Draft Regulatory Analysis for Proposed Rule: Amendments to Medical Use of Byproduct Material Regulations (10 CFR Parts 30, 32, and 35)

U.S. Nuclear Regulatory Commission

Office of Federal and State Materials and Environmental Management Programs

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Table of Contents

Executive Summary ii
Acronyms iv
1. Statement of the Problem and Objective of the Rulemaking 1
2. Identification and Preliminary Analysis of Alternative Approaches 2
2.1 Option 1: No Action 2
2.2 Option 2: Amend 10 CFR Parts 30, 32, and 35 2
3. Estimation and Evaluation of Benefits and Costs 8
3.1 Identification of Affected Attributes 8
3.2 Analytical Methodology 9
3.3 Detailed Results 14
4. Presentation of Results 40
4.1 Benefits and Costs 40
4.2 Backfitting 41
5. Decision Rationale 41
6. Implementation 42
7. References 42
Appendix A: Regulatory Flexibility Analysis 43
Appendix B: Assumptions by section determining impacted NRC licensees. 46

Executive Summary

The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend Parts 30, 32, and 35 of Title 10 of the *Code of Federal Regulations* (10 CFR) related to medical use of byproduct material. In this action the NRC addresses three ongoing rulemaking projects and several other related topics. First, this rule proposes amendments to the reporting and notification requirements for a medical event (ME) for permanent implant brachytherapy. Second, the rule proposes changes: (1) to the training and experience (T&E) requirements for authorized users (AUs), medical physicists, Radiation Safety Officers (RSOs), and nuclear pharmacists; (2) to the requirements for measuring molybdenum contamination and reporting of failed technetium and rubidium generators; and (3) to allow Associate Radiation Safety Officers (ARSOs) to be named on a medical license. Third, the rule proposes changes to address a request filed in a petition for rulemaking (PRM), PRM-35-20, to exempt certain board-certified individuals from certain T&E requirements (i.e., "grandfather" these individuals) so that they may be identified on a license or permit for materials and uses that they performed on or before October 24, 2005, the expiration date of the former Subpart J of Part 35 which contained the prior T&E requirements. Currently there are 1,085 NRC and 6,401 Agreement State medical use licensees and 52 NRC and 307 Agreement State radiopharmacy licensees that would be affected by this proposed rulemaking. Existing guidance documents (NUREG-1556, Volumes 9 and 13) would be revised to reflect these changes.

This draft regulatory analysis examines the benefits and costs of the proposed changes to these regulations. The analysis makes the following key findings:

- Cost to Industry. The proposed rule would result in a total one-time cost to the Industry of approximately $8.3 million followed by total annual costs of approximately $660,000. This results in costs of approximately $1,100 per licensee in one-time cost and approximately $100 per licensee in annual cost.

- Costs to the NRC. The proposed rule would result in a one-time cost to the NRC of approximately $400,000 followed by an annual savings of approximately $75,000.

- Cost to the Agreement States. The proposed rule would result in a one-time cost to the Agreement States of approximately $5.1 million followed by an annual savings of approximately $325,000.

- Decision Rationale. The NRC has determined that the proposed rule is cost-justified because the proposed regulatory initiatives potentially would reduce unnecessary radiation exposure to patients. Additionally, the proposed rule would update, clarify, and strengthen the existing regulatory requirements, and thereby promote public health and safety. Cost reductions would be realized by removing attestation requirements for certain board certified individuals, by modifying ME reporting criteria to ensure only significant events need to be reported, and by other proposed modifications to the regulations.

- The NRC evaluated the impact that a small entity would be expected to incur as a result of the rule. The proposed rule would have an average implementation cost of

approximately $1,100 per licensee and an annual cost impact of an estimated $100 per licensee. Therefore, even though the proposed rule would affect a substantial number of licensees that are small entities, it would not have a significant economic impact on these entities.

Acronyms

ACMUI	Advisory Committee on the Medical Uses of Isotopes
ADAMS	Agencywide Documents Access and Management System
AMP	Authorized medical physicist
ANP	Authorized nuclear pharmacist
ARSO	Associate Radiation Safety Officer
AU	Authorized user
CFR	*Code of Federal Regulations*
FR	*Federal Register*
FTE	full-time equivalent
ME	medical event
Mo-99	molybdenum-99
NRC	U.S. Nuclear Regulatory Commission
OMB	Office of Management and Budget
PRM	petition for rulemaking
Rb-82	rubidium-82
RSO	Radiation Safety Officer
SRM	Staff Requirements Memorandum
SSDR	Sealed Source and Device Registry
Sr-82	strontium-82
Sr-85	strontium-85
Tc-99m	technetium-99m
T&E	training and experience
WD	written directive

1. Statement of the Problem and Objective of the Rulemaking

The NRC is proposing to amend 10 CFR Parts 30, 32, and 35 related to the medical use of byproduct material. Medical use regulations in 10 CFR Part 35 were revised in their entirety in April 2002 (67 FR 20250). The T&E requirements in Part 35 were further revised through an additional rulemaking published in the *Federal Register* (70 FR 16336) on March 30, 2005. In implementing the regulations, the NRC staff, stakeholders, and the Advisory Committee on the Medical Uses of Isotopes (ACMUI) have identified numerous issues that need to be addressed through the rulemaking process.

In Staff Requirements Memorandum (SRM) dated May 15, 2008, entitled "Meeting with Advisory Committee on the Medical Uses of Isotopes (ACMUI), 1:30 p.m., Tuesday April 29, 2008," (Agencywide Documents Access and Management System (ADAMS) Accession No. ML081360319), the Commission directed the staff to work with the ACMUI and the Agreement States to provide recommendations to the Commission with regard to amending the NRC's requirements for preceptor attestation for both board certified individuals and for individuals seeking authorization via an alternate pathway. The staff was also directed to consider additional methods, such as the attestation being provided by consensus of an authoritative group.

Additionally, the Commission directed the staff in SRM-SECY-10-0062, dated August 10, 2010 (ADAMS Accession No. ML102220233), to work closely with the ACMUI and the medical community to develop event definitions for permanent implant brachytherapy that would protect the interests of patients, and allow physicians the flexibility to take actions that they deem medically necessary while preserving the NRC's ability to detect misapplications of radioactive material and failures in processes, procedures and training.

The amendment would establish separate ME criteria for permanent implant brachytherapy in terms of the total source strength administered (activity-based) rather than the dose delivered (dose-based). The ME criteria would also include absorbed doses to normal tissues located outside of the treatment site and those located within the treatment site. Other changes include amending preceptor attestation requirements, allowing ARSOs to be named on a medical use license, changing the requirements for measuring molybdenum contamination and reporting of failed technetium and rubidium generators, extending the 5-year inspection frequency for a gamma stereotactic radiosurgery unit to 7 years, and several clarifying amendments.

The proposed rulemaking would also consider issues that were raised in a petition for rulemaking (PRM-35-20, ADAMS Accession No. ML062620129) filed by E. Russell Ritenour, Ph.D., on behalf of the American Association of Physicists in Medicine on September 13, 2006. The petition requested that the training requirements for experienced RSOs and medical physicists in 10 CFR 35.57 be amended to recognize board certified physicists and RSOs as "grandfathered" for the modalities that they practiced as of October 24, 2005.

The proposed rulemaking addresses the petition and Commission direction to clarify the current regulations, provides greater flexibilities to licensees, revises medical event criteria for permanent implant brachytherapy without compromising patient, worker, and public health and safety.

This analysis presents background material, rulemaking objectives, alternatives considered, input assumptions, analysis of the costs and benefits of the proposed rule, and decision rationale. It describes the consequences of the rule language and alternative approaches necessary to accomplish the regulatory objectives.

2. Identification and Preliminary Analysis of Alternative Approaches

The following sections describe the two regulatory options that the NRC is considering to meet the rulemaking objective identified in Section 1.1. Section 3 presents a detailed cost and benefit analysis.

2.1 Option 1: No Action

Under Option 1, the no-action alternative, the NRC would not amend the current regulations in 10 CFR Parts 30, 32, and 35.

Option 1 would avoid costs and savings that the proposed rule would impose; however, the benefits from updating, clarifying, and consolidating the current requirements to enhance the current level of protection for public health and safety would not be realized. Also, there would be no changes made to improve regulatory efficiency and the resulting benefits to the medical use of byproduct material. Option 1, which is the no-action alternative, is the baseline for this draft regulatory analysis.

2.2 Option 2: Amend 10 CFR Parts 30, 32, and 35

The changes listed below are consistent with Option 2 to revise 10 CFR Parts 30, 32, and 35 and would result in incremental increase or decrease in cost or benefit.

Section 30.34(g). This new requirement would be added to require radiopharmacy licensees to report to the NRC the results of any test of generator elutions for molybdenum-99 (Mo-99) breakthrough or strontium-82 (Sr-82) and strontium-85 (Sr-85) contamination 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 as well as testing every elution is new, the requirement for licensees to test the first elution to ensure that it does not exceed the permissible concentration listed in § 35.204(a), and record the results of these tests, is already in current regulations. On several occasions in 2006, 2007, and 2008, medical licensees voluntarily reported to the NRC that generators had failed the Mo-99 breakthrough tests. In 2011, contamination issues were reported with Sr-82 rubidium-82 (Rb-82) generators. Because the reporting was voluntary, the NRC had difficultly determining the extent of the issues and the underlying cause. Breakthrough of Mo-99 and contamination of Sr-85 may lead to unnecessary exposure to radiation for patients. The proposed change would allow the NRC to assess the situation quickly and efficiently when issues occur with generators that may cause unwarranted radiation exposure to patients.

Section 35.12 (b)(1). This paragraph would be amended to remove the requirement to submit additional copies of NRC Form 313 when applying for a license. The proposed change would relieve cost to the licensees by requiring less paperwork to be submitted. This paragraph would

also add a requirement to submit information on an individual seeking to be identified on a license as an ARSO or as an ophthalmic physicist.

Section 35.12 (c). This paragraph would be amended to remove the requirement to submit an additional copy of NRC Form 313 or a letter containing information required by NRC Form 313 for license amendments or renewals. This change would relieve cost to the licensees by requiring less paperwork to be submitted.

Section 35.13(d). This new paragraph would require 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 who is authorized on the license. The NRC determined that allowing ARSOs to be named on a license would increase the number of individuals who would be available to serve as preceptors for individuals seeking to be appointed as RSOs or ARSOs. Also, by being named on a license, ARSOs could more easily become RSOs on other licenses for the types of uses for which they qualify.

Section 35.13(i). This new paragraph would allow licensees who are authorized for manual brachytherapy to receive certain sealed sources without seeking a license amendment. Specifically, a licensee would 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 its license. This change is proposed to make it easier for the licensee to obtain the appropriate sealed sources necessary for patient treatments in a timely manner.

Section 35.14(a). This paragraph would be amended to remove the requirement to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State when using the notification process.

Section 35.14(b)(1). This paragraph would be amended to require a licensee to notify the Commission within 30 days after an ARSO or ophthalmic physicist has a name change or discontinues performance of their duties under the license.

Section 35.14(b)(6). This new paragraph would require a licensee to notify the NRC no later than 30 days after receiving a sealed source from a new manufacturer or a new model number listed in the SSDR for manual brachytherapy for quantities and isotopes already authorized by the license.

Section 35.24(b). This paragraph would be modified to allow the licensee's management to appoint one or more qualified individuals to serve as ARSOs. These appointed ARSOs would have to be currently identified on a medical license or permit for the types of use of byproduct material for which the RSO would assign tasks and duties. Each ARSO would have to agree in writing to the tasks and duties assigned by the RSO.

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

Section 35.41(b)(5). This new paragraph would require licensees to add procedures for any administrations requiring a written directive (WD) to determine if an ME as defined in § 35.3045 has occurred.

Section 35.41(b)(6). Existing paragraph (b)(6) would be redesignated as paragraph (b)(7) and a new paragraph (b)(6) would be added. This new paragraph would require licensees to add procedures for permanent implant brachytherapy that include a procedure for determining dose/activity parameters within 60 calendar days from the date the implant was performed. If the licensee cannot make these determinations within the 60 calendar days because of the patient not being available, then the licensee must justify the reason for not making these determinations in writing.

Section 35.50(a). For individuals seeking to be named as an RSO or an ARSO, this paragraph would be amended to remove the requirement to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State.

Section 35.50(c)(3). This new paragraph would allow an individual who is qualified to be an AU, but is not named as an AU on a medical license or permit, to be named simultaneously as the RSO and the AU on the same new medical license. Under current § 35.50(c)(2), an AU identified on a medical license or permit can be named as the RSO for the same byproduct material for which the AU is authorized. This new provision would expand this principle and allow an individual who is qualified to be the AU, but is not named on a medical license or permit, to be named simultaneously as both the AU and the RSO for the same uses on a new medical license. The provision would make it easier for an individual qualified to be an AU to open a physician's office or a clinic and make medical procedures more widely available, especially in rural areas.

Section 35.51(a). This paragraph would be amended to remove the requirement for individuals seeking to be named as an authorized medical physicist (AMP) to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State.

Section 35.55(a). This paragraph would be amended to remove the requirement for individuals seeking to be named as an authorized nuclear pharmacist (ANP) to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State.

Section 35.57(a)(1). This paragraph would be modified to add AMPs and ANPs identified on a Commission or an Agreement State license or a permit issued by a Commission or an 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, as individuals that would not need to comply with the training requirements of §§ 35.50, 35.51, or 35.55, respectively.

Section 35.57(a)(2). This paragraph would be modified to recognize individuals certified by the named boards in the now removed Subpart J of Part 35 on or before October 24, 2005, who would not need to comply with the training requirements of § 35.50 to be identified as a RSO on a Commission or an 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. Training requirements excepted under this paragraph would be limited to those materials and uses these individuals performed on or before October, 24, 2005. Individuals excepted by this paragraph would still need to meet the recentness training requirements in § 35.59 and, for new materials and uses, the training requirements in § 35.50(d).

Section 35.57(a)(3). This paragraph would be modified to recognize individuals certified by the named boards in the now removed Subpart J of 10 CFR Part 35 on or before October 24, 2005, who would not need to comply with the training requirements of § 35.51 to be identified as an AMP on a Commission or an 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. Training requirements excepted under this paragraph would be limited to those materials and uses these individuals performed on or before October, 24, 2005. Individuals excepted by this paragraph would still need to meet the recentness training requirements in § 35.59 and, for new materials and uses, the training requirements in § 35.51(c).

Section 35.57(b)(1). This paragraph would be amended to change the date from October 24, 2002, to October 24, 2005, for individuals named on a license as AUs because during the 3-year time frame, applicants could have qualified under the old Subpart J or the new T&E requirements in Subparts D through H of 10 CFR Part 35 to qualify as AUs. Additionally, the paragraph would be amended to clarify that individuals authorized before, rather than just on, October 24, 2005, would not be required to comply with the T&E requirements in Subparts D through H of 10 CFR Part 35 for those materials and uses that they performed on or before that date.

Section 35.57(b)(2). This paragraph would be restructured and expanded to recognize physicians, dentists, or podiatrists who were certified by the named boards in the now-removed Subpart J of Part 35 on or before October 24, 2005, who would not need to comply with the training requirements of Subparts D through H of 10 CFR Part 35 to be identified as an AU on a Commission or an Agreement State license or Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

Section 35.65(b)(2). This new paragraph would prohibit the bundling or aggregating of single sealed sources to create a sealed source with an activity larger than that authorized by § 35.65. Sources that consist of multiple single sources greater than authorized by § 35.65 would be treated as one single source and would 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.

Section 35.190(a). This paragraph would be amended to remove the written attestation requirement for a physician who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State and is seeking to be named as an AU for byproduct material authorized under § 35.100.

Section 35.204(b). This paragraph has been modified to require licensees to measure the

Mo-99 concentration after each eluate from a Mo-99/Tc-99m generator. Generator manufacturers recommend testing each elution prior to use in humans. Mo-99 breakthrough measurements which exceed the permissible concentration listed in § 35.204(a) may cause unnecessary radiation exposures to patients.

Section 35.204(e). This new paragraph would require medical use licensees to report any measurement that exceeded the limits specified in § 35.204(a) for Mo-99/Tc-99m and Sr-82 Rb-82 generators. Although current regulations require licensees to measure Mo-99, Sr-82, and 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. The new reporting requirement would provide information that would allow the NRC to respond to the potential patient safety issue in a timely manner.

Section 35.290(a). This paragraph would be amended to remove the written attestation requirement for a physician who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State and is seeking to be named as an AU for byproduct material authorized under § 35.200.

Section 35.390(a). This paragraph would be amended to remove the written attestation requirement for a physician who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State and is seeking to be named as an AU for byproduct material authorized under § 35.300.

Section 35.392(a). This paragraph would be amended to remove the written attestation requirement for a physician who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State and is 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).

Section 35.394(a). This paragraph would be amended to remove the written attestation requirement for a physician who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State and is seeking to be named as an AU for the oral administration of sodium iodide I-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) requiring a WD.

Section 35.433(a)(2). This paragraph would be amended to add the T&E requirements for an ophthalmic physicist who is not an AMP, but who could be involved with ophthalmic treatments using strontium-90 sealed sources. These requirements are similar to the T&E requirements for an AMP, but would include only the requirements related to brachytherapy programs. The ophthalmic physicist would not need an attestation. This change would 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 calculation to support the ophthalmic treatment. This change would make the procedure involving use of strontium-90 sources for ophthalmic treatments available to more patients located in remote areas.

Section 35.490(a). This paragraph would be amended to remove the written attestation requirement for a physician who is certified by a specialty board whose certification process has

been recognized by the NRC or an Agreement State and is seeking to be named as an AU for byproduct material authorized under § 35.400.

Section 35.610(d)(1). This paragraph would be amended and restructured to add a new training requirement for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. This proposed amendment would require all individuals who would operate these units to receive vendor operational and safety instructions 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.

Section 35.655(a). This paragraph would be amended to extend the time interval for fully inspecting and servicing a gamma stereotactic radiosurgery unit from 5 years to 7 years.

Section 35.690(a). This paragraph would be amended to remove the written attestation requirement for a physician who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State and is seeking to be named as an AU for byproduct material authorized under § 35.600.

Section 35.2024(c)(1) and (2). This new paragraph would require the licensee to keep records of each ARSO assigned under § 35.24(b) for 5 years after the ARSO is removed from the license. These records would have to include the written document appointing the ARSO signed by the licensee's management, and each agreement signed by the ARSO listing the duties and tasks assigned by the RSO under § 35.24(b).

Section 35.2041. This section is impacted due to the recordkeeping requirements of the added procedures required in § 35.41(b)(5) and (6).

Section 35.3045(a)(2). In this amended section, separate criteria for reporting an ME for permanent implant brachytherapy procedures are established. The new criteria are expected to capture events that are clinically significant and would reduce the number of reportable MEs related to permanent implant brachytherapy resulting in cost reduction in § 35.3045(c), (d), and (e) related to event notification and follow-up reports.

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

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

Section 35.3045(e). The licensee reporting costs to the physician and patients would be reduced because the requirements for reporting an ME for permanent implant brachytherapy are changed in § 35.3045(a)(2). The new requirements would not capture events that are not

significant and would reduce the number of reportable MEs related to permanent implant brachytherapy.

Section 35.3204. This new section would be added to establish the reporting requirements for radiopharmacy licensees and medical use licensees to report to the NRC the results of any test of generator elutions for Mo-99 breakthrough or Sr-82 and Sr-85 contamination that exceeds the permissible concentration listed in § 35.204(a).

The NRC has estimated the benefits and costs of this option, which are described in Sections 3 and 4 of this regulatory analysis, and has pursued Option 2 for the reasons discussed in Section 5.

3. Estimation and Evaluation of Benefits and Costs

This section describes the analysis that the NRC conducted to identify and evaluate the benefits and costs of the two regulatory options. Section 3.1 identifies the attributes that the staff expects the proposed rulemaking to affect. Section 3.2 describes how the benefits and costs have been analyzed. Finally, Section 3.3 presents the detailed results of the projected benefits and costs.

3.1 Identification of Affected Attributes

This section identifies the factors within the public and private sectors that the final rule is expected to affect, using the list of potential attributes in Chapter 5 of NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook," issued January 1997, and in Chapter 4 of NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," Revision 4, issued September 2004. This evaluation considered each attribute listed in Chapter 5 of NUREG/BR-0184. The basis for selecting those attributes is presented below.

Affected attributes include the following:

- Industry Implementation - Under the proposed action, the industry would incur a one-time cost to implement the proposed rule.

- NRC Implementation - Under the proposed action, the NRC would develop the proposed rule package to be published by the Office of the *Federal Register* and prepare the final rule package that responds to comments from stakeholders and sets forth the final rule text for publication by the Office of the *Federal Register*. The NRC would revise guidance and inspection procedures to accommodate the requirements that would be added or modified by the rulemaking process.

- Industry Operations - The proposed changes to 10 CFR Parts 30, 32, and 35 would require licensees to meet the new and amended requirements discussed in Section 2.2.

- NRC Operations - The proposed changes would require the NRC to process and review submitted licensing amendments and reports.

- Other Government - The Agreement States would incur an implementation cost to issue compatible regulatory requirements and guidance. The Agreement States would incur annual operational cost as well.

- Regulatory Efficiency - The action would result in enhanced regulatory efficiency through regulatory and compliance improvements.

- Public Health (routine) - Several proposed amendments would reduce the potential radiation exposure to patients.

Attributes that the rulemaking options would not affect include the following: occupational health (routine), occupational health (accidents), public health (accidents), environmental considerations, general public, safeguards and security considerations, improvements in knowledge, offsite property, onsite property, antitrust considerations, and other considerations.

3.2 Analytical Methodology

This section describes the methodology used to analyze the benefits and costs associated with the proposed rule. The benefits include any desirable changes in the affected attributes. The costs include any undesirable changes in the affected attributes.

As described in Section 3.1, the attributes expected to be affected include the following:

- Industry Implementation
- Industry Operation
- NRC Implementation
- NRC Operations
- Regulatory Efficiency
- Other Government
- Public Health (routine)

The analysis evaluates several attributes on a quantitative basis. Quantitative analysis requires a baseline characterization, including factors such as the number of licensees affected, the nature of activities being conducted, and the types of new activities that licensees would implement as a result of the rule. The analysis proceeds quantitatively for these attributes by making general assumptions. Sections 3.2.1 – 3.3 describe the most significant analytical data and assumptions used in the quantitative analyses of these attributes.

The proposed rule includes changes that affect attributes in a positive but not easily quantifiable manner. For example, the attribute of Regulatory Efficiency would be enhanced by the proposed changes made in requirements for submitting an application for a license such as in § 35.50. In this section, the regulations would be changed to make it easier for a physician to open an office by allowing this individual to be the AU and the RSO on the same license application.

One way public health (routine) would be positively affected is by reducing the potential for unnecessary radiation exposure to patients with the changes to § 35.204. This section would

require licensees to test each eluate from a generator rather than just the first eluate. In the past several years, generators have had breakthrough issues that have resulted in unnecessary radiation exposure to patients.
The NRC's input assumptions used data and information from NRC workgroups, staff experience, and the NRC's databases to estimate the costs associated with implementation, and the costs associated with annual operations of industry and the NRC.

In accordance with guidance from the Office of Management and Budget (OMB) and NUREG/BR-0058, Revision 4, this regulatory analysis presents the results of the analysis using both 3 percent and 7 percent real discount rates. The real discounted rates or present-worth calculation simply determines how much society would need to invest today to ensure that the designated dollar amount is available in a given year in the future. By using present-worth, costs and benefits, regardless of when averted in time, are valued equally. Based on OMB guidance (OMB Circular No. A-4, September 17, 2003), present-worth calculations are presented using both 3 percent and 7 percent real discount rates. The 3 percent rate approximates the real rate of return on long-term government debt which serves as a proxy for the real rate of return on savings. This rate is appropriate when the primary effect of the regulation is on private consumption. Alternatively, the 7 percent rate approximates the marginal pretax real rate of return on an average investment in the private sector, and is the appropriate discount rate whenever the main effect of a regulation is to displace or alter the use of capital in the private sector. The NRC seeks public comments on the accuracy of these regulatory analysis assumptions and on the validity of the proposed rule's value and impact estimation methods.

3.2.1 Data and Assumptions

The analysis assumes that one-time implementation cost for Industry, the Agreement States and NRC-proposed changes to §§ 35.13(d) and 35.65(b)(1) would be incurred in calendar year 2015. The analysis assumes that NRC one-time implementation costs associated with rule development and guidance documents are incurred in years 2012-2015. The analysis assumes that ongoing costs related to revised and consolidated requirements in 10 CFR Parts 30, 32, and 35 would begin in 2015 and would be modeled on an annual cost basis. The analysis calculated cost and savings over a 10-year time horizon with each year's costs or savings discounted back at a 7 percent and 3 percent discount rate in accordance with NUREG/ BR-0058, Revision 4. Costs and savings are expressed in 2013 dollars.

Data/Affected Entities

The analysis assumes that the following entities would be affected by this rule:

- NRC
- NRC licensees
- Agreement States
- Agreement State licensees
- Manufacturers and/or distribution licensees
- Radiopharmacy licensees
- Authorized users
- Associate Radiation Safety Officers

- Radiation Safety Officers
- Authorized medical physicists
- Authorized nuclear pharmacists
- Medical patients

Number and Type of Licensees

Licensees regulated by the NRC (those licensed by the NRC to use radioactive materials including NRC Master Material Licensees) and the Agreement States (states who have assumed regulatory authority over the use of certain radioactive materials in their states) are equally impacted by the proposed rule. Table 1 provides data from NRC's License Tracking System on the number of NRC licensees, by category, as of November 2012. The number of Agreement State licensees is estimated at 5.9 times the number of NRC licensees, based on historical data obtained from NRC databases. This regulatory analysis is based on the assumption that all the Agreement States will adopt all of the proposed regulatory changes.

Table 1 Number and Type of Licenses

License Title	Program codes [1]	NRC[2]	Master Materials License[3]	Total NRC Licensees	Agreement States[4]	Total Licensees
Part 30						
Radiopharmacies	2500	52	0	52	307	359
Total Part 30						359
Part 35						
Medical Institution – Broad	2110	23	44	67	395	462
Medical Institution – WD Required	2120	257	81	338	1994	2332
Medical Institution – WD Not Required	2121	145	13	158	932	1090
Medical Private Practice – WD Required	2200	58	0	58	342	400
Medical Private Practice – WD Not Required	2201	286	0	286	1687	1973
Eye Applicators Strontium-90	2210	14	0	14	83	97
Mobile Medicine Service – WD Not Required	2220	41	0	41	242	283
High Dose-Rate Remote Afterloader	2230	85	0	85	502	587
Mobile Medical Service – WD Required	2231	2	0	2	12	14
Medical Therapy – Other Emerging Technology	2240	26	0	26	153	179
Teletherapy	2300	2	0	20	12	14
Gamma Stereotactic Radiosurgery	2310	8	0	8	47	55
Sub totals		947	138	1085	6401	
Total Part 35						7486

[1] NRC Material License Program Codes, November 2012.
[2] Data from NRC License Tracking System (LTS), November 2012.
[3] Master Material Licenses (such as Navy and Veterans Affairs)
[4] Estimated, based on 1 to 5.9 ratio of NRC licensees to Agreement State licensees

Assumptions

The analysis makes the following other assumptions:

- The NRC estimates that each licensee who elutes generators will have to perform and record the results for an additional 15 breakthrough tests each week.

- The NRC estimates that, on average, all licensees will have added 1 ARSO on their licenses.

- The NRC estimates that, on average, license amendments will take 0.5 hour of NRC/Agreement State time to review/process. To review the entire NRC Form 313/Application will take 4 hours.

- The NRC estimates that, on average, licensee application/NRC Form 313 submitted in its entirety will take 1 hour of physician time and 3 hours of clerical time to prepare and submit. To complete the proposed required amendments, portions of NRC Form 313 will need to be completed. The NRC estimates that it takes 0.5 hour to complete each section of the form.

- The NRC's labor rates are determined using the methodology in Abstract 5.2, "NRC Labor Rates," of NUREG/CR-4627, "Generic Cost Estimates, Abstracts from Generic Studies for Use in Preparing Regulatory Impact Analyses." This methodology considers only variable costs (including salary and benefits) that are directly related to the implementation, operation, and maintenance of the proposed amendments. Currently, the NRC's hourly labor rate is $121. The estimation of costs for rulemaking is based on professional NRC staff full-time equivalent (FTE). Based on actual data from the NRC's time and labor system, the number of hours in 1 year that directly relates to implementation of assigned duties is 1,375 (1,375 was derived by taking the annual number of hours (2,080) and accounting for leave, training, and completing administrative tasks). Therefore, an NRC professional staff FTE hourly rate is based on 1,375 hours.

- Agreement State labor rates were determined from the National Wage Data available on the Bureau of Labor Statistics Web site (www.bls.gov). Because exact hourly rates would be difficult to obtain for each of the 37 Agreement States and may not be sufficiently recent, nationwide mean hourly rates were used. For all Agreement State labor rates, $60.80/hour is used, which is from the Bureau of Labor Statistics Employer Costs for Employee Compensation data set, under the category "Lawyers." The rate was then increased using a multiplier of 1.5 to account for benefits (pension, insurance premiums, and legally required benefits) that resulted in an hourly rate of $91.20.

- Licensee labor rates were obtained from the National Wage Data available on the Bureau of Labor Statistics Web site (www.bls.gov). Depending on the industry and the occupation (e.g., manufacturing, health and safety, etc.), an appropriate mean hourly labor rate was selected. The rate was then increased using a multiplier of 1.5 to account for benefits (pension, insurance premiums, and legally required benefits). Because exact hourly rates would be difficult to obtain and may not be sufficiently recent, nationwide mean hourly rates were used. The bases for the labor rates are as follows. For licensee labor rates, three

labor rates are used. For clerical recordkeeping labor cost, $29.54/hour is used ($19.69 X 1.5), which is from the Compensation data set "Miscellaneous healthcare practitioner and

technical workers. For physician labor cost, $128.51/hour is used ($85.67 X 1.5), which is from the data set "Physician." For nuclear technician labor cost, $72.54/hour is used ($48.36 X 1.5), which is from the data set "Nuclear technician." As described in OMB Circular A-76, "Performance of Commercial Activities," the number of productive hours in one year is 1,776. As this actual value is likely to vary from state to state and no specific data was available, the FTE costs for the Agreement States are based on the number of hours estimated in OMB Circular A-76.

- Licensee turnover rates were obtained from Job Openings and Labor Turnover Survey Data available on the Bureau of Labor Statistics Web site (www.bls.gov). Based on this data, the NRC estimates the licensee turnover rate to be 3.0 percent annually. For the purpose of this analysis, the NRC estimates the total number of licensees to be constant over the 10-year analysis period.

- The analysis assumes that the final rule will be published in early 2015 and would be effective in mid-2015.

- The NRC estimates that 30 percent of the applicants and AMPs, AUs, and RSOs currently listed on NRC and Agreement State medical licenses are board certified. For ANPs, this estimate is 10 percent.

- For the purpose of this analysis, the NRC assumes a 10-year licensing period and a 10 percent renewal annually.

- The NRC estimates that 10 percent of licensees will submit an amendment annually to change tasks/duties of ARSOs on their licenses.

- The analysis calculated cost over a 10-year timeframe with each year's costs or savings discounted back at a 7 percent and 3 percent discount rate, in accordance with NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," Revision 4.

- To the extent practical, quantitative information (e.g., costs and savings) and qualitative information (e.g., the nature and magnitude of impacts) on attributes affected by the rule were obtained from, or developed in consultation with, the NRC staff.

3.3 Detailed Results

This section presents a detailed estimate of the impacts by attribute for the proposed rulemaking (Option 2). Some benefits and costs are addressed qualitatively for reasons discussed in Section 3.2. Exhibit 4-1 summarizes these results.

Option 1: No Action

By definition, this option does not result in any benefits or costs. The baseline for Option 2 is the No-Action Alternative. The baseline assumes full compliance with existing NRC requirements. This baseline is consistent with NUREG/BR-0058, which states that, "in evaluating a new requirement...the staff should assume that all existing NRC requirements have been implemented."

Option 2: Amend Regulations to Revise 10 CFR Parts 30, 32, and 35

For details of how the NRC determined the number of licensees and individuals affected by Option 2, see Appendix B.

Industry Implementation

Amendment for ARSO

Section 35.13(d) would require 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 NRC estimates that all 7,486 licensees will add an ARSO. Some of the larger medical licensees will have several ARSOs, while other smaller licensees will have none, but on average there will be 1 ARSO per licensee. The NRC determined that allowing ARSOs to be named on a license would increase the number of individuals who would be available to serve as preceptors for individuals seeking to be appointed as RSOs or ARSOs. Also, by being named on a license, ARSOs could more easily become RSOs on other licenses for the types of uses for which they qualify. This will be a 0.5 labor hour cost per licensee for processing an amendment.

Recordkeeping

Section 35.24(b) would require the written documentation of the RSO-delegated duties to an ARSO, management's appointment of an ARSO, and the ARSO acceptance of the duties and delegated tasks. This paragraph would be modified to allow the licensee's management to appoint one or more qualified individuals to serve as ARSOs. The NRC estimates this to be a 1 labor hour cost for all 7,486 impacted licensees.

Adding requirements to current procedures

Section 35.41(b)(5) would require that affected licensees add procedures for any administration requiring a WD to include procedures for determining if an ME, as defined in § 35.3045, has occurred. The NRC estimates that 4,140 licensees would add procedures to include this requirement and the associated cost would be 8 hours physician labor and 1 hour clerical labor.

Section 35.41(b)(6) would require the affected licensee to add procedures for permanent implant brachytherapy that include a procedure for determining dose/activity parameters within 60 calendar days from the date the implant was performed. If the licensee cannot make these determinations within the 60 calendar days because of the patient not being available, then the licensee would have to justify the reason for not making these determinations in writing. The

NRC estimates that 3,373 licensees will add procedures to include this requirement and the associated cost will be 8 physician labor hours and 1 clerical labor hour.

Licensee cost to meet additional requirements.

Section 35.65(b)(2) would be modified to require licensees that possess bundled or aggregated single sealed sources with greater than a specified activity to treat them as one single source. These sources with activities larger than authorized by § 35.65 would have to meet all the regulatory requirements for that of a 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. The cost for licensees would encompass recordkeeping of new leak test and security requirements under regulations, if appropriate. In addition, if bundled source activity is treated as a single source, an amendment to the license would be required. The NRC estimates the recordkeeping to be 2 labor hours and 0.5 labor hour for the required amendment. The NRC estimates this to impact 66 licensees.

Recordkeeping

Section 35.2041 would add a one-time recordkeeping cost for the added procedures now required in § 35.41(b)(5) and (6). The NRC estimates the cost for this recordkeeping requirement to be 0.10 labor hour for each of the 7,486 impacted licensees.

Table 2 Summary of Industry Implementation Cost

Description	# of Licensees	One-time cost	Notes
35.13(d)	7486	$110,568	Amend license to add ARSO
35.24(b)	7486	$221,136	RSO delegates duties to ARSO, ARSO accepts and management appoints ARSO
35.41(b)(5)	4140	$4,378,547	Add requirements to existing procedures
35.41(b)(6)	3373	$3,567,352	Add new procedures
35.65(b)(2)	66	$3,899	Recordkeeping for security and leak test requirements
35.65(b)(2)	66	$4,241	Amend license for select bundled single sources
35.2041	7486	$22,114	Recordkeeping cost for § 35.41(b)(5) and (6)
Total		$8,307,857	

NRC Implementation

Processing amendment for ARSO

Section 35.13(d) would require the NRC to process the licensee 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 NRC estimates that on average all 1,085 NRC licensees will add an ARSO. Some of the larger medical licensees will have several ARSOs while other smaller licensees will have none, but on average there will be 1 ARSO per licensee. This will be a 0.5 labor hour cost to the NRC per licensee for processing an amendment.

Processing amendment for bundled sources

Section 35.65(b)(2) would require licensees that possess bundled or aggregated single sealed sources with greater than a specified activity to treat them as one single source. These sources with activities larger than authorized by § 35.65 would 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 adequate controls for security and radiation safety are applied to these larger sources. If bundled source activity is treated as a single source an amendment to the license is required. The NRC estimates 0.5 labor hours to process the required amendments, and this will impact 10 licensees.

Develop rule package and revise guidance documents

The NRC would develop the proposed and final rule packages and revise guidance and inspection procedures to accommodate the requirements that would be added or modified by the rulemaking process. This effort will require 1.5 of an FTE (2,062.5 hours) for participating in the rulemaking activities over a 2-year period. To revise and update the guidance documents will take 0.5 FTE (687.5 hours). This is an approximately $400,000 one-time cost to the NRC. The analysis assumes that NRC one-time implementation costs associated with rule development and guidance documents are incurred in years 2013-2016.

The NUREG guidance documents listed below would be updated:

- NUREG-1556 Volume 9, Program-Specific Guidance About Medical Use Licenses (Revision 2).

- NUREG-1556 Volume 13, Program-Specific Guidance About Commercial Radiopharmacy Licenses (Revision 1).

- Inspection Procedure 87132.

Table 3 Summary of NRC Implementation Cost

Section	Description	One time cost in year 2013	One time cost in year 2014	One time cost in year 2015	Undiscounted cost	Total 3 Yr 3% NPV	Total 3 Yr 7% NPV
35.13(d)	Process amendment			$68,355	$68,355	$68,355	$68,355
35.65(b)(2)	Process amendment			$630	$630	$630	$630
	Rule development	$86,625	$86,625	$86,625	$259,875	$245,028	$227,331
	Guidance documents	$28,875	$28,875	$28,875	$86,625	$81,676	$75,777
	Total	$115,500	$115,500	$184,485	$415,485	$395,690	$372,094

Other Governments Implementation (Agreement States)

Amendment for ARSO

Section 35.13(d) would require 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 authorized on the license.

The NRC estimates that on average all 6,401 Agreement State licensees will add an ARSO. Some of the larger medical licensees will have several ARSOs, while other smaller licensees will have none, but on average there will be 1 ARSO per licensee. This will be a 0.5 hour cost per licensee for processing an amendment.

Processing amendment for bundled sources

Section 35.65(b)(2) would require licensees that possess bundled or aggregated single sealed sources with greater than a specified activity to treat them as one single source. These sources with activities larger than authorized by § 35.65 would 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 adequate controls for security and radiation safety are applied to these larger sources. If bundled source activity is treated as a single source an amendment to the license is required. The NRC estimates 0.5 labor hour to process the required amendments, and this will impact 56 licensees.

Develop rule package and revise guidance documents

The Agreement State staffs would develop the rule packages to accommodate the requirements that would be added or modified by the rulemaking process. Revised guidance and inspection procedures may or may not be required depending on each state's process. Some Agreement States adopt the NRC's guidance and inspection procedures without change. The rulemaking effort will require 0.5 of an FTE (888 hours) on average for each of the 37 Agreement States. To revise and update the guidance documents and inspection procedures will take 0.25 FTE (444 hours). This is an estimated $121,500 one-time cost to each of the 37 Agreement States.

Table 4 Summary of Agreement State Implementation Costs

Section	Description	One-time cost
35.13(d)	Process amendment	$583,771
35.65(b)(2)	Process amendment	$5,107
N/A	Update regulations	$2,996,467
N/A	Guidance documents	$1,498,234
	Total	$5,083,580

Industry Operation

Reporting requirement

Section 30.34(g)would require radiopharmacy licensees to report to the NRC/Agreement States the results of any test of generator elutions for Mo-99 breakthrough or Sr-82 and Sr-85 contamination that exceeds the permissible concentration listed in § 35.204(a). While this proposed reporting requirement as well as testing every elution is new, the requirement for licensees to test the first elution to ensure that it does not exceed the permissible concentration listed in § 35.204(a), and record the results of these tests, is already in current regulations. Issues have occurred with generators that may cause unwarranted radiation exposure to patients. This reporting requirement is included in § 35.204(e).

Savings for the licensees for no longer requiring a copy of application

Section 35.12 (b)(1) would be amended to remove the requirement to submit additional copies of the NRC Form 313 when applying for a license.

The NRC estimates the licensees averaged 0.25 hour to make and submit additional copies of their application. The NRC estimates that there will be 225 new applications submitted annually.

Cost for licensees to submit information on an ARSO

Section 35.12(b)(1) also would add a requirement to submit information on an individual seeking to be identified as an ARSO.

The NRC estimates that there will be 225 new applications submitted annually requiring applicants to submit information on an ARSO with a 0.5 hour cost per applicant.

Savings on copies of amendments or renewals of applications

Section 35.12(c)(1) would remove the requirement to submit an additional copy of NRC Form 313 or a letter containing information required by NRC Form 313 for license amendments or renewals.

The NRC estimates the licensees will save 0.25 hours to copy and submit an additional copy of NRC Form 313 for renewals. The renewal timeframe is 10 years. The NRC estimates that there will be on average 749 renewals submitted annually.

For copies of amendments which are submitted on NRC Form 313, the NRC estimates there will be 1 amendment per licensee for a total of 7,486 submitted annually.

Licensing amendments for new ARSOs

Section 35.13(d) would require 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 authorized on the license. For the purpose of this analysis, the NRC assumes a 3 percent licensee turnover rate. This would represent 225 total licensees. In addition, 10 percent of all ARSOs will have their duties and tasks amended annually. This will be a 0.5 hour cost per licensee.

Allow licensees to receive certain sealed sources without first seeking a license amendment

Section 35.13(i) would be added to this section to allow licensees to receive certain sealed sources without first seeking a license amendment. This change is proposed to make it easier for the licensee to obtain the sealed sources necessary for patient treatments in a timely manner. The NRC assumes that each affected licensee will receive 2 new sealed sources annually. This proposed amendment would allow licensees to save on submittals of 2 amendments/NRC Form 313s for a 1.0 labor hour savings annually. The NRC estimates this to affect 3,498 licensees annually.

Cost to licensee to process notification

Section 35.14(b)(1) would require a licensee to notify the NRC/Agreement States within 30 days after the ARSO or ophthalmic physicist is removed from the list of individuals that the licensee is required to report when the ARSO or ophthalmic physicist discontinues performance of duties under the license or has a name change.

The NRC estimates that 225 new ARSOs will be named annually due to turnover and 37 (0.5 percent of total) due to a name change. The NRC estimates this to be a 0.25 labor hour cost. The number of new ophthalmic physicists is too low to establish an estimated labor cost.

Costs for licensee to process notification

Section 35.14(b)(6) would require the 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 which is being removed under § 35.13(i). This notification is required for the NRC to have an accurate record of sealed sources possessed by a licensee.

The NRC estimates that 3.498 licensees will be impacted twice annually, and each notification will take 0.25 hour to process.

Recordkeeping for new ARSOs

Section 35.24(b) would require written documentation for managing appointments of ARSOs, ARSOs acceptance of the appointment, and the RSO assignment of tasks and duties. This paragraph would be modified to allow the licensee's management to appoint one or more qualified individuals to serve as ARSOs. The NRC estimates this to be a 1 hour cost for the 225 licensees impacted with turnover.

Adding new procedures

Section 35.41(b)(5) would require licensees to add procedures for any administration requiring a WD to include procedures for determining if an ME, as defined in § 35.3045, has occurred.

The NRC estimates that 124 licensees, due to turnover, will add procedures to meet this requirement and the associated cost will be 8 physician labor hours and 1 clerical labor hour.

Adding new procedures

Section 35.41(b)(6) would require a licensee to add procedures for permanent implant brachytherapy that would include a procedure for determining several dose/activity parameters within 60 calendar days from the date the implant was performed. If the licensee cannot make these determinations within the 60 calendar days because of the patient not being available, then the licensee would have to justify the reason for not making these determinations in writing.

The NRC estimates that 101 licensees, due to turnover, will add procedures to include this requirement and the associated cost will be 8 physician labor hours and 1 clerical labor hour.

Savings for removing attestation requirement for some individuals

Section 35.14(a) would remove the requirement to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been

recognized by the NRC or an Agreement State when using the notification process. The number of ophthalmic physicists is too low to establish an estimated labor savings.

Section 35.50(a) would remove the requirement for individuals seeking to be named as an RSO or ARSO (including medical physicists identified in § 35.50(c)(1)) to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. The NRC estimates that approximately 225 individuals will seek to become RSOs and ARSOs under § 35.50 annually. Of these, the NRC estimates that 30 percent, or 67, are individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. The NRC estimates a savings of 0.5 labor hour per licensee for no longer requiring the submittal of an amendment.

Licensee savings for processing only one application

Section 35.50(c)(3) would allow an individual who is qualified to be the AU, but is not named on a medical license or permit, to be named simultaneously as both the AU and RSO for the same uses on a new medical license. This new provision saves the applicant from submitting an amendment to the initial AU application to be named as an RSO. The NRC estimates this to affect 3 applicants annually at a savings of 0.5 hour per application.

Savings for removing the attestation requirement for some individuals

Section 35.51(a) would remove the requirement for individuals seeking to be named as an AMP to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. The NRC estimates that approximately 37 individuals annually will seek to become AMPs under § 35.51 with a savings of 0.5 labor hour per licensee for no longer requiring the submittal of an amendment.

Section 35.55(a) would remove the requirement for individuals seeking to be named as an ANP to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. The NRC estimates this to impact 7 licensees annually with a savings of 0.5 labor hour per licensee for no longer requiring the submittal of an amendment.

Savings for removing training requirements for certain AMPS and ANPs

Section 35.57(a)(1) would remove the requirement for AMPs and ANPs who are identified on a Commission or an Agreement State license or a permit issued by a Commission or an 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. The NRC estimates that 41 licensees will be impacted annually, and there will be a savings of 0.5 hour associated with the submittal of an amendment on NRC Form 313.

Savings for removing training requirement for certain RSOs

Section 35.57(a)(2) would recognize individuals certified by the named boards in the now removed Subpart J of Part 35 on or before October 24, 2005, who would not need to comply with the training requirements of § 35.50 to be identified as a RSO on a Commission or an Agreement State license or Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005. The NRC estimates that 75 licensees will be impacted annually, and there will be a savings of 0.5 hour associated with the submittal of an amendment on NRC Form 313.

Savings for removing training requirements for certain individuals

Section 35.57(a)(3) would be modified to 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 training requirements of § 35.51 to be identified as a AMP on a Commission or an Agreement State license or Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005. The NRC estimates that 41 licensees will be impacted annually, and there will be a savings of 0.5 hour associated with the submittal of an amendment on NRC Form 313.

Savings for removing T&E requirements for certain individuals

Section 35.57(b)(1) would be amended to clarify that individuals authorized before, rather than just on, October 24, 2005, would not be required to comply with the T&E requirements in Subparts D through H of 10 CFR Part 35 for those materials and uses that they performed on or before that date. The NRC estimates that 2,246 or 30 percent of all licensees, will be impacted on an annual basis. The 0.5 labor hour savings will be associated with each submittal of amendment on NRC Form 313.

Section 35.57(b)(2) would be restructured and expanded to recognize physicians, dentists, or podiatrists who were certified by the named boards in the now removed Subpart J of Part 35 on or before October 24, 2005, who would not need to comply with the T&E requirements of Subparts D through H of 10 CFR Part 35 to be identified as an AU on a Commission or an Agreement State license or Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005. The NRC estimates that 187, or 2.5 percent of all licensees, will be impacted on an annual basis. The 0.5 labor hour savings will be associated with each submittal of amendment on NRC Form 313.

Cost to possess certain bundled sources

Section 35.65(b)(2) would be modified to require licensees that possess bundled or aggregated single sealed sources with greater than a specified activity to treat 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. The cost for licensees will encompass recordkeeping of new leak tests and security requirements under regulations, if appropriate. In addition, if bundled source activity is

treated as a single source, an amendment to the license is required. The NRC estimates this to impact 10 licensees annually, for 2 hours of recordkeeping cost and 0.5 hour for submitting an amendment.

Savings for removing attestation requirement for some individuals

Section 35.190(a) would remove the written attestation requirement for a physician who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State and is seeking to be named as an AU for byproduct material authorized under § 35.100. The NRC estimates that this will impact 59 licensees on an annual basis with a savings of 0.5 labor hour for no longer requiring the submittal of a written attestation with the amendment request.

Recordkeeping cost

Section 35.204(b) would be modified to require licensees to measure the Mo-99 concentration after each eluate from a Mo-99/Tc-99m generator. Generator manufacturers recommended testing each elution prior to use in humans. Mo-99 breakthrough measurements which exceed the permissible concentration listed in § 35.204(a) may cause unnecessary radiation exposure to patients. The NRC assumes that each test will be conducted by a nuclear technician who is under the supervision of an ANP. The NRC estimates this to impact 331 medical use licensees and 359 radiopharmacy licensees who have the generators. The new requirements will require the affected licensees to keep records of their test measurements. The NRC estimates this to require 13 Medical Technician labor hours annually for each affected licensee.

Reporting requirement

Section 35.204(e) would require licensees to report any measurement that exceeded the limits specified in § 35.204(a) for Mo-99/Tc-99m and Sr-82/Rb-82 generators. Generator manufacturers recommended testing each elution prior to use in humans. Mo-99 breakthrough measurements which exceed the permissible concentration listed in § 35.204(a) may cause unnecessary radiation exposure to patients. The NRC estimates the affected licensees to report 7 occurrences on average annually. The reporting requirement includes an initial phone notification within 30 calendar days from occurrence, followed up with a written report due in 45 days. The NRC estimates this to be a 2.25 physician labor hour cost (0.25 hour for the phone call and 2 hours for the written report).

Savings for removing the attestation requirement for some individuals

Section 35.290(a) would remove the requirement for physicians seeking to be named as an AU of unsealed byproduct material for uses authorized under § 35.200 to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. The NRC estimates that this will impact 59 licensees on an annual basis with a savings of 0.5 physician labor hour per licensee for no longer requiring the submittal of a written attestation with the amendment request.

Savings for removing the attestation requirement for some individuals

Section 35.390(a) would remove the requirement for physicians 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 for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. The NRC estimates that this will impact 29 licensees on an annual basis with a savings of 0.5 physician labor hour per licensee for no longer requiring the submittal of a written attestation with the amendment request.

Savings for removing the attestation requirement for some individuals

Section 35.392(a) would remove the requirement for physicians 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 for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. The NRC estimates that this will impact 29 licensees on an annual basis with a savings of 0.5 physician labor hour per licensee for no longer requiring the submittal of a written attestation with the amendment request.

Savings for removing attestation requirement for some individuals

Section 35.394(a) would remove the requirement for physicians 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 for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. The NRC estimates that this will impact 29 licensees on an annual basis with a savings of 0.5 physician labor hour per licensee for no longer requiring the submittal of a written attestation with the amendment request.

Flexibility for AMP turnover

Section 35.433 would be amended and expanded to allow certain individuals who are not AMPs to calculate the activity of strontium-90 sources that is used to determine the treatment times for ophthalmic treatments. These individuals who are not AMPs would have to meet the T&E requirements detailed in the new paragraph (a)(2) of this section to perform the specified activities. These requirements are similar to the T&E requirements for an AMP, but include only the requirements related to brachytherapy programs. The NRC determined that this will increase the number of qualified individuals available to support the use of ophthalmic treatments. This will expand the pool of qualified individuals and provide the licensees greater flexibility with no associated cost.

Savings for removing attestation requirement for some individuals

Section 35.490(a) would remove the requirement for physicians seeking to be named as an AU of a manual brachytherapy source for the uses authorized under § 35.400 to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. The NRC estimates that this

will impact 31 licensees on an annual basis with a savings of 0.5 physician labor hour per licensee for no longer requiring the submittal of a written attestation with the amendment request.

Cost for training

Section 35.610(d)(1) would be restructured to add a new training requirement for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. This proposed amendment would require all individuals who would operate these 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 NRC assumes this will impact 172 licensees on an annual basis who will add a new unit or modify an existing unit. The NRC assumes this training to take 1 physician labor hour.

Change to inspections and servicing intervals

Section 35.655(a) would be amended to change the requirement for intervals for full inspection and servicing for gamma stereotactic radiosurgery units from 5 years to 7 years. The cost to replace the sources in a gamma stereotactic radiosurgery unit can be exorbitant. Licensees have routinely requested, and the NRC has granted, extensions for the full inspection service for these units beyond 5 years. The NRC does not anticipate any savings or cost to the licensees for this change.

Savings for removing attestation requirement for some individuals

Section 35.690(a) would remove the requirement for physicians seeking to be named as an AU for sealed sources for uses authorized under § 35.600 to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. The NRC estimates this to impact 10 licensees annually with a savings of 0.5 physician labor hour per licensee for no longer requiring the submittal of a written attestation with the amendment request.

Recordkeeping

Section 35.2024(c)(1) and (2) would require licensees to keep records of each ARSO assigned under § 35.24(b) for 5 years after the ARSO is removed from the license. These records would have to include the written document appointing the ARSO signed by the licensee's management and each agreement signed by the ARSO listing the duties and tasks assigned by the RSO under § 35.24(b). The NRC estimates that due to turnover, 225 ARSOs will be removed from licenses annually with a cost of 1 clerical labor hour.

Savings on phone notifications of MEs

Section 35.3045(c) would reduce telephone reporting costs to the NRC 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 of significance and will reduce the number of reportable MEs related to permanent implant brachytherapy. The

NRC estimates 7 licensees will be impacted annually with a saving of 0.5 medical technician labor hour on each notification.

Savings on written follow-up reports on MEs

Section 35.3045(d) would reduce written reporting costs to the NRC 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 of significance and will reduce the number of reportable MEs related to permanent implant brachytherapy. The NRC estimates 7 licensees will be impacted annually with a savings of 2 physician labor hours and 6 clerical labor hours on each report.

Savings for the licensee on reporting MEs

Section 35.3045(e) would reduce licensee reporting costs to the physician, 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 of significance and will reduce the number of reportable MEs related to permanent implant brachytherapy. The NRC estimates 18 licensees will be impacted annually with a total savings of 5 physician labor hours for each licensee.

Increased flexibility for AUs for use of sealed sources and devices for manual brachytherapy

Sections 35.400, 35.500, and 35.600 would be amended to allow AUs to use sealed sources and devices listed in SSDRs for manual brachytherapy for other medical uses that are not explicitly listed in the SSDR provided that these sources are used in accordance with the radiation safety conditions and limitations described in the SSDR. This increased flexibility is not quantifiable.

Table 5 Summary of Industry Annual Costs

Citation	Description	No. of Licensees Affected	Annual Costs
30.34(g)	Reporting requirement (also in § 35.204(e))	7	$2,024
30.34(g)	Cost to check generators for each elution	359	$338,638
35.12(b)(1)	Savings for no longer requiring copy of application	225	-$1,662
35.12(b)(1)	Cost for licensees to submit information on ARSO	225	$3,323
35.12 (c)(1)	Savings on copy of renewals	749	-$5,531
35.12 (c)(1)	Savings on copy of amendments	7486	-$55,284
35.13(d)	Licensing amendments for new ARSOs	225	$3,323
35.13(d)	Licensing amendments for new tasks/duties for existing ARSO	747	$11,033
35.13(i)	Savings exemption for need for amendment for sealed source	3498	-$51,665
35.14(b)(1)	Cost for notification for when ARSO or ophthalmic physicist leaves or changes name	262	$1,935
35.14(b)(6)	Notification costs for reporting	3498	$25,833
35.24(b)	Recordkeeping for new ARSOs	225	$6,647
35.41(b)(5)	Adding new procedures	124	$131,145
35.41(b)(6)	Adding new procedures	101	$106,820
35.50(a)	Savings for some RSO for attestation	67	-$4,305
35.50(c)(3)	Savings for processing only one application	3	-$193
35.51(a)	Savings for removing attestations for some individuals	37	-$2,377
35.55(a)	Savings for removing attestations for some individuals	7	-$450
35.57(a)(1)	Savings for individuals who want to be ANPs and AMPs	41	-$2,634
35.57(a)(2)	Savings for individuals certain RSOs	75	-$4,819
35.57(a)(3)	Savings for individuals who want to be identified as AMPs	41	-$2,634
35.57(b)(1)	Savings for AU on T&E from 10/24/02 to 10/24/05	2246	-$144,317
35.57(b)(2)	Savings for individuals who want to be AUs	187	-$12,016
35.65(b)(2)	Recordkeeping requirements for leak tests and security	10	$591
35.65(b)(2)	Cost requiring a licensee to submit an amendment	10	$148
35.190(a)	Savings for removing attestations for some individuals	59	-$3,791
35.204(b)	Cost to check generators for each elution	331	$312,226
35.204(e)	Reporting requirement (cost in § 35.3204)	7	$2,024
35.290(a)	Savings for removing attestations for some individuals	59	-$3,791

35.390(a)	Savings for removing attestations for some individuals	29	-$1,863
35.392(a)	Savings for removing attestations for some individuals	29	-$1,863
35.394(a)	Savings for removing attestations for some individuals	29	-$1,863
35.433(a)(2)	No additional cost	0	$0
35.490(a)	Savings for removing attestations for some individuals	31	-$1,992
35.610(d)(1)	Cost for training for operations and safety	172	$22,104
35.690(a)	Savings for removing attestations for some individuals	10	-$643
35.2024(c)	Recordkeeping cost (Removing ARSO)	225	$2,213
35.2024(c)(1)	Recordkeeping cost (ARSO appointment)	225	$2,213
35.2024(c)(2)	Recordkeeping cost (ARSO signed agreement)	225	$2,213
35.3045(c)	Phone notifications reduced	7	-$254
35.3045(d)	Written reports reduced	7	-$3,040
35.3045(e)	Physician notifications reduced	18	-$4,626
Total			$662,837

NRC Operation

Processing reports

Section 30.34(g) would require the NRC to process licensee reports of any test that exceeds the permissible concentration listed in § 35.204(a). This requirement is also included in § 35.204(e).

Processing licensee application due to turnover of ARSOs

Section 35.12(b)(1) would require an applicant to include T&E qualifications for each ARSO as part of its license application. The NRC estimates it will receive 29 new applications annually, and that it will take 0.25 hour to process each application.

Amendment processing due to turnover of ARSOs

Section 35.13(d) would require 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 NRC estimates it will receive 33 amendments annually and each amendment will take 0.5 hour to process.

Savings for processing amendments for sealed sources

Section 35.13(i) would allow licensees who are authorized for brachytherapy sources to receive certain sealed sources without first seeking a license amendment. This change is proposed to make it easier for the licensee to obtain the sealed sources necessary for patient treatments in a timely manner. The NRC will no longer need to review and process the license amendments,

and estimates it will receive 1,014 fewer amendments annually with each amendment saving 0.5 hour to process.

Processing of notifications of ARSOs

Section 35.14(b)(1) would require a licensee to notify the Commission within 30 days of removal of the ARSO or ophthalmic physicist from the list of individuals that the licensee is required to report when the ARSO discontinues performance of duties under the license or has a name change.

The NRC estimates that 37 notifications will be made annually due to turnover or name changes, and it will take 0.25 hour to process each notification. The number of ophthalmic physicist is too low to establish an estimated labor cost.

Processing of notifications of sealed sources

Section 35.14(b)(6) would require licensees 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, which is being removed under § 35.13(i). The NRC estimates this to impact 507 licensees each year, and each licensee will submit 2 notifications on average per year with an associated processing cost of 5 minutes. This cost is offset by the savings from not requiring an amendment in § 35.13(i).

Savings for processing attestations

Section 35.14(a) would remove the requirement to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State when using the notification process. The number of ophthalmic physicists is too low to establish an estimated labor savings.

Section 35.50(a) would remove the requirement for individuals seeking to be named as an RSO or ARSO to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. The NRC estimates that approximately 33 individuals will seek to become RSOs under § 35.50 annually. Of these, the NRC estimates that 30 percent, or 10, are individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. The NRC estimates that approximately 0.5 hour of the cost associated with processing the amendment will be saved for each applicant.

Savings for processing and reviewing applications

Section 35.50(c)(3) would allow an individual who is qualified to be the AU, but is not named on a medical license or permit, to be named simultaneously as both the AU and RSO for the same uses on a new medical license. This new provision saves the NRC from processing the license

amendment for adding an RSO. The NRC estimates this to affect 1 applicant annually at a savings of 0.5 hour for processing the amendment.

Savings for processing attestations

Section 35.51(a) would remove the requirement to obtain a written attestation, for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State, for individuals seeking to be named as an AMP.

The NRC estimates that approximately 5 individuals will seek to become AMPs under § 35.51 annually. NRC estimates that approximately 0.5 hour cost associated with reviewing the amendment will be saved for each applicant.

Section 35.55(a) would remove the requirement to obtain a written attestation, for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State, for individuals seeking to be named as an ANP. The NRC estimates this to impact 1 licensee annually with 0.5 hour of the cost associated with processing a written attestation with the amendment request.

Savings for processing amendments

Section 35.57(a)(1) would remove the requirement for an RSO, an AMP and an ANP identified on a NRC license or a permit issued by the NRC 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. The NRC estimates that 6 licensees will be impacted with a savings of 0.5 hour associated with the processing of each amendment.

Section 35.57(a)(2) would recognize individuals certified by the named boards in the now removed Subpart J of Part 35 on or before October 24, 2005, who would not need to comply with the training requirements of § 35.50 to be identified as an RSO on a Commission or an Agreement State license or Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005. The NRC estimates that 11 licensees will be impacted with a savings of 0.5 hour associated with the processing of each amendment.

Section 35.57(a)(3) would be modified to 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 training requirements of § 35.51 to be identified as a AMP on a Commission or an Agreement State license or Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005. The NRC estimates that 6 licensees will be impacted with a savings of 0.5 hour associated with the processing of each amendment.

Section 35.57(b)(1) would be amended to clarify that individuals authorized before, rather than just on, October 24, 2005, would not be required to comply with the T&E requirements in Subparts D through H of 10 CFR Part 35 for those materials and uses that they performed on or

before that date. The NRC estimates that 325 licensees will be impacted on an annual basis with a savings of 0.5 hour associated with the processing of each amendment.
Section 35.57(b)(2) would be restructured and expanded to recognize physicians, dentists, or podiatrists who were certified by the named boards in the now removed Subpart J of part 35 on or before October 24, 2005, who would not need to comply with the training requirements of Subparts D through H of 10 CFR part 35 to be identified as an AU on an NRC license or an NRC master material license permit for those materials and uses that these individuals performed on or before October 24, 2005. The NRC estimates that 27 licensees will be impacted on an annual basis with a savings of 0.5 hour associated with the processing of each amendment.

Processing amendments for bundled sources

Section 35.65(b)(2) would be modified to require licensees that possess bundled or aggregated single sealed sources with greater than a specified activity to treat 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. The NRC estimates this to impact 1licensee annually with the amendment requiring 0.5 hour to process.

Savings for processing attestations

Section 35.190(a) would remove the requirement to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC and for physicians seeking to be named as an AU of unsealed byproduct material for uses authorized under § 35.100. The NRC estimates that this will impact 8 NRC licensees on an annual basis with a savings of 0.5 labor hour for no longer requiring the submittal of a written attestation with the amendment request.

Cost to process new reporting requirement

Section 35.204(e) would require licensees to report any measurement that exceeded the limits specified in § 35.204(a) for Mo-99/Tc-99m and Sr-82/Rb-82 generators. Generator manufacturers recommended testing each elution prior to use in humans. Mo-99 breakthrough measurements which exceed the permissible concentration listed in § 35.204(a) may cause unnecessary radiation exposure to patients. The NRC estimates that this will impact 1 medical use licensee and 1 radiopharmacy licensee to report 1 occurrence each on average annually. The reporting requirement includes an initial phone notification to NRC within 30 calendar days from occurrence and followed up with a written report due in 45 days. The NRC estimates this to be a 2.25 labor hour cost (0.25 hour to process the phone call and 2 hours to review the written report).

Savings for processing attestations

Section 35.290(a) would remove the requirement for physicians seeking to be named as an AU of unsealed byproduct material for uses authorized under § 35.200 to obtain a written attestation

for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC. The NRC estimates that this will impact 8 licensees on an annual basis with a savings of 0.5 labor hour for no longer requiring the submittal of an amendment.
Savings for removing attestation requirement for some individuals

Section 35.390(a) would remove the requirement for physicians 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 for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. The NRC estimates that this will impact 4 licensees on an annual basis with a savings of 0.5 labor hour per licensee for no longer requiring the submittal of an amendment.

Savings for processing attestations

Section 35.392(a) would remove the requirement to obtain a written attestation, for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC, for physicians 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). The NRC estimates that this will impact 4 licensees on an annual basis with a savings of 0.5 labor hour for no longer requiring the submittal of a written attestation with the amendment request.

Savings for processing attestation

Section 35.394(a) would remove the requirement to obtain a written attestation, for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC, for physicians 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). The NRC estimates that this will impact 4 licensees on an annual basis with a savings of 0.5 labor hour for no longer requiring the submittal of an amendment.

Savings for processing attestation

Section 35.490(a) would remove the requirement to obtain a written attestation, for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC, for physicians seeking to be named as an AU of a manual brachytherapy source for the uses authorized under § 35.400. The NRC estimates that this will impact 5 licensees on an annual basis with a savings of 0.5 labor hour for no longer requiring the submittal of an amendment.

Savings for processing attestations

Section 35.690(a) would remove the requirement to obtain a written attestation, for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC, for physicians seeking to be named as an AU for sealed sources for uses authorized under § 35.600. The NRC estimates this to impact 2 licensees annually with a savings of 0.5 labor hour for no longer requiring the submittal of a written attestation with the amendment request.

Savings on phone notifications

Section 35.3045(c) would reduce telephone reporting cost to the NRC 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 of significance and will reduce the number of reportable MEs related to permanent implant brachytherapy. The NRC estimates this to impact 1 licensee annually with a savings of 2.5 NRC labor hours to process the ME notification.

Savings on written follow-up report to the NRC

Section 35.3045(d) would reduce written reporting costs to the NRC because the requirements for reporting an ME for permanent implant brachytherapy would be changed in § 35.3045(a)(2). The new requirements will not capture events that are not of significance and will reduce the number of reportable MEs related to permanent implant brachytherapy**.** The NRC estimates this to impact 1 licensee annually with a savings of 3 NRC labor hours to process the written report.

Other Governments' Operation (Agreement States)

The Agreement States are required to adopt the NRC regulations within 3 years after they go into effect. Although each state has its own regulations with unique sections and numbering systems, for the purpose of this regulatory analysis, the NRC section and numbering system is used.

Processing reports

Section 30.34(g) would require the Agreement States to process licensee reports of any test that exceeds the permissible concentration listed in § 35.204(a). This requirement is included in § 35.204(e).

Licensee application request processing

Section 35.12(b)(1) would require 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 NRC estimates the Agreement States will receive 192 amendment requests annually and that each will take 0.25 hours to process.

Licensee amendment processing

Section 35.13(d) would require 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 NRC estimates the Agreement States will receive 192 amendments annually and each amendment will take 0.5 hour to process.

Savings for processing amendments for sealed sources

Section 35.13(i) would allow licensees to receive certain sealed sources without first seeking a license amendment. This change is proposed to make it easier for the licensee to obtain the sealed sources necessary for patient treatments in a timely manner. The Agreement States will no longer need to review and process the license amendments. The NRC estimates that the Agreement States will receive 5,982 fewer amendments annually, with each amendment saving 0.5 hour to process.

Processing of notifications

Section 35.14(b)(1) would require a licensee to notify the Agreement States within 30 days of when the ARSO or the ophthalmic physicist is removed from the list of individuals that the licensee is required to report or when the ARSO or the ophthalmic physicist discontinues performance of duties under the license or has a name change.

The NRC estimates that 225 ARSOs will be named annually due to turnover or changing their names, and it will take 0.25 labor hour for the Agreement States to process each notification. The number of ophthalmic physicist is too low to establish an estimated labor cost.

Section 35.14(b)(6) would require licensees to notify the Agreement States if they receive certain sealed sources without first obtaining a license amendment. Specifically, a licensee would have to notify the Agreement State 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 which would be removed under § 35.13(i). This notification is required for the Agreement States to have an accurate record of sealed sources possessed by a licensee.

The NRC estimates this to impact 2,991 licensees each year; each licensee will submit 2 notifications on average per year. The NRC estimates that the associated Agreement State cost to process each notification is 0.08 labor hours. This cost would be offset by the savings outlined § 35.13(i).

Savings for processing attestations

Section 35.14(a) would remove the requirement to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State when using the notification process. The number of ophthalmic physicists is too low to establish an estimated labor savings.

Section 35.50(a) would remove the requirement for individuals seeking to be named as an RSO or ARSO to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by an Agreement State. The NRC estimates that approximately 192 individuals will seek to become RSOs under § 35.50 annually. Of these, the NRC estimates that 30 percent, or 57, are individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement

State. The NRC estimates that approximately 0.5 labor hour of the cost associated with processing each amendment will be saved by the Agreement States for each applicant.

Savings for processing and reviewing applications

Section 35.50(c)(3) would allow an individual who is qualified to be the AU, but is not named on a medical license or permit, to be named simultaneously as both the AU and RSO for the same uses on a new medical license. This new provision saves the Agreement States from processing the license amendment. The NRC estimates this to affect 2 applicants annually at a savings of 0.5 labor hour per application.

Savings for processing the attestations

Section 35.51(a) would remove the requirement to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State, for individuals seeking to be named as an AMP. The NRC estimates that approximately 32 individuals will seek to become AMPs annually and that 0.5 hour associated with reviewing the amendment will be saved for each applicant.

Savings for processing attestations

Section 35.55(a) would remove the requirement to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State, for individuals seeking to be named as an ANP. The NRC estimates this to impact 6 licensees annually, and 0.5 hour of the labor cost associated with processing a written attestation with the amendment request amendment would be saved.

Section 35.57(a)(1) would remove the requirement for an RSO, an AMP, and an ANP identified on an Agreement State license or a permit issued by an 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. The NRC estimates that 35 licensees will be impacted with a savings of 0.5 hour associated with the processing of a written attestation with the amendment request.

Savings for processing amendments

Section 35.57(a)(2) would recognize individuals certified by the named boards in the now removed Subpart J of Part 35 on or before October 24, 2005, who would not need to comply with the training requirements of § 35.50 to be identified as a RSO on a Commission or an Agreement State license or Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005. The NRC estimates that 64 licensees will be impacted with a savings of 0.5 hour associated with the processing of each amendment.

Section 35.57(a)(3) would be modified to 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 training requirements of § 35.51 to be identified as a AMP on a Commission or an Agreement State license or Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005. The NRC estimates that 35 licensees will be impacted with a savings of 0.5 hour associated with the processing of each amendment.

Section 35.57(b)(1) would be amended to clarify that individuals authorized before, rather than just on, October 24, 2005, would not be required to comply with the T&E requirements in Subparts D through H of 10 CFR Part 35 for those materials and uses that they performed on or before that date. The NRC estimates that 1,917 licensees will be impacted on an annual basis with a savings of 0.5 hour associated with the processing of each amendment.

Section 35.57(b)(2) would be restructured and expanded to recognize physicians, dentists, or podiatrists who were certified by the named boards in the now removed Subpart J of Part 35 on or before October 24, 2005, who would not need to comply with the training requirements of Subparts D through H of 10 CFR Part 35 to be identified as an AU on an NRC license or an NRC master material license permit for those materials and uses that these individuals performed on or before October 24, 2005. The NRC estimates that 160 licensees will be impacted on an annual basis with a savings of 0.5 hour associated with the processing of each amendment.

Cost for processing amendments

Section 35.65(b)(2) would be modified to require licensees that possess bundled or aggregated single sealed sources with greater than a specified activity to treat them as one single source. These sources with activities larger than authorized by § 35.65 would 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 Agreement States can ensure that adequate controls for security and radiation safety are applied to these larger sources. The NRC estimates this to impact 9 licensees annually with the amendment requiring 0.5 hour to process.

Savings for processing attestations

Section 35.190(a) would remove the requirement to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State, for physicians seeking to be named as an AU of unsealed byproduct material for uses authorized under § 35.100. The NRC estimates that this will impact 51 Agreement State licensees on an annual basis with a savings of 0.5 labor hour for no longer requiring the submittal of a written attestation with the amendment request.

Cost for processing new reporting requirement

Section 35.204(e) would require licensees to report any measurement that exceeded the limits specified in § 35.204(a) for Mo-99/Tc-99m and Sr-82/Rb-82 generators. Generator manufacturers recommended testing each elution prior to use in humans. Mo-99 breakthrough measurements which exceed the permissible concentration listed in § 35.204(a) may cause unnecessary radiation exposure to patients. The NRC estimates that this will impact 6 medical

use licensees and 6 radiopharmacy licensees to report 1 occurrence each on average annually. The reporting requirement includes an initial phone notification to the Agreement State within 30 calendar days from occurrence and followed up with a written report due in 45 days. The NRC estimates this to be a 2.25 labor hour cost (0.25 hours to process the phone call and 2 hours to review the written report).

Savings for processing attestations

Section 35.290(a) would remove the requirement to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State, for physicians seeking to be named as an AU of unsealed byproduct material. The NRC estimates that this will impact 51 licensees on an annual basis with a savings of 0.5 labor hour for no longer requiring the submittal of a written attestation with the amendment request.

Savings for removing attestation requirement for some individuals

Section 35.390(a) would remove the requirement to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State, for physicians seeking to be named as an AU of unsealed byproduct material which requires a WD for uses authorized under § 35.300. The NRC estimates that this will impact 25 licensees on an annual basis with a savings of 0.5 labor hour per licensee for no longer requiring the submittal of a written attestation with the amendment request.

Savings for processing attestations

Section 35.392(a) would remove the requirement to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State, for physicians 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). The NRC estimates that this will impact 25 licensees on an annual basis with a savings of 0.5 labor hour for no longer requiring the submittal of a written attestation with the amendment request.

Section 35.394(a) would remove the requirement to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the Agreement State, for physicians 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). The NRC estimates that this will impact 25 licensees on an annual basis with a savings of 0.5 labor hour for no longer requiring the submittal of a written attestation with the amendment request.

Section 35.490(a) would remove the requirement to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by an Agreement State, for physicians seeking to be named as an AU of a manual brachytherapy source for the uses authorized under § 35.400. The NRC estimates that this will

impact 26 licensees on an annual basis, with a savings of 0.5 labor hour for no longer requiring the submittal of a written attestation with the amendment request.

Section 35.690(a) would remove the requirement to obtain a written attestation for those individuals who are certified by a specialty board whose certification process has been recognized by the Agreement State, for physicians seeking to be named as an AU for sealed sources for uses authorized. The NRC estimates this to impact 8 licensees annually with a savings of 0.5 labor hour for no longer requiring the submittal of a written attestation with the amendment request.

Saving on phone notifications

Section 35.3045(c) would reduce telephone reporting cost to the Agreement State because the requirements for reporting an ME for permanent implant brachytherapy would be changed in § 35.3045(a)(2). The new requirements will not capture events that are not of significance and will reduce the number of reportable MEs related to permanent implant brachytherapy. The NRC estimates this to impact 6 licensees annually with a savings of 2.5 labor hours to process the ME notification.

Saving on written follow-up report to the Agreement State

Section 35.3045(d) would reduce written reporting costs to the Agreement State because the requirements for reporting an ME for permanent implant brachytherapy would be changed in § 35.3045(a)(2). The new requirements will not capture events that are not of significance and will reduce the number of reportable MEs related to permanent implant brachytherapy. The NRC estimates this to impact 6 licensees annually with a savings of 3 hours to process the written report.

Regulatory Efficiency

The proposed rule includes changes that would affect regulatory efficiency in a positive, but not easily quantifiable, manner. For example, regulatory efficiency would be enhanced by the proposed changes made in requirements for submitting an application for a license, such as in § 35.50. In this section, the regulations would be changed to make it easier for a physician to open an office by allowing the physician to be the AU and RSO on the same license application. Additionally, the proposed rule would update, clarify, and strengthen the existing regulatory requirements. Cost reductions would be realized by removing attestation requirements for certain board certified individuals, modifying ME reporting criteria to insure that only significant events would be reported, and by other proposed modifications to the regulations.

Public Health (routine)

Several proposed amendments would result in reducing the potential for radiation exposure to patients, but it is difficult to quantify the actual number in rems reduced. An example is the proposed change to § 35.204(b) and (e) which would require licensees to measure the Mo-99 concentration after each eluate from a Mo-99/Tc-99m generator and to report any measurement to the NRC that exceeds the limits specified in § 35.204(a). During October 2006 through February 2007, and again in January 2008, medical licensees reported to the NRC that

numerous generators had failed the Mo-99 breakthrough tests. One generator manufacturer voluntarily reported 116 total elution test failures in 2008. The administration of higher levels of Mo-99 provides no benefit and could increase the radiation exposure to the patient, as well as have an adverse effect on nuclear medicine image quality and medical diagnosis.

Another example is the proposed requirement in § 35.41(b)(5) for licenses to have procedures for any administration requiring a WD to include procedures for determining if an ME, as defined in § 35.3045, has occurred. An ME could have occurred because the patient received more or less radiation dose than was planned, with possible detrimental effect to the patient. The timely review and identification of an ME may result in prompt corrective actions.

4. Presentation of Results

4.1 Benefits and Costs

This section summarizes the benefits and costs estimated for these regulatory options. To the extent that the affected attributes could be analyzed quantitatively, the net effect of each option has been calculated and is presented below. However, some benefits and costs could be evaluated only on a qualitative basis.

The benefits of this proposed rule are associated with the potential reduction in unnecessary radiation exposure to patients. Additionally, the proposed rule would update, clarify, and strengthen the existing regulatory requirements, and thereby promote public health and safety. Cost reductions would be realized by removing attestation requirements for certain board certified individuals, modifying ME reporting criteria to insure that only significant events would be reported, and by other proposed modifications to the regulations.

Exhibit 4-1 summarizes the results of the analysis by attribute. Relative to the no-action alternative (Option 1), Option 2 would result in a net quantitative impact estimation over the 10-year analysis period of approximately $17 million at a 3 percent discount rate and $16 million at a 7 percent discount rate.

Exhibit 4-1
Summary Results by Attribute
at Discount Rates of 3 Percent and 10 Percent for a 10-Year Period

Quantitative Attribute	One-time Implementation Costs	Annual Operating Costs	Total combined Implementation and Annual Cost for 10-year period at 3% discount rate	Total combined Implementation and Annual Cost for 10-year period at 7% discount rate
Industry Costs Option 1	$0	$0	$0	$0
Industry Costs Option 2	$8,307,858	$662,837	$13,961,989	$12,963,345
Agreement States Option 1	$0	$0	$0	$0
Agreement States Option 2	$5,083,580	-$323,600	$2,323,207	$2,810,750
NRC Costs Option 1	$0	$0	$0	$0
NRC Costs Option 2	$415,485	-$76,832	-$231,374	-$117,124
Total Option 1	$0	$0	$0	$0
Total Option 2	$13,806,922	$263,405	$16,053,822	$15,656,970

4.2 Backfitting

The backfit rule (which is found in the regulations at §§ 50.109, 70.76, 72.62, 76.76, and in 10 CFR Part 52) does not apply to this final rule. Parts 30, 32, and 35 of Title 10 of CFR do not contain a backfit requirement. Therefore, a backfit analysis is not required.

5. Decision Rationale

Several proposed amendments would reduce the potential radiation exposure to patients; for example, the proposed changes to § 30.34(g) and § 35.204(b) and (e) which would require licensees to measure the Mo-99 concentration after each eluate from a Mo-99/Tc-99m generator and to report any measurement that exceeds the limits specified in § 35.204(a). During October 2006 through February 2007, and again in January 2008, medical licensees reported to the NRC that numerous generators had failed the Mo-99 breakthrough tests. One generator manufacturer voluntarily reported 116 total elution test failures in 2008. The administration of higher levels of Mo-99 provides no benefit and could increase the radiation exposure to the patient as well as have an adverse effect on nuclear medicine image quality and medical diagnosis.

Another example is the proposed requirement in § 35.41(b)(5) for licensees to have procedures for determining if an ME, as defined in § 35.3045, has occurred. An ME could have occurred because the patient received more or less radiation dose than was planned for, with possible detrimental effect to the patient.

Additional benefits of the proposed rule include allowing ARSOs to be named on a license, which would increase the number of individuals who would be available to serve as preceptors for individuals seeking to be appointed as RSOs or ARSOs. Also, by being named on a license, ARSOs could more easily become RSOs on other licenses for the types of uses for which they qualify. Another benefit is the increased flexibility for AUs to use sealed sources and devices for manual brachytherapy for other medical uses that are not explicitly listed in the SSDR, provided that these sources are used in accordance with the radiation safety conditions and limitations described in the SSDR. Providing this flexibility will allow AUs to use medical judgment in determining the medical uses of these sealed sources and devices.

The decision rationale is based on how the benefits and costs have been analyzed. Relative to the no-action alternative, Option 2 would result in a one-time implementation cost to the industry of approximately $8.3 million and a net annual cost to the industry of approximately $660,000. Offsetting the net cost, the NRC determined that Option 2 would result in substantial non-quantifiable benefits related to regulatory efficiency and public health (routine). Although costs would be incurred as a result of the rule, the qualitative benefits associated with the rule would outweigh its cost. The NRC determined that the rule is cost-justified because the proposed regulatory initiatives would promote public health and safety.

6. Implementation

Generally, the NRC allows an adequate time for a final rule to become effective. The time would depend on the scope of the rulemaking, the availability of the conforming guidance, and the complexity of the final rule. The NRC proposes that the final rule become effective 180 days from its publication in the *Federal Register*. For this analysis, the final rule effective date is late 2015.

7. References

- NUREG/BR-0184, “Regulatory Analysis Technical Evaluation Handbook, Final Report,” U.S. Nuclear Regulatory Commission, Washington, DC, January 1997.

- NUREG/BR-0058, “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission,” Revision 4, U.S. Nuclear Regulatory Commission, Washington, DC, September 2004.

- NUREG/CR-4627, “Generic Cost Estimates, Abstracts from Generic Studies for Use in Preparing Regulatory Impact Analyses.”

- OMB Circular No. A-4, September, 17, 2003.

- Department of Labor (U.S.), Bureau of Labor Statistics. Occupational Employment Statistics, Occupational Employment and Wages.

- 2011-2012 Information Digest, NUREG-1350, Volume 24.

- NUREG-1556, Vol. 20, Appendix G: LTS Program Code Descriptions.

Appendix A: Regulatory Flexibility Analysis

1. Steps Taken to Mitigate Economic Impacts on Small Entities

The NRC is required by the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) as amended by the Small Business Regulatory Enforcement Fairness Act, to consider the impact of its rulemakings on small entities and evaluate alternatives that would accomplish regulatory objectives without unduly burdening small entities or erecting barriers to competition. This section describes the assessment of the small entity impacts expected to be incurred by 10 CFR Parts 30, 32, and 35 licensees as a result of the proposed rule. This analysis describes (1) the NRC's definition of “small entities,” including “small businesses,” “small governmental jurisdictions,” ”small educational institutions,” and “small organizations;” (2) what number constitutes a "substantial number" of these entities; (3) whether “significant impacts” will be incurred by licensees under the rule; and (4) the measures that NRC has adopted in the rule to mitigate impacts on small entities.

1.1 Defining “Small Entities” Affected by the Rule

The NRC established its size standards for small entities on December 9, 1985 (50 FR 50241). On November 6, 1991 (56 FR 56671), the NRC conformed its format for size standards to mirror the definitions of small entities in the Regulatory Flexibility Act of 1980, as amended. In a direct final rule published in the *Federal Register* on August 10, 2007 (72 FR 44951), the NRC adjusted its receipts-based small business size standard to conform to the Small Business Act (SBA) size standard for nonmanufacturing industries. This size standard reflects the most commonly used SBA size standard for nonmanufacturing industries. On July 3, 2012, the NRC increased its receipts-based, small business size standard from $6.5 million to $7 million to conform to the standard set by the SBA.

The NRC uses the size standards contained in 10 CFR 2.810 to determine whether a licensee qualifies as a small entity in its regulatory programs.

The size standards pertinent to Parts 30, 32, and 35 licensees impacted by this proposed rule under 10 CFR 2.810 are:

A small business is a for-profit concern and is a:

> (1) Concern that provides a service or a concern not engaged in manufacturing with average gross receipts of $7 million or less over its last 3 completed fiscal years; or
>
> (2) Manufacturing concern with an average number of 500 or fewer employees based upon employment during each pay period for the preceding 12 calendar months.

A small organization is a not-for-profit organization which is independently owned and operated and has annual gross receipts of $7 million or less.

A small governmental jurisdiction is a government of a city, county, town, township, village, school district, or special district with a population of less than 50,000.

A small educational institution is one that is supported by a qualifying small governmental jurisdiction or is not state or publicly supported and has 500 or fewer employees.

The proposed rule will affect 7,486 NRC/Agreement State licensees. The licenses are issued principally to medical institutions and individual private medical practitioners.

Because NRC licensees with annual gross receipts below $7 million pay reduced fees, the NRC has data on the number of affected licensees who certified that they qualified as small entities for reduced fee purposes. Based on data from the NRC Financial Accounting and Integrated Management Information System in December 2012, 294 affected licensees reported that their annual gross receipts were below $7 million. Using the ratio explained in Section 3.2.1 of this document, the NRC estimates that 1,735 NRC/Agreement State licensees are classified as small entities.

In total, therefore, the proportion of impacted licensees that are small entities is estimated to be 23 percent.

1.2 Determining What Number Constitutes a Substantial Number

The NRC has not established a quantitative definition of the number or proportion of licensees that constitutes a substantial number. However, for the purpose of this rulemaking, the NRC assumes that 23 percent of all licensees constitutes a “substantial number” of small entities likely to be impacted by this rule. A substantial number of both of the two categories of licensees considered, medical institutions and individual private medical practitioners, would be impacted by the rule.

1.3 Measuring “Significant Impacts”

To evaluate the impact that a small entity would be expected to incur as a result of the rule, the ratio of annualized costs was calculated as a percentage of estimated gross receipts. The NRC has not established a quantitative cutoff for “significant impact.” For the purpose of this rulemaking, the NRC assumes “significant’ impact if the ratio of annualized costs to estimated annual gross receipts for a licensee exceeds 1 percent.

The proposed rule would have an estimated $8.3 million implementation cost impact on the industry. This cost would be spread over the 7,845 impacted licensees or an average implementation cost of approximately $1,100 per licensee. The proposed rule would have an annual cost impact on the industry as well of an estimated $660,000 or an average cost of an estimated $100 per licensee.

The NRC assumes that all affected licensees have annual revenues greater than $110,000; therefore the estimated cost impacts do not exceed the 1 percent criterion for “significant impacts.” Therefore, even though the proposed rule would affect a substantial number of licensees that are small entities it would not have a significant economic impact on these entities.

1.4 Steps Taken to Mitigate Economic Impacts on Small Entities

The NRC has taken a number of actions in this rule to ensure that the selected alternative is the least costly alternative that adequately protects workers and patients from radiation exposure. As the Regulatory Analysis prepared for this rule demonstrates, many of the proposed amendments eliminate existing costs, and the remaining proposed amendments which would add cost would not place a significant economic impact on small entities.

Appendix B: Assumptions by section determining impacted NRC licensees.

The below tables outlines by section the assumptions which determined the number of impacted NRC licensees. To obtain the number of licensees impacted in the Agreement States, use a multiplier of 5.9**,** which is the ratio of NRC licensees to Agreement State licensees from Table 1 - Number and Type of Licenses.

Part 30 Licensees

Section	Annual Totals
30.34(g)	Recordkeeping burden covered under 35.2204 for 2500 = 52
30.34(g)	Reporting burden covered under 25.3204 for 2500 1% estimated to report (52 X 1%) = 1

Part 35 Licensees

Section	Annual Totals
35.12(b) Add ARSOs	3% of all licensees (1085) = 33
35.12(b) Remove copy	3% of all licensees (1085) = 33
35.12(c)(1) Renewals	10% of all licensees (1085) = 108
35.12(c)(1) Amendments	1 response from all licensees = 1085
35.13(d) (Turnover)	3% of all licensees (1085 X 3%) = 33
35.13(d) (Amendments)	10 % of all licensees (1085 X 10%) = 108
35.13(i)	2 responses from each licensee in 2120, 2200, 2230, 2240 (507 X 2) = 1014
35.14(b)(1)	Turnover – 3% of all licensees (1085 X 3% = 33) + Name changes - 0.5% of all licensees (1085 X 0.5% =5) = 37 for ARSOs The number of ophthalmic physicists is estimated to be low to calculate.
35.14(b)(6)	2 responses from 2120, 2200, 2230, 2240 (507 X 2) = 1014
35.24(b)	Cost covered in 35.2024(c)
35.41(a)	Cost covered in 35.2041 35.41(b)(5) and 35.41(b)(6) = 33
35.41(b)(5)	Turnover – 3% of 2110, 2120, 2200, 2210, 2230, 2231, 2240, 2300, 2310 (600 X 3% = 18
35.41(b)(6)	Turnover – 3% of 2110, 2120, 2200, 2240 (489 X 3% = 15)
35.50(a)	30% of all applicants will be board certified. Turnover - 3% of all licensees (1085) =33 X 30% = 10 (rounded)
35.50(c)(1)	Subset of 35.50(a)
35.50(c)(3)	1 responded from 2201 (286) = 1
35.51(a)	30% of all applicants will be board certified. Turnover – 3% of 2110, 2120, 2200, 2210, 2230, 2231, 2240, 2300, 2310 (600) =18 X 30% = 5 (rounded)
35.55(a)	10% of all applicants are board certified. 15% of 2110 and 2120 have ANP (405 X 10% = 41 X 15%) = 6 Turnover – 3% X 6 = 1
35.57(a)(1)	1% of 2210, 2120, 2200, 2210, 2230, 2231, 2240, 2300, 2310 (600)= 6

35.57(a)(2)	1% of all licensees (1085) = 11
35.57(a)(3)	1% of 2210, 2120, 2200, 2210, 2230, 2231, 2240,2300, 2310 (600) = 6
35.57(b)(1)	30% of all licensees (1085) = 325
35.57(b)(2)	2.5% of all licensees (1085) = 27
35.65(b)(2)	One time cost -1% of 2110, 2120, 2121, 2200, 2201, 2220, 2231 (950) = 10 Annual cost - 0.15% of 2110, 2120, 2121, 2200, 2201, 2220, 2231 (950) = 1.5
35.190(a)	30% of all applicants will be board certified. Turnover – 3% of 2110, 2120, 2121, 2200, 2201, 2220 (948) = 28 X 30% = 8 (rounded)
35.204(b)	Covered under 35.2204 for 5% of 2110, 2120, 2121,2200, 2201, 2220, 2231 (950) have generators
35.204(e)	5% of 2110, 2120, 2121,2200, 2201, 2220, 2231 (950) have generators = 48 X 1% estimated to report = 1 (rounded)
35.290(a)	30% of all applicants will be board certified. Turnover – 3% of 2110, 2120, 2121, 2200, 2201, 2220 (948) = 28 X 30% = 8 (rounded)
35.390(a)	30% of all applicants will be board certified. Turnover – 3% of 2110, 2120, 2200, 2231 (465) = 14 X 30% = 4 (rounded)
35.392(a)	30% of all applicants will be board certified. Turnover – 3% of 2110, 2120, 2200, 2231 (465) = 14 X 30% = 4
35.394(a)	30% of all applicants will be board certified. Turnover – 3% of 2110, 2120, 2200, 2231 (465) = 14 X 30% = 4
35.433	No Additional Cost
35.490(a)	30% of all applicants will be board certified. Turnover - 3% of 2110, 2120, 2200, 2210, 2240 (503) = 15 X 30% = 5
35.610(d)	Cost in 35.2310 for 2110, 2120, 2230, 2300, 2310 = 500
35.655(a)	No change in cost
35.690(a)	30% of all applicants will be board certified. Turnover - 3% of 2110, 2230, 2300, 2310 (162) = 5 X 30% = 2 (rounded)
35.2024(c)	Turnover – 3% of all licensees = 33
35.2041	From 35.41(a) = 33
35.2204	From 30.34(g) (52) +35.204(b) (48) = 100
35.2310	From 35.610(d) = 500 X 5% = 25
35.3045(a)(2)	Cost in 35.3045(c), (d), and (e)
35.3045(c)	Avg number of ME's each year for permanent implant brachytherapy = 14 X 50% reduction from new criterion = 7 (1 NRC and 6 Agreement States)
35.3045(d)	Avg number of MEs each year for permanent implant brachytherapy = 14 X 50% reduction from new criterion = 7 (1 NRC and 6 Agreement States)
35.3045(e)	Avg number of MEs each year reported to patients = 48 X 35% reduction from new criterion = 18 (3 NRC and 15 Agreement States)
35.3204(a)	From 30.34(g) (1) + 35.204(e) (1) = 2
35.3204(b)	From 30.34(g) (1) + 35.204(e) (1) = 2