

DRAFT OMB SUPPORTING STATEMENT
FOR
NRC FORM 313, "APPLICATION FOR MATERIALS LICENSE,"
AND NRC FORMS 313A (RSO), 313A (AMP), 313A (ANP), 313A (AUD), 313A (AUT),
AND 313A (AUS)

(3150-0120)

EXTENSION

Description of the Information Collection

In order for a person to be licensed to possess, use, or distribute licensed material, the person must submit an application that will permit the U.S. Nuclear Regulatory Commission (NRC) to determine whether the applicant has training, experience, equipment, facilities, and procedures for the use of radioactive material that are adequate to protect the public health and safety. NRC Form 313, "Application for Materials License," is used to provide the information required.

For medical use and commercial nuclear pharmacy applicants, the NRC Form 313 may include the following NRC Form 313A series of forms:

- NRC Form 313A (RSO), "Radiation Safety Officer Training and Experience and Preceptor Attestation [10 CFR 35.50]"
- NRC Form 313A (AMP), "Authorized Medical Physicist Training and Experience and Preceptor Attestation [10 CFR 35.51]"
- NRC Form 313A (ANP), "Authorized Nuclear Pharmacist Training and Experience and Preceptor Attestation [10 CFR 35.55]"
- NRC Form 313A (AUD), "Authorized User Training and Experience and Preceptor Attestation (for uses defined under 35.100, 35.200, and 35.500) [10 CFR 35.190, 35.290, and 35.590]"
- NRC Form 313A (AUT), "Authorized User Training and Experience and Preceptor Attestation (for uses defined under 35.300) [10 CFR 35.390, 35.392, 35.394, and 35.396]"
- NRC Form 313A (AUS), "Authorized User Training and Experience and Preceptor Attestation (for uses defined under 35.400 and 35.600) [10 CFR 35.490, 35.491, and 35.690]"

The NRC issues a license, if the information on the NRC Form 313 (which includes the NRC Form 313A series of forms) fulfills the substantive requirements stated elsewhere in the regulations.

Final Rule, "10 CFR PARTS 30, 40, 70, 170, and 171, "Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions (3150-AH15)," effective July 2, 2013.

A. JUSTIFICATION

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

The filing of an application for a specific license for possession, use, and distribution of byproduct or source material on NRC Form 313, "Application for Materials License," for a specific license is provided in 10 CFR 30.14, 30.15, 30.18, 30.19, 30.20, 30.21, 30.32, 30.37, 30.38, 32.11, 32.14, 32.18, 32.21, 32.22, 32.26, 33.12, 34.11, 35.12, 36.11, 39.11, 40.31, 40.43, and 40.44. The filing of training and experience information on NRC Form 313 (which may include the NRC Form 313A series of forms) is provided in 10 CFR 35.12. The information required under training and experience for the medical use and commercial nuclear pharmacy applicant or licensee is found in 10 CFR 32.72, 35.50, 35.51, 35.55, 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.490, 35.491, 35.590, and 35.690.

The information submitted on the NRC Form 313 (which may include the NRC Form 313A series of forms) is reviewed by the NRC staff to determine whether the applicant is qualified by training and experience. Also, the NRC staff assesses whether the applicant has equipment, facilities, and procedures which are adequate to protect the health and safety of the public and minimize danger to life or property.

2. Agency Use of Information

The NRC reviews the information submitted in order to determine whether the applicant's training, personnel experience, equipment, facilities, and procedures for the use of byproduct or source material are adequate to protect the public health and safety as required by the Atomic Energy Act, as amended, the Energy Reorganization Act of 1974, as amended, and the Energy Policy Act of 2005 so that the Commission may determine whether to issue, amend, or renew a license.

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. The NRC issued 10 CFR 30.6, "Communications," 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. It is estimated that approximately 5% 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. The 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

While a number of licensees are considered small businesses, the health and safety consequences of improper use of radioactive material are the same for large and small entities. There is a minimum amount of information that must be provided in order for the Commission to determine if an applicant's facilities, equipment, and procedures are adequate to protect the public health and safety. Therefore, it is not possible to reduce the burden on small businesses by less frequent submission or less complete applications.

6. Consequences to Federal Program or Policy Activities if the Collection is not Conducted or is Conducted Less Frequently

Applications for a new license are submitted only once, while applications for renewal of a license are submitted every ten years. Amendments are submitted as needed by the licensee. This is the minimum frequency necessary to assure that licensees will continue to conduct programs in a manner that will assure adequate protection of the public health and safety. If the information is not collected, the NRC will have no way to determine the adequacy of licensees' programs to protect the public health and safety.

7. Circumstances which Justify Variation from OMB Guidelines

There are no variations from OMB guidelines.

8. Consultations Outside the NRC

Opportunity for public comment on the information collection requirements for this clearance package has been 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).

11. Justification for Sensitive Questions

Sensitive information is not requested under these regulations.

12. Estimated Burden and Burden Hour Cost

A. NRC Licensees

The burden associated with the use of NRC Form 313 and NRC Form 313A series of forms for new licenses, amendments and renewals is based on the estimated 2,000 NRC licensing actions completed each year, as listed in the NRC's Congressional Budget Justification for the 2015 fiscal year (FY) 2015.

Based on this number of licensing actions, the industry burden for licensing is estimated to be 8,600 hours (4.3 hours per licensing action x 2,000 licensing actions). The annual cost to all affected NRC licensees is estimated to be \$2,399,400 (8,600 hours x \$279 per hour).

B. Agreement State Licensees

The NRC estimates that there is approximately 6.2 times the number of Agreement State licensees as there are NRC licensees. This estimate based on the estimate of 2,900 NRC byproduct material licensees (including NRC Master Material License permits) and 18,000 Agreement State licenses.

The number of Agreement State licensing actions is estimated from the number of NRC licensing actions times the 6.2 ratio of Agreement State licenses to NRC licenses. This results in an estimated 12,400 licensing actions each year. Additionally, the NRC estimates that the amount of time that the Agreement States will need to prepare an application and the associated costs will be the same as for NRC licensees.

The total burden for Agreement State licensees is estimated to be 53,320 hours (4.3 hours per licensing action x 12,400 licensing actions).

The estimated annual cost to the Agreement State licensees to prepare applications and submit required information on forms equivalent to NRC Form 313 (which may include the NRC Form 313A series of forms) is estimated to be \$14,876,280 (53,320 hours x \$279 per hour).

C. Total

The total burden for NRC and Agreement State licensees combined is 61,920 hours (8,600 hours for NRC licensees + 53,320 hours for Agreement State licensees). The estimated total cost is \$17,275,680 (61,920 hours x \$279 per hour).

13. Estimate of Other Additional Costs

There are no additional costs.

14. Estimated Annualized Cost to the Federal Government

It is estimated that the review of the information on NRC Forms 313 (which for medical use and commercial nuclear pharmacy applicants and licensees may include the NRC Form 313A series of forms) will take an average of approximately 4.3 hours/application. Based on an anticipated 2,000 licensing actions at a cost of \$279 per hour, the cost to perform the licensing review would be \$2,399,400 (2,000 licensing actions x 4.3 hours per licensing action x \$279 per hour). This cost is fully recovered through license fees charged to NRC licensees pursuant to 10 CFR Parts 170 and/or 171.

15. Reasons for Changes in Burden or Cost

The overall burden for completing NRC Form 313 (which includes the NRC 313A series of forms) will decrease by 21,856 hours, from 83,776 hours (10,287 for NRC licensees + 73,489 for Agreement States) to 61,920 hours (8,600 for NRC licensees + 53,320 for Agreement States), with a resulting decrease in the number of respondents/responses by 5,051 from 19,451 to 14,400 responses.

The reduction in burden associated with the use of NRC Form 313 and NRC Form 313A series of forms for new licenses, amendments and renewals is based on the decrease in the estimated number of licensing actions completed each year, as listed in the NRC's Congressional Budget Justification for the 2015 fiscal year (FY) 2015. The decrease in form submissions may be attributed to natural fluctuations in the needs of NRC and Agreement State licensees and license applicants from year-to-year.

In addition, the fee rate increased from \$272 to \$279 per 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 Forms 313 and NRC Form 313A series of forms.

18. Exceptions to the Certification Statement

There are no exceptions.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Not applicable.

TABLE 1

Annualized Reporting Burden for NRC Licensees

Section	Number of Respondents	Responses/ Respondent	Total Responses	Burden/ Response	Total Annual Burden Hours
NRC Form 313 and 313A Series Licensing Actions	2,000	1	2,000	4.3	8,600
TOTAL			2,000		8,600

TABLE 2

Annualized Reporting Burden for Agreement States

Section	Number of Respondents	Responses/ Respondent	Total Responses	Burden/ Response	Total Annual Burden Hours
NRC Form 313 and 313A Series Licensing Actions	12,400	1	12,400	4.3	53,320
TOTAL			12,400		53,320

Total Responses: 14,400 (2,000 reporting/NRC Licensees)
(12,400 reporting/Agreement States)

Total Respondents: 14,400 (2,000 NRC Licensees + 12,400 Agreement States)

Total Burden Hours: 61,920 (8,600 NRC Licensees hours reporting)
(53,320 Agreement States hours reporting)