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NUCLEAR REGULATORY COMMISSION

[NRC-2023-0101]

Information Collection: NRC Form 483, Registration Certificate - In Vitro Testing with Byproduct Material under General License

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, NRC Form 483, "Registration Certificate - In Vitro Testing With Byproduct Material Under General License."

DATES: Submit comments by **[INSERT DATE 30 DAYS AFTER 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 <https://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; email: Infocollects.Resource@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID **NRC-2023-0101** 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 Website:** Go to <https://www.regulations.gov> and search for Docket ID **NRC-2023-0101**.

- **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, at 301-415-4737, or by email to PDR.Resource@nrc.gov. A copy of the collection of information and related instructions may be obtained without charge by accessing ADAMS Accession No. ML23214A355. The supporting statement is available in ADAMS under Accession No. ML24045A325.

- **NRC's PDR:** The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1-800-397-4209 or 301-415-4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

- **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 C. Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-2084; email: Infocollects.Resource@nrc.gov.

B. Submitting Comments

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to

<https://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.

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, NRC Form 483, “Registration Certificate - In Vitro Testing With Byproduct Material Under General License.” 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 October 27, 2023, 88 FR 73881.

1. *The title of the information collection:* NRC Form 483, Registration Certificate - In Vitro Testing With Byproduct Material Under General License.
2. *OMB approval number:* 3150-0038.
3. *Type of submission:* Extension.
4. *The form number, if applicable:* NRC Form 483.

5. *How often the collection is required or requested:* There is a one-time submittal of information to receive a validated copy of the NRC Form 483 with an assigned registration number. In addition, any changes in the information reported on the NRC Form 483 must be reported in writing to the NRC within 30 days after the effective date of the change.

6. *Who will be required or asked to respond:* Any physician, veterinarian in the practice of veterinary medicine, clinical laboratory, or hospital which desires a general license to receive, acquire, possess, transfer, or use specified units of byproduct material in certain in vitro clinical or laboratory tests.

7. *The estimated number of annual responses:* 6.

8. *The estimated number of annual respondents:* 3.

9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 0.65 hours (0.5 hours reporting + 0.15 hours recordkeeping)

10. *Abstract:* Section 31.11 of title 10 of the *Code of Federal Regulations* (10 CFR), established a general license authorizing any physician, clinical laboratory, veterinarian in the practice of veterinary medicine, or hospital to possess certain small quantities of byproduct material for in vitro clinical or laboratory tests not involving the internal or external administration of the byproduct material or the radiation therefrom to human beings or animals. Possession of byproduct material under 10 CFR 31.11 is not authorized until the physician, clinical laboratory, veterinarian in the practice of veterinary medicine, or hospital has filed the NRC Form 483 and received from the Commission a validated copy of the NRC Form 483 with a registration number. The licensee can use the validated copy of the NRC Form 483 to obtain byproduct material from a specifically licensed supplier. The NRC incorporates this information into a database which is used to verify that a general licensee is authorized to receive the byproduct material.

Dated: March 18, 2024.

For the Nuclear Regulatory Commission.

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

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