

Draft Supporting Statement
for
NRC Form 313
Application for Material License
and
NRC Form 313A
Training and Experience and Preceptor Statement

(3150-0120)

Revision to Clearance Extension Request

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 "Training and Experience and Preceptor Statement," 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 Forms 313A and 313B were approved by OMB in November 2001. NRC Forms 313A and 313B have been combined as NRC Form 313A to align with the new requirements of 10 CFR Part 35. The NRC Form 313A adds a section for one-year full-time training/work experience for the radiation safety officer and the medical physicists. In addition, the certification was added to the Preceptor Statement.

A final rule amending 10 CFR Part 35 entitled, "Medical Use of Byproduct Material," was issued October 2001. This final rule is being revised to allow licensees, as an alternative to the revised training and experience requirements in Subparts B and D-H, to continue to use the current Subpart J training and experience requirements for a period of two years.

This final rule also adds new burden for emerging medical use technologies (new modalities). Emerging technologies are those uses not currently included in Subparts C, D, E, F, G, H, and I of 10 CFR Part 35. The regulatory differences between the new technologies and existing well-defined medical uses may range from minimal to extensive. The elements for a radiation safety program that need to be addressed for new modalities include, but are not limited to: Authorized user training and experience, authorized physicist training and experience; definitions of output, prescribed dosage, and prescribed dose; information needed in the written directive: development of new procedures for administrations if a written directive is needed; facility diagram, equipment identification and description; radiation safety precautions and instructions; methodology for measurement of dosages or doses to be administered to patients or human research subjects; calibration, maintenance, and repair of instruments and equipment necessary for radiation safety; measurement of source leakage; labeling of syringes, syringe shields, vials and vial shield for unsealed radioactive material or radioactive materials in such containers that are not radioactive drugs.

A. JUSTIFICATION

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

10 CFR Sections 30.32, 30.37, 30.38, 32.11, 33.12, 34.11, 35.12, 35.13, 35.50, 35.51, 35.55, 35.190, 35.290, 35.292, 35.390, 35.392, 35.394, 35.490, 35.491, 35.590, 35.690, 35.981, 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."

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 with the use of information technology. However, there are no current information technology applications that would reduce the burden of these information collection requirements. The NRC encourages applicants and licensees to use new automated information technology when it would be beneficial to them. However, because of the types of information and the infrequency of submission, the applications may not lend themselves readily to the use of automated information technology for their submission. Consequently, the current percentage of electronic submission is zero.

4. Effort to Identify Duplication and Use Similar Information

The Information Requirements Control Automated System was searched to determine duplication. None was found. The 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 has been published in the Federal Register.

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 2.790 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

Information for determining the burden associated with the use of NRC Forms 313 and 313A is based on information on the number of licensing actions in fiscal 2001. There were 269 new, 2,819 amendment, and 655 renewal applications for the possession, use, and initial distribution of byproduct and source material received during fiscal 2001, for a total of 3,743 licensing actions. It is estimated that each applicant will spend an average of 7 hours to prepare the health and safety elements of an application.

Based on 3,743 licensing actions per year for recordkeeping, the industry burden for licensing is estimated to be 26,201 hours (7 hrs/licensing action x 3,743 licensing actions). The average annual cost to each respondent to comply with the information collection requirements is estimated to be \$1,008 (7 hrs per respondent x \$144 /hr). The annual cost to all affected licensees is estimated to be \$3,772,944 (26,201 hrs x \$144/hr).

B. Agreement State Licensees

NRC estimates that there are approximately 2.5 times the number of Agreement State licensees as there are NRC licensees. Agreement States are not implementing a rule allowing for a one-time five-year extension of certain byproduct, source, and special nuclear materials licenses. Therefore, for Agreement State licensees, it is estimated that there are 9,357 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 industry recordkeeping burden for licensing is estimated to be 65,499 hours (9,357 licensing action x 7 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 \$9,431,856 (65,499 hrs x \$144/hr).

C. New Modalities

When submitting an application or an amendment for an emerging technology the applicant needs to provide information on the NRC Form 313 about the technology, radiation safety considerations, training and experience, and unique regulatory aspects that are not covered in existing guidance or by the savings in NUREG 1556, Vol 9. Therefore, it is estimated that it takes 18 hours to complete the Form 313 for emerging technologies. This value should be considered an average between the hours needed to describe an emerging technology that is almost identical to an existing medical use and one that is vastly different.

There should be more medical devices than radioactive drugs falling under the emerging technology umbrella, because the regulations for radioactive drugs are written loosely enough to encompass new drugs that may otherwise be considered an emerging technology. It is estimated that about 5 percent of all

medical use licensees with quality management programs may request use of an emerging technology each year, therefore, approximately 54 medical use applications are anticipated for new modalities ($0.05 \times 1,080$). The estimated burden for emerging technologies is 972 (18×54).

The estimated annual cost for new modalities for some medical use licensees to submit a new application and a renewal is \$139,968 ($972 \text{ hrs} \times \$144/\text{hr}$).

The total estimated burden for NRC licensees, Agreement States, and New Modalities is 92,672 hours ($26,201 + 65,499 + 972$) at a cost of \$13,344,786 ($\$3,772,944 + \$9,431,856 + \$139,968$).

13. Estimate of Other Additional Cost

NRC has determined that the storage and equipment costs per foot are approximately \$45. The quantity of records to be maintained is roughly proportional to the recordkeeping burden. Based on the number of pages maintained for a typical clearance, the records storage cost has been determined to be equal to 0.4 percent of the recordkeeping burden cost. Therefore, the storage cost for this clearance is \$37.06 which is insignificant ($26,201 \text{ recordkeeping hours for NRC licensees} + 65,499 \text{ hours for Agreement State licensees and } 972 \text{ hours for new modalities} = 92,672 \text{ recordkeeping hours} \times .0004 = 37.06$).

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 7 hours per application. Based on an anticipated 3,743 licensing actions per year, at a cost of \$144 per hour, the cost to perform the licensing review would be \$3,772,944 ($3,743 \text{ licensing actions} \times 7 \text{ hrs/licensing action} \times \$144/\text{hr}$). 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 overall estimated burden increased from 67,325 to 92,672 because of the following: (1) the burden for licensee licensing actions increased from 18,856 to 26,201 hours because the actual number of NRC licensing actions received increased from 2,694 to 3,743; (2) the burden for Agreement State licensing actions also increased from 48,469 to 65,499 hours because the actual number of licensing actions received increased from 6,924 to 9,357; and (3) the estimated addition of 54 medical use licensees for 10 CFR Part 35 New Modalities increased the burden by 972 hours. The hourly cost has increased from \$121 to \$144 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 313A.

18. Exceptions to the Certification Statement

There are no exceptions.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Not applicable.