

Final 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 April 24, 2002 (67 FR 20249, with an effective date of October 24, 2002). 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 30.15, 30.19, 30.20, 30.32, 30.36, 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 was published in the Federal Register on April 30, 2002 (67 FR 21281). Twenty-six comments were received. The following provides the comments received and the NRC response to each.

Comment 1:

Since the final rule allows for a two-year transition for the existing subpart J training and experience requirements, American College of Radiology (ACR) recommends that NRC review Form 313A when a decision is reached on the final training and experience requirements.

Response:

Any change to the requirements that results in a corresponding change in the information collected will be addressed when a final decision is made.

Comment 2:

In view of the proposed changes in Training and Experience requirements, the American Association of Physicists in Medicine (AAPM) suggests the NRC delay the implementation of the new form.

Response:

The form needs to be available for use when the New Part 35 takes effect on October 24, 2002. If the proposed changes currently being discussed are finalized, the NRC Form 313A will be evaluated to see if modifications are needed to conform to regulatory changes. This process is not expected to be complete before the New Part 35 takes effect especially considering the time needed to both reach a consensus on changes to the training and experience requirements and conform with the Administrative Procedures Act to revise these requirements.

Comment 3:

Form 313A is extremely confusing and should be separated into separate forms for the categories of Authorized User, Authorized Medical Physicist, Authorized Nuclear Pharmacist and Radiation Safety Officer (RSO).

Response:

Separate forms for the Radiation Safety Officer, Authorized Medical Physicists, and the Authorized Nuclear Pharmacist may reduce the confusion for these groups; however, the forms would have considerable overlap. Most of the complexity of the forms is due to the five unique sets of requirements for the Authorized Users and the two year extension of the training and experience requirements in 10 CFR Part 35, Subpart J.

Further, there is considerable overlap in certain areas of the form (i.e., professional board certification, radiation safety classroom and laboratory topics, supervised work experience areas, and preceptor statements) for each group. This makes it more efficient to develop one form instead of the eight individual forms needed to document training and experience of the individuals applying for authorized status under each unique set of requirements. Therefore, the form will not be separated into separate forms. Clarifying information will be provided in NUREG-1556, Volume 9, "Consolidated Guidance About Materials Licenses: Program Specific Guidance About Medical Use Licenses," to assist individuals, applicants and licensees with filling out the form. The NUREG is currently under revision and will be available before the effective date of the rule.

Comment 4:

As drafted, it will be difficult to have one form satisfy the various training and experience requirements for authorized users, authorized nuclear pharmacists, and authorized medical physicists.

Response:

As written the form does provide a standard format for the four different professional groups (including the nine different types of authorized users) to record their training and experience. There is a place for the applicant to address each requirement that needs to be documented.

Comment 5:

Overall this document is overly complex and confusing for cardiologists who are applicants for authorized user status or preceptors.

Response:

The NRC recognizes that NRC Form 313A is complex because it is intended to be used to record the training and experience of four distinct professional groups, i.e., physicians, medical physicists, nuclear pharmacists, and radiation safety officers. Further, the physicians can be divided into 9 additional groups based upon the particular medical use they are seeking authorized user status for. Additional instructions will be provided in NUREG-1556, Volume 9, "Consolidated Guidance About Materials Licenses: Program Specific Guidance About Medical Use Licenses," on how to fill-out the form to make this task easier; the NUREG is currently under revision and will be available before the effective date of the rule.

Comment 6:

Part 1, "Training and experience," Item 1, "Name of individual, Proposed Authorization (e.g., Radiation Safety Officer) and Applicable Training Requirements (e.g., 10 CFR 35.50)" perhaps other "e.g.," examples could be used, such as those applying for an authorized user license.

Response:

Clarifying information will be provided in NUREG-1556, Volume 9.

Comment 7:

Part 1, "Training and experience," Item 2 for Physicians, Podiatrists, Dentists, Pharmacists -- State or Territory Where Licensed," add "to practice" after licensed to clarify that the question refers to a medical license or allied health professional license.

Response:

NRC requires physicians, podiatrist, dentists, and pharmacists to be licensed to prescribe drugs in the practice of medicine, to practice podiatry, to practice dentistry, or practice pharmacy respectively. It does not require these individual to be licensed to practice in the State, Territory, District of Columbia, or Commonwealth of Puerto Rico in which they are located. NRC's Federal Licensees may require these professionals to be licensed but because they practice only on Federal Facilities, they may not be required to be licensed in the State where they are assigned. Further, NRC makes it clear that licensees are not relieved from complying with the applicable requirements governing radioactive drugs or devices by the States.

Comment 8:

Part 1, "Training and experience," Item 2, "For Physicians, Podiatrists, Dentists, Pharmacists -- State or Territory Where Licensed," the form as written recognizes

licensure for Physicians, Podiatrists, Dentists, Pharmacists, but does not recognize licensure for licensed physicists.

Response:

The form does not include the medical physicist in Item 2 because NRC regulations do not require the authorized medical physicist to be licensed. Inclusion of the medical physicist in Item 2 could be interpreted as a requirement that is not supported by a regulatory requirement.

Comment 9:

Part 1, "Training and experience," Item 3, "Certification," it is unclear what is meant by this category. Some guidance is needed here.

Response:

Some specialty boards have multiple subspecialties such as board certifications by the American Osteopathic Board of Radiology in Diagnostic Radiology or Radiology or board certifications by the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology. The particular requirements for some subspecialties may not be sufficient to meet the training and experience requirements for another subspecialty. Clarifying information will be provided in NUREG-1556, Volume 9.

Comment 10:

Part 1, "Training and experience", Item 3, "Certification," many physicians' boards have rather lengthy titles which do not fit in the Specialty Board column. As the month and year certified can be clearly written in as little as five characters (e.g. AUG99), the proportions of the columns should be adjusted.

Response:

The size of the columns was adjusted.

Comment 11:

Part 1, "Training and experience," Item 4, "Didactic or Classroom and Laboratory training (Optional for Medical Physicists)," applicants will generally misunderstand the form and try to fill in the detailed information concerning training and experience that was required in the past (as well as perhaps misunderstanding the rule's new requirements).

Response:

Until October 25, 2004, the applicant may apply for authorized user, authorized nuclear pharmacists, authorized medical physicists or radiation safety officer status by meeting either the training and experience requirements of 10 CFR Part 35, Subpart B, "General Administrative Requirements," Subpart D, "Unsealed byproduct material - written directive not required," Subpart E, "Unsealed byproduct material - written directive required," Subpart F, "Manual brachytherapy," Subpart G, "Sealed sources for

diagnosis,” Subpart H, “Photon -emitting remote afterloaders units, teletherapy units, and gamma stereotactic radiosurgery units,” or Subpart J, “Training and Experience requirements. Therefore, if the applicant elects to seek authorized user, authorized nuclear pharmacists, authorized medical physicists or radiation safety officer status under Subpart J, the same detailed information needs to be provided that was provided prior to the revision of 10 CFR Part 35. NRC Form 313A was designed to document this information as well as the new requirements in the Subparts B, D, E, F , G, and H. Clarifying information will be provided in NUREG-1556, Volume 9.

Comment 12:

Part 1, “Training and experience,” Item 4, “Didactic or Classroom and Laboratory training (Optional for Medical Physicists),” the entry for “Chemistry of byproduct Material for Medical Use” is not appropriate because "Chemistry" is not a subject that has radiation safety relevance for these users. For Nuclear Medicine, "radiopharmacy" (i.e., dosages, dosimetry, radiopharmaceutical QA) would be more appropriate. Another suggestion might be "internal/external dosimetry," which could apply to all categories.

Response:

The term “chemistry” and not “radiopharmacy” appears in 10 CFR Parts 35.55, 35.190, 35.290, 35.390. These sections specifically require the individual to have classroom and laboratory training in “Chemistry of byproduct material for medical use.”

Comment 13:

Part 1, “Training and experience,” Item 4, “Didactic or Classroom and Laboratory training (Optional for Medical Physicists)” a parenthetical phrase should be added to “OTHER” indicating that it is not applicable for diagnostic authorized user candidates.

Response:

Clarifying information will be provided in NUREG-1556, Volume 9.

Comment 14:

Part 1, “Training and experience,” Item 4, “Didactic or Classroom and Laboratory training (Optional for Medical Physicists).” This portion of the document makes it appear that the 200 hour didactic course requirement is still in place. It would be nearly impossible to give the information you ask for in this section without a didactic course. The blocks on location, clock hours, and dates of training should be eliminated in favor of one block that the preceptor may check labeled “requirement satisfied.”

Response:

This part of the form is used to record either the “didactic” or “classroom and laboratory” training of the physicians, nuclear pharmacists, and radiation safety officers. In some cases the requirement is for “didactic training” and in others it is for “classroom and laboratory training.” The nuclear cardiologist is required by 10 CFR 35.290 to have a total of 700 hours of training and experience that includes “classroom and laboratory

training,” and “work experience.” The applicant has to demonstrate that they have a total of 700 hours and that among those hours are hours for the subjects listed in Item 4. Clarifying information will be provided in NUREG 1556, Volume 9. Different combinations of hours of training on topics important to safety may be used to satisfy the requirement for a total of 700 hours, and that at least some time in the total of 700 hours was devoted to each of the required topics detailed under Items 5a and 5b. The “location” and “clock hours” columns are intended to aid the applicant in documenting completion documentation of the requirements and provide flexibility for those that received the “classroom and laboratory” training on the subjects identified at different times and different locations.

Comment 15:

Part 1, “Training and experience,” Item 5a, “Work experience with Radiation,” should list the various categories for Authorized Medical Physicist activities. This would allow the individual to document his/her training in each specialty requested.

Response:

The entries in the “Description of Experience” column were left blank so that the applicant could list the specific work experience requirements that need to be met. Therefore, Item 5 could be used to document the various categories of authorized medical physicist activities.

Comment 16:

Part 1, “Training and experience,” Item 5b., “Supervised Clinical Case Experience” Page two, number 5b add “therapeutic only” after Supervised Clinical Case Experience. Otherwise this part of the document will be confusing to those applying for a diagnostic authorized user license.

Response:

While the requirement for a specific number of cases is required for therapeutic uses (10 CFR §§ 35.390, 392, 394, 491, 930, 932, 934, and 941), some facilities may find it convenient to document “administering dosages of radioactive drugs to patients or human research subjects” in this space and as well as demonstrating adequate experience in the use of materials under 35.1000. Clarifying information will be provided in NUREG 1556, Volume 9.

Comment 17:

Part 1, “Training and experience”, Item 5, Work Experience with Radiation,” should be clarified to indicate that the use of “Clock Hours” is not relevant to medical physicist or RSO training & experience.

Response:

The “clock hours” columns are intended to aid the applicant in documenting completion of the requirements. If the medical physicist or radiation safety officer applicant

completed his/her work experience in one location, he/she may use either Part 1, Item 7 or Item 8, as appropriate, to document the one-year full time training/work experience. If however that training/work experience was obtained at more than one location, the applicant has the flexibility to record time that may add up to one-year full-time in item 5.

Comment 18:

Part 1, "Training and experience", Item 5, Work Experience with Radiation," the term Supervising Individual should be defined as this is not a term used in the regulation.

Response:

Although the term "supervising individual" is not specifically used in the regulations, it is used in the form to designate the person referred to in the phrase "under the supervision of an authorized user who meets the requirements of ... (individual identified as an RSO, individual meeting the requirements of an authorized medical physicist) in the supervised "clinical training" or "work experience" sections of the requirements in §§ 35.50, 35.51, 35.190, 35.290, 35.390, 35.392, 35.394, 35.490, 35.491, and 35.690. Further, the requirements in 10 CFR Part 35 Subpart J require experience (either work or clinical as appropriate) under the supervision of a Radiation Safety Officer, authorized user, or medical physicist, as appropriate.

Comment 19:

Part 1, "Training and experience", Item 5, Work Experience with Radiation," it is unclear what the requirements are for a Supervising Individual.

Response:

The requirements of the supervising individual are provided in the regulations for each appropriate section. The requirement for the supervising individual are specified in the supervised "clinical training" or work experience parts of §§ 35.50, 35.51, 35.190, 35.290, 35.390, 35.392, 35.394, 35.490, 35.491, and 35.690. Further, the requirements in 10 CFR Part 35, Subpart J, require experience (either work or clinical as appropriate) under the supervision of a Radiation Safety Officer, authorized user, or medical physicist, as appropriate.

Comment 20:

Part 1 "Training and experience," Item 7, "Radiation Safety Officer -- One-Year Full-Time Training/Work Experience," the word time is misspelled.

Response:

The correction has been made.

Comment 21:

Part 1, "Training and experience", Item 9, "Supervising Individual - Identification and Qualifications," and Part II, "Preceptor Statement," Item 12, "Preceptor Approval and

Certification," clarify who is the preceptor and who is the supervisor and why two attestations are required. Number 9 now requires the signature of a "supervising individual" but no definition is given.

Response:

The requirements in 10 CFR Part 35 paragraphs 35.50, 35.51, 35.190, 35.290, 35.390, 35.392, 35.394, 35.490, 35.491, 35.690 require "full-time radiation safety experience," "work experience," or "supervised clinical experience" under the supervision of a specifically qualified individual. The requirements in 10 CFR Part 35 Subpart J require experience (either work or clinical as appropriate) under the supervision of a Radiation Safety Officer, authorized user, or medical physicist, as appropriate.

Item 9 provides the applicant a place to identify the supervising individual, the supervisor's qualifications required in the regulation, and identify the license number and location where the supervising individual works. The regulations do not require the supervising individual to be the same person that provides the preceptor statement in 10 CFR Part 35 paragraphs 35.50, 35.55, 35.51, 35.190, 35.290, 35.390, 35.392, 35.394, 35.490, 35.491, 35.690. and 35.980. Further, the regulations do not require the supervising individual to attest to the "work experience" or "clinical experience" documented in Items 5a and 5b. Two attestations are not required because Item 9 does not include a signature block.

Item 12 provides the preceptor a place to certify the applicant has completed the training and experience requirements and is competent to function independently in the appropriate Radiation Safety Officer, authorized nuclear pharmacist, medical physicist, or user position and that the preceptor meets the requirements to be a preceptor for that particular use of byproduct material.

If the supervising individual and the preceptor are the same individual, then the information only has to be provided once.

Comment 22:

Part II, "Preceptor Statement," Item 10 refers to "independently operate a nuclear pharmacy" but the regulations do not use this term. Change to "function as a nuclear pharmacist."

Response:

There are two different preceptor statements for the applicant seeking to be an authorized nuclear pharmacist. The preceptor statement in §35.55 says "function as a nuclear pharmacist," and the preceptor statement in § 35.980 (which is still in the regulations for 2 years) says "independently operate a nuclear pharmacy." The Note above Item 10 explains the preceptor statement in Item 10 that must be used for nuclear pharmacists meeting the requirements of Subpart J and Item 11 is used for nuclear pharmacists meeting the requirements of §35.55 (as well as all other individuals for which a preceptor statement is required).

Comment 23:

NUREG-1556, Volume 9, Appendix G: NRC Forms 313A and 313B. This section should be redrafted to reflect that the existing Subpart J is valid for a two-year transition period.

Response:

The current regulation permits the use of 10 CFR Part 35, Subpart J until October 25, 2004. The NRC is currently examining how to address the training and experience requirement issues associated with the specialty boards listed in Subpart J. The form reflects the current training and experience requirements in the new rule and will be modified as necessary if the NRC determines that changes are needed.

Comment 24:

At a minimum the form should indicate that medical physicists are licensed in some states.

Response:

NRC does not require medical physicists to be licensed and adding a requirement for the licensing of medical physicists to the form may be considered imposing a requirement on licensees that is not in the regulations. No change will be made to the form.

Comment 25:

The NRC needs to make these forms capable of being completed electronically via a personal computer (PC). Current forms can be printed out via PC but cannot be completed electronically.

Response:

NRC is developing electronic versions of the form which will be made available on the NRC web site around October 2003.

Comment 26:

Estimated Burden and Burden Hour Cost - NRC should provide an explanation of the basis for their assumption that "each applicant will spend an average of 7 hours to prepare the health and safety elements of an application." From experience, it takes MUCH longer than seven hours (< 1 day) to prepare a license application especially for broad scope medical licenses. Based on NRC's cost figures, a one-hour increase in preparation time is a 14% increase in the ANNUAL cost estimate. That is \$539,000 to NRC licensees and \$1.3 Million to Agreement States annually just for licensing costs.

Response:

The estimated burden for NRC Form 313A is a part of the overall burden for completing NRC Form 313. The burden for NRC Form 313 is based on the average burden for all NRC licensees. NRC has a significant number of licensees in its material use program

that can complete the NRC Form 313 in much less than 7 hours and a smaller number of licensees with larger programs that require much more than 7 hours to complete the tasks. The NRC used the 7 hour estimate as an average.

The NRC Form 313A is only used for a small percentage of all NRC licensees and within that group, it is only needed the first time a person seeks recognition by NRC as an authorized user, authorized nuclear pharmacist, authorized medical physicist or radiation safety officer. Once an individual is listed on a license, they are no longer required to complete the Form.

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

The burden associated with the use of NRC Forms 313 and 313A is based on the number of licensing actions processed during fiscal year 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, 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 \$1,064 (7 hrs per respondent x \$152/hr). The annual cost to all affected licensees is estimated to be \$3,982,552 (26,201 hrs x \$152/hr).

B. Agreement State Licensees

NRC estimates that there are approximately 3.4 times the number of Agreement State licensees as there are NRC licensees. The change from 2.5 to 3.4 is based on the most recent number of actual Agreement State and NRC byproduct material 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 12,726 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 States licensees is estimated to be 89,082 hours (12,726 licensing actions 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 \$13,540,464 (89,082 hrs x \$152/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 X 1,080). The estimated burden for emerging technologies is 972 hours (18 X 54).

The estimated annual cost for new modalities for some medical use licensees to submit a new application and a renewal is \$147,744 (972 hrs x \$152/hr).

The total estimated burden for NRC licensees, Agreement States, and New Modalities is 116,255 hours (26,201 + 89,082 + 972) at a cost of \$17,670,760 (\$3,982,552 + \$13,540,464 + \$147,744).

13. Estimate of Other Additional Cost

There are 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 7 hours per application. Based on an anticipated 3,743 licensing actions per year, at a cost of \$152 per hour, the cost to perform the licensing review would be \$3,982,552 (3,743 licensing actions x 7 hrs/licensing action x \$152/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 116,255 hours 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 89,082 hours because the actual number of licensing actions received increased from 6,924 to 12,726; this increase is a result of the increase in the ratio of Agreement State licensees to NRC licensees, 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 \$152 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.