FINAL OMB SUPPORTING STATEMENT

NRC FORM 313, APPLICATION FOR MATERIAL LICENSE
AND
NRC FORM 313A SERIES (RSO, AMP, ANP, AUD, AUT, AND AUS)

(3150-0120)

BURDEN REVISIONS

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 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 Material License," and NRC Form 313A, “Medical Use Training and Experience and Preceptor Attestation,” is used to provide the information required. Only a person to be licensed to possess and use licensed material for medical uses or a commercial nuclear pharmacy must submit among other things an application that will permit the NRC to determine whether the applicant has training and experience for the medical or commercial nuclear pharmacy uses of radioactive material that are adequate to protect the public health and safety. The NRC is replacing the currently used NRC Form 313A with a series of medical use training and experience and preceptor attestation forms as listed below to provide the information required. If the information fulfills the substantive requirements stated elsewhere in the regulations, the NRC issues a license.

The NRC Form 313A series of medical use training and experience and preceptor attestation forms consist of six individual forms with the following titles:

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], and

NRC Form 313A, (AUS), “Authorized User Training and Experience and Preceptor Attestation” (for uses defined under 35.490 and 35.600) [10 CFR 35.490, 35.491, and 35.690].”

NRC Form 313 remains unchanged. The revised NRC Form 313A was approved by OMB in

October 2005 as a part of the burden for the NRC Form 313. NRC Form 313A was revised on April 29, 2005, to align with the final rule 10 CFR Part 35, “Medical Use of Byproduct Material--Recognition of Specialty Boards," issued March 30, 2005 (70 FR 16335), with an effective date of April 29, 2005. The rule revised the training and experience requirements in 10 CFR Part 35 Subparts B and D-H. This clearance addresses the replacment of the single NRC Form 313A used by medical Radiation Safety Officers, medical physicist, nuclear pharmacists and nine different types of physicians, with six distinct new NRC Form 313A’s. The information required to complete the forms is unchanged**.** The change in the burden reflects easier to use forms and guidance**.** Each new form may be used by a medical use applicant or licensee to document the training and experience of an individual within a group with similar levels of training and experience aligned with the requirements in the 2005 revision of 10 CFR Part 35. NRC Form 313A(ANP) is also used by commercial nuclear pharmacy licensees when requesting an individual be identified for the first time as ANP.

NRC Technical Report NUREG-1556, Volume 9, Revision 2, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance about Medical Use Licenses,” will update the revised guidance on filling out the replacement forms. The revised NUREG also removes all references to requirements in 10 CFR Part 35, Subpart J, which terminated on October 24, 2005, and was removed from 10 CFR Part 35 on March 27, 2006 (71 FR 15009). The NUREG is being revised and is intended to facilitate the license application, amendment and renewal processes. While the NUREG is being revised, guidance for the replacement forms will be provided in a Regulatory Issue Summary. The new guidance will aid applicants in filling out the six replacement forms. This guidance is intended to facilitate the process of using the replacement forms during new license applications, license amendments, and renewals.

A. JUSTIFICATION

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

10 CFR 30.32, 30.37, and 30.38, provide for the filing of an application for a specific license for possession, use and distribution of byproduct material on NRC Form 313, "Application for Material License." 10 CFR Sections 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 include the information required to be provided for training and experience by the medical use and commercial nuclear pharmacy applicant or licensee. This information may be submitted by filing the appropriate form or forms, of the six replacement NRC Forms 313A series of medical use training and experience and preceptor attestation forms. These forms are a part of the NRC Form 313.

Each new form may be used by a medical use or commercial nuclear pharmacy applicant or licensee to document the training and experience of an individual within a group with similar levels of training and experience aligned with the requirements in the 2005 revision of 10 CFR Part 35.

NRC Form 313A(RSO) is used by an individual seeking to be a Radiation Safety Officer(RSO) at a medical use facility. The individual must meet one of the 6 distinct sets of training and experience requirements in 10 CFR 35.50. NRC Form 313A(RSO) provides a clear format to document all the components of each of these sets, as well as a clear format for his/her preceptor RSO to attest to the completion of the training and experience and ability of the individual to function independently as an RSO.

NRC Form 313A(AMP) is used by a physicist seeking to be an authorized medical physicist (AMP) at a medical use facility. The physicist must meet one of 3 distinct sets of training and experience requirements in 10 CFR 35.51. NRC Form 313A(AMP) provides a clear format to document all the components of each of these sets, as well as a clear format for his/her preceptor medical physicist to attest to the completion of the training and experience and ability of the individual to function independently as an AMP.

NRC Form 313A(ANP) is used by a nuclear pharmacist seeking to be an authorized nuclear pharmacist (ANP) at a medical use facility or a commercial nuclear pharmacy. There are only 2 distinct sets of training and experience requirements in 10 CFR 35.55. NRC Form 313A(ANP) provides a clear format to document all the components of each of these sets, as well as a clear format for his/her preceptor ANP to attest to the completion of the training and experience and ability of the individual to function independently as an ANP.

NRC Form 313A(AUD), NRC Form 313A(AUT), and NRC Form 313A(AUS) are used by physicians (and a few podiatrist and dentist) seeking to be authorized users(AUs) for specific medical uses at a medical facility.

NRC Form 313A(AUD) is used by physicians (and a few podiatrists and dentists) that meet one of 7 distinct sets of training and experience requirements in 10 CFR 35.190, 35.290, or 35.590.

NRC Form 313A(AUT) is used by physicians that meet one of 8 distinct sets of training and experience requirements in 10 CFR 35.390, 35.392, 35.394, or 35.396.

NRC Form 313A(AUS)is used by physicians that meet one of 5 distinct sets of training and experience requirements in 10 CFR 35.490, 35.491, or 35.690.

NRC Form 313A(AUD), NRC Form 313A(AUT), and NRC Form 313A(AUS) provide a clear format to document all the components of each of these sets of requirements, as well as a clear format for the preceptor authorized user to attest to the completion of the training and experience and ability of the individual to function independently as an AU.

The information submitted on NRC Forms 313 (which may include the NRC Form 313A) Is reviewed by the NRC staff to determine whether the applicant is qualified by training and experience and has equipment, facilities, and procedures which are adequate to protect the health and safety of the public and minimize danger to life or property. Specifically, the medical use and commercial nuclear pharmacy applicants submit the training and experience using the NRC Form 313A series of forms. These forms are reviewed by the NRC staff to determine whether the medical use or commercial nuclear pharmacy applicant is qualified by training and experience to protect the health and safety of the public and minimize danger to life or property.

The new NRC 313A series of forms makes it easier for the estimated 336 board certified individuals to determine the information needed and the parts of the form to be filled out. However the complexity of the single NRC Form 313A was not a factor for the board certification pathway. Therefore the new NRC Form 313A series is not expected to have a measurable change in the burden for this pathway. The board certification pathway also was not affected by the revision of the guidance, because most of the instructions in the current guidance did not apply to the board certification pathway.

The alternate pathway not only requires providing the most information but also the previous guidance and NRC Form 313A were the most difficult to review and fill out for this pathway. Providing clearer guidance and longer but clearer forms to licensees will result in the greatest reduction in burden and improve the quality of the information submitted by the estimated 604 individuals using the alternate pathway. The guidance is provided for each form so each group will know how to fill out their form.

2. Agency Use of Information

NRC reviews the information submitted in order to determine whether the applicant is qualified and has the training, experience, equipment, facilities, and procedures in place that are adequate to protect the health and safety of the public and minimize danger to life or property as required by the Atomic Energy Act, as amended, and the Energy Reorganization Act of 1974, as amended. This information will assist the Commission in determining 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. 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 none of the potential responses will be filed electronically.

4. Effort to Identify Duplication and Use Similar Information

There is no duplication of requirements. 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, under the NRC's current definitions, 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 training and experience 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. Information on an individual's training and experience is submitted only when the individual is first identified as an RSO, AMP, ANP, or AU and again to provide additional information when the individuals to be identified with a new authorization on a limited specific medical use license. The information is also submitted by medical broad scope licensees when identifying a new individual as an RSO or adding an additional RSO authorization for the individual and a commercial nuclear pharmacy when requesting an individual be identified for the first time as ANP. This submittal may occur when applying for a new license, amendment, or renewal. 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' radiation safety program and training and experience 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

The opportunity for public comment on the information collection requirements was published in the Federal Register on September 8, 2005 (70 FR 53396). 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

No sensitive information is requested under these regulations.

12. Estimated Burden and Burden Hour Cost

A. NRC Licensees

There are 4,531 NRC licensees (including NRC Master Materials License permittees) that use NRC Form 313 for new license, amendment and renewal applicants based on fiscal year (FY) 2005 data. The 2,958 medical use and commercial nuclear licensing actions (including NRC's Master Materials License medical use permitting actions) is based on the number of new and amendment request processed during fiscal year 2005 and the renewals are based on the number of NRC medical use and commercial nuclear pharmacy materials licenses averaged over the 10 year license renewal period. Because NRC did not redistribute these renewals over the entire 10 year period, almost all licenses are renewed during the first 5 years of this period. The 998 individuals filling

the NRC Form 313A series of forms is estimated from the medical use and commercial nuclear pharmacy licensing actions in FY 2005. The number of licensing actions is greater than the NRC Form 313A series usage because once individuals are listed on a limited specific license, an MML permit or a broad scope permit as an RSO, AMP, ANP, or AU, they may move to another license by showing the license or permit that identified the individual for that activity.

The burden associated with the use of NRC 313A series of medical use training and experience and preceptor attestation forms is included in the 4.4 hour average burden for all applicants filling out NRC Form 313. This burden is estimated to be 12,719 hours for 2,958 NRC licensees. The burden associated with the NRC Form 313A series of forms is independent of the type of application, i.e., new application, amendment, or renewal because the information needed for an individual to be recognized for the first time as an RSO, AMP, ANP, or AU remains the same. The same is true for the individual seeking a new authorization.

The burden for the NRC Form 313A series of forms is dependent on whether the individual to be recognized for the first time as an RSO, AMP, ANP, or AU is providing documentation of the individual's training and experience by the specialty board certification pathway or must document the specific hours spent on specific topics during training and supervised work experience programs referred to as the alternate pathway. The burden also depends on whether individuals are seeking a new authorization.

There is no measurable reduction in burden for the NRC Form 313A, ANP because the information provided by the pharmacists is simpler than for others and essentially remained unchanged during the 2002 and 2005 revisions of Part 35. The burden for the other 599 individual using the new NRC Form 313A series of forms for this pathway is expected to be reduced by 0.4 hours for each. The total burden reduction for this pathway is 240 hours.

The licensee using NRC Form 313A, RSO, NRC Form 313A, AMP, NRC Form 313A, AUD, NRC Form 313A, AUT or NRC Form 313A, AUS, to seek an additional authorization, for an estimated 58 individuals, only has to provide supplemental information to support the new authorization. The forms and the guidance now clearly identify the information needed for each additional authorization and should reduce the burden to licensees by 0.2 hours per individual. The total burden reduction when seeking an additional authorization is 12 hours. The NRC Form 313A, ANP is not included in this consideration because an authorized nuclear pharmacist seeking authorization as an RSO would use the NRC Form 313A, RSO form.

Therefore, it is estimated that when the effects of the replacement NRC Form 313A series of forms and the revised guidance are considered, 2,958 applicants will spend 12,719 hours completing the health and safety elements of an application for an average of 4.3 hours per applicant.

Based on 2,958 licensing actions per year, the industry burden for licensing is estimated to be 12,719 hours (4.3 hrs/licensing action x 2,958 licensing actions). The average annual cost to each respondent to comply with the information collection requirements is estimated to be $920 (4.3 hrs per respondent x $214 /hr). The annual cost to all affected licensees is estimated to be $2,721,866 (12,719 hrs x $214/hr).

B. Agreement State Licensees

NRC estimates that there are approximately 3.9 times the number of Agreement State licensees as there are NRC licensees. The change from 3.6 to 3.9 is based on the most recent number of actual Agreement State and NRC byproduct material licensees (including NRC Master Material License permittees). The Agreement States retained a 5-year license renewal period for its byproduct, source, and special nuclear materials licenses. Therefore, for Agreement State licensees, it is estimated that there are 13,290 licensing actions annually. Additionally, NRC estimates that the amount of time 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 57,147 hours (13,290 licensing actions x 4.3 hrs/licensing action). The estimated annual cost to the Agreement State licensees to prepare applications and submit required information on forms equivalent to NRC Forms 313 and 313A is estimated to be $12,229,458 (57,147 hrs x $214/hr).

13. Estimate of Other Additional Cost

There is no additional cost.

14. Estimated Annualized Cost to the Federal Government

It is estimated that the review of the information on NRC Forms 313 and 313A, will take an average of approximately 4.3 hours per application. Based on an anticipated 2,958 licensing actions per year, at a cost of $214 per hour, the cost to perform the licensing review would be $2,721,866 (2,958 licensing actions x 4.3 hrs/licensing action x $214/hr). 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

Since the last renewal clearance request which was approved on 10/19/05, NRC replaced the currently used NRC Form 313A, a single form with a series of six distinct forms for medical use training and experience and preceptor attestation. The replacement forms are easier to complete and provide clearer guidance for each licensee type to complete as well as align with the requirements of 10 CFR Part 35, Medical Use of Byproduct Material – Recognition of Specialty Boards Final Rule (70 FR 16335), which became effective April 29, 2005.

The burden for NRC licensees is expected to decrease by 807 hours from 13,526 to 12,719 hours because the actual number of licensing actions received decreased by 116 from 3,074 to 2,958 with a decrease in burden to complete an application from 4.4 to 4.3 hours because of the improved forms and guidance. The burden for Agreement State licensees is expected to increase by 651 hours from 56,496 to 57,147 because of an increase in the number of Agreement State licensees, which resulted in an increase of 450 licensing actions received from 12,840 to 13,290. Although the burden increased, the burden to complete an application decreased from 4.4 to 4.3 hours due to the improved forms and guidance.

The total estimated burden for completing NRC Form 313 and 313A decreased by 156 hours, from 70,022 to 69,866 hours (12,719 hours for NRC Licensees plus 57,147 hours

for Agreement State Licensees) and an increase in the number of responses from 15,914 to 16,248 (2,958 for NRC Licensees plus 13,290 for Agreement State Licensees). The hourly cost increased from $156 to $214 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 Form 313, NRC Form 313A(RSO), NRC Form 313A(AMP), NRC Form 313A(ANP), NRC Form 313A(AUD), NRC Form 313A(AUT), and NRC Form 313A(AUS)

18. Exceptions to the Certification Statement

There are no exceptions.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Not applicable.

Table 1. NRC Form 313/313A for NRC Licensees

Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Burden Hour per Response	Total Annual Reporting Burden (Hrs)	Cost @ $214/Hour
Form 313	1,960	1	1,960	4.3	8,428	1,803,592
Form 313A(RSO)	222	1	222	4.3	955	204,370
Form313A(AMP)	140	1	140	4.3	602	128,828
Form 313A(ANP)	39	1	39	4.3	168	35,952
Form 313A(AUD)	298	1	298	4.3	1,281	274,134
Form 313A(AUT)	128	1	128	4.3	550	117,700
Form 313A(AUS)	171	1	171	4.3	735	157,290
TOTAL	2,958		2,958		12,719	2,721,866

Table 2 NRC Form 313/313A for Agreement State Licensees

Section	No. of Respondents	No. of Responses Per Respondent	Total Annual Responses	Burden Hour per Response	Total Annual Reporting Burden (Hrs)	Cost @ $214/Hour
Form 313	9,269	1	9,269	4.3	39,857	8,529,398
Form 313A(RSO)	905	1	905	4.3	3,891	832,674
Form 313A(AMP)	550	1	550	4.3	2,365	506,110
Form 313A(ANP)	160	1	160	4.3	688	147,232
Form 313A(AUD)	1,174	1	1,174	4.3	5,048	1,080,272
Form 313A(AUT)	530	1	530	4.3	2,279	487,706
Form 313A(AUS)	702	1	702	4.3	3,019	646,066
TOTAL	13,290		13,290		57,147	12,229,458

Net Burden Change
Revised NRC Licensees: 807 burden hour decrease/116 responses decrease
Revised Agreement State Licensees: 651 burden hour increase/450 responses increase

Net Burden Change: -807 + 651 = -156 hours
Net Response Change: -116 + 450 = 334 responses

Total Burden Change : 70,022 - 156 = 69,866 hours
Total Response Change: 15,914 + 334 = 16,248 responses.
Total Number of Respondents: 16,248