the Nuclear Regulatory Commission.

/RA/

Annette Vietti-Cook,
Secretary of the Commission.

Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date. You may also e-mail comments to [Danielle Y. Jones@omb.eop.gov](mailto:Danielle.Y.Jones@omb.eop.gov) or comment by telephone at 202-395-1741.

Dated at Rockville, Maryland, this day of August, 2014.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,
Secretary of the Commission.

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