[7590-01-P]

NUCLEAR REGULATORY COMMISSION

[NRC-2019-0164]

Information Collection: Medical Use of Byproduct Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of submission to the Office of Management and Budget; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has recently submitted a request for renewal of an existing collection of information to the Office of Management and Budget (OMB) for review. The information collection is entitled, “Medical Use of Byproduct Material.”

DATES: Submit comments by **[INSERT DATE 30 DAYS FROM DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: David Cullison, NRC Clearance Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-2084; e-mail: INFOCOLLECTS.Resource@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID **NRC-2019-0164** when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- **Federal Rulemaking Web Site:** Go to https://www.regulations.gov and search for Docket ID **NRC-2019-0164**. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC-2019-0164 on this Web site.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly-available documents online in the ADAMS Public Documents collection at https://www.nrc.gov/reading-rm/adams.html. To begin the search, 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 supporting statement and burden spreadsheet are available in ADAMS under Accession Nos. ML20128J890 and ML20128J891.

- **NRC's Clearance Officer:** A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-2084; e-mail: INFOCOLLECTS.Resource@NRC.GOV.

B. Submitting Comments

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at https://www.regulations.gov and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the OMB, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC recently submitted a request for renewal of an existing collection of information to OMB for review entitled, 10 CFR part 35, "Medical Use of Byproduct Material."

The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The NRC published a *Federal Register* notice with a 60-day comment period on this information collection on February 26, 2020 (85 FR 11125).

1. *The title of the information collection:* 10 CFR Part 35, "Medical Use of Byproduct Material."

2. *OMB approval number:* 3150-0010.

3. *Type of submission:* Extension.

4. *The form number if applicable:* Not applicable.

5. *How often the collection is required or requested:* Reports of medical events, doses to an embryo/fetus or nursing child, or leaking source are reportable on occurrence. A specialty board certifying entity desiring to be recognized by the NRC must submit a one-time request for recognition and infrequently revise the information.

6. *Who will be required or asked to respond:* Physicians and medical institutions holding an NRC license authorizing the administration of byproduct material or radiation from this material to humans for medical use. A specialty board certification entity desiring to have its certifying process and board certificate recognized by NRC.

7. *The estimated number of annual responses:* 299,266 (292,182 reporting responses + 7,019 recordkeepers + 65 third party disclosure responses.)

8. *The estimated number of annual respondents:* 7,021 (856 NRC licensees + 6,163 Agreement State licensees + 2 specialty board certification entity.)

9. *An estimate of the total number of hours needed annually to comply with the information collection requirement or request:* 1,166,695 hours (69,391 reporting + 1,097,177 recordkeeping + 127 third party disclosure.)

10. *Abstract:* 10 CFR part 35, “Medical Use of Byproduct Material,” contains NRC’s requirements and provisions for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. Part 35 contains mandatory

requirements that apply to NRC licensees authorized to administer byproduct material or radiation to humans for medical use. These requirements also provide voluntary provisions for specialty boards to apply to have their certification processes recognized by the NRC so that their board certified individuals can use the certifications as proof of training and experience.

Dated: July 2, 2020.

For the Nuclear Regulatory Commission.

David C. Cullison,
NRC Clearance Officer,
Office of the Chief Information Officer.

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