DRAFT SUPPORTING STATEMENT
FOR 10 CFR PARTS 30, 32, AND 35 -
MEDICAL USE OF BYPRODUCT MATERIAL
MEDICAL EVENT DEFINITIONS, TRAINING AND EXPERIENCE,
AND CLARIFYING AMENDMENTS,
PROPOSED RULE

(3150-0010, 3150-0017, and 3150-0120)

Description of the Information Collection

This Supporting Statement is for information collection requirements that would result from a proposed rule to amend the existing Title 10 of the *Code of Federal Regulations* (10 CFR) Parts 30, 32, and 35. The proposed rule would amend the U.S. Nuclear Regulatory Commission (NRC) regulations related to the training and experience (T&E) requirements for authorized users (AUs), medical physicists, Radiation Safety Officers (RSOs), and nuclear pharmacists; testing for and reporting of failed technetium and rubidium generators; and allowing Associate Radiation Safety Officers (ARSOs) to be named on a medical use license. The proposed rule would also complete action on a petition for rulemaking (PRM-35-20) and would modify the written directive (WD) requirements in 10 CFR 35.40 and medical event (ME) definitions in 10 CFR 35.3045 for permanent implant brachytherapy. Other proposed revisions include numerous minor amendments to Part 35, and conforming changes to Parts 30 and 32.

Currently there are 1085 NRC and 6401 Agreement State medical use licensees and 52 NRC and 307 Agreement State radiopharmacy licensees that would be affected by this proposed rule. These proposed modifications, which are discussed in detail below, are required to protect the public health and safety. The details of the modifications to the recordkeeping and reporting sections are described in the justification section.

The information included in the license applications, and reports and records required by the proposed rule will be reviewed by the NRC and Agreement State staff to assess the adequacy of the applicant's or licensee's physical plant, equipment, organization, training, experience, procedures and plans for protection of public health and safety. The NRC review and the findings derived there from form the basis for NRC licensing and inspection decisions. Information concerning the requirements imposed by specific sections is provided below.

A. JUSTIFICATION

1. Need for and Practical Utility of the Information Collection

Agreement States are required to adopt the NRC regulations within three years after they go into effect. Although each state has their own regulations with unique sections and numbering systems, for the purpose of this information collection, the NRC section and numbering system is used.

Section 30.34(g) requires radiopharmacy licensees to report to the NRC the results of any test that exceeds the permissible concentration listed in § 35.204(a). Reporting would be in accordance with the reporting and notifications in § 35.3204. While this proposed reporting requirement is new, the requirement for licensees to test eluates to ensure that they do not exceeds the permissible concentration listed in § 35.204(a) and record the results of these

tests are already required. This change is being proposed to provide the information to allow the NRC to assess the situation quickly and efficiently when issues occur with generators that may cause unwarranted radiation exposure to patients.

Section 32.72 (a)(4) is not a new requirement. The change clarifies that applicants commit to following the label requirements rather than satisfying the label requirements.

Section 32.72(b)(5)(i) removes the requirement for individuals seeking to be named as an authorized nuclear pharmacist (ANP) to obtain a written attestation if they are certified by a specialty board whose certification process has been recognized by the NRC or Agreement State. This is a conforming change to the removal of the attestation requirement in § 35.55(a) for a board certified ANP.

Section 32.72(d) is not a new requirement. The change clarifies that the labeling requirements that applicants commit to in paragraph (a) of this section are also applicable to current licensees.

Section 35.12 (b)(1) removes the requirement to submit additional copies of the NRC Form 313 when applying for a license. The change will reduce the burden on the applicant by requiring less paperwork to be submitted.

Section 35.12 (b)(1) requires applicants to submit T&E qualifications for an individual seeking to be identified as an ARSO on the license. The information is required so that the NRC can determine whether the individual has adequate training and experience to serve as an ARSO.

Section 35.12(c)(1) removes the requirement to submit an additional copy of the NRC Form 313 or a letter containing information required by the NRC Form 313 for license amendments or renewals. This change would reduce the burden on the licensee by requiring less paperwork to be submitted.

Section 35.13(d) requires a licensee to apply for and receive a license amendment prior to permitting an individual to work as an ARSO or before the RSO assigns different tasks and duties to an ARSO currently authorized on the license. The information is required so that the NRC can determine whether the individual has adequate T&E to serve as an ARSO.

Section 35.13(i) removes the requirement that licensees must have a license amendment before receiving certain sealed sources. Specifically, a licensee will be able to receive sealed sources from a new manufacturer or a new model number for a sealed source listed in the Sealed Source and Device Registry (SSDR) used for manual brachytherapy for quantities and isotopes already authorized by their license. This change will make it easier for the licensee to obtain the sealed sources necessary for patient treatments in a timely manner.

Section 35.14 (b)(1) requires a licensee to notify the Commission within 30 days of when an ARSO discontinues performance of duties under the license or has a name change. The report is required in order to maintain the license file with a current record of individuals responsible for the safe use of byproduct material.

Section 35.14(b)(6) requires a licensee to notify the NRC if it receives certain sealed sources without first obtaining a license amendment. Specifically, a licensee would have to notify the NRC no later than 30 days after receiving a sealed source from a new manufacturer or a new model number for a sealed source listed in the SSDR used for manual brachytherapy for quantities and isotopes already authorized by the license. The notification is used in lieu of a license amendment requirement which is being removed under § 35.13(i). This notification is required in order for the NRC to have an accurate record of sealed sources possessed by a licensee.

Section 35.24(b) requires a licensee's management to appoint any individual it may want to serve as an ARSO and maintain a record of it. These appointed ARSOs will have to be currently identified on a medical license or permit for the types of use of byproduct material for which the RSO will assign tasks and duties. Management approval is necessary to ensure that actions affecting the radiation protection program have been reviewed by responsible licensee officials. Each ARSO will have to agree in writing to the tasks and duties assigned by the RSO. The written agreement from the ARSO is needed to record the acceptance by the ARSO of all of the obligations of the post. The recordkeeping burden is captured in § 35.2024(c).

Section 35.41(a) is not being amended in this proposed rule. However, it is impacted due to the added procedures required in § 35.41(b)(5) and (6).

Section 35.40(b)(6) is not a new requirement. This new paragraph clarifies the specific information that must be recorded on a WD for permanent implant brachytherapy.

Section 35.41(b)(5) requires licensees to develop, implement, and maintain written procedures for any administration requiring a WD to determine if a medical event, as defined in § 35.3045, has occurred. A licensee will retain a copy of these procedures in accordance with § 35.2041. These written procedures are necessary to provide high confidence that each administration is in accordance with the WD to ensure patient safety.

Section 35.41(b)(6) requires licensees to develop, implement, and maintain written procedures for permanent implant brachytherapy. The procedures must include determining within 60 calendar days from the date the implant was performed; 1) The total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation WD; 2) The absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue located outside the treatment site; and 3) The maximum absorbed dose to any 5 contiguous cubic centimeters of each normal tissue structure located within the treatment site. A licensee will retain a copy of these procedures in accordance with § 35.2041. These written procedures are necessary to provide high confidence that each administration is in accordance with the WD to ensure patient safety.

Section 35.50(a) removes the requirement for individuals seeking to be named as an RSO or ARSO to obtain a written attestation provided they are certified by a specialty board whose certification process has been recognized by the NRC or Agreement State. The change will reduce the burden on the applicant by requiring less paperwork to be submitted.

Section 35.50(c)(1) removes the requirement for medical physicists seeking to be named as an RSO or ARSO to obtain a written attestation provided they are certified by a specialty

board whose certification process has been recognized by the NRC or Agreement State. The change of burden is a subset of § 35.50(a).

Section 35.51(a) removes the requirement for individuals seeking to be named as an authorized medical physicist (AMP) to obtain a written attestation provided they are certified by a specialty board whose certification process has been recognized by the NRC or Agreement State. The change will reduce the burden on the applicant by requiring less paperwork to be submitted.

Section 35.55(a) removes the requirement for individuals seeking to be named as an authorized nuclear pharmacist (ANP) to obtain a written attestation if they are certified by a specialty board whose certification process has been recognized by the NRC or Agreement State. The change will reduce the burden on the applicant by requiring less paperwork to be submitted.

Section 35.57(a)(1) removes the requirement for AMPs and ANPs identified on a Commission or Agreement State license or a permit issued by a Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope on or before October 24, 2005, to comply with the training requirements of §§ 35.50, 35.51, or 35.55, respectively. This reduces the paperwork burden for these individuals when applying to be named on a medical license.

Section 35.57(a)(2) removes the requirement for individuals certified by the named boards in the now removed Subpart J of Part 35 on or before October 24, 2005, to comply with the training requirements of § 35.50 in order to be identified as a RSO on a Commission or Agreement State license or Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005. This reduces the paperwork burden for these individuals when applying to be named on a medical license.

Section 35.57(a)(3) removes the requirement for individuals certified by the named boards in the now removed Subpart J of Part 35 on or before October 24, 2005, to comply with the training requirements of § 35.51 in order to be identified as a AMP on a Commission or Agreement State license or Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005. Removal of Subpart J from 10 CFR Part 35 was effective on October 24, 2005. This reduces the paperwork burden for these individuals when applying to be named on a medical license.

Section 35.57(b)(1) removes the requirement for AUs to comply with the training requirements of Subparts D through H of Part 35 provided they were identified on a Commission or Agreement State license, a permit issued by a Commission master material licensee, a permit issued by a Commission or Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee before October 24, 2005, and only perform those medical uses for which they were authorized on or before that date. This reduces the paperwork burden for these individuals when applying to be named on a medical license.

Section 35.57(b)(2) removes the requirement for physicians, dentists, or podiatrists not identified on a medical use license to comply with the training requirements of Subparts D through H of Part 35 provided they were certified by the named boards in the now removed Subpart J of part 35 on or before October 24, 2005, and only perform those medical uses for

which they were authorized on or before that date. This reduces the paperwork burden for these individuals when applying to be named on a medical license.

Section 35.65(b)(2) requires licensees that possess bundled or aggregated single sealed sources to treated them as one single source. These sources with activities larger than authorized by § 35.65 will have to meet all the regulatory requirements for that single source including, if appropriate, listing on a specific medical license, leak testing, and security requirements. This requirement is necessary so the NRC can ensure that adequate controls for security and radiation safety are applied to these larger sources.

Section 35.190(a) removes the requirement for individuals seeking to be named as an AU of unsealed byproduct material for uses authorized under § 35.100 to obtain a written attestation if they are certified by a specialty board whose certification process has been recognized by the NRC or Agreement State. The change will reduce the burden on the applicant by requiring less paperwork to be submitted.

Section 35.204(b) requires licensees to measure the molybdenum-99 (Mo-99) concentration after each eluate from a Mo-99/technetium-99m (Tc-99m) generator. Generator manufacturers recommended testing each elution prior to use in humans. Mo-99 break-through measurements which exceed the permissible concentration listed in § 35.204(a) may cause unnecessary radiation exposures to patients.

Section 35.204(e) requires licensees to report any measurement that exceeded the limits specified in § 35.204(a) for Mo-99/Tc-99m and strontium-82 (Sr-82)/rubidium-82 (Rb-82) generators. Although current regulations require licensees to measure Mo-99, Sr-82, and strontium-85 (Sr-85) concentrations and record the results, there is no provision to report when a result exceeds the regulatory limits. Reporting would be in accordance with the reporting and notifications in § 35.3204. This reporting requirement will provide information that will allow the NRC to respond to the potential patient safety issue in a timely manner.

Section 35.290(a) removes the requirement for individuals seeking to be named as an AU of unsealed byproduct material for uses authorized under § 35.200 to obtain a written attestation provided they are certified by a specialty board whose certification process has been recognized by the NRC or Agreement State. The change will reduce the burden on the applicant by requiring less paperwork to be submitted.

Section 35.390(a) removes the requirement for individuals seeking to be named as an AU of unsealed byproduct material which requires a WD for uses authorized under § 35.300 to obtain a written attestation provided they are certified by a specialty board whose certification process has been recognized by the NRC or Agreement State. The change will reduce the burden on the applicant by requiring less paperwork to be submitted.

Section 35.390(b)(1)(ii)(G) does not add any additional burden. This paragraph clarifies the categories of parenteral administrations of radionuclides in which work experience is required for an individual seeking to be an AU for uses under § 35.300.

Section 35.392(a) removes the requirement for individuals seeking to be named as an AU for the oral administration of sodium iodide I-131 requiring a WD in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries) to obtain a written attestation provided they are certified by a specialty board whose certification process has been recognized by the NRC

or Agreement State. The change will reduce the burden on the applicant by requiring less paperwork to be submitted.

Section 35.394(a) removes the requirement for individuals seeking to be named as an AU for the oral administration of sodium iodide I-131 requiring a WD in quantities greater than 1.22 Gigabecquerels (33 millicuries) to obtain a written attestation provided they are certified by a specialty board whose certification process has been recognized by the NRC or Agreement State. The change will reduce the burden on the applicant by requiring less paperwork to be submitted.

Section 35.433(a)(2) does not add burden as it retains the ability for an AMP to continue to support ophthalmic treatments using strontium-90 sealed sources. It adds T&E requirement for individuals who are not AMPs who want to be involved with ophthalmic treatments. These requirements are similar to the T&E requirements for an AMP but include only those requirements related to brachytherapy programs. This will increase the number of qualified individuals available to support the use of strontium-90 sources for ophthalmic treatments. Often, AUs who work in remote areas do not have ready access to an AMP to perform the necessary calculations to support the ophthalmic treatment. This change will make the procedure involving the use of strontium-90 sources for ophthalmic treatments available to more patients located in remote areas.

Section 35.490(a) removes the requirement for individuals seeking to be named as an AU of unsealed byproduct material for uses authorized under § 35.400 to obtain a written attestation provided they are certified by a specialty board whose certification process has been recognized by the NRC or Agreement State. The change will reduce the burden on the applicant by requiring less paperwork to be submitted.

Section 35.610(d)(1) requires all individuals who will operate remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units to receive vendor operational and safety training prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit. The training must be provided by the device manufacturer or by individuals certified by the device manufacturer to provide the training. This training is necessary to ensure that operators of these devices have adequate training to protect patient safety.

Section 35.655(a) is not a new requirement. The amended paragraph clarifies the requirement for fully inspecting and servicing intervals to assure proper functioning of the source exposure mechanism for gamma stereotactic radiosurgery units is 7 years.

Section 35.690(a) removes the requirement for individuals seeking to be named as an AU of sealed byproduct material for uses authorized under § 35.600 to obtain a written attestation provided they are certified by a specialty board whose certification process has been recognized by the NRC or Agreement State. The change will reduce the burden on the applicant by requiring less paperwork to be submitted.

Section 35.2024(c) requires the licensee to keep the written documents signed by the licensee's management for each ARSO appointed under § 35.24(b) and each agreement signed by the ARSO listing the duties and tasks assigned by the RSO under § 35.24(b) for 5 years after the ARSO is removed from the license. These records are important to show that the ARSO had sufficient authority, time, resources, and management prerogative to ensure

that radiation safety activities were being performed in accordance with licensee-approved procedures and regulatory requirements.

Section 35.2041 burden is increased due to the new requirements in 35.41(b)(5) and (b)(6) for licensees to maintain written procedures for any administration requiring a WD related to MEs and permanent implant brachytherapy.
Section 35.2310 is not a new requirement. The change clarifies that the operational and safety instructions required by § 35.610 must be included in the record.

Section 35.2655 is amended to conform to the clarifying changes in § 35.655(a).

Section 35.3045(a)(1) is not a new requirement. This new paragraph has the criteria for reporting an ME for administrations that require a WD other than permanent implant brachytherapy. The criteria for reporting an ME for administrations that require a WD for permanent implant brachytherapy are now in paragraph (a)(2) of this section. The reporting burden from this paragraph will not change the reporting burdens in § 35.3045(c), (d) or (e).

Section 35.3045(a)(2) is not a new requirement. In this new paragraph, the criteria for reporting an ME for administrations that require a WD for permanent brachytherapy procedures are set out separate from all other brachytherapies. The new requirements will not capture events that are not significant and will reduce the number of reportable MEs related to permanent implant brachytherapy with reporting burden reduction in § 35.3045(c), (d) or (e).

Section 35.3045(c) telephone reporting burdens to the NRC are reduced because the requirements for reporting an ME for permanent implant brachytherapy are changed in § 35.3045(a)(2). The new requirements will not capture events that are not significant and will reduce the number of reportable MEs related to permanent implant brachytherapy.

Section 35.3045(d) written reporting burdens to the NRC are reduced because the requirements for reporting an ME for permanent implant brachytherapy are changed in § 35.3045(a)(2). The new requirements will not capture events that are not significant and will reduce the number of reportable MEs related to permanent implant brachytherapy.

Section 35.3045(e) licensee reporting burdens to the physician and patients are reduced because the requirements for reporting an ME for permanent implant brachytherapy are changed in § 35.3045(a)(2). The new requirements will not capture events that are not significant and will reduce the number of reportable MEs related to permanent implant brachytherapy.

Section 35.3204(a) requires radiopharmacy and medical use licensees to notify both the NRC Operations Center and the manufacturer/distributer of the generator by telephone within 30 days after discovery that an eluate exceeds the permissible concentration listed in § 35.204(a). Breakthrough of Mo-99 and contamination of Sr-82 and Sr-85 can lead to unnecessary exposure to radiation to patients. This notification requirement will allow the NRC to assess the situation so that appropriate actions may be taken to avoid unwarranted radiation exposure to patients.

Section 35.3204(b) requires radiopharmacy and medical use licensees to submit a written report to the appropriate NRC Regional Office listed in § 30.6 within 45 days after discovery

of an eluate exceeding the permissible concentration listed in § 35.204(a). This report is a follow up on the requirement under § 35.3204(a) to notify the NRC within 30 days after discovery that an eluate exceeds the permissible concentration listed in § 35.204(a). This reporting requirement will allow the NRC to determine appropriate actions to take to avoid unwarranted radiation exposure to patients.

2. Agency Use of the Information

Information required to be submitted with license applications or with applications for amendments to those licenses is used by the NRC in evaluating compliance with licensing requirements.

The records that 10 CFR Parts 30, 32, and 35 require the licensees to maintain are reviewed during inspections, license renewals, and license amendment reviews to evaluate compliance with NRC requirements.

Reports of significant safety events are used by the agency in evaluating the protective actions required to avoid exposures to patients and the public that could exceed regulatory limits and, therefore, impact public health and safety and the environment. Additionally, certain events are of such significance that they must be reported to the NRC, to patients or human research subjects, and to referring physicians. Collection of this information enables the NRC to determine what steps must be taken by other licensees to prevent such events, whether required notifications have been made, and whether corrective actions have been taken. The NRC also has the responsibility, pursuant to section 208 of the Energy Reorganization Act of 1974, as amended, to inform Congress and the public of those events constituting "abnormal occurrences" and to also inform NRC medical use licensees of generic issues identified by the NRC review of medical events.

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. However, because of the types of information and the infrequency of submission, the applications and other reports may not lend themselves readily to the use of automated information technology for submission. It is estimated that approximately 10% of the potential responses are filed electronically.

4. Effort to Identify Duplication and Use Similar Information

No sources of similar information are available. There is no duplication of requirements. NRC has in place an ongoing program to examine all information collections with the goal of eliminating all duplication and/or unnecessary information collections.

5. Effort to Reduce Small Business Burden

While a number of 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 public health and safety and common defense and security. The NRC estimates that 23% of the impacted respondents are small businesses.

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

Required reports are collected and evaluated on a continuing basis as events occur. An application for a new license or an amendment to an existing license is submitted only once. Applications for renewal of licenses are generally submitted every ten years. Information submitted in previous applications may be referenced without being resubmitted. The schedule for collecting the information is the minimum frequency necessary, currently not exceeding 10 years, to assure that licensees will continue to conduct programs in a manner that will assure adequate protection of the public health and safety.

7. Circumstances Which Justify Variation from OMB Guidelines

Record Retention The proposed rule would require licensees to maintain certain records until termination of the license; although, OMB Guidelines are three years. These are records that will be used by inspectors to assess regulatory compliance and in cases where historic information is used to assess patient exposures to radiation.

8. Consultations Outside the NRC

An opportunity for public comment on the information collection requirements has been published in the Federal Register.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of Information

Confidential and proprietary information is protected in accordance with NRC regulations at 10 CFR 9.17(a) and 10 CFR 2.390(b).

11. Sensitive Questions

None.

12. Estimated Burden and Burden Hour Cost

The cost to licensees and applicants is calculated at a rate of $274 per hour for professional staff for the technical reports, recordkeeping, and records prepared in response to the 10 CFR Part 30, 32, and 35 information collection requirements. This rate is based on NRC's fully recoverable fee rate.

Currently there are 1085 NRC and 6401 Agreement State medical use licensees and 52 NRC and 307 Agreement State radiopharmacy licensees that would be affected by this proposed rule. The proposed rule would affect three OMB information collection clearances, OMB 3150-0010 (Part 35), OMB 3150-0017 (Part 30), and OMB 3150-0120 (NRC Form 313).

The **total burden** for the proposed rule is 33,038.33 hours at a cost of $9,052,503 (33,038.33 hours x $274/hr). Burden totals are as follows:

	Reporting Burden	Recordkeeping Burden	3rd Party Disclosure Burden	Total	Cost at $274/hr
10 CFR Part 30	3.50	4,667.00	0.00	4,670.50	$1,279,717
10 CFR Part 35	1,734.75	31,849.33	-32.50	33,551.58	$9,193,134
Form 313	-5,183.75	0.00	0.00	-5,183.75	-$1,420,348
Total:	-3,445.50	36,516.33	-32.50	33,038.33	$9,052,503

Further burden detail can be found in Tables 1-25. Burden for this proposed rule is broken down according to whether it is incurred on an ongoing annual basis (Table 19) or as a one-time implementation burden which is annualized for a three-year OMB clearance period (Table 22). Burden is further broken down according to the type of respondent (NRC licensee or Agreement State licensee).

13. Estimate of Other Additional Costs

NRC has determined that the records storage cost is roughly proportional to the recordkeeping burden cost. Based on a typical clearance, the recordkeeping storage cost has been estimated to be equal to .0004 percent of the annual recordkeeping burden. Therefore, the additional annual recordkeeping storage cost for the proposed rule is estimated to be $4,002 (36,516.33 annual recordkeeping hours [Table 23] x $274 x .0004).

14. Estimate of Cost to the Federal Government and Agreement States

It is estimated in the regulatory analysis that there would be a reduction in annual cost for the NRC and Agreement States of approximately $400,000 ($75,000 NRC / $325,000 Agreement State). The total reduction in annual cost to the Federal Government is accounted for under 10 CFR Part 35, Medical Use of Byproduct Material. This reduction would result from the many changes to the regulations that would reduce the number of license amendments submitted, reports received, and other actions that are now being processed. There is no impact from the proposed rule on the NRC and the Agreement

State cost to license and inspect the licensees affected by the proposed new requirements.

15. Reasons for Change in Burden

The proposed rule would increase burden by 33,038 hours. The proposed amendments to 10 CFR Parts 30, 32, and 35 that affect the burden and/or cost for complying with the regulations constitute the elements of a safety program the NRC considers essential to provide a risk-informed, performance-based approach for regulating the medical use of byproduct material. This proposed rule would reduce the potential unwarranted radiation exposure to patients, provide greater flexibility to licensees, reduce the paperwork burden for licensees, and clarify current regulations. Examples are listed below.

Reducing the Potential Unwarranted Radiation Exposure to Patients

The proposed rule would add new requirements to test each elution of each generator rather than just the first one (a generator may be eluted multiple times) and report any result that exceeds the limits in § 35.204(a) and would add burden for recordkeeping and notifications. This change would provide the information to allow the NRC to assess the situation quickly and efficiently when issues occur with generators that may cause unwarranted radiation exposure to patients.

Another increase in burden related to reducing potential unwarranted radiation exposure to patients is requiring licensees to develop, implement, and maintain written procedures for any administration requiring a WD to determine if the treatment has resulted in a medical event. These procedures are generally therapeutic in nature with the greatest potential for causing harm to patients. Additionally, for permanent implant brachytherapy, licensees must make certain assessments to determine if a ME has occurred within 60 calendar days from the date the implant was performed. This is to ensure that the patient received the appropriate radiation therapy in the prescribed location.

Provide Greater Flexibility to Licensees

A new requirement that requires a licensee to notify the NRC when it receives certain sealed sources actually reduces burden. Current regulations require the licensee to first submit and have approved a license amendment prior to receiving these sealed sources. Under the proposed rule, a licensee who is authorized to possess certain sealed sources may notify the NRC when it receives the sealed sources not listed on the license rather than submitting a license amendment. The new sources must be approved in the SSDR and the activity must be within the authorized limit of the license. This reduces the burden and gives the licensee greater flexibility in acquiring new sources in a timely manner.

Changing the regulations to allow medical licensees to identify ARSOs on their license is a burden with benefits for the licensees. The burden is increased because the licensee would have to submit an amendment to name each ARSO. However, the licensee benefits by having qualified individuals to assist the RSO in the day-to-day oversight of the radiation safety program. Additionally, these identified ARSOs can serve as preceptors for other individuals seeking to be appointed as RSOs and ARSO’s

A proposed change to the regulations adds T&E requirement for individuals who are not AMPs who may support ophthalmic treatments using strontium-90 sealed sources. Licensees in remote areas do not have ready access to an AMP to support the ophthalmic treatment programs. Increasing the number of qualified individuals would make the ophthalmic treatments using strontium-90 available to more patients located in remote areas.

Reduce the Paperwork Burden for Licensees

The proposed rule would remove the requirement for submitting a written attestation for individuals seeking to be named as an RSO, ARSO, AU, AMP, or ANP provided they are certified by a specialty board whose certification process has been recognized by the NRC or Agreement State. This reduces the burden for licensees preparing paperwork for adding these individuals to their medical license.

Another change would remove the requirement for individuals certified by the named boards in the now removed Subpart J of Part 35 on or before October 24, 2005, to comply with the current training requirements to be identified as a RSO, AU, AMP, or ANP for those materials and uses that these individuals performed on or before October 24, 2005. This reduces the burden for licensees preparing paperwork for adding these individuals to their medical license.

Paperwork burden would also be reduced by removing the requirement that applicants and licensees submit additional copies of the NRC Form 313 when applying for a license or amendment.

Clarify Current Regulations

Multiple changes are proposed to clarify current regulations. These changes include clarifying the specific information that must be recorded on a WD for permanent implant brachytherapy, that licensees follow the label requirements rather than satisfy the label requirements, and the requirement for fully inspecting and servicing intervals for gamma stereotactic radiosurgery units is not to exceed 7 years.

16. Publication for Statistical Use

None.

17. Reason for Not Displaying Expiration Date

The requirements will be contained in a regulation. Amending the CFR 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

None.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

Statistical methods are not used in this collection of information.

ANNUAL REPORTING

Table 1 – Reporting Burden for NRC Licensees for Part 35 (3150-0010)

Section	Number of Respondents	Responses Per Respondent	Total Number of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Cost @ $274/Hour
35.14(b)(1)	37	1	37	0.25	9.25	2,535
35.14(b)(6)	507	2	1,014	0.25	253.50	69,459
35.204(e)	Burden covered in 35.3204(a) & (b)					
35.3045(a)(2)	Burden covered in 35.3045(c), (d) & (e)					
35.3045(c)	1	1	1	-0.50	-0.50	-137
35.3045(d)	1	1	1	-8.00	-8.00	-2,192
35.3045(e)	3	1	3	-2.00	-6.00	-1,644
35.3204(a)	1	1	1	0.25	0.25	69
35.3204(b)	1	1	1	2.00	2.00	548
Total	551		1,058		250.50	$68,637

Table 2 – Reporting Burden for NRC Licensees Part 30 (3150-0017)

Section	Number of Respondents	Responses Per Respondent	Total Number of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Cost @ $274/Hour
30.34(g)	1	1	1	0.50	0.50	137
Total	1		1		0.50	$137

Table 3 – Reporting Burden for NRC Licensees for NRC Form 313 (3150-0120)

Section	Number of Respondents	Responses Per Respondent	Total Number of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Cost @ $274/Hr
35.12(b)	33	1	33	0.25	8.25	$2,261
35.12(b)	33	1	33	-0.25	-8.25	-$2,261
35.12(c)(1)	108	1	108	-0.25	-27.00	-$7,398
35.12(c)(1)	1085	1	1,085	-0.25	-271.25	-$74,323
35.13(d)	33	1	33	0.50	16.50	$4,521
35.13(d)	108	1	108	0.50	54.00	$14,796
35.13(i)	507	2	1,014	-0.50	-507.00	-$138,918
35.50(a)	10	1	10	-0.50	-5.00	-$1,370
35.50(c)(1)	Burden covered in 35.50(a)					$0
35.50(c)(3)	1	1	1	-0.50	-0.50	-$137
35.51(a)	5	1	5	-0.50	-2.50	-$685
35.55(a)	1	1	1	-0.50	-0.50	-$137
35.57(a)(1)	6	1	6	-0.50	-3.00	-$822
35.57(a)(2)	11	1	11	-0.50	-5.50	-$1,507
35.57(a)(3)	6	1	6	-0.50	-3.00	-$822
35.57(b)(1)	325	1	325	-0.50	-162.50	-$44,525
35.57(b)(2)	27	1	27	-0.50	-13.50	-$3,699
35.65(b)(2)	2	1	2	0.50	1.00	$274
35.190(a)	8	1	8	-0.50	-4.00	-$1,096
35.290(a)	8	1	8	-0.50	-4.00	-$1,096
35.390(a)	4	1	4	-0.50	-2.00	-$548
35.392(a)	4	1	4	-0.50	-2.00	-$548
35.394(a)	4	1	4	-0.50	-2.00	-$548
35.490(a)	5	1	5	-0.50	-2.50	-$685
35.690(a)	2	1	2	-0.50	-1.00	-$274
Total	2,336		176		-947.25	-$259,547

NOTE: Grayed numbers indicate new responses to complete NRC Form 313. Other responses are a reduction in the time associated with completing the form for existing respondents.

Table 4 – Reporting Burden for Agreement States Licensees for Part 35 (3150-0010)

Section	Number of Respondents	Responses Per Respondent	Total Number of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Cost @ $274/Hour
35.14(b)(1)	225	1	225	0.25	56.25	15,413
35.14(b)(6)	2991	2	5,982	0.25	1,495.50	409,767
35.204(e)	Burden covered in 35.3204(a) & (b)					
35.3045(a)(2)	Burden covered in 35.3045(c), (d) & (e)					
35.3045(c)	6	1	6	-0.50	-3.00	-822
35.3045(d)	6	1	6	-8.00	-48.00	-13,152
35.3045(e)	5	3	15	-2.00	-30.00	-8,220
35.3204(a)	6	1	6	0.25	1.50	411
35.3204(b)	6	1	6	2.00	12.00	3,288
Total	3,245		6,246		1,484.25	$406,685

Table 5 – Reporting Burden for Agreement States Licensees for Part 30 (3150-0017)

Section	Number of Respondents	Responses Per Respondent	Total Number of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Cost @ $274/Hour
30.34(g)	1	6	6	0.50	3.00	822
Total	1		6		3.00	$822

Table 6 – Reporting Burden for Agreement States Licensees for NRC Form 313 (3150-0120)

Section	Number of Respondents	Responses Per Respondent	Total Number of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Cost @ $274/Hour
35.12(b)	192	1	192	0.25	48.00	13,152
35.12(b)	192	1	192	-0.25	-48.00	-13,152
35.12(c)(1)	369	1	369	-0.25	-92.25	-25,277
35.12(c)(1)	6401	1	6,401	-0.25	-1,600.25	-438,469
35.13(d)	192	1	192	0.50	96.00	26,304
35.13(d)	639	1	639	0.50	319.50	87,543
35.13(i)	2991	2	5,982	-0.50	-2,991.00	-819,534
35.50(a)	57	1	57	-0.50	-28.50	-7,809
35.50(c)(1)	Burden covered in 35.50(a)					
35.50(c)(3)	2	1	2	-0.50	-1.00	-274
35.51(a)	32	1	32	-0.50	-16.00	-4,384
35.55(a)	6	1	6	-0.50	-3.00	-822
35.57(a)(1)	35	1	35	-0.50	-17.50	-4,795
35.57(a)(2)	64	1	64	-0.50	-32.00	-8,768
35.57(a)(3)	35	1	35	-0.50	-17.50	-4,795
35.57(b)(1)	1917	1	1,917	-0.50	-958.50	-262,629
35.57(b)(2)	160	1	160	-0.50	-80.00	-21,920
35.65(b)(2)	9	1	9	0.50	4.50	1,233
35.190(a)	50	1	50	-0.50	-25.00	-6,850
35.290(a)	50	1	50	-0.50	-25.00	-6,850
35.390(a)	25	1	25	-0.50	-12.50	-3,425
35.392(a)	25	1	25	-0.50	-12.50	-3,425
35.394(a)	25	1	25	-0.50	-12.50	-3,425
35.490(a)	27	1	27	-0.50	-13.50	-3,699
35.690(a)	8	1	8	-0.50	-4.00	-1,096
Total	13,503		1,032		-5,522.50	-$1,513,165

NOTE: Grayed numbers indicate new responses to complete NRC Form 313. Other responses are a reduction in the time associated with completing the form for existing respondents.

RECORDKEEPING

Table 7 – Recordkeeping Burden for NRC Licensees for Part 35 (3150-0010)

Section	No. of NRC Recordkeepers	Number of Records per Licensee	Total Number of Records	Burden Hours per Record	Total Annual Burden Hours	Cost @ $274/Hour	Record Retention Period
35.24(b)	Burden covered in 35.2024(c)						
35.41(a)	Burden covered in 35.2041						
35.41(b)(5)	Covered in 35.41(a)						
35.41(b)(6)	Covered in 35.41(a)						
35.65(b((2)	2	1	2	2.50	5.00	1,370	Inventory and leak testing 3 years
35.204(b)	Covered under 35.2204						
35.610(d)	Covered in 35.2310						
35.2024(c)	33	1	33	1.00	33.00	9,042	5 years after ARSO is removed from license
35.2041	33	1	33	9.00	297.00	81,378	Duration of the license
35.2204	48	1	48	13.00	624.00	170,976	3 years
35.2310	25	1	25	1.00	25.00	6,850	3 years
Total	141		141		984.00	$269,616	

Table 8 – Recordkeeping Burden for NRC Licensees for Part 30 (3150-0017)

Section	No. of NRC Recordkeepers	Number of Records per Licensee	Total Number of Records	Burden Hours per Record	Total Annual Burden Hours	Cost @ $274/Hour	Record Retention Period
30.34(g)	52	1	52	13.00	676.00	185,224	3 years
Total	52		52		676.00	$185,224	

Table 9 – Recordkeeping Burden for Agreement State Licensees for Part 35 (3150-0010)

Section	No. of Agreement State Recordkeepers	Number of Records per Licensee	Total Number of Records	Burden Hours per Record	Total Annual Burden Hours	Cost @ $274/Hour	Record Retention Period
35.24(b)	Burden covered in 35.2024(c)						
35.41(a)	Burden covered in 35.2041						
35.41(b)(5)	Covered in 35.41(a)						
35.41(b)(6)	Covered in 35.41(a)						
35.65(b((2)	8	1	8	2.50	20.00	5,480	Inventory and leak testing 3 years
35.204(b)	Covered under 35.2204						
35.610(d)	Covered in 35.2310						
35.2024(c)	192	1	192	1.00	192.00	52,608	5 years after ARSO is removed from license
35.2041	194	1	194	9.00	1,746.00	478,404	Duration of the license
35.2204	283	1	283	13.00	3,679.00	1,008,046	3 years
35.2310	147	1	147	1.00	147.00	40,278	3 years
Total	824		824		5,784.00	$1,584,816	

Table 10 – Recordkeeping Burden for Agreement State Licensees for Part 30 (3150-0017)

Section	No. of Agreement State Recordkeepers	Number of Records per Licensee	Total Number of Records	Burden Hours per Record	Total Annual Burden Hours	Cost @ $274/Hour	Record Retention Period
30.34(g)	307	1	307	13.00	3,991.00	1,093,534	3 years
Total	307		307		3,991.00	$1,093,534	

ANNUAL THIRD PARTY DISCLOSURE BURDEN

Table 11 – Third-party Disclosure Burden for NRC Licensees (3150-0010)

Section	Number of Respondents	Responses Per Respondent	Total Number of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Cost @ $274/Hr
35.3045(e)	1	3	3	-2.00	-6.00	-$1,644
35.3204(a)	2	1	2	0.25	0.50	$137
Total	3	4	5		-5.50	-$1,507

Table 12 – Third-party Disclosure Burden for Agreement State Licensees (3150-0010)

Section	Number of Respondents	Responses Per Respondent	Total Number of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Cost @ $274/Hr
35.3045(e)	5	3	15	-2.00	-30.00	-$8,220
35.3204(a)	12	1	12	0.25	3.00	$822
Total	17	4	27		-27.00	-$7,398

ONE-TIME REPORTING BURDEN

Table 13 – One-Time Implementation Reporting Burden for NRC Licensees for NRC Form 313 (3150-0120)

Section	Number of Respondents	Responses Per Respondent	Total Number of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Cost @ $274/Hr
35.13(d)	1,085	1	1,085	0.50	542.50	$148,645
35.65(b)(2)	10	1	10	0.50	5.00	$1,370
Total	2,095		1,095		547.50	$150,015
Annualized Total			365.00		182.50	$50,005

Table 14 – One-Time Implementation Reporting Burden for Agreement State Licensees for NRC Form 313 (3150-0120)

Section	Number of Respondents	Responses Per Respondent	Total Number of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Cost @ $274/Hr
35.13(d)	6,401	1	6,401	0.50	3,200.50	$876,937
35.65(b)(2)	55	1	55	2.00	110.00	$30,140
Total	6,456		6,456		3,310.50	$907,077
Annualized Total			2,152.00		1,103.50	$302,359

ONE-TIME RECORDKEEPING BURDEN

Table 15 – On-Time Implementation Recordkeeping Burden for Agreement State Licensees for Part 35 (3150-0010)

Section	No. of NRC Recordkeepers	Number of Records per Licensee	Total Number of Records	Burden Hours per Record	Total Annual Burden Hours	Cost @ $274/Hour	Record Retention Period
35.24(b)	Burden covered in 35.2024(c)						
35.41(a)	Burden covered in 35.2041						
35.41(b)(5)	Covered in 35.41(a) (3540)						
35.41(b)(6)	Covered in 35.41(a) (2885)						
35.41(c)	Covered in 35.2041						
35.65(b)(2)	56	1	56	2.00	112.00	$30,688	Inventory and leak testing 3 years
35.2024(c)	6401	1	6,401	1.00	6,401.00	$1,753,874	5 years after ARSO is removed from license
35.2041	6425	1	6,425	9.00	57,825.00	$15,844,050	Duration of the license
Total			12,882.00		64,338.00	$17,628,612	
Annualized Total					21,446.00	$5,876,204	

Table 16 – One-Time Implementation Recordkeeping Burden for NRC Licensees for Part 35 (3150-0010

Section	No. of NRC Recordkeepers	Number of Records per Licensee	Total Number of Records	Burden Hours per Record	Total Annual Burden Hours	Cost @ $274/HR	Record Retention Period
35.24(b)	Burden covered in 35.2024(c)						
35.41(a)	Burden covered in 35.2041						
35.41(b)(5)	Covered in 35.41(a) (600)						
35.41(b)(6)	Covered in 35.41(a) (489)						
35.41(c)	Covered in 35.2041						
35.65(b)(2)	10	1	10	2.00	20.00	$5,480	Inventory and leak testing 3 years
35.2024(c)	1085	1	1,085	1.00	1,085.00	$297,290	5 years after ARSO is removed from license
35.2041	1089	1	1,089	9.00	9,801.00	$2,685,474	Duration of the license
Total			2,184.00		10,906.00	$2,988,244	
Annualized Total					3,635.33	$996,081	

TOTAL RECURRING ANNUAL BURDEN

Table 17 – Total Recurring Annual Burden in Hours for NRC Licensees				
	Reporting Burden	Recordkeeping Burden	3rd Party Disclosure Burden	Total
10 CFR Part 30	0.50	676.00	0.00	676.50
10 CFR Part 35	250.50	984.00	-5.50	1,229.00
Form 313	-947.25	0.00	0.00	-947.25
Total:	-696.25	1,660.00	-5.50	958.25

Table 18 – Total Recurring Annual Burden in Hours for Agreement State Licensees				
	Reporting Burden	Recordkeeping Burden	3rd Party Disclosure Burden	Total
10 CFR Part 30	3.00	3,991.00	0.00	3,994.00
10 CFR Part 35	1,484.25	5,784.00	-27.00	7,241.25
Form 313	-5,522.50	0.00	0.00	-5,522.50
Total:	-4,035.25	9,775.00	-27.00	5,712.75

Table 19 – Total Recurring Annual Burden in Hours for All Licensees				
	Reporting Burden	Recordkeeping Burden	3rd Party Disclosure Burden	Total
10 CFR Part 30	3.50	4,667.00	0.00	4,670.50
10 CFR Part 35	1,734.75	6,768.00	-32.50	8,470.25
Form 313	-6,469.75	0.00	0.00	-6,469.75
Total:	-4,731.50	11,435.00	-32.50	6,671.00

TOTAL ONE-TIME IMPLEMENTATION BURDEN

Table 20 – Total One-Time Burden in Hours for NRC Licensees (Annualized)			
	Reporting Burden	Recordkeeping Burden	Total
10 CFR Part 30	0.00	0.00	0.00
10 CFR Part 35	0.00	3,635.33	3,635.33
Form 313	182.50	0.00	182.50
Total:	182.50	3,635.33	3,817.83

Values from Tables 13 & 16

Table 21 – Total One-Time Burden in Hours for Agreement State Licensees (Annualized)			
	Reporting Burden	Recordkeeping Burden	Total
10 CFR Part 30	0.00	0.00	0.00
10 CFR Part 35	0.00	21,446.00	21,446.00
Form 313	1,103.50	0.00	1,103.50
Total:	1,103.50	21,446.00	22,549.50

Values from Tables 14 & 15

Table 22 – Total One-Time Burden in Hours for All Licensees (Annualized)			
	Reporting Burden	Recordkeeping Burden	Total
10 CFR Part 30	0.00	0.00	0.00
10 CFR Part 35	0.00	25,081.33	25,081.33
Form 313	1,286.00	0.00	1,286.00
Total:	1,286.00	25,081.33	26,367.33

BURDEN TOTALS (ANNUAL + ANNUALIZED ONE-TIME)

Table 23:TOTAL BURDEN FOR PROPOSED RULE				
	Reporting Burden	Recordkeeping Burden	3rd Party Disclosure Burden	Total
10 CFR Part 30	3.50	4,667.00	0.00	4,670.50
10 CFR Part 35	1,734.75	31,849.33	-32.50	33,551.58
Form 313	-5,183.75	0.00	0.00	-5,183.75
Total:	-3,445.50	36,516.33	-32.50	33,038.33

Values from Tables 19 & 22

	Table 24 – Total Annual Responses for All Licensees						
	NRC Licensees			Agreement State Licensees			TOTAL
	Responses	Recordkeepers	Total	Responses	Recordkeepers	Total	
10 CFR Part 30 (OMB 3150-0017)	1	52	53	6	307	313	366
10 CFR Part 35 (OMB 3150-0010)	1,063	141	1,204	6,273	824	7097	8,301
Form 313 (OMB 3150-0120)	541	0	541	3,184	0	3184	3,725
Total:			1,798			10,594	12,392

Table 25 – Total Respondents			
	Number of Respondents NRC	Number of Respondents Agreement States	Total
10 CFR Part 30 (OMB 3150-0017)	52	307	359
10 CFR Part 35 (OMB 3150-0010)	1,085	6,401	7,486
Form 313 (OMB 3150-0120)	1,085	6,401	7,486
***Unduplicated total:**			7,845

***The respondents for Part 35 and Form 313 are the same licensees.**