

**OMB SUPPORTING STATEMENT
FOR PROPOSED AMENDMENT TO
10 CFR PART 35
MEDICAL USE OF BYPRODUCT MATERIAL -
RECOGNITION OF SPECIALTY BOARDS
(3150-0010)
AND BURDEN REVISION TO
NRC FORM 313A,
TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT
(3150-0120)**

DESCRIPTION OF THE INFORMATION COLLECTION

The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations governing the medical use of byproduct material to change its requirements for recognition of medical specialty boards whose certifications may be used to demonstrate the adequacy of the training and experience (T&E) of individuals to serve as radiation safety officers (RSOs), authorized medical physicists (AMPs), authorized nuclear pharmacists (ANPs), or authorized users (AUs). This rulemaking is necessary to address issues identified by the Advisory Committee on Medical Uses of Isotopes (ACMUI) including the issue of medical specialty boards' certification programs not meeting the requirements in the current regulations regarding preceptor certification and work experience. The proposed regulations were developed following consultations with the ACMUI, specialty boards, the Agreement States, and other members of the public.

Current regulations require individuals to have adequate T&E before working as RSOs, AMPs, ANPs, or AUs. Licensees must demonstrate that individuals meet the T&E requirements through either board certification by a specialty board recognized by the NRC or an Agreement State (called the certification pathway) or through meeting the explicit T&E requirements in the regulations (called the alternate pathway).

The proposed rule would also revise requirements for some of the alternate pathways. Most of these changes are minor and would clarify the requirements for training and experience. The proposed rule would incorporate a recommendation from the ACMUI that, in addition to meeting minimum training and experience requirements, authorized individuals should have training or experience in the use of byproduct material or specific modalities (types of use), as appropriate, for which a licensee is authorized. This requirement is necessary to ensure that a licensee's staff has adequate training to fulfill the duties for which they are responsible.

The current regulations also require each individual to obtain a written certification, signed by a preceptor (preceptor statement), that the individual has completed the T&E requirements and has achieved a sufficient level of competency to function independently as an RSO, AMP, ANP, or AU. Applicants for licenses and amendments to licenses must currently submit preceptor statements to the NRC or an Agreement State only when individuals meet the T&E requirements for RSOs, AMPs, ANPs or AUs through the alternate pathway and not when individuals meet the T&E requirements through the certification pathway.

Under the proposed regulations, the NRC would amend § 35.14(a) to add a requirement for licensees to submit preceptor statements to the NRC or an Agreement State when an individual meets the T&E requirements through the certification pathway.

This clearance package also covers the burden for a specialty board to submit an application to be recognized by the NRC or an Agreement State that the board's certification process constitutes recognized training. Submission of an application letter by a specialty board for recognition is expected to be a one-time burden.

A. Justification

10 CFR Part 35 requires that licensees only permit individuals to work as RSOs, AMPs, ANPs, or AUs if the individuals meet requirements for T&E to ensure that the individuals possess adequate knowledge and experience to fulfill the duties for which they are responsible. The reports required by 10 CFR Part 35 are the least burdensome way for licensees to demonstrate compliance with the NRC's requirements.

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

§ 35.13 License amendments

Section 35.13(b) indicates the excepted categories of authorized individuals for which the licensee does not have to submit a license amendment. The proposed rule would make conforming changes to this section to align all references to other sections that are being moved or modified by the proposed rule. There is no change in the current burden which is cleared under OMB Clearance No. 3150-0120.

§ 35.14 Notifications

Section 35.14(a) requires that licensees provide to the Commission a copy of the board certification, the Commission or Agreement State license, the permit issued by an NRC master material licensee, the permit issued by a licensee of broad scope, or the permit issued by an NRC master material license broad scope permittee for each individual no later than 30 days after the date the licensee permits the individual to work as an AMP, ANP, or AU. Under the proposed rule, licensees would also be required to provide the Commission a copy of a written certification signed by a preceptor (preceptor statement) for board-certified individuals. This information is required so that the NRC can determine whether the licensee has individuals with adequate T&E to use byproduct material safely.

The proposed rule burden for licensees to submit preceptor statements for board-certified individuals is included in Table 1 as a revision to the clearance for 10 CFR Part 35 (OMB Clearance No. 3150-0010).

§ 35.50 Training for Radiation Safety Officer

Sections 35.50(c) and 35.50(d)(2)(ii): Section 35.50(a) of the current rule requires specialty boards to meet specific criteria that include obtaining preceptor statements from certification candidates. The proposed rule would eliminate the requirement for specialty boards to obtain preceptor statements and instead, in §§ 35.50(c) and 35.50(d)(2)(ii), would require board-

certified individuals to obtain preceptor statements for submission to the NRC or an Agreement State under proposed § 35.14(a). This preceptor statement is necessary to ensure that an individual fulfilling the responsibilities of an RSO has met the necessary T&E requirements in § 35.50.

The burden under the proposed rule for a board-certified individual to obtain the preceptor statement is included in Tables 3 (NRC licensees) and 4 (Agreement State licensees) as a revision to the clearance for NRC Form 313A (OMB Clearance No. 3150-0120).

Section 35.50(e): Section 35.50(e) of the proposed rule would require an individual seeking authorization as an RSO to have training in the radiation safety, regulatory issues, and emergency procedures for the type(s) of use for which a licensee seeks approval.

A description of the training meeting the new requirements of proposed § 35.50(e) would be submitted as part of a licensee's application under §§ 35.12 and 35.13 together with the preceptor statement. Review of the training specific to the type(s) of use is necessary to ensure that an individual has adequate training to fulfill the duties for which they are responsible.

The burden for a licensee to report an individual's training that meets the new requirement of proposed § 35.50(e) is included in Tables 3 (NRC licensees) and 4 (Agreement State licensees) as a revision to the clearance for NRC Form 313A (OMB Clearance No. 3150-0120) as part of the estimated burden for the preceptor statement and type of use training.

§ 35.51 Training for an authorized medical physicist

Section 35.51(c): Section 35.51(a) of the current rule requires specialty boards to meet specific criteria that include obtaining preceptor statements from certification candidates. The proposed rule would eliminate the requirement for specialty boards to obtain preceptor statements and instead, in § 35.51(c), would require board-certified individuals to obtain preceptor statements for submission to the NRC or an Agreement State under proposed § 35.14(a). This preceptor statement is necessary to ensure that an individual fulfilling the responsibilities of an AMP has met the necessary T&E requirements in § 35.51.

The burden under the proposed rule for a board-certified individual to obtain the preceptor statement is included in Tables 3 (NRC licensees) and 4 (Agreement State licensees) as a revision to the clearance for NRC Form 313A (OMB Clearance No. 3150-0120).

Section 35.51(d): Section 35.51(d) of the proposed rule would require an individual seeking authorization as an AMP to have training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system.

A description of an individual's training meeting the new requirements of proposed § 35.51(d) would be submitted as part of a licensee's application under §§ 35.12 and 35.13 together with the preceptor statement. Review of the training specific to the type(s) of use is necessary to ensure that an individual has adequate training to fulfill the duties for which they are responsible.

The burden for a licensee to report an individual's training that meets the new requirement of proposed § 35.51(d) is included in Tables 3 (NRC licensees) and 4 (Agreement State licensees) as a revision to the clearance for NRC Form 313A (OMB Clearance No. 3150-0120) as part of the estimated burden for the preceptor statement and type of use training.

§ 35.55 Training for an authorized nuclear pharmacist

Section 35.55(c): Section 35.55(a) of the current rule requires specialty boards to meet specific criteria that include obtaining preceptor statements from certification candidates. The proposed rule would eliminate the requirement for specialty boards to obtain preceptor statements and instead, in § 35.55(c), would require board-certified individuals to obtain preceptor statements for submission to the NRC or an Agreement State under proposed § 35.14(a). This preceptor statement is necessary to ensure that an individual fulfilling the responsibilities of an ANP has met the necessary T&E requirements in § 35.55.

The burden under the proposed rule for a board-certified individual to obtain the preceptor statement is included in Tables 3 (NRC licensees) and 4 (Agreement State licensees) as a revision to the clearance for NRC Form 313A (OMB Clearance No. 3150-0120).

§ 35.190 Training for uptake, dilution, and excretion studies

Section 35.190(a): Section 35.190(a) of the current rule requires specialty boards to meet specific criteria that include obtaining preceptor statements from certification candidates. The proposed rule would eliminate the requirement for specialty boards to obtain preceptor statements and instead would require board-certified individuals to obtain preceptor statements for submission to the NRC or an Agreement State under proposed § 35.14(a). This preceptor statement is necessary to ensure that an individual fulfilling the responsibilities of an AU has met the necessary T&E requirements in § 35.190.

The burden under the proposed rule for a board-certified individual to obtain the preceptor statement is included in Tables 3 (NRC licensees) and 4 (Agreement State licensees) as a revision to the clearance for NRC Form 313A (OMB Clearance No. 3150-0120).

§ 35.290 Training for imaging and localization studies

Section 35.290(a): Section 35.290(a) of the current rule requires specialty boards to meet specific criteria that include obtaining preceptor statements from certification candidates. The proposed rule would eliminate the requirement for specialty boards to obtain preceptor statements and instead would require board-certified individuals to obtain preceptor statements for submission to the NRC or an Agreement State under proposed § 35.14(a). This preceptor statement is necessary to ensure that an individual fulfilling the responsibilities of an AU has met the necessary T&E requirements in § 35.290.

The burden under the proposed rule for a board-certified individual to obtain the preceptor statement is included in Tables 3 (NRC licensees) and 4 (Agreement State licensees) as a revision to the clearance for NRC Form 313A (OMB Clearance No. 3150-0120).

§ 35.390 Training for use of unsealed byproduct material for which a written directive is required

Section 35.390(c): Section 35.390(a) of the current rule requires specialty boards to meet specific criteria that include obtaining preceptor statements from certification candidates. The proposed rule would eliminate the requirement for specialty boards to obtain preceptor statements and instead, in § 35.390(c), would require board-certified individuals to obtain preceptor statements for submission to the NRC or an Agreement State under proposed § 35.14(a). This preceptor statement is necessary to ensure that an individual fulfilling the responsibilities of an AU has met the necessary T&E requirements in § 35.390.

The burden under the proposed rule for a board-certified individual to obtain the preceptor statement is included in Tables 3 (NRC licensees) and 4 (Agreement State licensees) as a revision to the clearance for NRC Form 313A (OMB Clearance No. 3150-0120).

§ 35.392 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries)

Section 35.392(a): Section 35.392(a) of the current rule requires specialty boards to meet specific criteria that include obtaining preceptor statements from certification candidates. The proposed rule would eliminate the requirement for specialty boards to obtain preceptor statements and instead would require board-certified individuals to obtain preceptor statements for submission to the NRC or an Agreement State under proposed § 35.14(a). This preceptor statement is necessary to ensure that an individual fulfilling the responsibilities of an AU has met the necessary T&E requirements in § 35.392.

The burden under the proposed rule for a board-certified individual to obtain the preceptor statement is included in Tables 3 (NRC licensees) and 4 (Agreement State licensees) as a revision to the clearance for NRC Form 313A (OMB Clearance No. 3150-0120).

§ 35.394 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries)

Section 35.394(a): Section 35.394(a) of the current rule requires specialty boards to meet specific criteria that include obtaining preceptor statements from certification candidates. The proposed rule would eliminate the requirement for specialty boards to obtain preceptor statements and instead would require board-certified individuals to obtain preceptor statements for submission to the NRC or an Agreement State under proposed § 35.14(a). This preceptor statement is necessary to ensure that an individual fulfilling the responsibilities of an AU has met the necessary T&E requirements in § 35.394.

The burden under the proposed rule for a board-certified individual to obtain the preceptor statement is included in Tables 3 (NRC licensees) and 4 (Agreement State licensees) as a revision to the clearance for NRC Form 313A (OMB Clearance No. 3150-0120).

§ 35.490 Training for use of manual brachytherapy sources

Section 35.490(c): Section 35.490(a) of the current rule requires specialty boards to meet specific criteria that include obtaining preceptor statements from certification candidates. The proposed rule would eliminate the requirement for specialty boards to obtain preceptor

statements and instead, in § 35.490(c), would require board-certified individuals to obtain preceptor statements for submission to the NRC or an Agreement State under proposed § 35.14(a). This preceptor statement is necessary to ensure that an individual fulfilling the responsibilities of an AU has met the necessary T&E requirements in § 35.490.

The burden under the proposed rule for a board-certified individual to obtain the preceptor statement is included in Tables 3 (NRC licensees) and 4 (Agreement State licensees) as a revision to the clearance for NRC Form 313A (OMB Clearance No. 3150-0120).

§ 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units

Section 35.690(c): Section 35.690(a) of the current rule requires specialty boards to meet specific criteria that include obtaining preceptor statements from certification candidates. The proposed rule would eliminate the requirement for specialty boards to obtain preceptor statements and instead, in § 35.690(c), would require board-certified individuals to obtain preceptor statements for submission to the NRC or an Agreement State under proposed § 35.14(a). This preceptor statement is necessary to ensure that an individual fulfilling the responsibilities of an AU has met the necessary T&E requirements in § 35.690.

The burden under the proposed rule for a board-certified individual to obtain the preceptor statement is included in Tables 3 (NRC licensees) and 4 (Agreement State licensees) as a revision to the clearance for NRC Form 313A (OMB Clearance No. 3150-0120).

Section 35.690(d): Section 35.690(d) of the proposed rule would require an individual seeking authorization as an AU to have received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. A description of the training meeting the new requirements of proposed § 35.690(d) would be submitted as part of a licensee's application under §§ 35.12 and 35.13 together with the preceptor statement. Review of the training specific to the type(s) of use is necessary to ensure that an individual has adequate training to fulfill the duties for which they are responsible.

The burden for a licensee to report an individual's training that meets the new requirement of proposed § 35.690(d) is included in Tables 3 (NRC licensees) and 4 (Agreement State licensees) as a revision to the clearance for NRC Form 313A (OMB Clearance No. 3150-0120) as part of the estimated burden for the preceptor statement and type of use training.

Sections Related to Recognition of Specialty Boards

§ 35.50(a) Training for Radiation Safety Officer

§ 35.51(a) Training for an authorized medical physicist

§ 35.55(a) Training for an authorized nuclear pharmacist

§ 35.190(a) Training for uptake, dilution, and excretion studies

§ 35.290(a) Training for imaging and localization studies

§ 35.390(a) Training for use of unsealed byproduct material for which a written directive is required

§ 35.392(a) Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries)

§ 35.394(a) Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries)

§ 35.490(a) Training for use of manual brachytherapy sources

§ 35.590(a) Training for use of sealed sources for diagnosis

§ 35.690(a) Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units

The proposed rule would modify the criteria for recognizing board certifications under each of the above-listed sections. In order to be recognized by the NRC, specialty boards are required to demonstrate that their certification processes include all of the requirements for T&E specified for an RSO, AMP, ANP or AU for the medical use of byproduct material. Therefore, the above-listed sections implicitly require specialty boards seeking recognition to prepare and submit a letter demonstrating that their certification processes include the criteria required by that section. This is necessary because twenty-two of twenty-three specialty boards cannot meet the T&E requirements of the current rule.

This is expected to be a one-time submission. The reporting requirements for this one-time submission are estimated below in Item 12 for OMB Clearance No. 3150-0010. This submission is necessary to ensure that the NRC or an Agreement State can ascertain that an individual certified by a particular specialty certification board for a particular medical use of byproduct material has received adequate T&E to function independently as an RSO, AMP, ANP, or AU.

The NRC currently reviews event reports to monitor trends in medical events and to determine if observed trends are attributable to inadequate training related to the certification training. If the NRC staff believes that a medical event trend is associated with deficiencies in the radiation safety training aspects of a specialty certification board's certification process, then the NRC staff would assess the adequacy of the board's certification process to determine if the board should be delisted. To assess if a specialty board should be delisted, the NRC staff may request that the board provide information related to the board's T&E requirements. This submission is necessary for the NRC or an Agreement State to determine if a specialty board's certification process should continue to be listed as meeting the T&E requirements for individuals being permitted to work as RSOs, AMPs, ANPs, or AUs.

2. Agency Use of Information

The NRC uses the information submitted to determine whether individuals permitted to work as RSOs, AMPs, ANPs, or AUs have satisfactorily completed T&E necessary to fulfill the duties of their positions.

3. Reduction of Burden Through Information Technology

There are no legal obstacles to reducing the burden associated with this information collection. Applicants and licensees may use electronic information processing systems to prepare and submit required information.

4. Effort to Identify Duplication and Use Similar Information

The proposed requirements at § 35.14(a) for licensees to submit preceptor statements for board-certified individuals would not duplicate information currently collected by the NRC. The Information Requirements Control Automated System (IRCAS) was searched and no duplication was found.

5. Effort to Reduce Small Business Burden

While a number of medical licensees are considered small businesses under the NRC's current definitions, the health and safety consequences of improper use of byproduct material are the same for large and small entities. It is not possible to reduce the burden on small businesses by less frequent or less complete reporting, recordkeeping, or accounting and control procedures while maintaining the required level of safety.

6. Consequences to Federal Program or Policy Activities if the Collection is Not Conducted or is Conducted Less Frequently

If the information is not collected, the NRC will not be in a position to assess whether individuals serving as RSOs, AMPs, ANPS, or AUs for the medical use of byproduct material have satisfactorily completed adequate T&E to fulfill the duties of their positions.

Applications are required to be submitted for the initial license, for amendments, and for renewals. The review and submission of the information required for the application is essential to the NRC's determination of whether the applicant's staff has adequate T&E to protect the public health and safety. Collection of specific information at the required frequency from licensees that administer byproduct material to patients or human research subjects is essential to protect the health and safety of workers, patients and human research subjects, and the public.

7. Circumstances Which Justify Variation from OMB Guidelines

There are no variations from OMB guidelines.

8. Consultations Outside the Agency

During development of revised 10 CFR Part 35, published as a proposed rule on August 13, 1998 (63 FR 43516) and as a final rule on April 24, 2002 (67 FR 20249), there was a general belief that the boards recognized by the NRC would meet, or could make adjustments to meet, the new requirements established by that rulemaking governing recognition of specialty boards by the NRC and that these boards would continue to be recognized by the NRC. However, when applications for recognition were received the NRC staff determined that, except for one board, the boards did not meet all the requirements specified in the final rule. Specifically, the boards' certification processes failed to meet the requirements in the final rule regarding preceptor certification and experience. The NRC staff then held several discussions with the boards to determine whether the boards would modify their certification processes to meet all the requirements specified in the rule. Except for one board, no board indicated that it would modify its certification process.

The ACMUI formed a subcommittee to develop recommendations on the T&E issue. A public subcommittee meeting was held on June 21, 2002, at NRC headquarters in Rockville, Maryland. Representatives from 13 boards, associations, and societies participated in the meeting. In addition, 8 boards and societies provided written comments to the ACMUI subcommittee on its recommendations. After considering the comments from the meeting and letters, the subcommittee developed final recommendations and submitted them to the ACMUI for consideration.

The ACMUI full committee discussed the subcommittee's recommendations in a public teleconference meeting on July 8, 2002. Members of the public and representatives from the Society of Nuclear Medicine participated in the teleconference. The ACMUI approved the recommendations of the subcommittee and submitted them in a report to the NRC on August 1, 2002.

On May 20, 2003, a public meeting was held to solicit early input on this proposed rule from representatives of professional specialty boards and other interested stakeholders. The meeting was conducted as a facilitated, roundtable discussion with representatives of specialty boards; members of the public also had the opportunity to present their views. The NRC staff also made a presentation to the ACMUI on May 20, 2003, regarding the NRC staff's approach to the proposed rule; subsequent to this, further input was obtained from the Chair of the ACMUI and the Chair of the ACMUI subcommittee. Comment was also received via e-mail from a participant in the meeting with the boards. All comments were considered in the development of this proposed rule.

A draft of the proposed rule was sent to the Agreement States and the ACMUI for 30-day review and comment. A teleconference between the NRC staff and the ACMUI was held on July 17, 2003. Approximately 12 Agreement State representatives participated in this conference which was noticed in the Federal Register on July 14, 2003 (68 FR 41665). During this teleconference, the ACMUI members continued to voice concern about having recognition of boards' certifications conditioned on requiring candidates for certification to obtain written attestation of competency signed by a preceptor. The ACMUI recommended that if the Commission still maintained that it was necessary to include a preceptor statement for all authorized positions named in 10 CFR Part 35, this requirement would be separated from the criteria for recognition of board certifications, as well as the alternative pathway. Agreement State representatives participating in the teleconference agreed with this recommendation and the recommendation was incorporated into this rulemaking.

Comments of the ACMUI, Agreement States, board members, and members of the public provided useful information to the NRC in preparing the proposed regulations. A person from the State of Alabama represented the Organization of Agreement States and participated as a member of the working group with the NRC staff in the development of this proposed rule.

Opportunity to comment on the proposed rule's information collection requirements has been published in the Federal Register.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of the Information

None, except for proprietary or safeguards information.

11. Justification for Sensitive Questions

There are no sensitive questions.

12. Estimated Burden and Burden Hour Cost

The information in this section summarizes the changes to the burden information in Tables 1 through 4 for 10 CFR Part 35 and Form 313A for NRC and Agreement State licensees. The information also summarizes the burden to specialty boards as a result of the proposed changes to 10 CFR Part 35.

Burden for 10 CFR Part 35/Clearance No. 3150-0010

Under the proposed rule the NRC would amend § 35.14(a) to require licensees to submit preceptor statements for board-certified individuals. Based on an estimated 849 board-certified individuals (194 NRC licensees and 655 Agreement State licensees) applying annually the total additional burden on licensees is estimated to be 213 hours (849 preceptor statements x 0.25 hours/preceptor statement) and \$33,654 (\$158 per hour x 213 hours) as shown in Table 1.

Table 1 - Reporting Requirements for Submittal of Preceptor Statements

Section	No. of Licensees Responses Annually	Licensee Staff Hours per Submittal	Total Licensee Burden Hours	Total Costs at \$158 per hour
35.14(a) - NRC licensees	194	0.25	49	\$7,742
35.14(a) - Agreement State licensees	655	0.25	164	\$25,912
Total	849		213	\$33,654

The NRC currently recognizes only one specialty certification board. That board and all other specialty boards are expected to request a one-time recognition under the proposed changes to 10 CFR Part 35. For the requested clearance period the annualized burden and cost to the specialty boards to prepare their requests for recognition is estimated to be 123 hours (16 hours/request x 23 requests = 368 hours / 3 years) at a cost of \$19,434 (\$158 per hour x 123 hours) annualized over the 3-year clearance period as shown in Table 2. The NRC anticipates that all of the specialty boards will submit for NRC recognition and none will submit for Agreement State recognition. If any boards are recognized by an Agreement State, the burden is expected to be the same as that for NRC recognition.

For the requested clearance period, the annualized burden and cost to the recognized specialty boards to prepare their requests for information supporting an assessment for delisting a board recognized under the proposed changes to 10 CFR Part 35 is estimated to be 5 hours (16 hours/request x 1 request = 16 hours/3 years) at a cost of \$790 (\$158 per hour x 5 hours) annualized over the 3-year clearance period as shown in Table 2.

Table 2 - Voluntary Submittals by Specialty Boards to the NRC

Section	No. of Boards Responses (Annualized)	Board Staff Hours per Submittal	Total Annualized Board Burden Hours	Total Costs at \$158 per hour
35.50 - 35.690 Application for recognition	7.7	16	123	\$19,434
35.50 - 35.690 Information for assessments	0.3	16	5	\$790
Total	8		128	\$20,224

Additional Burden for NRC Form 313A/Clearance No. 3150-0120

Under the proposed regulations the number of applicants obtaining preceptor statements for submission to the NRC by licensees increases by 194 annually and to Agreement States increases by 655 annually. The total additional burden and cost for NRC Form 313A, as reflected in the information in Table 3 for NRC licensees and in Table 4 for Agreement State licensees, is 889 hours (203 hours + 686 hours) and \$140,462 (\$158 per hr x 889 hours).

Table 3 - Annual Third Party Requirements for Individual Preceptor Certifications and Type of Use Training - NRC Licensees (OMB Clearance No. 3150-0120)

Section	Number of Applicants	Number of Records per Applicant	Hours per Record	Total Recordkeeping (Hours)
35.50(c), 35.50(d)(2)(ii), and 35.50(e)	39	1	1.1	43
35.51(c) and 35.51(d)	20	1	1.1	22
35.55(c)	4	1	1	4
35.190(a)	23	1	1	23
35.290(a)	Burden in 35.190(a)	–	–	–
35.390(c)	22	1	1	22
35.392(a)	20	1	1	20
35.394(a)	Burden in 35.392(a)	–	–	–
35.490(c)	33	1	1	33
35.690(c) and 35.690(d)	33	1	1.1	36
Total	194			203

Table 4 - Annual Third Party Requirements for Individual Preceptor Certifications and Type of Use Training - Agreement State Licensees (OMB Clearance No. 3150-0120)

Section	Number of Applicants	Number of Records per Applicant	Hours per Record	Total Recordkeeping (Hours)
35.50(c), 35.50(d)(2)(ii), and 35.50(e)	132	1	1.1	145
35.51(c) and 35.51(d)	70	1	1.1	77
35.55(c)	14	1	1	14
35.190(a)	76	1	1	76
35.290(a)	Burden in 35.190(a)	–	–	–
35.390(c)	73	1	1	73
35.392(a)	70	1	1	70
35.394(a)	Burden in 35.392(a)	–	–	–
35.490(c)	110	1	1	110
35.690(c) and 35.690(d)	110	1	1.1	121
Total	655			686

**Summary Table of Part 35 Burden Changes (3150-0010)
Reporting Requirements**

Requirement	Burden Hour Changes
Submit NRC Licensee Preceptor Statements to NRC	49
Submit Agreement State Licensee Preceptor Statements to Agreement States	164
Board Certification Submittals for NRC Recognition (annualized)	123
Board Certification Submittals for NRC Assessment (annualized)	5
Total Part 35 Burden Increase	341

**Summary Table of NRC Form 313A Burden Changes (3150-0120)
Third Party Requirements (Recordkeeping)**

Requirement	Burden Hour Changes
Obtain Preceptor Statement (NRC Licensees)	203
Obtain Preceptor Statement (Agreement State Licensees)	686
Total NRC Form 313A Increase	889

The burden estimates are based on the NRC staff's best estimate of the time required to perform information collection activities. Cost estimates are based on the rate used in the NRC's license fee rule.

13. Estimate of Other Additional Costs

The quantity of records to be maintained under OMB Clearance No. 3150-0120 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 .0004 times the recordkeeping burden cost. Therefore, the storage cost for this clearance is estimated to be \$56 (889 hours x \$158/hour x .0004) and is insignificant. There is no additional recordkeeping burden and therefore, no additional storage cost under OMB Clearance No. 3150-0010.

14. Estimated Annualized Cost to the Federal Government

Burden for 10 CFR Part 35/Clearance No. 3150-0010

The NRC currently recognizes only one specialty certification board. That board and all other specialty boards are expected to request recognition under the proposed changes to 10 CFR Part 35. As shown below in Table 5, for the requested clearance period the total annualized burden and cost to the NRC staff for review of one-time requests for recognition of specialty boards under 10 CFR Part 35 is estimated to be 31 hours (92 hours/3 year clearance period) and \$4,898 (\$158 per hour x 31 hours). This cost is fully recovered through fee assessments to NRC licensees pursuant to 10 CFR Parts 170 and 171.

Table 5 - Total NRC Burden for Recognition of Specialty Boards

Section	Number of Specialty Boards Seeking Recognition by the NRC	NRC Burden Per Recognition Request (Hours)	Total NRC Recognition Burden (Hours)
35.50(a)	5	4	20
35.51(a)	2	4	8
35.55(a)	2	4	8
35.190(a)	5	4	20
35.290(a)	Same as 35.190	–	–
35.390(a)	1	4	4
35.392(a)	2	4	8
35.394(a)	Same as 35.392	–	–
35.490(a)	3	4	12
35.590(a)	Counted under other sections	–	–
35.690(a)	3	4	12
Total Board Applications:	23	4	92
Annualized One-Time Burden (92 hours/3 years)			31

If the NRC staff believes that a medical event trend is associated with deficiencies in the radiation safety training aspects of a specialty certification board’s certification process, the NRC staff would assess the adequacy of the board’s certification process to determine if the board should be delisted. For the requested clearance period the total annualized burden and cost to the NRC staff for assessment of specialty boards for delisting is estimated to be 5.3 hours (16 hours/assessment x 1 assessment/3 years) at a cost of \$837 (\$158 per hour x 5.3 hours) annualized over the 3-year clearance period. This cost is fully recovered through fee assessments to NRC licensees pursuant to 10 CFR Parts 170 and 171.

Additional Burden for NRC Form 313A/Clearance No. 3150-0120

It is estimated that the review of the information on NRC Form 313A will increase by an average of 1 hour per application for individuals meeting the T&E requirements through the board certification pathway. Based on an anticipated 849 such requests per year, at a cost of \$158 per hour, the cost to review the additional preceptor statements would be \$134,142 (849 requests x 1 hour/request x \$158/hour). This cost is fully recovered through fee assessments to NRC licensees pursuant to 10 CFR Parts 170 and 171.

15. Reasons for Changes in Burden and Cost

The revision is a net upward adjustment in annual burden for 10 CFR Part 35, Clearance No. 3150-0010, of 341 hours as a result of the proposed revision of the 10 CFR Part 35 requirements for recognition of specialty boards. The hourly cost has increased from \$143 to \$158 per hour.

The revision is an upward adjustment in annual burden for NRC Form 313A, Clearance OMB 3150-0120, of 889 hours for proposed changes to applicant preceptor certifications and other medical uses. The hourly cost has increased from \$154 to \$158 per hour.

16. Publication for Statistical Use

There is no application to statistics in the information collected. There are no plans for publication of this information.

17. Reason for Not Displaying the Expiration Date

The expiration date for information collected on NRC Form 313A is displayed on that form.

The requirement for other information collections will be contained in a regulation. Amending the Code of Federal Regulations to display information that, in an annual publication, could become obsolete would be unduly burdensome and too difficult to keep current.

18. Exceptions to the Certification Statement

There are no exceptions.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Statistical methods are not used in this collection of information.