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 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.

In addition to completion of NRC Form 313, "Application for Materials License" (see NUREG-1556, Volume 9, Appendix B), applicants can also use the appropriate NRC 313A form to document training and experience. The following are the six NRC Form 313A forms which can be used to document training and experience to request authorization for different individuals:

- NRC Form 313A (AMP)—Authorized Medical Physicist or Ophthalmic Medical Physicist
- NRC Form 313A (ANP)—Authorized Nuclear Pharmacist
- NRC Form 313A (AUD)—Authorized User requesting authorization for diagnostic uses defined under 10 CFR 35.100, 10 CFR 35.200, or 10 CFR 35.500.
- NRC Form 313A (AUS)—Authorized User requesting authorization for use of sealed sources defined under 10 CFR 35.400 or 10 CFR 35.600.
- NRC Form 313A (AUT)—Authorized User requesting authorization for use of unsealed radioactive material for therapy defined under 10 CFR 35.300.
- NRC Form 313A (RSO)—Radiation Safety Officer or Associate Radiation Safety Officer

The 313A forms provide a template to answer item #7 "Individuals Responsible for the Radiation Safety Program and Their Training and Experience" on the Form 313. The specific 313A form completed is dependent on the type of license. The forms are specific to medical licensees, nonmedical licensees must provide similar information although there is not a specific form for these licensees.

The NRC utilizes the Web-Based Licensing (WBL) System to store and manage information collected by Form 313 and to track and manage progress associated with the license, amendment, or renewal of a license for byproduct or source material. The online Form 313 is linked to the NRC's WBL System and, for applicants requesting an amendment or renewal of a license for byproduct or source material, information from WBL will pre-populate Form 313 accordingly. To prevent fraudulent requests for byproduct or source materials licenses, users will be credentialed for access to WBL's online form. The online Form 313 is being separated into Tabs with a step through process to assist the applicant. The information request by the online form has not changed from Form 313. The appropriate 313A series form would be uploaded into the system.

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.

NRC materials license renewals are submitted every 15 years for NRC licensees. Licensees in Agreement states submit license renewals every 10 years.

In addition, Section 274 of the AEA provides 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. The mechanism for the transfer of the NRC's authority to a State is an agreement between the Governor of the State and the NRC. To date, 39 states have become "Agreement States." These Agreement States now regulate approximately 88 percent of byproduct, source and special nuclear material licenses in the United States, as permitted by Section 274 of the AEA. Persons located in agreement states send applications to the NRC only if they wish to possess and use licensed material in states subject to NRC jurisdictions.

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 canuse 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*, Revision 9 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 90% 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 reducethe burden on small businesses by less frequent submission or less complete applications. It is estimated that approximately 33% of materials licensees are considered small businesses.

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

All applicable applicants and licensees need to consider and address Items 1 through 13 of NRC Form 313, as appropriate. 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 of 4.3 hours per response 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.

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 during fiscal year 2021, as determined by querying the agency’s Web-based Licensing system.

Table 1: Submissions by NRC Licensees

	Number of Respondents	Burden per response	Responses	Total Burden
New license applications	32	4.3	1	137.6
Amendments	940	4.3	1	4,042.0
Renewals	202	4.3	1	868.6
Total	1174			5,048.2

Of the 940 amendment requests in 2021, there were 401 total amendment requests in 2021 from medical use licensees. (Data on amendments from medical use licensees is used to estimate 3rd party burden in section C below.)

Based on this number of licensing actions, the burden for NRC licensees licensing is estimated to be 5,048 hours (4.3 hours per licensing action x 1,174 licensing actions).

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 thissupporting statement as "Agreement State Licensee."

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 16,000 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 to the total number of Agreement State licensees to estimate the number of Agreement State amendment licensing actions. This ratio is 1:7.3 It is based on 2,200 total NRC licensees and 16,000 Agreement State licensees. 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 is based on dividing the total number of Agreement State licensee by the 5 year renewal frequency.

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.

Table 2: Submissions by Agreement States Licensees

	Responses	Burden per response	Responses	Total Burden
New license applications	234	4.3	1	1,006.2
Amendments	6,862	4.3	1	29,506.6
Renewals	3,200	4.3	1	13,760.0
Total	10,296			44,272.8

The reporting burden for Agreement State licensees is estimated to be 44,273 hours (4.3 hours per licensing action x 10,296 licensing actions).

C. Third party

The medical use applicant and licensee is the only one that requires information needed 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.

Attestation is required for all individuals to meet the requirements in 10 CFR 35.396 and for individuals seeking authorization under the alternate training and experience pathway for 10 CFR 35.390 and 10 CFR 35.690. Other than for individuals qualifying under 10 CFR Part 35, Subpart G, the applicant must submit a Preceptor Attestation for all non-board certified individuals. The attestation is part of all of the NRC Form 313A series of forms.

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, 752, is estimated to be a fourth of the annual estimated medical use license amendments submitted [(401 for NRC and 2,607 for Agreement States) /4] The total estimated burden is 38 hours (752 responses x 0.05 hours). The estimated annual cost to the third party is
$10,944 (38 hours x $288).

D. Total

Table 3. Total annualized burden

	Reporting burden	Third Party burden	Total burden	Cost at $288/hr
NRC licensees	5,048	5	5,053	$ 1,455,264
Agreement State Licensees	44,273	33	44,306	$ 12,760,128
Total	49,320	38	49,358	$ 14,215,104

Table 4. Total annual responses

	Reporting responses	Third Party Responses	Total responses
NRC licensees	1,174	100	1,274
Agreement State Licensees	10,296	652	10,948
Total	11,470	752	12,222

Total Responses: 12,222 (1,174 reporting/NRC Licensees) + (10,296 reporting/Agreement States) + (752 Third Party)

Total Respondents: 12,222 (1,174 NRC Licensees + 10,296 Agreement States + 752 Third Party)

Total Burden Hours: 49,358 (49,320 hours reporting + 38 hours recordkeeping) at a cost of $14,215,104 (49,358 hours x $288/hr)

The $288 hourly rate used in the burden estimates is based on the NRC'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 2021 (86 FR 32146-32183, June 16, 2021). The final rule became effective August 16, 2021.

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 onstaff 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 1174 licensing actions at a cost of $288 per hour, the cost to

perform the licensing review would be $1,453,882 (1174 licensing actions x 4.3 hours per licensing action x $288 per hourhour).

15. Reasons for Changes in Burden or Cost

The burden for the information collection has increased from 35,634 hours and 8,904 responses to 49,358 hours and 12,222 responses, an increase of 13,724 hours and 3,318 responses. The burden for this collection was estimated using actual data from the agency's web based licensing system from 2021. Compared to the data estimated in the previous OMB clearance package, the number of respondents for license amendments has increased from 695 to 940. NRC staff believes that some materials licensees may not have been included in the total reported in the last clearance cycle. The current data correctly includes all materials licensees.

The ratio used to estimate the number of Agreement State amendment licensing actions also increased from 5.3 to 7.3, based on an annual count of the number of licensees in Agreement States.

The number of NRC licensee licensing actions changed from 1,049 to 1,174. The number of Agreement licensing actions changed from 7,231 to 10,296. The number of 3rd party attestations changed from 624 to 752.

The burden for the annual estimated medical use license amendments has increased since the last OMB clearance by 104 from 297 to 401 total amendment requests. In the last clearance cycle this data was estimated, because there was new rule including amendment requests to add Associate Radiation Safety officers and ophthalmic physicists and the number of these was estimated. Now, the NRC staff is able to pull actual data on the number of these submissions.

There were changes to the Forms 313A - AMP and 313A - RSO as follows:

- Form NRC 313A RSO under Part I.2, the last section of option B was deleted. An option C was added; "if not board certified and not listed on a medical use license as an RSO before January 14, 2019, skip to and complete Part II Preceptor Attestation.
- Form NRC 313A RSO under Part I.3, option C was deleted and substituted by "Stop here".
- Form NRC 313A AMP under Part I.2, two new options were added "b. If board-certified, provide a copy of the certificate and stop here" and "c. If listed on a license or permit before January 14, 2019, as an authorized medical physicist, stop here. The last option was deleted.

MMLs are not affected by Form 313 and do not use the form, nor have they used it to add permittees in the past. References to MMLs have been removed from this information collection request.

These changes are not anticipated to change the burden per response to complete these forms.

In addition, the fee rate increased from $275 to $288 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 offorms.

18. Exceptions to the Certification Statement

There are no exceptions.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Not applicable.

GUIDANCE DOCUMENTS FOR
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Title	Accession number
Nureg-1556, Vol. 9, Rev. 3, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses" Final Report.	ML19256C219
Guidance for Electronic Submissions to the NRC, Revision 9	ML13031A056