



[7590-01-P]

NUCLEAR REGULATORY COMMISSION

[NRC-2017-0166]

**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." NRC Form 483 will be revised to update instructions and regulatory language.

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:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov> and search for Docket ID **NRC-2017-0166**. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; e-mail: Carol.Gallagher@nrc.gov. For technical questions, contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **Mail comments to:** David Cullison, Office of the Chief Information Officer, Mail Stop: T-5 F53, 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 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.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID **NRC-2017-0166** 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 <http://www.regulations.gov> and search for Docket ID **NRC-2017-0166**. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID **NRC-2017-0166** 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 <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. A copy of the collection of information and related instructions may be obtained without charge by accessing ADAMS under Accession No. ML17128A454. The supporting statement is available in ADAMS under Accession No. ML17128A131.

- **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.

- **NRC's Clearance Officer:** A copy of the collection of information and related instructions may be obtained without charge by contacting 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

Please include Docket ID **NRC-2017-0166** in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC posts all comment submissions at <http://www.regulations.gov> as well as entering the comment submissions into ADAMS. The NRC does not routinely edit comment submissions 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 the NRC does not routinely edit comment submissions to remove such information

before making the comment submissions available to the public or entering the comment submissions 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:* Revision.
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 NRC Form 483 with an assigned registration number. In addition, any changes in the information reported on 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:* 6.
9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 1.10 hours.

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 test 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 NRC Form 483 and received from the Commission a validated copy of NRC Form 483 with a registration number. The licensee can use the validated copy of 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?
2. Is the estimate of the burden of the information collection 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 on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated at Rockville, Maryland, this 23rd day of August, 2017.

For the Nuclear Regulatory Commission.

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