DRAFT OMB SUPPORTING STATEMENT
FOR
NRC FORM 483
REGISTRATION CERTIFICATE --
IN VITRO TESTING WITH BYPRODUCT MATERIAL
UNDER GENERAL LICENSE
10 CFR 31.11
(3150-0038)

EXTENSION REQUEST

Description of the Information Collection

Section 31.11 of 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 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 NRC Form 483 and received from the Commission a validated copy of NRC Form 483 (Registration Certificate) with a registration number. 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, "Registration Certificate -- In Vitro Testing with Byproduct Material Under General License," 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.

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, 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 testing. 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 NRC. The licensee must then receive a validated copy of 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, clinical laboratory, veterinarian in the practice of veterinary medicine, 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 data base. This data base 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

There are no legal obstacles to reducing the burden associated with this information collection. The NRC encourages respondents to use information technology when it would be beneficial to them. NRC issued a regulation on October 10, 2003 (68 FR 58791), consistent with the Government Paperwork Elimination Act, which allows its licensees, vendors, applicants, and members of the public the option to make submissions electronically via CD-ROM, e-mail, special Web-based interface, or other means. However, NRC Form 483 does not lend itself readily to the use of automated information technology for submission because of the type of information and the infrequency of submission. Consequently, the current percentage of electronic submissions is zero.

4. Effort to Identify Duplication and Use Similar Information

The collection of the specified information is not a duplication of other information that the affected licensee must submit for other purposes. The nature of the information being requested is unique to NRC's activities at the facilities. There is no similar information available to the NRC that can be used to keep track of the general licensees authorized under Section 31.11 of 10 CFR Part 31 to possess small quantities of byproduct material for certain in vitro clinical or laboratory tests. NRC has in place an ongoing program to examine all information collections with the goal of eliminating all duplication and/or unnecessary information collections.

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 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.

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

If NRC Form 483 is not submitted, the NRC will not have 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 addresses and phone numbers for its general licensees. Up-to-date information on NRC Form 483 is required for 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

The opportunity for public comment on the information collection requirements was published in the Federal Register.

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

NRC licensees:
The NRC receives approximately 15 registration certificates annually from persons who wish to be general licensees. The time required for completion of NRC Form 483 is approximately 8 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.

The total burden for all general licensees is approximately 2 hours annually (15 registrations/yr using Form 483 X 8 minutes per Form 483). Since preparation of the form is essentially an administrative/clerical function, the cost is estimated to be approximately $47 per hour. Therefore, the total annual cost for preparation of the 15 certificates is approximately $94 (2 hours X $47/hr).

Agreement State licensees:

The Agreement State licensees submit approximately 70 registration certificates annually. This estimate is based on an actual sampled data. The total annual burden for all the Agreement State licensees is approximately 9.3 hours (70 registrations certificates per year X 8 minutes). Therefore, the total annual cost for the preparation of the 70 registration certificates by the administrative/clerical staff of the Agreement State licensees is approximately $ 437 (9.3 hours X $47/hr).

The total estimated responses are 85 responses (15 NRC licensees + 70 Agreement State licensees). The total estimated burden is 11.3 hours (2 hours + 9.3 hours). The total burden hour cost is $531 ($94 + $437).

Licensees maintain an authorized copy of the license. Therefore, NRC estimates that approximately ten percent of the reporting burden is equal to the recordkeeping burden. Total estimated recordkeeping burden to the licensees is estimated to be $53 (1.13 hours X $47).

13. Estimate of Other Additional Costs

The quantity of records to be maintained is roughly proportional to the recordkeeping burden. Based on the number of pages maintained for a typical clearance, the records storage cost has been determined to be equal to .0004 times the recordkeeping burden cost. Therefore, the storage cost for this clearance is insignificant $0.11 (1.13 recordkeeping hours x .0004 x $238).

14. Estimated Annualized Cost to the Federal Government

The average time needed for processing an NRC Form 483 is approximately 20 minutes, resulting in a burden of 5hrs. This time includes researching the files to check for duplicate registration certificates, maintaining and updating the data base on registration certificates, and preparing the letter and validated copy of NRC Form 483 for each licensee. At a rate of $238 per hour for professional staff, the annual cost to the Federal government to process the 15 registration certificates is $1,190 (15 registrations/yr using Form 483 X 20 minutes per Form 483 = 5hrs X $238/hr). This cost is fully recovered through fee assessments to NRC licensees pursuant to 10 CFR Parts 170 and/or 171.

15. Reasons for Changes in Burden or Cost

The overall hourly burden estimate for NRC Form 483 is expected to decrease during the next 3 years. The expected decrease in estimated hourly burden is primarily due to results obtained from a NRC internal review and study based on available NRC Form 483 submissions to the agency and a sample of annual NRC

Form 483 returns provided by 6 Agreement States. The internal review/study and samples showed that the estimated number of registration certificates that NRC is expecting to receive annually will drop from 104 to 15 and the annual registration certificates received by the Agreement States will drop from 260 to 70.

Therefore, the total hourly burden has decreased by 29.6 hours, from 42 hours submitted in the previous renewal package to OMB in 2005 to 12.4 hours. The total cost for this package has decreased by $5,323 from $8,274 in 2005 to $2,951 in 2008.

However, the estimated burden cost since the last OMB approval of this package has increased from $197 to $238/hour, due to an increase in the hourly fee rate.

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.