



## **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:** Renewal of existing information collection; request for comment.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) invites public comment on the renewal of Office of Management and Budget (OMB) approval for an existing collection of information. 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 60 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:** You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the **Federal rulemaking website**:

- **Federal rulemaking website:** Go to <https://www.regulations.gov> and search for Docket ID **NRC-2023-0101**. Address questions about Docket IDs in Regulations.gov to Stacy Schumann; telephone: 301-415-0624; email: [Stacy.Schumann@nrc.gov](mailto:Stacy.Schumann@nrc.gov). For technical questions, contact the individual listed in the "For Further Information Contact" section of this document.

- **Mail comments to:** David C. Cullison, Office of the Chief Information Officer, Mail Stop: T-6 A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

**FOR FURTHER INFORMATION CONTACT:** 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.

**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**. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID **NRC-2023-0101** on this website.

- **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](mailto: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. ML23214A375.

- **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](mailto: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

The NRC encourages electronic comment submission through the **Federal rulemaking website** (<https://www.regulations.gov>). Please include Docket ID **NRC-2023-0101**, in your comment submission.

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 NRC, 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

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC is requesting public comment on its intention to request the OMB's approval for the information collection summarized below.

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:* 3.

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:* 0.51 hours annually, (3 registrations/year using NRC Form 483 x 0.17 hrs. per NRC Form 483 = 0.51 hrs.).

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.

### **III. Specific Requests for Comments**

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility? Please explain your answer.

2. Is the estimate of the burden of the information collection accurate? Please explain your answer.

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 on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated: October 24, 2023.

For the Nuclear Regulatory Commission.

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

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