FINAL OMB SUPPORTING STATEMENT
FOR NRC FORM 313
APPLICATION FOR MATERIAL LICENSE
AND
NRC FORM 313A
TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT
(3150-0120)

CLEARANCE EXTENSION WITH 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 Forms 313, and 313A, "Application for Material License," and "Medical Use Training and Experience and Preceptor Attestation," respectively, are used to provide the information required. If the information in the application fulfills the substantive requirements stated elsewhere in the regulations, the NRC issues a license.

NRC Form 313A was approved by OMB in October 2002 and 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 additional reporting burden added to the revised NRC Form 313A because of the separation of clinical experience, training, and the preceptor attestation from the speciality board requirements and complexity the rule added to documenting an individuals training and experience. The new revised NRC Form 313A adds sections for required additional training/clinical experience and preceptor attestations for individuals who are certified by a specialty board recognized by NRC or who are already authorized users, authorized medical physicists, authorized nuclear pharmacists or Radiation Safety officers that are seeking additional authorizations.

Between 1997 and 2002, NRC produced 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 renewals. They provided a comprehensive source of reference information about materials regulation for the applicant, licensee, and NRC. 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 included in this clearance because the series was not completed until after the last OMB clearance and was not reflected in earlier clearances.

The regulatory burden for emerging medical use technologies (new modalities) that were addressed separately in the last OMB clearance are now integrated into the NRC license application, renewal, and amendment data.

A. JUSTIFICATION

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

10 CFR Sections 30.15, 30.19, 30.20, 30.32, 30.36, 30.37, 30.38, 32.11, 33.12, 34.11, 35.12, 35.13, 36.11, 39.11, 40.31, 40.43, and 40.44 provide for 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 Material License," for a specific license. 10 CFR Section 35.12 also provides for the filing of training and experience information on NRC Form 313 of which NRC Form 313A is a part. The information required under training and experience for the medical use and commercial nuclear pharmacy applicant or licensee is found in 10 CFR Sections 35.50, 35.51, 35.55, 35.190, 35.290, 35.292, 35.390, 35.392, 35.394, 35.396, 35.490, 35.491, 35.590, and 35.690.

The information submitted on NRC Forms 313 and 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.

2. Agency Use of Information

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, and the Energy Reorganization Act of 1974, as amended, so that the Commission may determine whether to issue, amend, or renew a broad scope 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. The current percentage of electronic submission is about 5 percent.

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. 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.

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 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

The opportunity for public comment on the information collection requirements was published in the Federal Register on June 21, 2005 (70 FR 35734). No comments were received.

9. Payment or Gift to Respondents

Not applicable

10. Confidentiality of the Information

This information is usually not confidential. If it were, the information would be handled as proprietary in accordance with 10 CFR 2.390 of the NRC regulations.

11. Justification for Sensitive Questions

No sensitive information is requested under these regulations.

12. Estimated Burden and Burden Hour Cost

A. NRC Licensees

The burden associated with the use of NRC Forms 313 and 313A for new licenses and amendments is based on the number of licensing actions (including NRC's Master Materials License permitting actions) processed during fiscal year 2004. The burden associated with the use of NRC Forms 313 and 313A for license renewals is based on the number of NRC 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. There were 253 new and 2,358 amendment applications for the possession, use, and initial distribution of byproduct and source material during fiscal 2004. There were an average of 463 renewal applications for the same period. The total estimated number of licensing actions for this period was 3,074.

Before considering the effects of the NUREG-1556 series and the effects of the revision of 10 CFR Part 35, it is estimated that each applicant will spend an average of 7 hours to prepare the health and safety elements of an application. The effect of the NUREG-1556 series was to produce new, amendment, and renewals application in an estimated 62 percent of the effort of pre-NUREG-1556 series submissions or 13,341 hours.

The revision of the 10 CFR Part 35 affected NRC's estimated 1735 medical use licensing actions (including NRC's Master Materials License permitting actions). It is estimated that 25 percent of medical use licensing actions (433 actions) would include addition of an Authorized User, Authorized Medical Physicist, Authorized Nuclear Pharmacist, or Radiation Safety Officer that required providing the additional information specified in the new final rule. The additional time needed to prepare this information, including review of the guidance for filling out NRC Form 313A in NUREG-1556, Vol 9, Revision 1, is estimated to be 20 minutes. The burden resulting from the new revision of 10 CFR Part 35 will add 143 hours (433 licensing actions X 0.33) to the entire burden of completing the NRC Form 313A.

Therefore, it is estimated that when the effects of the NUREG-1556 series and the revision of 10 CFR Part 35 are considered, applicants will spend 13,484 hours completing the health and safety elements of an application for an average of 4.4 hours per applicant.

Based on 3,074 licensing actions per year, the industry burden for licensing is estimated to be 13,526 hours (4.4 hrs/licensing action x 3,074 licensing actions). The average annual cost to each respondent to comply with the information collection requirements is estimated to be $686 (4.4 hrs per respondent x $156 /hr). The annual cost to all affected licensees is estimated to be $2,110,056 (13,526 hrs x $156/hr).

B. Agreement State Licensees

NRC estimates that there are approximately 3.6 times the number of Agreement State licensees as there are NRC licensees. The change from 3.4 to 3.6 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 12,840 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 56,496 hours (12,840 licensing actions x 4.4 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 $8,813,376 (56,496 hrs x $156/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 4.4 hours per application. Based on an anticipated 3,074 licensing actions per year, at a cost of $156 per hour, the cost to perform the licensing review would be $2,109,994 (3,074 licensing actions x 4.4 hrs/licensing action x $156/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

The burden for NRC licensees is expected to decrease by 12,675 hours from 26,201 to 13,526 hours because the actual number of licensing actions received decreased by 669 from 3,743 to 3,074. Additionally, as a result of the improved guidance given in the NUREG-1556 series, there is a reduction from 7 hours to 4.4 hours in the burden hours needed to complete the application process resulting in an additional burden decrease of more than 1,700 hours.

There are more licensing actions for Agreement States because of the increase in the number of Agreement State licensees. The number of licensing actions received increased by 114 from 12,726 to 12,840. However, as a result of the improved guidance given in the NUREG-1556 series, there is an estimated reduction from 7 hours to 4.4 hours in the burden hours needed to complete the application process. Overall, the burden for Agreement States will decrease by 32,586 hours from 89,082 to 56,496 hours.

The total estimated burden for completing NRC Form 313 and 313A will decrease by 47,122 hours, from 117,144 to 70,022 hours. The hourly cost has increased from $152 to $156 per hour.

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

70,022 burden hours for 15,914 responses (13,526 burden hours for 3,074 NRC licensees plus 56,496/12,840 Agreement State licensees.)

15,914 respondents (3,074 NRC licensees plus 12,840 Agreement State licensees.)

The burden decreased due to a reduction in the actual number of licensing actions received (downward adjustment of 5,746 hours) and a reduction in the number of hours to complete an application from 7 hours to 4.4 hours (programmatic reduction of 41,376 hours).

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 313A.

18. Exceptions to the Certification Statement

There are no exceptions.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Not applicable.