

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)

REVISION

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 licenses 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. These states are called Agreement States.

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.

The different versions of Form 313A are being revised to better reflect recent changes in the requirements in 10 CFR Parts 30 and 35. The revisions minimize ore eliminate unnecessary information requests and assist applicants in complying with rule requirements. The revisions do this by clarifying the minimum information that is needed to demonstrate adequate training and education for various disciplines."

Medical use and commercial nuclear pharmacy applicants and licensees may use following NRC Form 313A series of optional supplemental forms to provide the required training and experience information required under Item 7 of the NRC Form 313:

- NRC Form 313A (RSO), "Radiation Safety Officer or Associate Radiation Safety Officer Training, Experience and Preceptor Attestation [10 CFR 35.57, 35.50]"
- NRC Form 313A (AMP), "Authorized Medical Physicist and Ophthalmic Physicist, Training, Experience and Preceptor Attestation [10 CFR 35.51, 35.57(a)(3), and 35.433]"
- NRC Form 313A (ANP), "Authorized Nuclear Pharmacist Training, Experience, and Preceptor Attestation [10 CFR 35.55]"

- NRC Form 313A (AUD), “Authorized User Training, Experience and Preceptor Attestation (for uses defined under 35.100, 35.200, and 35.500) [10 CFR 35.57, 35.190, 35.290, and 35.590]”
- NRC Form 313A (AUT), “Authorized User Training, Experience, and Preceptor Attestation (for uses defined under 35.300) [10 CFR 35.57, 35.390, 35.392, 35.394, and 35.396]”
- NRC Form 313A (AUS), “Authorized User Training, Experience and Preceptor Attestation (for uses defined under 35.400 and 35.600) [10 CFR 35.57, 35.490, 35.491, and 35.690]”

The NRC issues a materials license, if the information as part of the NRC Form 313 (which for medical and commercial nuclear pharmacy applicants only 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 and previous versions of this clearance.

On July 16, 2018, the NRC published a Final Rule “10 CFR Parts 30, 32, and 35 Medical uses of Byproduct Material – Medical Event Definitions and Training and Experience,” related to the possession, use, and distribution of byproduct material for medical uses. The final rule is effective January 14, 2019. The rule included changes to the training and experience requirements that affect the specific information needed to complete item 7 of the NRC Form 313 for medical use and commercial nuclear pharmacy applicants and licensees. Therefore, the NRC form 313A series of forms were revised to conform to these rule changes. These changes include: adding the training and experience information needed for the Associate Radiation Safety Officer to the NRC Form 313A (RSO); adding the training and experience information needed for the ophthalmic physicist to the NRC Form 313A (AMP); adding the training and experience information needed for all individuals board certified prior to October 24, 2005, to all the NRC Form 313A series of forms except the NRC Form 313A (ANP); deleting need to submit the preceptor information for most board certified individuals from all the NRC Form 313A series of forms; revising the preceptor attestation statement for all the NRC Form 313A series of forms; adding the information needed for the residency program director to sign the attestation on NRC Forms 313A (AUD), 313A (AUT) and 313A (AUT); and clarifying the clinical category experience information needed for the NRC Form 313A (AUT). These rule changes resulted in changes to all of the NRC Form 313A series of forms. The new rule did not affect NRC Form 313 or the information submitted for the other items on the form for any materials applicants and licensees. This clearance addresses the changes in the reporting burden, due primarily to the reduction in the number of all materials NRC licensees and all NRC materials licensing actions, in the submission of the NRC Form 313 and NRC Form 313A series by all of these licensees.

NRC changed the frequency for its materials license renewals from a ten year to fifteen year frequency since the last OMB clearance. The Agreement States have not adopted this change in the renewal frequency.

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, 32.72, 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, 35.433, 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

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 approximately 25% of the 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

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 fifteen 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

The \$275 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 (83 FR 29622, June 25, 2018).

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 for all materials licensees is based on the total number of licensing actions processed by the NRC and NRC's Master Material License licensees during fiscal year 2018 and estimated increase in amendments for the associate Radiation Safety Officer and ophthalmic physicist to medical use licenses, approximately 1049 licensing actions (including all new licenses, amendments, and renewals, and the assumed increase of amendments based on just adding new Associate Radiation Safety Officers and ophthalmic physicist to medical use licenses). There were 197 total amendment request in 2018 from medical use licensees. Some licensees are projected to include amendment request to add Associate Radiation Safety Officers and ophthalmic physicists with other changes to their programs so it is estimated that there will be an additional 100 amendment request per year as a result of the new rule. Based on this number of licensing actions, the industry burden for licensing is estimated to be 4,510 hours (4.3 hours per licensing action x 1049 licensing actions). The annual cost to all affected NRC licensees is estimated to be \$1,240,250 (4,510 hours x \$275 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 16,531 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 two ratios to provide this estimate. The first is the ratio of the sum of the total number of NRC licensees and NRC MML permittees to the total number of Agreement State licensees to estimate the number of Agreement State amendment licensing actions. This ratio is 1:5.3. It is based on 3,120 total NRC licensees and NRC MML permittees and 16,531 Agreement State licensees. Based on this ratio, the estimated number of Agreement State amendment licensing actions is 3,683 (695 NRC amendment licensing actions x 5.3). The second ratio is ratio of the total number of NRC licensees (excluding NRC MML permittees) to the total number of Agreement State licensees to estimate the number of Agreement State new licensing. The NRC MML licensees do not add new permittees. This ratio is 1:5.9 and is based on 2,795 NRC licensees and 16,531 Agreement State licensees. Based on this ratio, the estimated number of Agreement State new licensing actions is 242 (41 NRC new licensing actions x 5.9). The Agreement State renewal periods are different from that of the NRC and the Agreement State estimate was based on a five year renewal frequency. The estimate for the Agreement States renewal licensing action 3,306 is based on dividing the total number of Agreement State licensee by the 5 year renewal frequency (16,531/5). Therefore the total Agreement State estimated number of licensing actions is 7,231 (3,683 amendment + 3,306 renewal + 242 new licensing actions).

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 31,093 hours (4.3 hours per licensing action x 7,231 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 \$8,550,575 (31,093 hours x \$275 per hour).

C. Third party

The medical use applicant and licensee is the only one that requires information need to complete the NRC Form 313 be provided from a third party. The medical use licensees must provide preceptor attestation for certain individuals seeking to be recognized as authorized users, authorized medical physicist, authorized nuclear pharmacists, and Radiation Safety Officers for the first time and for certain additional authorizations at a later time. The preceptor providing the attestation is not a licensee and it is estimated the preceptor will need 0.05 hour to complete the attestation. The total number of attestations, 624, is estimated to be a third of the annual estimated medical use license amendments submitted [(297 for NRC and 1574 for Agreement States) /3]. The total estimated burden is 31.2 hours (624 responses x 0.05 hours). The estimated annual cost to the third party is \$8,580 (31.2 hours x \$275).

D. Total

The total burden for NRC and Agreement State licensees and third parties combined is 35,634 hours (4,510 hours for NRC licensees + 31,093 hours for Agreement State licensees + 31.2 hours for third parties). The estimated total cost is 9,790,825 (\$1,240,250 NRC + 8,550,575 AS +8,580 3rd party).

13. Estimate of Other Additional Costs

There are no additional costs.

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.

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 1049 licensing actions at a cost of \$275 per hour, the cost to perform the licensing review would be \$1,240,442 (1049 licensing actions x 4.3 hours per licensing action x \$275 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 3,192 hours from 7,702 to 4,510 hours as a result of the decrease in licensing actions received by 1,664 from 2,713 to 1,049. The NRC expects the number of submitted licensing actions to remain at the fiscal year 2018 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 8,189 from 15,420 to 7,231. Overall, the burden for Agreement States will decrease by 20,417 hours from 51,510 to 31,093 hours.

The total estimated burden for completing NRC Form 313 and 313A will decrease by 25,100 hours, from 60,703 to 35,603-hours.

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

35,603 burden hours for 8,280 responses (4,510 burden hours for 1,049 NRC licensing actions plus 31,093 Agreement State licensee burden hours for 7,231 estimated Agreement State licensing actions.)

8,280 respondents (1,049 NRC licensee respondents plus 7,231 Agreement State licensee respondents.)

The burden decreased due to a reduction in the actual number of licensing actions received (downward adjustment of 25,100 hours).

The burden for the third parties was not included in the last OMB clearance. The burden is expected to decrease because board certified individuals will no longer be required to have preceptor attestations.

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 increased from \$268 to \$275 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	1,049	1	1,049	4.3	4,510
TOTAL			1,049		4,510

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	7,231	1	7,231	4.3	31,093
TOTAL			7,231		31,093

TABLE 3

Annualized Third Party Burden

Section	Number of Respondents	Responses/ Respondent	Total Responses	Burden/ Response	Total Annual Burden Hours
NRC Form 313 and 313A Series Licensing Actions	624	1	624	0.05	31.2
TOTAL			624		31.2

Total Responses: 8,904 (1,049 reporting/NRC Licensees) +
(7,231 reporting/Agreement States) + (624 Third Party)

Total Respondents: 8,904 (1,049 NRC Licensees + 7,231 Agreement States + 624 Third Party)

Total Burden Hours: 35,634 (4,510 NRC Licensees hours reporting) +
(31,093 Agreement States hours reporting) + 31 Third Party