

FINAL 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)

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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.

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 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. 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 was published in the Federal Register on October 13, 2011 (76 FR 63667). No comments were received.

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

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 number of licensing actions processed during fiscal year (FY) 2010.

The estimated number of NRC licenses for 2011 through 2014 is based on the number of NRC materials and Master Materials License permits at the end of FY 2010 adjusted for Virginia and New Jersey becoming Agreement States in 2009. This resulted in a total estimated number of 3,067 NRC licensees.

For each year starting with 2011 through 2014, the number of new NRC licenses and amendments were estimated from the number of NRC licensing actions in FY 2010 and addition of NRC Master Materials License permit amendments. This resulted in an estimated 206 new licenses and 1,849 amendment applications per year for the possession, use, and initial distribution of byproduct and source material. The burden associated with the use of NRC Forms 313 and 313A series of forms for license renewals each year is based on the estimated number of NRC licenses averaged over the 10 year license renewal period. This results in an estimated 307 renewal applications (3,067 total estimated NRC licenses ÷ 10 year license renewal period). Therefore, the total estimated number of NRC licensing actions each year for 2011 through 2014 is 2,362 (206 new licenses + 1,849 amendment application + 307 renewal applications).

Based on the 2,362 NRC licensing actions each year, the industry burden for licensing is estimated to be 10,157 hours (4.3 hours/licensing action x 2,362 licensing actions). The annual cost to all affected NRC licensees is estimated to be \$2,772,861 (10,157 x \$273 fee rate/hour).

B. Agreement State Licensees

The NRC estimates that there is approximately 6.4 times the number of Agreement State licensees as there are NRC licensees, since Virginia and New Jersey became Agreement States. The change from the previous estimate of 4.6 to the recent estimate of 6.4 is based on the most recent estimate of 3,067 NRC byproduct material licensees (including NRC Master Material License permits) and 19,591 Agreement State licenses.

The numbers of Agreement State new license and amendment applications are estimated from the number of NRC licensing actions times the 6.4 ratio of Agreement State licenses to NRC licenses. This resulted in an estimated 1,318 new licenses (206 NRC new licenses x 6.4 ratio) and 11,834 amendment applications (1,849 NRC amendment applications x 6.4 ratio). The Agreement States retained an average 5-year license renewal period for its byproduct, source, and special nuclear materials licenses. The estimated number of Agreement State renewals is 3,918 (19,591 Agreement States licenses ÷ 5-year license renewal periods). Therefore, the total estimated number of Agreement State licensing actions annually is 17,070 (1,318 new

Agreement States licenses + 11,834 Agreement States amendment applications + 3,918 Agreement States renewals). 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 73,401 hours (4.3 hrs/licensing action x 17,070 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 \$20,038,473 (73,401 hours x \$273 fee rate/hour).

C. Total

The total burden for NRC and Agreement State licensees combined is 83,558 hours (10,157 hours for NRC licensees + 73,401 hours for Agreement State licensees). The estimated total cost is \$22,811,334 (83,558 hours x \$273 fee rate/hour).

13. Estimate of Other Additional Costs

The NRC has determined that the quantity of records to be maintained is roughly proportional to the recordkeeping burden and, therefore, can be used to calculate approximate records storage costs. Based on the number of pages maintained for a typical clearance, the records storage cost has been determined to be equal to 0.0004 times the recordkeeping burden cost. Because the recordkeeping burden is estimated to be 0 hours, the storage cost for this clearance is \$00.00 (0 hours x 0.0004 x \$273/hour).

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 2,362 licensing actions at a cost of \$273 fee rate/hour, the cost to perform the licensing review would be \$2,772,752 (2,362 licensing actions x 4.3 hours/licensing action x \$273 fee rate/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 increase by 18,334 hours, from 65,224 hours (10,205 for NRC licensees + 55,019 for Agreement State licensees) to 83,558 hours (10,157 for NRC licensees + 73,401 for Agreement States), with a resulting increase in the number of respondents/responses by 4,305 from 15,127 to 19,432 responses.

During this renewal period, the NRC is adding two new fields to NRC Form 313 to request a business cellular phone number and a business email address. The addition of the two new fields should not impact in the amount of time needed by a licensee to complete NRC Form 313. The burden on NRC licensees already takes into account that many different types of licensees use NRC Form 313 some licensees require more time than others. The anticipated amount of time needed to provide additional contact information is expected to be negligible.

#### NRC Licensees

The burden for NRC licensees is expected to decrease from 10,205 to 10,157 hours because of the reduction in licensing actions by an estimated 2 actions, from 2,364 to 2,362. At 4.3 hours per licensing action, this is a reduction of approximately 9 hours (2 actions x 4.3 hours = 8.6). This reduction in licensing actions is because there are fewer NRC licensees as a result of Virginia and New Jersey becoming Agreement States, while the number of overall licensing actions has not significantly changed.

#### Agreement State Licensees

The burden for Agreement States is expected to increase because of an increase in the number of Agreement State licensees as a result of Virginia and New Jersey becoming Agreement States. The estimated number of Agreement States licensing actions increased by 4,312 from 12,758 to 17,070. At 4.3 hours/licensing action, this is an increase of 18,542 hours (4,312 actions x 4.3 hours = 18,542).

In addition, the fee rate increased from \$238 to \$273/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 | 2,362                 | 1                     | 2,362           | 4.3              | 10,157                    |
| <b>TOTAL</b>                                   |                       |                       | 2,362           |                  | 10,157                    |

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 | 17,070                | 1                     | 17,070          | 4.3              | 73,401                    |
| <b>TOTAL</b>                                   |                       |                       | 17,070          |                  | 73,401                    |

Total Responses: 19,432 (2,362 reporting/NRC Licensees + 0 recordkeepers)  
(17,070 reporting/Agreement States + 0 recordkeepers)

Total Respondents: 19,432 (2,362 NRC Licensees + 17,070 Agreement States)

Total Burden Hours: 83,558 (10,157 NRC Licensees hrs reporting + 0 recordkeeping)  
(73,401 Agreement States hrs reporting + 0 recordkeeping)