

FINAL OMB SUPPORTING STATEMENT
FOR
NRC FORM 483
REGISTRATION CERTIFICATE --
IN VITRO TESTING WITH BYPRODUCT MATERIAL
UNDER GENERAL LICENSE

(3150-0038)

EXTENSION

Description of the Information Collection

Section 31.11 of Title 10 of the Code of Federal Regulations (10 CFR) Part 31 establishes a general license authorizing any physician, veterinarian in the practice of veterinary medicine, clinical laboratory, or hospital to receive, acquire, possess, transfer, or use 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 or use of byproduct material under 10 CFR 31.11 is not authorized until the physician, veterinarian in the practice of veterinary medicine, clinical laboratory, or hospital has filed The U.S. Nuclear Regulatory Commission (NRC) Form 483, "Registration Certificate In-Vitro Testing with Byproduct Material Under General License," and received from the Commission a validated copy of NRC Form 483 with a registration number assigned. A registration certificate is usually validated within 7 days of its receipt and is used by the licensee to obtain byproduct material from a specifically licensed supplier.

NRC Form 483 contains the terms and conditions of the general license and provides a means of assurance to the U.S. Nuclear Regulatory Commission (NRC) that the general licensee is aware of those terms and conditions prior to the receipt of byproduct material.

A. JUSTIFICATION

1. Need for and Practical Utility of the Collection of Information

Section 31.11(a) provides for a general license for the possession and use of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, selenium-75, mock iodine-125 reference or calibration sources, and cobalt-57 by any physician, veterinarian in the practice of veterinary medicine, clinical laboratory, or hospital for the purpose of certain *in vitro* clinical or laboratory tests. The general license sets forth the conditions pertaining to possession, use, and storage of the byproduct material.

Section 31.11(b) specifies that in order for the physician, veterinarian in the practice of veterinary medicine, clinical laboratory, or hospital to use the general license, NRC Form 483, "Registration Certificate -- In Vitro Testing with Byproduct Material Under General License" must be completed and submitted to the NRC. The licensee must then receive a validated copy of the NRC Form 483 with a registration number to complete the licensing process.

Suppliers of byproduct material are required to determine that the person receiving the material is authorized to receive it. The validated certificate, maintained by the licensee, serves as evidence for the supplier that a physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital is a general licensee authorized to receive the byproduct material.

Section 31.11(e) requires that a general licensee under this section report in writing any change in a previously validated registration certificate. The licensee must report the change to the NRC within 30 days after the effective date of such a change.

Updating the information on the registration certificate is necessary so that NRC is aware of any changes in either the name or the location of all persons authorized to receive radioactive byproduct material under Section 31.11.

2. Agency Use of the Information

The information derived from NRC Form 483 provides NRC with the name of each physician, clinical laboratory, veterinarian, or hospital using byproduct material under the general license. The registration certificate contains the terms and conditions of the general license and provides a means of assurance to the NRC that the general licensee is aware of those terms and conditions prior to the receipt of byproduct material. The NRC incorporates the information from Form 483 into a database - General License Tracking System (GLTS). This database is used when manufacturers and suppliers call NRC to verify that a physician, clinical laboratory, veterinarian, or hospital is authorized to receive byproduct material.

3. Reduction of Burden through Information Technology

The NRC has issued [Guidance for Electronic Submissions to the NRC](#) which provides direction for the electronic transmission and submittal of documents to the NRC. Electronic transmission and submittal of documents can be accomplished via the following avenues: the Electronic Information Exchange (EIE) process, which is available from the NRC's "Electronic Submittals" Web page, by Optical Storage Media (OSM) (e.g. CD-ROM, DVD), by facsimile or by e-mail. It is estimated that none of the potential responses are filed electronically.

4. Effort to Identify Duplication and Use Similar Information

No sources of similar information are available. There is no duplication of requirements.

5. Effort to Reduce Small Business Burden

The majority of the registrants who use byproduct material are small businesses. The health and safety consequences of improper use or handling of radioactive byproduct material are the same for large and small entities. The burden of providing the small amount of information required on the NRC Form 483 is minimal. In addition, NRC Form 483 is only submitted once, unless there is a change of information from a previously registered license. Therefore, it is not possible to reduce the burden on small businesses by less frequent or less complete submittal. The NRC staff estimates that all (100%) of respondents will be small businesses.

6. Consequences to Federal Program or Policy Activities if the Collection Is Not Conducted or Is Conducted Less Frequently

If the NRC Form 483 is not submitted, the NRC will not have the necessary information to certify general licensees authorized under Section 31.11 of 10 CFR Part 31 to possess, use, and store byproduct material. If the information on NRC Form 483 is collected less frequently, it could result in the NRC having outdated contact information for its general licensees. Up-to-date information on the NRC Form 483 is required for the NRC to fulfill its responsibility to ensure adequate protection of the public health and safety during the possession, use, or transfer of radioactive byproduct material.

7. Circumstances Which Justify Variation from OMB Guidelines

Contrary to OMB guidelines in 5 CFR 1320.5(d), Section 31.11(e) requires general licensees to report in writing any change in a previously validated registration certificate within 30 days after the effective date of such a change. The NRC needs this information within 30 days to keep current on where the radioactive material is being used in order to reach users immediately in the event of a problem, and to provide registrants with immediate notification when there is a generic problem involving the radioactive material.

8. Consultations Outside the NRC

Opportunity for public comment on the information collection requirements for this clearance package was published in the Federal Register on October 27, 2023 (88 FR 73881). As part of the consultation process, the NRC staff directly contacted, via email, four potential respondents. One comment was received that expressed general support for the information collection.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of the Information

Confidential and proprietary information is protected in accordance with NRC regulations at 10 CFR 9.17(a) and 10 CFR 2.390(b). However, no information normally considered confidential or proprietary is requested.

11. Justification for Sensitive Questions

This information collection does not involve sensitive questions.

12. Estimated Burden and Burden Hour Cost

Section 31.11(b) requires the submittal of NRC Form 483, "Registration Certificate In-Vitro Testing with Byproduct Material Under General License." Below is the breakdown of the burden for NRC licensees, based on submittals to the NRC in the last 3 years. The Agreement States are not required by the NRC to implement 10 CFR 31.11 for compatibility purposes; therefore, any

Agreement State usage of forms similar to NRC Form 483 is not included in the burden calculations.

The NRC receives approximately 3 registration certificates annually from persons who wish to be general licensees. The time required for completion of NRC Form 483 is approximately 10 minutes. Completion of the form requires filling in the name and address, checking one of the categories of licensees, signing, and dating the registration certificate and mailing it.

The reporting burden for all general licensees is 30 minutes (0.5 hrs) annually, as shown in the table below (3 registrations/year using NRC Form 483 x 10 minutes per NRC Form 483 = 0.5 hrs). Therefore, the total annual cost for preparation of the 3 certificates is approximately \$145 (0.5 hours x \$290/hour).

Recordkeeping

Licensees maintain an authorized copy of the license. Therefore, NRC estimates that approximately 10 percent of the annual reporting burden is equal to the recordkeeping burden (3 minutes). Total estimated recordkeeping burden to the licensees is estimated to be 9 minutes (3 minutes x 3 responses = 9 minutes), or 0.15 hours.

There are 6 total responses (3 reporting responses + 3 recordkeepers). The total estimated burden is approximately 39 minutes or 0.65 hours. The total burden hour cost is \$189 (

	Hours	Responses	Cost @ \$290/hr
Reporting	0.5	3	\$ 145.00
Recordkeeping	0.15	3	\$ 44.00
Total	0.65	6	\$ 189.00

The \$290 hourly rate used in the burden estimates is based on the Nuclear Regulatory Commission's fee for hourly rates as noted in 10 CFR 170.20 "Average cost per professional staff-hour." For more information on the basis of this rate, see the Revision of Fee Schedules; Fee Recovery for Fiscal Year 2018 (87 FR 37197, June 22, 2022).

13. Estimate of Other Additional Costs

The quantity of records to be maintained is roughly proportional to the recordkeeping burden. Based on the estimated number of pages maintained for a this clearance, the records storage cost is estimated to be negligible.

14. Estimated Annualized Cost to the Federal Government

The staff has developed estimates of annualized costs to the Federal Government related to the conduct of this collection of information. These estimates are based on staff experience and subject matter expertise and include the burden needed to review, analyze, and process the collected information and any relevant operational expenses.

Previous experience shows that the average time needed for NRC staff to process an NRC Form 483 is approximately 30 minutes, resulting in a burden of 1.5 hours per year. This time includes researching the files to check for duplicate registration certificates, maintaining and updating the GLTS database on registration certificates, and preparing the letter and validated copy of the NRC Form 483 for each licensee. At a rate of \$290 per hour for professional staff, the annual cost to the Federal government to process the three registration certificates is \$435 (3 registrations/year using Form 483 x 30 minutes per NRC Form 483 = 1.5 hours x \$290/hour).

15. Reasons for Changes in Burden or Cost

The NRC staff is revising the estimate from six submissions annually to three submissions annually based on data from the past three years of submissions. The NRC expects the same pace of submissions to continue during this clearance period. In the last submission, recordkeepers were not included in the count of responses (6 responses = 6 reporting responses + 0 recordkeepers). In the current submission, the responses correctly include recordkeepers as responses (6 responses = 3 reporting responses + 3 recordkeepers). Thus, although the number of reporting responses decreased, the total number of responses in the system has remained the same due to this correction.

Due to rounding in ROCIS, the overall burden for the clearance will continue to round to one hour.

The estimated hourly burden cost has increased from \$279 to \$290/hour.

16. Publication for Statistical Use

This information will not be published for statistical use.

17. Reason for Not Displaying the Expiration Date

The expiration date is displayed on NRC Form 483.

18. Exceptions to the Certification Statement

There are no exceptions.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Not applicable.