

1FINAL 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

The U.S. Nuclear Regulatory Commission (NRC) is responsible for licensing and regulating nuclear facilities and material and for conducting research in support of the licensing and regulatory process, as mandated by the Atomic Energy Act (AEA) of 1954, as amended, and other related Acts such as the Energy Reorganization Act of 1974, as amended, and the Energy Policy Act of 2005. Under the aforementioned Acts, the NRC license and regulates medical, industrial, and academic uses of nuclear materials through a combination of regulatory requirements and safety oversight programs (including inspection). In addition, Section 274 of the AEA provides a statutory bases under which NRC relinquishes to States portions of its regulatory authority to license and regulate byproduct materials (radioisotopes), source materials (uranium and thorium), and certain quantities of special nuclear materials.

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 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, as applicable. NRC Form 313, "Application for Materials License," is used to provide the information required.

For medical use and commercial nuclear pharmacy applicants and licensees, the NRC Form 313 may include the following NRC Form 313A series of optional supplemental 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 as part of the NRC Form 313 (which includes the NRC Form 313A series of forms) fulfills the substantive requirements stated elsewhere in the regulations.

Between 1997 and 2007, NRC produced the original versions of a series of technical reports (NUREG-1556 series, “Consolidated Guidance About Materials Licenses”) to provide program specific guidance for materials applicants. These guidance documents were intended to facilitate the process of developing new license applications, license amendments, and license renewals. They provide a comprehensive source of reference information about materials regulation for the applicant, the licensee, and the NRC staff and are updated, as appropriate. The documents also apply NRC’s risk informed performance based approach to materials licensing which simplifies the information collection burden on applicants and licensees. The effect of the NUREG-1556 series is factored into this clearance and previous versions of this clearance.

On May 29, 2013, the NRC published a revised Final Rule related to the possession, use, transfer, and distribution of source or byproduct material entitled, “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” (Source Material Final Rule) that became effective on August 27, 2013. The final rule established new requirements for 1) initial distributors of source material a) to persons exempt from the regulations or b) for use under a general license in 10 CFR 40.22 and 2) requires those initial distributors to apply for a new distribution license. The NRC requires applicants and licensees to demonstrate the ability to comply with the Source Material Final Rule through the submission of NRC Form 313. This clearance addresses the additional reporting burden added from the requirements to apply for the distribution license via NRC Form 313, which includes information about the product(s) being distributed, quality assurance methods, and labeling, so that the NRC can ensure that the product can be safely distributed.

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, 32.30, 32.51, 32.53, 32.57, 32.61, 32.74, 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 as part of 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, as applicable.

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.

The NRC uses the information submitted to develop reports on licenses issued. The NRC also uses the information to respond to public and congressional inquiries, develop and guide its policies, and formulate its budgets. The NRC can use initial license information along with additional documentation to aid in the inspections, identifying compliance violations, and enforcement activities.

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.

The NRC has an online mechanism for submitting application documentation. Specifically, applications may be submitted via the NRC's Electronic Information Exchange or CD-ROM. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at <http://www.nrc.gov/site-help/e-submittals.html>. It is estimated that approximately 5% of the potential responses are filed electronically.

4. Effort to Identify Duplication and Use Similar Information

The collection of the specified information is not a duplication of other information the affected licensee must submit for other purposes. No sources of similar information are available. The nature of the information being requested is unique to licensed activities at the facilities, and is necessary so that the Commission may determine whether to issue, amend, or renew a license.

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 NRC 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 9, 2014 (79 FR 61106); further the NRC directly contacted by email five licensees who are potential respondents to obtain their input. One general comment was received through the regulations.gov docket from Travis Barr on November 19, 2014, as follows:

Comment

Please add future dockets and necessary steps to allow discussions for private industrial use of nuclear wastes to produce helium gas, more specifically to identify those wastes with grades sufficient decay to allow for helium separation, concentration, and collection.

Response

This comment is outside of the scope of the information solicited from the public for this OMB clearance package; therefore the NRC has no formal response to this comment at this time.

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 number of licensing actions processed by the NRC during fiscal year 2015, approximately 2,065 licensing actions (including new licenses, amendments, and renewals). Because the Source Material Final Rule became effective on August 27, 2013, the fiscal year 2015 data captures the effects of this rule. The number of licensing actions is expected to stay at the fiscal year 2015 levels.

Based on this number of licensing actions, the industry burden for licensing is estimated to be 8,880 hours (4.3 hours per licensing action x 2,065 licensing actions). The annual cost to all affected NRC licensees is estimated to be \$2,379,840 (8,880 hours x \$268 per hour). The estimate of 4.3 hours per licensing action factors in the guidance given in the NUREG-1556 series, because it reduces the time needed to complete the application.

B. Agreement State Licensees

Section 274 of the Atomic Energy Act of 1954 provides a statutory basis under which NRC relinquishes to the States portions of its regulatory authority to license and regulate byproduct materials (radioisotopes); source materials (uranium and thorium); and certain quantities of special nuclear materials. The mechanism for the transfer of NRC's authority to a State is an agreement signed by the Governor of the State and the Chairman of the Commission, in accordance with section 274b of the Act. A map of Agreement States and non-Agreement states is located on NRC's Web site: <https://scp.nrc.gov/>. Licensees operating in these "Agreement States" are referred to in this supporting statement as "Agreement State Licensees."

The NRC has established compatibility requirements for Agreement States to implement their own regulations in a manner consistent with NRC regulations. Annually, the NRC requests that all Agreement States provide the number of specific radioactive material licenses currently active under their jurisdiction. The total number of Agreement State licensees is based on the data provided by the Agreement States. For this renewal, the NRC used an estimate of 17,500 Agreement State material licensees.

The number of Agreement State licensees who submit required information on Agreement State forms equivalent to NRC Form 313 is not known to the NRC and must be estimated. NRC uses the ratio of the total number of NRC licensees to the total number of Agreement State licensees to estimate the number of Agreement State licensing actions. The current ratio, 1:6.4 (NRC licensees: Agreement State licensees) is based on 2,750 total NRC licensees and 17,500 Agreement State licensees. Based on this ratio, the estimated number of Agreement State licensing actions is 13,216 (2,065 NRC licensing actions x 6.4).

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.

Therefore, the total burden for Agreement State licensees is estimated to be 56,829 hours (4.3 hours per licensing action x 13,216 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 \$15,230,172 (56,829 hours x \$268 per hour).

C. Total

The total burden for NRC and Agreement State licensees combined is 65,709 hours (8,880 hours for NRC licensees + 56,829 hours for Agreement State licensees). The estimated total cost is \$17,610,012 (65,709 hours x \$268 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 optional forms) will take an average of approximately 4.3 hours/application. Based on an anticipated 2,065 licensing actions at a cost of \$268 per hour, the cost to perform the licensing review would be \$2,379,706 (2,065 licensing actions x 4.3 hours per licensing action x \$268 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 burden for NRC licensees is expected to decrease by 1,407 hours from 10,287 to 8,880 hours as a result of the expected decrease in licensing actions received by 310 from 2,375 to 2,065. The NRC expects the number of submitted licensing actions to remain at the fiscal year 2015 levels.

There are fewer licensing actions expected for Agreement States due to a decrease in the number of Agreement State respondents. The estimated number of licensing actions received will decrease by 3,860 from 17,076 to 13,216. Overall, the burden for Agreement States will decrease by 16,660 hours from 73,489 to 56,829 hours.

The total estimated burden for completing NRC Form 313 and 313A will decrease by 18,067 hours, from 83,776 to 65,709 hours.

The total burden for completing NRC Form 313 and 313A is as follows:

65,709 burden hours for 15,281 responses (8,880 burden hours for 2,065 NRC licensing actions plus 56,829 Agreement State licensee burden hours for 13,216 estimated Agreement State licensing actions.)

15,281 respondents (2,065 NRC licensee respondents plus 13,216 Agreement State licensee respondents.)

The burden decreased due to a reduction in the actual number of licensing actions received (downward adjustment of 18,067 hours).

For background on NRC Form 313 and the calculation of estimated burden, all applicable applicants and licensees need to consider and address Items 1 through 13 of NRC Form 313, as appropriate. Also, the NRC developed the optional supplemental NRC Form 313A series to make it easier for medical use and commercial nuclear pharmacy licensees and applicants to provide information to be submitted as part of Item 7 (“Individual(s) Responsible for Radiation Safety Program and Their Training and Experience”) and Item 8 (“Training for Individuals Working In or Frequenting Restricted Areas”) of NRC Form 313. This estimated burden for NRC Form 313 (calculated above) includes the burden for the optional supplemental NRC Form 313A series due to the supplementary nature of the NRC Form 313A. Therefore, the burden for the NRC Form 313A series is not presented separately.

In addition, the fee rate decreased from \$273 to \$268 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	2,065	1	2,065	4.3	8,880
TOTAL			2,065		8,880

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	13,216	1	13,216	4.3	56,829
TOTAL			13,216		56,829

Total Responses: 15,281 (2,065 reporting/NRC Licensees) +
(13,216 reporting/Agreement States)

Total Respondents: 15,281 (2,065 NRC Licensees + 13,216 Agreement States)

Total Burden Hours: 65,709 (8,880 NRC Licensees hours reporting) +
(56,829 Agreement States hours reporting)