February 11, 2002

The Honorable George V. Voinovich
United States Senate
Washington, D.C. 20510

Dear Senator Voinovich:

I am responding on behalf of the U.S. Nuclear Regulatory Commission (NRC) to your letter dated December 13, 2001, concerning the proposed revisions to 10 CFR Part 35 as they relate to diagnostic nuclear medicine. As you are aware, NRC was directed not to implement certain parts of the recently revised 10 CFR Part 35 relating to diagnostic nuclear medicine until the NRC had provided a report to Congress explaining why the regulatory burden could not be reduced further without adversely affecting public health and safety. Your letter also supported preparation of a regulatory analysis of the benefits and costs related to the 10 CFR Part 35, as suggested by the Office of Management and Budget (OMB), and encouraged the NRC to engage in a deliberative review process that should include collaboration with the Society of Nuclear Medicine, the American College of Nuclear Physicians, and other members of the nuclear medicine community.

As directed by the "Energy and Water Development Appropriations Act, 2002," (PL 107-66), the NRC has provided the enclosed letter and report to the House and Senate Committees on Appropriations. As you will see, we conclude that the revised Part 35 has generally achieved a significant reduction in the regulatory burden associated with diagnostic nuclear medicine, although certain requirements are maintained. The NRC believes that the regulatory burden of the revised rule for diagnostic nuclear medicine is commensurate with the low risk of adverse impact on health and safety from these procedures. As described in the report, we believe that further reduction of regulatory burden beyond that currently proposed in the revised rule has the potential to increase the risk to public health and safety. As part of the NRC's rulemaking process for 10 CFR Part 35, as for all rules that the NRC promulgates, a regulatory analysis was prepared which included an evaluation of the benefits and costs. The report describes our further regulatory analysis and its conclusions.

Nonetheless, we acknowledge that our stakeholders have identified substantial concerns related to the perceived burden of the guidance and inspection programs that will implement the new rule. We believe that many of these concerns are more reflective of licensing and inspection practices under the current rule -- practices we seek to modify in connection with the revised rule. Based on this feedback, the NRC agrees that the licensing and inspection guidance should be improved and that the license reviewers and inspectors will need to be trained to implement the revised rule effectively and efficiently. We have committed to undertake this reform.

The revised Part 35 includes only minimal requirements that are unique for diagnostic nuclear medicine, and most of the requirements listed in the staff's report apply to any licensee

that has a specific license from NRC for medical uses of byproduct material. Consequently, the Commission believes that health and safety and reduction of unnecessary regulatory burden will best be served by implementing the revised Part 35. In the meantime, we are revising the implementing guidance to accommodate many of the concerns that have been raised, and we are committed to work with stakeholders to ensure the licensing and inspection procedures implementing the new rule continue to enhance the burden reduction offered by revised Part 35. In addition, consideration of future rule changes will remain possible through the NRC's established rulemaking processes as experience with the rule is gained by NRC staff and licensees. This rule would not be effective until 6 months thereafter, which should allow time for the guidance to be revised.

Although the Act permitted NRC to implement some aspects of the revised rule before reporting to Congress, the NRC has not implemented any portion of the revised Part 35 for medical licensees at this time. We concluded that fragmentation of the rule would be resource intensive and would introduce a confusing, dual regulatory system. The Commission therefore plans to submit the revised Part 35 to the Office of the Federal Register, for publication, in approximately 30 days.

Please feel free to contact me if you have any questions.

Sincerely,

/RA/

Richard A. Meserve

Enclosure: Letter to Congress transmitting NRC's report on Part 35 burden

Enclosure

February 11, 2002

The Honorable Sonny Callahan, Chairman
Subcommittee on Energy and Water Development
Committee on Appropriations
United States House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

In response to the direction in the Conference Report on H.R. 2311, "Energy and Water Development Appropriations Act, 2002," I am pleased to provide the enclosed report, which was prepared by the U. S. Nuclear Regulatory Commission staff, to the House and Senate Committees on Appropriations. As you are aware, NRC was directed not to implement certain parts of the recently revised 10 CFR Part 35 relating to diagnostic nuclear medicine until the NRC had provided a report to Congress explaining why the regulatory burden could not be reduced further without adversely affecting public health and safety.

The revised Part 35 has generally achieved a significant reduction in the regulatory burden associated with diagnostic nuclear medicine, although certain requirements are maintained. The NRC believes that the regulatory burden of the revised rule for diagnostic nuclear medicine is commensurate with the low risk of adverse impact on health and safety from these procedures. As shown in the enclosed report, we believe that further reduction of regulatory burden beyond that currently proposed in the revised rule has the potential to increase the risk to public health and safety.

Nonetheless, we acknowledge that our stakeholders have identified substantial concerns related to the perceived burden of the guidance and inspection programs that will implement the new rule. We believe that many of these concerns are more reflective of licensing and inspection practices under the current rule -- practices we seek to modify in connection with the revised rule. Based on this feedback, the NRC agrees that the licensing and inspection guidance should be improved and that the license reviewers and inspectors will need to be trained to implement the revised rule effectively and efficiently. We have committed to undertake this reform.

The revised Part 35 includes only minimal requirements that are unique for diagnostic nuclear medicine, and most of the requirements listed in the staff's report apply to any licensee that has a specific license from NRC for medical uses of byproduct material. Consequently, the Commission believes that health and safety and reduction of unnecessary regulatory burden will best be served by implementing the revised Part 35. In the meantime, we are revising the implementing guidance to accommodate many of the concerns that have been raised, and we are committed to work with stakeholders to ensure the licensing and inspection procedures implementing the new rule continue to enhance the burden reduction offered by revised Part 35. In addition, consideration of future rule changes will remain possible through the NRC's

established rulemaking processes as experience with the rule is gained by NRC staff and licensees.

Although the Act permitted NRC to implement some aspects of the revised rule before reporting to Congress, the NRC has not implemented any portion of the revised Part 35 for medical licensees at this time. We concluded that fragmentation of the rule would be resource intensive and would introduce a confusing, dual regulatory system. The Commission therefore plans to submit the revised Part 35 to the Office of the Federal Register, for publication, in approximately 30 days. The rule would not become effective until 6 months thereafter, which should allow time for the guidance to be revised.

Please feel free to contact me if you have any questions.

Sincerely,

/RA/

Richard A. Meserve

Enclosure:
"Report to Congress Regarding the
Revised 10 CFR Part 35"

cc: Representative Peter J. Visclosky

Identical letter to:

The Honorable Sonny Callahan, Chairman
Subcommittee on Energy and Water Development
Committee on Appropriations
United States House of Representatives
Washington, D.C. 20515

cc: Representative Peter J. Visclosky

The Honorable Harry Reid, Chairman
Subcommittee on Energy and Water Development
Committee on Appropriations
United States Senate
Washington, D.C. 20510

cc: Senator Pete V. Domenici

REPORT TO CONGRESS

REGARDING THE REVISED 10 CFR PART 35

February 11, 2002

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Regarding the Revised 10 CFR Part 35

REPORT TO CONGRESS REGARDING THE REVISED 10 CFR PART 35

EXECUTIVE SUMMARY

The purpose of this report is to respond to the provision, in PL 107-66, wherein the Congress prohibits the U. S. Nuclear Regulatory Commission (NRC) from implementing or enforcing any part of the revised 10 CFR Part 35, with respect to diagnostic nuclear medicine, except those parts that establish training and experience requirements for persons seeking licensing as authorized users, until NRC explains, in a report to Congress, why the imposed burden could not be reduced further.

Section 1.0 describes the purpose of the report. Section 2.0 outlines the authority and rationale for NRC's regulation of the medical use of byproduct material. Section 3.0 refers to operating experience that illustrates that certain requirements pertaining to diagnostic nuclear medicine are important for maintaining safety and increasing public confidence in the medical use of byproduct material. The approach to the NRC's revision of 10 CFR Part 35 is presented in Section 4.0 while Section 5.0 summarizes the regulatory burden in the revised Part 35 associated with diagnostic nuclear medicine. Section 6.0 discusses why such regulatory burden in the revised Part 35 cannot be reduced further without adversely affecting public health and safety. The issue of specific licenses versus general licenses is discussed in Section 7.0, and Section 8.0 provides the overall conclusion of the report.

As used in this report, the term "diagnostic nuclear medicine" usually refers to 10 CFR 35.100, "Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required," and 10 CFR 35.200, "Use of byproduct material for imaging and localization studies for which a written directive is not required." The use for diagnostic purposes of I-131 sodium iodide greater than 1.11 Megabecquerels (30 microcuries) is recognized and reflected in Table 1 and the Appendix. However, because its use involves higher risks to public health and safety and its use is under the requirements for Subpart E, "Unsealed Byproduct Material–Written Directive Required," for the purposes of this report its use is generally not included in the term "diagnostic nuclear medicine".

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) advises the Commission on regulating and licensing issues of radionuclides in medicine. The staff consulted with the ACMUI throughout the rulemaking process through the use of public meetings.
The Commission has retained regulatory requirements in the revised Part 35 only where it believes they are necessary to assure radiation safety for workers and the public, including patients and human research subjects. This report demonstrates that only minimal requirements will apply to diagnostic nuclear medicine under the revised 10 CFR Part 35, beyond those general requirements that apply to all of the NRC's medical or radioactive materials licensees. For example, 10 CFR Part 20 requirements apply to all NRC licensees concerning radiation protection of workers and members of the public. In revising Part 35, the NRC obtained extensive stakeholder input, and retained regulatory requirements only where the NRC believes such requirements are necessary. The report concludes that the revised Part 35 is necessary to establish requirements that specifically authorize medical professionals who are trained and experienced in radiation safety to administer unsealed byproduct material for diagnostic purposes, while at the same time providing for radiation safety of the workers and of the general public to include patients and human research subjects. The NRC believes that the interaction between the applicant and NRC in the specific licensing process plays an essential safety role by defining the links in the chain of accountability for radiation protection before a licensee obtains radioactive material. Although the Commission recognizes that physicians

have primary responsibility for the protection of their patients, NRC also has a necessary role and need to fulfill its statutory obligations regarding the radiation safety of workers and the public, including patients.

In revising Part 35, the NRC used a "risk-informed" approach to regulatory decision making; that is, we considered risk insights together with other factors to establish requirements that better focus licensee and regulatory attention on design and operational issues commensurate with their importance to health and safety. The regulation of the diagnostic uses of radioactive material, as proposed in revised Part 35, is consistent with the state of knowledge concerning the risks of these uses of radioactive materials. Although a thorough, quantitative risk analysis of the medical uses of radioactive material has not been performed, because of insufficient data and lack of consensus techniques to support such an analysis, Part 35 applies qualitative risk insights to ensure a baseline level of safety, but at the same time to focus additional requirements on higher-risk activities.

The minimal additional requirements in the revised Part 35 will be sufficient to protect health and minimize danger to life or property from uses of unsealed byproduct material in diagnostic nuclear medicine. Therefore, the Commission cannot reduce regulatory burden further on diagnostic nuclear medicine licensees, for to do so might adversely affect public health and safety.

1.0 Purpose of this Report

The Conference Report for H.R. 2311, "Energy and Water Development Appropriations Act, 2002" (PL 107-66, November 12, 2001) directed the Commission to review the revised 10 CFR Part 35, "Medical Use of Byproduct Material," and report to Congress why the regulatory burden for diagnostic nuclear medicine requirements could not be reduced further without adversely affecting public health and safety. The following provision appears in that Conference Report:

> The conference agreement includes language prohibiting the implementation or enforcement of the revised 10 CFR Part 35, as adopted by the Nuclear Regulatory Commission on October 23, 2000, with respect to diagnostic nuclear medicine, except for those parts of the new rule which [that] establish revised training and experience requirements for persons seeking licensing as authorized users, until after the Commission has provided a report to the House and Senate Committees on Appropriations explaining why the regulatory burden could not be reduced further in the new rule without adversely affecting public health and safety. The conferees direct the Commission to submit this report not later than January 31, 2002. The language included in the conference agreement is only an interim measure until a more permanent solution can be reached, either by the authorization committees or through a revised rulemaking.

Accordingly, this report provides the NRC's response to the Congressional direction, and, for context, provides a brief description of NRC's statutory authority, Strategic Plan, and applicable regulations and policies regarding diagnostic nuclear medicine. Also explained are the approach used by the NRC to develop the revised Part 35 and the methodology used to review the requirements in the revised Part 35 that are applicable to diagnostic nuclear medicine and reevaluate the regulatory burden of these requirements. Finally, this report includes a consideration of the appropriate licensing regime (specific versus general).

The revised Part 35 does not use or define the term "diagnostic nuclear medicine." In the revised Part 35, medical uses are categorized according to the written directive requirement and physical form of byproduct material (unsealed material or sealed sources). Sealed sources are further classified according to whether the materials are subject to manual handling or instead to remote handling in a device or unit. Diagnostic nuclear medicine procedures using byproduct material are understood to be described or referenced in Subpart D, "Unsealed Byproduct Material–Written Directive Not Required"; in 10 CFR 35.100, "Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required"; and in 10 CFR 35.200, "Use of byproduct material for imaging and localization studies for which a written directive is not required." As used in this report, the term "diagnostic nuclear medicine" refers to 10 CFR 35.100 and 35.200, and the term "patients" refers to either a patient or a human research subject.

2.0 Authority and Rationale for NRC Regulation of Medical Use of Byproduct Material

This section describes the basis for NRC's regulation of the medical use of byproduct material. It includes the NRC's statutory authority, considerations related to the NRC's Strategic Plan, and relevant background from the NRC's Policy Statement on the Medical Use of Byproduct Material.

2.1 The Atomic Energy Act of 1954, as amended

NRC's principal statutory authority for regulating medical use of byproduct material is derived from sections 81, 161, 182, and 183 of the Atomic Energy Act of 1954, as amended (AEA). (See 42 U.S.C. 2111, 2201, 2232, and 2233.) The Commission is bound by statute to regulate byproduct material (as well as source and special nuclear material) to protect health and minimize danger to life or property. This statutory standard applies to the myriad uses of byproduct material, including not only medical use, but also, for example, academic, industrial, engineering, and research uses. Section 81 of the AEA prohibits, without NRC authorization, the manufacture, production, transfer, receipt in interstate commerce, acquisition, ownership, possession, import, and export of byproduct material (42 U.S.C. 2111). Section 161 of the AEA authorizes the Commission to establish, by rule, regulation, or order, such standards and instructions to govern the possession and use of special nuclear material, source material, and byproduct material as the Commission may deem necessary or desirable to protect health or to minimize danger to life or property [42 U.S.C. 2201(b)]. Section 161.i. authorizes the Commission to prescribe such regulations or orders as it may deem necessary to govern any activity authorized pursuant to the Act, including standards and restrictions governing the design, location, and operation of facilities used in the conduct of such activities, in order to protect health and minimize danger to life or property [42 U.S.C. 2201(i)].

2.2 NRC Strategic Plan (Fiscal Year 2000 - Fiscal Year 2005)

The NRC Strategic Plan (Fiscal Year 2000 - Fiscal Year 2005) includes strategic goals, performance goals, and strategies and measures for the various arenas that comprise the Agency. The performance goals for regulating the nuclear materials safety arena are relevant for diagnostic nuclear medicine licensees and include: (1) maintain safety; (2) increase public confidence; (3) make NRC activities and decisions more effective, efficient, and realistic; and (4) reduce unnecessary regulatory burden on stakeholders. The NRC Strategic Plan promotes evaluation and adjustment of the current regulatory approach to align Part 35 with the strategic plan by risk-informing (see Section 4.1) the types of use and focusing on the performance goals

listed above. NRC recognizes that diagnostic nuclear medicine is a mature industry with an excellent safety record and low risk of adverse impact on workers and the public. As such, this type of medical use was a candidate for streamlined regulatory processes and reduction of unnecessary regulatory burden, while maintaining safety and enhancing public confidence. Such considerations were included in the revision of Part 35.

2.3 Applicable Regulations and Policies for Medical Use of Byproduct Material

For the most part, the regulations in 10 CFR Parts 30 through 39 carry out the broad statutory mandate for byproduct materials. In addition, the public and occupational dose limits in 10 CFR Part 20, "Standards for Protection Against Radiation," apply whether the use of byproduct material is for medical or other purposes. However, 10 CFR 20.1002, "Scope," states that the radiation dose limits in Part 20 do not apply to doses from any medical administration an individual has received, or from voluntary participation in a medical research program as a human research subject (e.g., doses intended by an authorized user physician for diagnostic purposes). The Commission's policy is that the medical administration of radiation or radioactive materials to any individual, even an individual not supposed to receive a medical administration, is governed by NRC's regulations for the medical use of byproduct material in Part 35, rather than by the dose limits in Part 20. Part 35 also contains requirements that allows licensees flexibility with respect to certain Part 20 requirements. For example, pursuant to 10 CFR 35.75, a licensee that releases a patient containing byproduct material is not constrained by the public dose limit in Part 20 [i.e., 1 millisievert per year (100 millirem per year)], but is allowed to release a patient who is not likely to expose another member of the public (e.g., a family member) to more than 5 millisieverts (500 millirem), total effective dose equivalent.

Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," 10 CFR 30.2, "Resolution of conflict," requires that any conflict between the general requirements in Part 30 and the specific requirements in another part are governed by those specific requirements. 10 CFR 35.1, "Purpose and scope," states that the requirements in the revised Part 35 are designed to provide for the radiation safety of workers, the general public, patients, and human research subjects and reflect the broad statutory standard in the AEA, discussed above.

The Commission published the revised "Policy Statement on the Medical Use of Byproduct Material" (MPS) (65 FR 47654; August 3, 2000). The MPS informs NRC licensees, other Federal and State agencies, and the public, of the Commission's general intentions regarding the regulation of the medical use of byproduct material. The Commission expects that NRC rulemaking activities in the medical area and NRC involvement with other Federal and State agencies will adhere to the MPS. This NRC policy promotes a more risk-informed approach to regulation of byproduct material. The revision of the MPS is a component of the Commission's overall program for revising its regulatory framework for medical use, and the revision of Part 35 is consistent with the revision of the MPS. A key assumption in the Commission's policy is that a patient, like everyone else who is not exposed as part of their employment functions, is a member of the public to be protected by NRC. The focus of NRC regulation--to protect the patient's health and safety--is primarily to ensure that the authorized user physician's directions are followed as they pertain to the administration of the radionuclide. The underlying premise of NRC regulations is that authorized user physicians will understand radiation safety principles and practices and will make decisions that are in the best interests of their patients.

3.0 Operational Experience

Current operational experience indicates that workers and the public can be unintentionally exposed to radiation. For example, contamination levels reported by licensees have indicated spilled byproduct material used for diagnostic nuclear medicine procedures that resulted in excessive exposure rates within restricted areas of the licensee's facilities [e.g., surface radiation exposure rates in the range of 0.5 millisieverts per hour to 2 millisieverts per hour (50 millirem per hour to 200 millirem per hour) or 5 microsieverts per hour (5 millirem per hour) at a distance of one meter]. Although there was no resulting exposure above Part 20 limits, there was a potential for spread of contamination and exposure of personnel.

In addition, patients and members of the general public also have received unintended radiation exposures from errors that were made by supervised individuals and authorized users in diagnostic nuclear medicine. For example, a patient undergoing diagnostic nuclear medicine procedure was administered a different radionuclide than prescribed which was then incorrectly measured prior to administration of the dosage, such that the patient received a total effective dose equivalent above the reporting threshold as well as excessive doses to several organs. In another case, a child was given a dosage that was more than 10 times the dosage that was recommended for the child for a diagnostic nuclear medicine procedure. In another example, the diagnostic nuclear medicine licensee ordered a dosage from a commercial nuclear pharmacy. The licensee received a different radionuclide that was intended for oral administration. However, the dosage was drawn into a syringe by the licensee's supervised individual and injected into the patient. The consulting physicist estimated that the patient received an unintended dose to an organ that was nearly 100 times greater than the reporting threshold. Another case involved a nursing child. The patient noted on a hospital form that she was breast-feeding; however, the licensee's supervised individual failed to observe the note and administered a dosage for the diagnostic nuclear medicine procedure. The consulting physician estimated a range of organ doses to the nursing child that exceeded the reporting threshold.

The examples listed previously demonstrate that even with our existing regulations, significant unintended radiation exposures can occur in areas such as diagnostic nuclear medicine, which we agree has low risk in general. Although there is justification to reduce regulatory burden for low risk arenas, there is also justification to maintain a minimal amount of regulatory control. Clearly, regulations will not prevent all unintended exposures. But the requirements will serve to remind licensees that the have certain responsibilities, and the requirements implement a series of checks and balances to ensure the detection and proper response to unintended exposures.

4.0 Approach to Revising Part 35

The approach includes three key elements: (1) a risk-informed, performance-based approach, (2) significant opportunities for stakeholder involvement and input, and (3) involvement of the Advisory Committee on the Medical Uses of Isotopes and Agreement States.

4.1 The Risk-Informed, Performance-Based Approach

In March 1997, the Commission directed the revision and restructuring of Part 35 into a more risk-informed and, where appropriate, more performance-based regulation. This direction was part of the Commission's overall decision to decrease oversight of low-risk activities, such as diagnostic nuclear medicine, while retaining oversight of higher-risk activities.

A “risk-informed” approach to regulatory decisionmaking represents a philosophy that considers risk insights together with other factors to establish requirements that better focus licensee and regulatory attention on design and operational issues commensurate with their importance to health and safety.

In revising Part 35, the Commission used risk insights from available risk information. The Commission considered the completeness and reliability of the available risk information and balanced the insights drawn from this information against other factors, such as decades of licensing and inspection experience, the States’ perspectives, statutory requirements, and public and stakeholder interests, in developing regulations.

Before initiating the rulemaking, the Commission thoroughly reviewed several assessments, including the external review conducted by the National Academy of Sciences, Institute of Medicine, and the related report, “Radiation in Medicine, A Need for Regulatory Reform”, a 1993 NRC internal senior management review and report, and the Commission’s Strategic Assessment and Rebaselining initiative. During the development of the overall revision of Part 35, NRC considered information on risk provided by members of the public and professional societies, professional medical standards of practice, and event databases maintained by NRC to determine where oversight of lower-risk activities could be decreased and where continuation, or even broadening, of the regulations governing higher-risk activities was needed. In addition, throughout the development of the proposed rule and associated proposed guidance, public workshops were held and early opportunities for comment from potentially affected parties were provided. These interactions included significant discussions on the risk associated with medical uses of byproduct material.

In consideration of the low radiation risks in the diagnostic area, NRC has reduced the unnecessary regulatory burden for diagnostic nuclear medicine licensees by either eliminating or decreasing the prescriptiveness of the regulations that apply to them. NRC is relying on a performance-based approach that emphasizes the training and experience of the authorized user (AU), authorized nuclear pharmacist (ANP), and Radiation Safety Officer (RSO). Although the NRC did not perform a formal risk assessment, the Commission believes the risks associated with use of byproduct material in medicine were adequately evaluated and considered based on the risk insights that were available, along with experiences in licensing and inspection of medical licensees by NRC and the Agreement States. Further, NRC agrees that the risk associated with the use of byproduct material in diagnostic nuclear medicine is low. For this reason, the final rule is more permissive than the current rule.

In recent years, NRC changed the focus of its medical inspections from a detail oriented inspection to a more performance-based inspection. Under this approach, inspectors are directed to focus more on observations, interviews, and measurements than on record reviews to assess program adequacy. The inspection policy also requires inspectors to extend the time between inspections for good performers, as well as those licensees that have relatively few violations for several inspections in succession and no escalated enforcement actions.

NUREG-1556, Volume 9, “Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Medical Use Licenses” (NUREG) was developed, along with the revised Part 35, to combine and supersede the licensing guidance previously found in various regulatory guides and policy and guidance directives. Similar “Consolidated Guidance” NUREGs have been prepared for the various types of NRC materials licensees. NUREG-1556, Vol. 9, provides a compiled, concise source of information that can be used by NRC staff in

reviews and by licensees to help develop radiation safety programs or license applications. However, the guidance neither implies nor represent additional regulatory requirements, and alternative approaches may be used by applicants and licensees. Consistent with the revised Part 35, the NUREG reduces the amount of information needed from an applicant for diagnostic nuclear medicine. The NRC intends to issue the NUREG for public comment upon issuance of the new rule, such that the eventual, final NUREG will have benefitted from stakeholder input and experience gained (by NRC licensing and inspection staff and applicants/licensees) in implementing new Part 35.

4.2 Opportunities for Stakeholder Input

The Commission believes that the regulated community had numerous opportunities to participate and provide input during development of revised Part 35 requirements. The Commission directed that the process begin with facilitated public workshops conducted before publication of the proposed rule and Medical Policy Statement (MPS). The proposed revisions of Part 35 and the MPS were published for comment in the Federal Register on August 13, 1998 (63 FR 43516 and 63 FR 43580). The notice of proposed rulemaking solicited public comment on the proposed rule; discussed the issues that were considered during the development of the proposed rule and associated guidance; and summarized the input that was received during the facilitated workshops in developing the proposed rule and MPS from the public, potentially affected parties, professional medical organizations, the Advisory Committee on the Medical Uses of Isotopes (ACMUI), Organization of Agreement States (OAS), and Conference of Radiation Control Program Directors. These issues included patient notification, precursor events, the Radiation Safety Committee, the quality management program, and training and experience for authorized users.

In addition to publishing the proposed rule and MPS in the Federal Register for comment, the Commission also held three facilitated public meetings, during the comment period in August, September, and October 1998, to discuss the Commission's resolution of the major issues. The Commission also held a public workshop after the comment period in February 1999, to solicit additional comments on implementation issues associated with the proposed revisions of the training and experience requirements. The Commission was specifically interested in information on the process and criteria for recognizing medical specialty boards.

4.3 Advisory Committee on the Medical Uses of Isotopes and Agreement State Involvement

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) advises the NRC staff on regulating and licensing uses of radionuclides in medicine. The membership is comprised of individuals from the medical community (e.g., authorized user physicians representing nuclear medicine, nuclear cardiology, endocrinology, and radiation oncology; authorized nuclear pharmacist; hospital administrator; authorized medical physicist; radiation safety officer), and individuals representing the States, patient advocacy, and FDA. Besides the nuclear medicine physician on the ACMUI, the NRC staff contracted with another nuclear medicine physician to participate in the Part 35 Working Group that developed the revised regulatory framework (i.e., rule, guidance, and MPS).

In February 1999, the ACMUI diagnostic and therapeutic subcommittees held public meetings to review the public comments and a draft final rule that addressed the comments. The full ACMUI held a public meeting in March 1999 to discuss specific issues that the Part 35 Working Group wanted the ACMUI to review and comment on before the NRC staff forwarded a draft final rule to the Commission for its consideration. The ACMUI presented its position on these and other issues at its annual briefing of the Commission in March 1999. In October 1999, the

ACMUI briefed the Commission on specific issues that it wanted to bring to the Commission's attention (i.e., radiation safety committee, training and experience, medical event, unintentional exposure to embryo/fetus/nursing child, notifications, and implementation challenges).

The Agreement States were also involved throughout the rulemaking process. Thirty-two States, known as Agreement States, have entered into an agreement with NRC to regulate the use of byproduct material (as authorized by section 274 of the AEA). The Agreement State regulations are required to be compatible with the NRC regulations. As of February 2001, there were about 6000 medical licensees, nationwide, and about 4200 (70 percent) were under Agreement State jurisdiction. Both the Working Group and Steering Group that developed the revision of Part 35 included representatives of the Agreement States. A draft compatibility chart for Agreement States' regulations was published for comment with the proposed rule (63 FR 43516; August 13, 1998). The NRC staff discussed the States' rulemaking issues with representatives of the Agreement States at the OAS annual meeting in 1999. Further, OAS participated in a briefing of the Commission on revised Part 35 issues in 2000 when the draft final rule was given to the Commission.

5.0 Regulatory Burden Associated with Diagnostic Nuclear Medicine Associated with the Revised 10 CFR Part 35

The NRC reviewed the revised Part 35 (as adopted on Oct. 23, 2000) and identified the requirements that are applicable to diagnostic nuclear medicine. The function of each requirement and the type of burden imposed by each requirement was considered. The requirements were considered for further reduction of unnecessary regulatory burden.

Table 1, in Attachment 1, lists each requirement in the revised Part 35 that applies to diagnostic nuclear medicine. The requirements are grouped according to regulatory burden imposed on the licensees and are further explained in the paragraphs below. Table 1, Part I lists those requirements that impose burden that directly protect health and safety of workers and the public, including patients. To eliminate these requirements would adversely affect protection of health and safety. Table 1, Part II lists those requirements that provide licensees flexibility from Part 20 and Part 30 requirements. Table 1, Part III lists those requirements that provide for the specific licensing process to authorize medical use of byproduct material.

The requirements listed in Table 1, Part I, are in Subparts A, B, C, D, and M of revised Part 35. The specifics of these Subparts are discussed in the Appendix to Table I.

Subpart A, "General Information," contains requirements to protect individuals who are administered byproduct material as human research subjects[1]. Also in Subpart A are requirements to protect patients, the public, and workers by establishing the specific license regime, along with details about applications, amendments, notifications, and issuance of a specific license.

Subpart B, "General Administrative Requirements," contains requirements about authority and responsibilities for the radiation protection program, supervision of individuals, and training and experience requirements for an RSO and an ANP.

[1]The Federal Policy for Human Subjects (Federal Policy) requires that these individuals are protected by prior review and approval of the research project by an Institutional Review Board and informed consent of the human research subject for federally conducted, funded, supported, or regulated research. This reflects the Commission's voluntary compliance with Executive Order 12975, dated October 3, 1995. See 58 FR 33396, 33401, and 59 FR 61767, 61772.

Subpart C, “General Technical Requirements,” provides for identification and accuracy of prepared dosages to protect patients from being administered an incorrect dosage.

Subpart D, “Unsealed Byproduct Material–Written Directive Not Required,” identifies diagnostic nuclear medicine procedures and commensurate training and experience requirements for physicians who desire to be authorized for medical use for these procedures.

Subpart M, “Reports,” includes requirements for report and notification of a medical event or a dose to an embryo/fetus or a nursing child, and a report for a leaking source.

The requirements listed in Table 1, Part II, are in Subparts A and B and provide licensee flexibility and regulatory relief from certain requirements in Parts 20 and 30. Section 35.19, “Specific exemptions,” states the Commission’s willingness to consider an application for an exemption from the requirements in Part 35. The Commission may grant such an exemption request after determining that workers and the public, including patients, will not be endangered and that such a request is otherwise in the public interest. With respect to Part 20 requirements, a medical licensee is not constrained by the dose limit in 10 CFR 20.1301 for a member of the public if the licensee releases an individual who was administered byproduct material. The Commission previously determined that adequate protection of public health and safety would be provided by giving medical licensees more flexibility on this issue. Also, Part 20, Subpart K, “Waste Disposal,” requirements were streamlined for radioactive waste from medical use of byproduct material by providing 10 CFR 35.92, “Decay-in-storage,” that gives medical licensees flexibility to hold byproduct material for a period of radioactive decay before release. With regard to Part 30 requirements, medical licensees are given flexibility in 10 CFR 35.26 to make changes to their radiation protection programs without Commission approval, under specified limitations. Also, in 10 CFR 35.65, authorization to possess certain types and quantities of calibration, transmission, and reference sources has been given to medical licensees. A licensee need not request an amendment to its license for these types of sources that are used in these ways.

The requirements listed in Table 1, Part III, are in Subparts A and N and provide for basic, common understanding of the purpose and scope of Part 35; specific terms that are used in the regulations, expectations for the quality and retention of records that document radiation safety of workers and the public, including patients, and other Federal and State requirements that are incidental to medical use of byproduct material; and clarification of implementation schedules and potential misunderstandings. Subpart N, “Enforcement,” states the legal process available to NRC for individuals who violate certain requirements in certain ways.

Table 2, in Attachment 2, provides cost values extracted from the Regulatory Analysis (RA) that accompanied the revised Part 35. The extracted values are for sections that affect diagnostic nuclear medicine. For each regulatory change described in the RA, the table lists the corresponding estimated total annual costs avoided or total costs added (i.e., the change in costs from the current rule), for a particular section of the rule. The diagnostic nuclear medicine portion of the total changed value for each requirement is indicated in Table 2. The appendix in Attachment 2 indicates the current and revised requirements applicable to diagnostic nuclear medicine along with the cost impact and benefit of each change.

6.0 Why Regulatory Burden could not be Reduced Further Without Adversely Affecting Public Health and Safety

This section discusses the importance of the requirements in the revised Part 35, the changes in regulatory burden from the current rule to the revised rule (Table 2), and possible adverse effects on public health and safety that could result from further reduction of the regulatory requirements. In the revised Part 35, the Commission exerted considerable effort to reduce regulatory burden while maintaining appropriate regulatory controls to protect public health and safety. As discussed previously, the Commission staff received extensive public comments, some of which were conflicting comments, concerning appropriate levels of regulatory control. The following sections describe areas where the Commission does not believe that the regulatory burden should be reduced further as further reductions might have an adverse affect on public health and safety. Such wording is not meant to imply that the Commission will not consider further regulatory burden reductions if new information justifies further reductions. However, any such potential changes, if and when proposed, should be considered in future rulemakings and not delay the implementation of current revisions.

6.1 Importance to Health and Safety of the Requirements in the Revised Part 35

Key elements for a radiation safety program are responsibility, accountability, and authority. It is important to the radiation safety of workers and the public, including patients to designate certain individuals (i.e., an Authorized Nuclear Pharmacist (ANP), an Authorized User (AU), and a Radiation Safety Officer (RSO)) who have adequate training and experience in radiation safety principles as applied to diagnostic nuclear medicine to reduce unnecessary radiation exposures while obtaining diagnostic information that will benefit the patient. Section 35.2, "Definitions," defines these key individuals who have met the regulatory requirements to handle byproduct material safely. Without a process that defines the links in the chain of accountability for radiation protection before a licensee obtains radioactive material, public health and safety may be adversely affected.

The specific license is the mechanism by which NRC assures that radiation safety is established and maintained in diagnostic nuclear medicine involving byproduct material. A set of administrative requirements is essential for effective and efficient processing of applications from individuals and institutions who desire to be licensed and/or given authority to use byproduct material for medical purposes. Alternatives to the specific license regime (e.g., general licensing or exempting diagnostic nuclear medicine altogether from regulatory oversight) are not adequate, except in limited cases, to assure the safety of workers and the public, including patients. As explained below, NRC does not favor the general license regime because of control and security issues relating to these quantities of byproduct material. Without a specific license regime, public health and safety may be adversely affected.

Training and experience requirements are essential for identifying individuals who may be recognized as ANPs, AUs, and RSOs. Minimal requirements for radiation safety training and experience are intended to ensure consistent radiation protection for workers and the public, including patients. In their duties and responsibilities, these authorized individuals will often supervise a team of individuals who are involved in medical use. The authorized individual must have knowledge and skills in radiation safety practices and procedures to direct the supervised individuals to ensure that unsealed byproduct material is handled safely.

Several aspects of patient radiation safety are directly related to the requirements that ensure that each patient dosage is prepared and administered as intended by the AU for the specific patient (e.g., the amount of radioactivity, chemical/physical form, and radionuclidic purity).

Necessarily, equipment used in these determinations must be accurately calibrated and operable, and the prepared dosages must be shielded, readily identifiable, and correctly handled for administration to the intended patient. These requirements are adapted for mobile medical services that extend diagnostic nuclear medicine capabilities into many communities.

In all cases, a radiation survey program must be implemented to control radioactive contamination and evaluate radiological hazards. There must be requirements to ensure that unused dosages and other forms of radioactive waste are properly stored and secured and eventually discarded in an appropriate manner. Mistakes in preparing dosages and mishandling of dosages may deliver unintended radiation exposures to workers and the public, including patients, and require additional handling by technicians and may increase amounts of radioactive waste. Without requirements addressing these matters as provided in revised Part 35, public health and safety may be adversely affected.

6.2 Changes in Regulatory Burden from the Current Part 35 to the Revised Part 35

Table 1 attached to this report identifies burden affecting radiation safety of workers and the public, including patients. Subpart A, "General Information," 10 CFR 35.1 through 35.19, applies to all medical licensees. Section 35.13, "License amendments," paragraph (e), states that licensees are not required to request an amendment for changes of area of use for diagnostic nuclear medicine. The current regulatory burden is being reduced under the revised Part 35, and instead of an amendment request to NRC, a licensee need only send to NRC a written notification required by 10 CFR 35.14(b)(4) for these types of changes. The effect of these two requirements results in less burden for diagnostic nuclear medicine licensees.

To further reduce administrative requirements may contribute to an ineffective licensing regime that would adversely affect public safety. For example, if a written notification were not required under 10 CFR 35.14(b)(4), then the locations where byproduct material are used would not be known to NRC, information important to implement an effective oversight program.

Subpart B, "General Administrative Requirements," 10 CFR 35.24 through 35.59, applies to all medical licensees, except that written directives referred to in 10 CFR 35.40 and 35.41 would not apply to 10 CFR 35.100 (i.e., uptake, dilution, and excretion studies) and to 10 CFR 35.200 (imaging and localization studies).[2] Section 35.24 eliminated the radiation safety committee requirement for about 20 percent of the licensees that are authorized only for diagnostic nuclear medicine procedures. This burden reduction saves about $1.8 million per year for clinics and small hospitals. Medical licensees authorized for two or more different types of therapeutic uses of byproduct material under Subparts E, F, and H or two or more different types of units under Subpart H are required to establish a radiation safety committee and further reduction was not possible in such cases because diagnostic nuclear medicine is part of an integrated program and needs to be incorporated as part of the whole radiation protection program. In such cases, the regulatory burden was reduced because revised Part 35 is less prescriptive and more performance based and fewer radiation safety committee meetings may be needed than is now required under the current Part 35. Section 35.27 produced a net burden reduction of about $1.2 million per year after adding the requirement to instruct the supervised individual

[2]For the purposes of this report to Congress, use of I-131sodium iodide greater than 1.11 Megabequerels (30 microcuries) was not included because such use is under the requirements for Subpart E, "Unsealed Byproduct Material–Written Directive Required." However, it is recognized that I-131 sodium iodide is used for diagnostic purposes by medical licensees and requirements in 10 CFR 35.40 and 35.41 for written directives and associated procedures would apply to medical diagnostic uses of I-131 sodium iodide. Burden imposed by these requirements was also reduced in revised Part 35, but is not explained further in this report.

in NRC regulations applicable to diagnostic nuclear medicine and the conditions of the license and after eliminating the requirement to periodically evaluate the performance of a supervised individual. Further reduction of the burden of the requirement (e.g., eliminating the requirement to instruct the supervised individual in NRC regulations applicable to diagnostic nuclear medicine and the conditions of the license) could adversely impact public health and safety because the supervised individual would be unaware of requirements that are important to radiation safety (e.g., requirements for surveys, security and control, measurement of patient dosages, labeling vials and syringes, permissible molybdenum-99 concentration). Sections 35.50 and 35.55 are the training and experience requirements for RSOs and ANPs, respectively, and there is an increased regulatory burden of $7000 and $3000, respectively, because of the cost to obtain a preceptor's signature. These costs could not be reduced further because it would be an unnecessary burden to require these individuals to meet the training and experience requirements by certification from a medical specialty board. Public health and safety could be adversely affected if there were fewer individuals who could be authorized as RSOs or ANPs which might be the case if the only means for such authorization were through medical specialty board certification.

Subpart C, "General Technical Requirements," 10 CFR 35.60 through 35.92, applies to all medical licensees. For 10 CFR 35.60, "Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material," a licensee would not need to purchase and maintain a dose calibrator to measure single unit dosages if the dosages were received from a manufacturer or radiopharmacy as ready to administer without further adjustment of the dosage. Daily checks on survey instruments would not be required. This change produced about $521,000 burden reduction for diagnostic nuclear medicine licensees. Section 35.61, "Calibration of survey instruments," eliminated daily checks ($136,000) and the burden cannot be reduced further because that requirement was totally removed. In 10 CFR 35.67, the sealed source inventory interval was relaxed from quarterly to semiannually because the sealed sources are required to be leak-tested at 6-month intervals, which also serves as an inventory record. In addition, the sealed sources would be measured frequently during the 6-month period for quality control purposes (e.g., to standardize the dose calibration instrument). This burden cannot be reduced further because the inventory requirement is associated with the leak test requirement. Section 35.69, "Labeling of vials and shields," requires syringes and vials and shields to be labeled to identify the radioactive drug. The requirements are more specific than the general requirement in 10 CFR 20.1904, "Labeling containers," and do not allow the exemption from labeling requirements in 10 CFR 20.1905. This requirement is necessary to prevent wrong dosage administration and patient safety would be adversely affected without the requirement. In 10 CFR 35.70, "Surveys of ambient radiation exposure rate," the survey requirements of the current rule that apply to diagnostic nuclear medicine use were removed and the general survey requirements in 10 CFR 20.1501 will apply directly to such use. No change in cost for a survey program for diagnostic nuclear medicine would be expected as licensees continue to implement their survey program. Because of the importance of contamination control to workers and public, including patients, the burden cannot be further reduced. Under 10 CFR 35.75, "Release of individuals containing unsealed byproduct material or implants containing byproduct material," diagnostic nuclear medicine administrations are already mainly unaffected by the patient release criteria. The imposed burden provides for instructions to a patient with a nursing child where the child (considered a member of the public) could incidentally receive radiation exposures by ingesting the breast milk. No cost changes were noted, and burden cannot be reduced further because the child must be protected from radiation exposure as a member of the public. Under 10 CFR 35.92, "Decay-in-storage," burden was reduced ($2000) because the radionuclide half-life criterion was increased from 65 days to 120 days so that fewer license amendments would be needed in the future, as many licensees had already requested this change to their individual licenses.

Subpart D, “Unsealed Byproduct Material–Written Directive not Required,” 10 CFR 35.100 through 35.290, describes the uses common to diagnostic nuclear medicine, and the training and experience requirements for authorization of same. Burden increased for certain individuals, under 10 CFR 35.190 and 35.290, which described training and experience requirements for authorized users because the alternative of obtaining a preceptor’s signature was provided as an alternative to certification by a medical specialty board that was recognized by NRC or an Agreement State. However, burden was reduced by $238,000 under 10 CFR 35.290, because of the reduction in the required total hours of training and experience from 1200 hours to 700 hours. The burden cannot be reduced further, without reducing the level of knowledge and skills for radiation protection, to provide nuclear medicine services, thus adversely affecting public safety. Under 10 CFR 35.204, “Permissible molybdenum-99 concentration,” the burden could not be reduced further than $993,000 because testing the eluant of a molybdenum-99/technetium-99m generator system at least once, before administration of dosages to patients, is necessary, to prevent unnecessary radiation exposure to patients from a failed generator system. Cost savings were noted for reducing the test for molybdenum-99 concentration from each eluant of the generator system (e.g., daily) to only the initial eluant upon first use after receiving the generator from the manufacturer.

Subpart L, “Records,” contains requirements associated with the sections in Subparts B, C, and D that, in some manner, may pertain to diagnostic nuclear medicine (e.g., records of changes to the radiation protection program, calibrations of instruments, administration of dosages, inventory and leak testing of sealed sources, radioactive waste disposal, and molybdenum-99 concentration). Because the requirements in Subparts B, C, and D were reduced, the associated recordkeeping burdens in Subpart L were also reduced. For example, under 10 CFR 35.2024, fewer records would be generated because there may be fewer radiation safety committee meetings. However, records associated with diagnostic nuclear medicine would most likely be minimal as compared to other aspects of the program applicable to Subparts E through H. Under 10 CFR 35.2026, “Records of radiation protection program changes,” the record retention requirement was shortened to 5 years. For practical reasons based on NRC’s inspection interval, the burden could not be reduced further because an inspector may need to evaluate program changes related to an event or allegation important to the safety of the public. Under 10 CFR 35.2204, “Records of molybdenum-99 concentrations,” the burden reduction ($12,000) cannot be reduced further because experience has shown that it parallels the reduction in the number of tests (e.g., one per generator system). It is not practical, based on the NRC inspection interval, to further reduce the 3-year retention period.

Subpart M, “Reports,” contains requirements for reports and notification of medical events, reports and notification of a dose to an embryo/fetus or a nursing child. Because of the threshold levels in these requirements and the operating experience, it is appears that the burden on diagnostic nuclear medicine licensees is minimal. The regulatory burden can not be reduced further because the reports are necessary to track abnormal occurrences, identify generic issues, and report the information to Congress. The report of a leaking source is also included in Subpart M and regulatory burden can not be reduced because NRC must evaluate the generic aspects of a leaking source in order to protect workers and the public, including patients from unnecessary radiation exposure.

The final Regulatory Analysis (RA) for the revised Part 35 contains cost information about the requirements applicable to diagnostic nuclear medicine. Section 5 of the RA explains the revisions to regulatory text and consequences of changes from the current rule to the revised rule. It discusses sections of the current rule that were removed from the revised rule or where regulatory text in the current rule was combined into a different section in the revised rule. The Appendix to Table 2 in Attachment 2 reflects the change information for requirements

applicable to diagnostic nuclear medicine. Many of the prescriptive requirements that are applicable to diagnostic nuclear medicine were removed. Regulatory Analysis, Table 6-1, "Summary of Rule Cost Effects," contains estimated annual cost values for the changes. Values pertaining to the diagnostic nuclear medicine licensees were extracted from Table 6-1 and incorporated into Table 2 of this report (Attachment 2) which shows the estimated annual total cost savings for all medical licensees, and the portion of the total change that is associated with diagnostic nuclear medicine. A factor of 0.9[3] was applied to the total values to obtain the diagnostic portion because it was estimated that about 90 percent of the burden would be attributed to diagnostic nuclear medicine. The total changed cost savings value for the requirements affecting diagnostic nuclear medicine is about $4.8 million.

Based on the review of the regulatory analysis, the Commission believes that regulatory burden for diagnostic medical use of unsealed byproduct material is significantly reduced from the current requirements to the revised Part 35. The total annual cost savings are $5.4 million for the sections affecting diagnostic nuclear medicine in Part 35.

6.3 Possible adverse affects on patient safety if medical use licensees were subject only to Part 20 implementation and enforcement without minimal additional requirements of the revised Part 35 requirements for diagnostic nuclear medicine

There are no specific requirements in Part 20 to authorize various professionals who are responsible for the radiation safety program. Only Part 35 contains minimum training and experience criteria for knowledge and skills in radiation safety that are important to protect patients, the public, and workers in diagnostic nuclear medicine. To remove from Part 35 the requirements for ANPs, AUs, and RSOs would remove authority and responsibility for the licensee to provide reasonable assurance of radiation health and safety for workers and the public, including patients.

Part 20 does not provide specific requirements for radiation health and safety from unsealed byproduct material that is administered to patients and human research subjects. Part 35 specifically requires that licensees supervise and instruct individuals in their radiation protection program for diagnostic nuclear medicine and the applicable NRC regulations and conditions of the license for diagnostic nuclear medicine to provide reasonable assurance of protection for health and safety of workers and the public, including patients. Part 35 requires accuracy of patient dosages prior to administration to the patient for diagnostic nuclear medicine, and requires calibration of instruments used to measure patient dosages. Further, Part 35 has a more specific requirement than Part 20 about labeling of syringes and vials that contain byproduct material for medical use to prevent administration of wrong dosages to patients.

These requirements are examples illustrating how revised Part 35 directly furthers control of unnecessary radiation exposure to workers and the public, including patients, a feature that the more general requirements in Part 20 do not specifically address.

[3]RA, Section 4, "Underlying Data and Assumptions," indicates the number and types of licensees. RA, Table 1 shows the NRC material license program codes and corresponding number of licensees within NRC jurisdiction and for Agreement States. The values for NRC licensees were taken from the NRC License Tracking System, February 2001. The values for the Agreement State licensees are estimated, based on a 1 to 2.5 ratio of NRC licensees to Agreement State licensees. For the purposes of this report to Congress, it was assumed that a diagnostic nuclear medicine component would be likely in NRC materials program codes 2110, 2120, 2121, 2200, 2201, and 2220. The number of licensees in these program codes is about 90 percent of the total number of licensees in RA, Table 1.

7.0 Specific License versus General License

For the most part, the specific license regime for diagnostic nuclear medicine[4] use is based on NRC's statutory mandate to regulate byproduct material to protect health and minimize danger to life or property. A specific license application review process provides NRC with information for decision-making about the capabilities of an individual or organization to safely handle byproduct material for use in diagnostic nuclear medicine and to reasonably assure radiation protection of workers and the public, including patients.

NRC must determine that the applicant's users, nuclear pharmacist, and Radiation Safety Officer possess adequate knowledge and skills to ensure day-to-day radiation safety for diagnostic nuclear medicine. NRC must understand where byproduct material will be used and the facilities and equipment that are in place to safely store, secure, and survey diagnostic medical use of unsealed byproduct material to protect workers and the public, including patients from unnecessary radiation exposure.

NRC does not favor a general license regime for diagnostic nuclear medicine because of control and security issues associated with unsealed material in amounts that are necessary for diagnostic nuclear medicine procedures. In a general license regime, concerns for control and security issues would remain because there would be no confirmation of the actual individual involved with licensed activities and his or her level of understanding of radiation safety principles and practices, the location and facilities to secure unsealed licensed material, and equipment to complete surveys and measure dosages.

Agreement State representatives who commented on the proposed rule (63 FR 43516, August 13, 1998) were opposed to the use of a general license in the medical use area.

8.0 Overall Conclusion

In the revised Part 35, the NRC has reduced the current level of regulatory burden for diagnostic medicine to provide effective and efficient regulation for low-risk use of byproduct material. The Commission believes the regulatory burden in the revised Part 35 is commensurate with the low risk of diagnostic nuclear medicine procedures. At the facilitated public workshops, the staff and stakeholders interacted on relevant issues to promote streamlining the current rule, and the staff carefully reviewed about 1000 comments that were received in response to the proposed rule, in developing the revised Part 35.

The revised Part 35 is necessary to establish requirements that specifically authorize medical professionals who are trained and experienced in radiation safety to administer unsealed byproduct material to patients and human research subjects for diagnostic purposes, while at the same time providing for radiation safety of workers and the public, including patients. The NRC believes that the interaction between the applicant and NRC in the specific licensing process plays an essential safety role by defining the links in the chain of accountability for radiation protection before a licensee obtains radioactive material. Although the Commission recognizes that physicians have primary responsibility for the protection of their patients, NRC

[4]For the purpose of this report to Congress, it was recognized that 10 CFR 30.21 provides an exemption for any person for capsules containing carbon-14 urea [37 kilobecquerels (1 microcurie)] for "in vivo" diagnostic use in humans. Any person is exempt from the requirements for a license set forth in Section 81 of the AEA and from the regulations in 10 CFR Part 30 and Part 35. Further, 10 CFR 31.11 issues a general license to any physician, clinical laboratory, or hospital for use of byproduct material for certain in vitro clinical or laboratory testing in accordance with certain provisions in 10 CFR 31.11.

also has a necessary role and need to fulfill its statutory obligations regarding the radiation safety of workers and the public, including patients.

The Commission has retained regulatory requirements in the revised Part 35 only where it believes they are necessary to assure radiation safety for workers and the public, including patients and human research subjects. Part 20 requirements apply to all NRC licensees and generally provide for radiation protection of workers and members of the public. Part 20 requirements also do not provide specific criteria to address training and experience, control of unsealed material and assay of material before administration in order to assure that qualified users obtain, use, store, and dispose of the material. Licensee compliance with the applicable Part 20 requirements and the minimal additional requirements in the revised Part 35, will be sufficient to protect health and minimize danger to life or property from uses of unsealed byproduct material in diagnostic nuclear medicine. The Commission is concerned that efforts to reduce regulatory burden further on diagnostic nuclear medicine licensees could adversely affect public health and safety.

Attachments:

1. Table 1, Revised 10 CFR Part 35 Regulatory Burden for Diagnostic Nuclear Medicine (10 CFR 35.100, 200)

2. Table 2, Cost Comparison and Differences Between the Current and the Revised 10 CFR Part 35 and Appendix on Associated Costs Impact

Part I: Burden that directly protects health and safety.

Section No. and Title These requirements are necessary to directly protect health and safety of the patient, the public at large, and/or the workers, as indicated. Elimination of these requirements would adversely affect protection of health and safety.		Radiation Safety Requirements		
		Members of the General Public		Worker
		Patient	Public	
Subpart A–General Information				
35.6	Provisions for research involving human subjects.	✓		
35.11	License required.	✓	✓	✓
35.12	Application for license, amendment, or renewal.	✓	✓	✓
35.13	License amendments.	✓	✓	✓
35.14	Notifications.	✓		
35.18	License issuance.	✓	✓	✓
Subpart B–General Administrative Requirements				
35.24	Authority and responsibilities for the radiation protection program.	✓	✓	✓
35.27	Supervision.	✓	✓	✓
35.50	Training for Radiation Safety Officer.	✓	✓	✓
35.55	Training for an authorized nuclear pharmacist.	✓	✓	✓
35.59	Recentness of training.	✓		
Subpart C–General Technical Requirements				
35.60	Possession, use, calibration, and check of instruments to measure the activity of unsealed byproduct material.	✓		
35.61	Calibration of survey instruments.		✓	✓
35.63	Determination of dosages of unsealed byproduct material for medical use.	✓		
35.67	Requirements for possession of sealed sources and brachytherapy sources.		✓	✓
35.69	Labeling of vials and syringes.	✓		✓
35.80	Provision of mobile medical service.	✓	✓	✓

Subpart D–Unsealed Byproduct Material–Written Directive Not Required				
35.100	Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.	✓		
35.190	Training for uptake, dilution, and excretion studies.	✓		
35.200	Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.[5]	✓		
35.204	Permissible molybdenum-99 concentration.	✓		
35.290	Training for imaging and localization studies.	✓		
Subpart M–Reports[6]				
35.3045	Report and notification of a medical event.	✓	✓	✓
35.3047	Report and notification of a dose to an embryo/fetus or a nursing child.		✓	
35.3067	Report of a leaking source.	✓	✓	✓

Records that are necessary to document compliance with licensed activity requirements are in Subpart L, “Records,” 10 CFR 35.2024, 35.2060, 35.2061, 35.2063, 35.2067, 35.2080, and 35.2204.

[5]For the purposes of this report to Congress, use of I-131sodium iodide greater than 1.11 Megabequerels (30 microcuries) was not included because such use is under the requirements for Subpart E, ”Unsealed Byproduct Material–Written Directive Required.” However, it is recognized that I-131 sodium iodide is used for diagnostic purposes by medical licensees and requirements in 10 CFR 35.40 and 35.41 for written directives and associated procedures would apply to medical diagnostic uses of I-131 sodium iodide. Burden imposed by these requirements was also reduced in revised Part 35, but is not explained further in this report.

[6]Because of the radiation dose threshold values indicated in the requirements in Subpart M, it is not likely that reports and notifications would be received as a result of a diagnostic nuclear medicine procedure, except in the most extreme case. The regulatory burden imposed by these requirements on diagnostic nuclear medicine licensees is trivial.

Part II: Relief of burden from Part 20 or Part 30 requirements is provided by special sections in the revised Part 35.

Section No. and Title	Provision for flexibility to relieve regulatory burden.
Subpart A–General Information	
35.19--Specific exemptions.	The Commission may, upon application of any interested person or upon its own initiative, grant exemptions from the regulations in this part that it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.
Subpart B–General Administrative Requirements	
35.26--Radiation protection program changes.	Within the specified limitations, a licensee may revise its radiation protection program without Commission approval.
35.65--Authorization for calibration, transmission, and reference sources.	A medical use licensee is authorized certain types and quantities of sources without a specific request to amend their license.
35.75--Release of individuals containing unsealed byproduct material or implants containing byproduct material.	Licensees are not constrained by the dose limit for an individual member of the public in 10 CFR 20.1301, i.e., 1 millisievert (100 millirem) total effective dose equivalent (TEDE). Under specified conditions, the licensee may release a patient if the TEDE to any other individual from exposure to the patient is not likely to exceed 5 millisieverts (500 millirem).
35.92--Decay-in-storage.	Under specified conditions, a licensee may hold byproduct material before disposal without regard to its radioactivity.

Records that are necessary to document licensed activities are in Subpart L, “Records,” 10 CFR 35.2026, 35.2075, and 35.2092.

Part III: Burden that facilitates an effective and efficient process for a specific license that authorizes medical use of byproduct material.

Section No. and Title	Provision for Effectiveness and Efficiency
Subpart A–General Information	
35.1--Purpose and scope.	Provides a declaration of purpose and scope in order to recognize specific licensees and the requirements that pertain to medical use of byproduct material.
35.2--Definitions.	Provides for common understanding of unique terms
35.5--Maintenance of records.	Provides for consistent quality and retention of necessary documentation of the radiation safety aspects of the medical use of byproduct material.
35.7--FDA, other Federal, and State requirements.	Provides clarification that this part does not eliminate a licensee's responsibility to other agencies which also control byproduct material.
35.8--Information collection requirements: OMB approval.	Provides documentation of NRC's authorization to impose information collection burden upon licensees.
35.10--Implementation.	Provides implementation schedules and clarifies existing license conditions and exemptions.
Subpart N–Enforcement	
34.4001–Violations.	The Commission may obtain a court order or injunction to prevent violations.
35.4002–Criminal penalties.	Criminal sanctions are provided for willful or attempted violations, or conspiracy to violate certain regulations in Part 35.

APPENDIX TO TABLE 1
PART 1: BURDEN THAT DIRECTLY PROTECTS HEALTH AND SAFETY.

The requirements listed in Table 1, Part I, are in Subparts A, B, C, D, and M of revised Part 35. Subpart A, "General Information," contains requirements to protect individuals who are administered byproduct material as human research subjects. The Federal Policy for Human Subjects (Federal Policy) requires that these individuals are protected by prior review and approval of the research project by an Institutional Review Board and informed consent of the human research subject for federally conducted, funded, supported, or regulated research. Section 35.6 requires this level of protection whether or not the research is conducted, funded, supported, or regulated by another federal agency which has implemented the Federal Policy. Also in Subpart A are requirements to protect workers and the public, including patients by establishing the specific license regime, along with details about applications, amendments, notifications, and issuance of a specific license. These requirements include details about who will use byproduct materials for medical use; what their credentials are with respect to radiation safety for protection of workers and the public, including patients; and where medical use is located. Specific radiation safety procedures for diagnostic nuclear medicine are not required to be submitted in an application for a specific license.

Subpart B, "General Administrative Requirements," contains requirements about authority and responsibilities for the radiation protection program supervision of individuals, and training and experience requirements for an RSO and an ANPO. These requirements pertain to protection of health and safety for workers and the public, including patients by stating the responsibility of licensee management to select and empower qualified individuals to oversee the day-to-day radiation safety activities. This includes supervision of technical and support staff who follow the instructions of the authorized user physician. The regulations provide details to ensure that a licensee provides a sufficient level of oversight to protect health and safety from diagnostic nuclear medicine.

Subpart C, "General Technical Requirements," provides for identification and accuracy of prepared dosages to protect patients from being administered an incorrect dosage. A calibrated dose measurement system is required for licensees that prepare patient dosages. A working survey instrument is required to provide confidence in the licensee's control of contamination to protect the workers and the public, including patients from unnecessary radiation exposures. Along with the requirements for calibration sources for the instrumentation used to measure patient dosages and survey areas of use, there are requirements for leak tests and performing physical inventories to protect workers and the public, including patients from leaking sources or misplaced, lost, or stolen sources.

Subpart D, "Unsealed Byproduct Material-Written Directive Not Required," identifies diagnostic nuclear medicine procedures and commensurate training and experience requirements for physicians who desire to be authorized for medical use for these procedures. Protection of workers and the public, including patients is provided by requiring physicians to acquire certain knowledge and skills for radiation safety for these procedures.

Subpart M, "Reports," includes requirements for report and notification of a medical event or a dose to an embryo/fetus or a nursing child, and a report for a leaking source. Through these reports the workers and the public, including patients are protected by: (1) evaluating the exposure to an individual, (2) notifying the referring physician, and (3) by notifying the affected individual. Because of the radiation dose threshold values indicated in the requirements, it is not likely that reports and notifications would be received as a result of a diagnostic nuclear medicine procedure, except in the most extreme case. The regulatory burden imposed by these requirements on diagnostic nuclear medicine licensees is trivial.

Table 2 Cost Comparison and Differences Between the Current and the Revised 10 CFR Part 35

Summarized in the table appearing below are data extracted from the Regulatory Analysis that accompanies the proposed revision to 10 CFR Part 35. The extracted data are for sections that may affect diagnostic nuclear medicine; they show the estimated values and impacts of the revisions to 10 CFR Part 35. For each regulatory change described in the Regulatory Analysis, the table lists estimated total annual costs avoided (-) or total costs added (+), i.e., the change in costs from the current rule, for a particular section of the rule.

Sections Affecting Diagnostic Nuclear Medicine and Estimated Cost Savings			
Section No. and Title		Change in Licensee Costs (nominal $)	Diagnostic Nuclear Medicine Portion[1] of Licensee Change
Subpart A–General Information			
35.1	Purpose and scope.	0	0
35.2	Definitions.	0	0
35.5	Maintenance of records.	0	0
35.6	Provisions for the protection of human research subjects	0	0
35.7	FDA, other Federal, and State requirements.	0	0
35.8	Information collection requirements: OMB approval.	0	0
35.10	Implementation.	0	0
35.11	License required.	0	0
35.12	Application for license, amendment, or renewal	-1,000	-900
35.13	License amendments	-82,000	-73,800
35.14	Notifications	8,000	7,200
35.18	License issuance.	0	0
35.19	Specific exemptions	0	0
Subpart B–General Administrative Requirements			
35.24	Authority and responsibilities for the radiation protection program	-2,167,000	-1,806,000
35.26	Radiation protection program changes	-14,000	-12,600
35.27	Supervision	-1,158,000	-1,042,200
35.50	Training for Radiation Safety Officer	5,000	4,500
35.55	Training for an authorized nuclear pharmacist	2,000	1,800
35.59	Recentness of training.	0	0
Subpart C–General Technical Requirements			
35.60	Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material	-521,000	-468,900
35.61	Calibration of survey instruments	-136,000	-122,400
35.63	Determination of dosages of unsealed byproduct material for medical use	0	0
35.65	Authorization for calibration, transmission, and reference sources	-5,000	-5,000
35.67	Requirements for possession of sealed sources and brachytherapy sources	-56,000	-50,400
35.69	Labeling of vials and syringes	0	0
35.80	Provision of mobile medical service	0	0
35.92	Decay-in-storage	-1,000	-900

Sections Affecting Diagnostic Nuclear Medicine and Estimated Cost Savings			
Section No. and Title		Change in Licensee Costs (nominal $)	Diagnostic Nuclear Medicine Portion[1] of Licensee Change
Subpart D–Unsealed Byproduct Material–Written Directive Not Required			
35.190	Training for uptake, dilution, and excretion studies	5,000	5,000
35.204	Permissible molybdenum-99 concentration	-993,000	-993,000
35.290	Training for imaging and localization studies	-238,000	-238,000
Subpart L–Records			
35.2024	Records of authority and responsibilities for radiation protection programs	-9,000	-8,100
35.2026	Records of radiation protection program changes	-17,000	-15,300
35.2060	Records of calibrations of instruments used to measure the activity of unsealed byproduct materials	0	0
35.2061	Records of radiation survey instrument calibrations	0	0
35.2063	Records of dosages of unsealed byproduct material for medical use	0	0
35.2067	Records of leak tests and inventory of sealed sources and brachytherapy sources	-3,000	-2,700
35.2080	Records of mobile medical services	0	0
35.2092	Records of decay-in-storage	0	0
35.2204	Records of molybdenum-99 concentrations	-12,000	-12,000
Subpart M–Reports			
35.3045	Report and notification of a medical event.	0	0
35.3047	Report and notification of a dose to an embryo/fetus or a nursing child	4,000	3,600
35.3067	Report of a leaking source	0	0
TOTALS		-5,388,000	-4,830,100

[1] If the Regulatory Analysis (RA) did not specifically indicate a value for diagnostic nuclear medicine, then the total value was assumed to apply to diagnostic nuclear medicine, in order to indicate the extent of possible savings to licensees from revised Part 35. The RA indicated that about 90 percent of medical licensees have a diagnostic nuclear medicine component in their radiation protection program. Accordingly, a factor of 0.9 was applied to the estimated cost change for those requirements that did not specify the portion of the estimate for diagnostic nuclear medicine.

APPENDIX
PROPOSED REVISIONS TO PART 35 APPLICABLE TO DIAGNOSTIC NUCLEAR MEDICINE AND ASSOCIATED COSTS IMPACT

SUBPART A--GENERAL INFORMATION

Section 35.1, "Purpose and scope"

This section currently provides that 10 CFR Part 35 contains requirements for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of public health and safety.

The final rule substitutes the words "radiation safety of workers, the general public, patients, and human research subjects" for "protection of the public health and safety." The final rule adds 10 CFR Part 171 to the list of Parts that apply to applicants and licensees subject to Part 35.

Cost Impacts: None anticipated.

Benefits: Provides improved clarity and precision as well as consistency with revisions to the Medical Policy Statement.

Section 35.2, "Definitions"

This section currently sets out the applicable definitions for Part 35.

The final rule deletes the definitions of "ALARA," "Diagnostic clinical procedures manual," "Mobile nuclear medical service," and "Ministerial change."

The final rule revises the definitions of "Area of use," "Authorized nuclear pharmacist," "Authorized user," "Management," "Medical use," "Prescribed dosage," and "Radiation Safety Officer."

The final rule adds definitions for "Authorized medical physicist," "Client's address," "Mobile Medical service," "Preceptor," "Sealed Source and Device Registry," "Structured educational program," "Temporary jobsite," "Type of use," and "Unit dosage."

Cost Impacts: None anticipated.

Benefits: Provide improved clarity and precision.

Section 35.5, "Maintenance of records"

This section currently specifies that records required by Part 35 must be legible throughout the retention period. It also specifies that the record may be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period.

The final rule revises the phrase "Records such as letters, drawings, specifications, must include all pertinent information . . . " to read "Records such as letters, drawings, and specifications . . . ."

Benefits: Improved clarity.

Section 35.6, "Provisions for the protection of human research subjects"

This section currently provides that a licensee may conduct research involving human subjects using byproduct material if requirements specified in the section are met.

The final rule provides that a licensee may conduct research involving human research subjects only if using the byproduct materials specified on its license for the uses authorized on its license. Before commencing with the research, the licensee shall obtain approval from an "Institutional Review Board" and obtain "informed consent" from the human research subject. The final rule clarifies that nothing in this section relieves licensees from complying with the other requirements in Part 35 and that all relevant radiation safety provisions of Part 35 are applicable to research involving human subjects.

Cost Impacts: None anticipated.

Benefits: Improved clarity.

Section 35.8, "Information collection requirements: OMB approval"

This section currently specifies the Office of Management and Budget (OMB)-approved information collection requirements contained in 10 CFR Part 35, and specifies that OMB has approved the information collection requirements in Part 35 under control number 3150-0010.

The final rule changes section numbers in 10 CFR 35.8(b) to conform with the final rule. Section 35.8(c) of the final rule adds Nuclear Regulatory Commission (NRC) Forms 313A and 313B to the information collection approved under control number 3150-0120 for 10 CFR 35.12. The final rule deletes 10 CFR 35.8(d) referring to OMB control number 3150-0171, which covered the information collection requirements contained in Sections 35.32 and 35.33, which are eliminated in the final rule.

Cost Impacts: None anticipated.

Benefits: Conforming change for restructuring of Part 35.

Section 35.10, "Implementation"

The final rule adds a new section, 10 CFR 35.10, which provides implementation schedules, as follows: (a) requires licensees to implement the provisions in Part 35 on or before 6 months from publication of the final rule. (b) allows licensees currently exempted from a provision in the current Part 35 to continue to be exempt under the final regulations, and (c) provides that if a requirement in an existing license condition differs from a requirement in the revised Part 35, the requirements in the final revised Part 35 govern.

Cost Impacts: None anticipated.

Benefits: Provides licensees time to implement new requirements.

Section 35.11, "License required"

This section currently provides that a person may not manufacture, produce, acquire, receive, possess, use, or transfer byproduct material for medical use except in accordance with a specific license issued by the Commission or an Agreement State, or as allowed in paragraphs (b) or (c) of 10 CFR 35.11. Section 35.11(b) currently specifies that an individual may receive, possess, use, or transfer byproduct material in accordance with the regulations in Part 35 under the supervision of an authorized user, as specified in the requirements on supervision in 10 CFR 35.25, unless prohibited by license condition. Section 35.11(c) currently provides that an individual may prepare unsealed byproduct material for medical use in accordance with the regulations in Part 35, under the supervision of an authorized nuclear pharmacist or authorized user, as provided in 10 CFR 35.25, unless prohibited by license condition.

Section 35.11(a) of the final rule provides that a person may manufacture, produce, acquire, receive, possess, use, or transfer byproduct material for medical use only in accordance with a specific license or as allowed in 10 CFR 35.11(b)(1) or (b)(2) of this section.

Section 35.11(b) of the final rule provides that a specific license is not needed: (a) for an individual who receives, possesses, uses, or transfers byproduct material in accordance with the regulations in this chapter, under the supervision of an authorized user as provided in 10 CFR 35.27, unless prohibited by license condition, or (b) for an individual who prepares unsealed byproduct material for medical use, in accordance with the regulations in this chapter under the supervision of an authorized nuclear pharmacist or authorized user, as provided in 10 CFR 35.27, unless prohibited by license condition. Section 35.11(b)(2) incorporates the provisions currently included in Section 35.11(c).

Cost Impacts: None anticipated.

Benefits: Improved clarity.

Section 35.12, "Application for license, amendment, or renewal"

This section currently specifies the procedures for license application, amendment, or renewal: (a) if the application is for medical use sited in a medical institution, only the institution's management may apply or if the application is for medical use not sited in a medical institution, any person may apply, and (b) an application for medical use of byproduct material for diagnostic nuclear medicine must be made by filing NRC Form 313.

The final rule provides that the application must be signed by the applicant's or licensee's management and eliminates the reference to application by "any person." The final rule adds a new paragraph (d), which establishes requirements for license applications for other medical

uses of byproduct material, as described in 10 CFR 35.1000, “Other medical uses of byproduct material or radiation from byproduct material,” requires that, in addition to the information currently required in NRC Form 313, "Application for a Materials License," the applicant must also supply the following: (1) any information regarding any radiation safety aspects of the medical use of the material that is not addressed in Subparts A through C of 10 CFR Part 35; (2) any specific information necessary for (i) radiation safety precautions and instructions; (ii) methodology for measurement of dosages or doses to be administered to patients or human research subjects; and (iii) calibration, maintenance, and repair of instruments and equipment necessary for radiation safety; and (3) any other information requested by the Commission in its review of the application.

Cost Impacts: NRC intends for this provision to allow applicants and licensees to submit license applications for medical uses not specifically addressed in Subparts D-H of the final rule. Thus, license applications for new or emerging technologies could be submitted under 10 CFR 35.12(d) instead of requiring applicants or licensees to submit an exemption request under 10 CFR 35.19. However, because of the nature of emerging technologies, all of the information needed for approval of such technologies cannot be specified in advance.

Cost savings may result for applicants or licensees from a reduction in time to prepare applications for new or emerging technologies not addressed in Subparts D-H, compared with time necessary to seek approval via an exemption.

Total Annual Cost Savings from amendment to 10 CFR 35.12(d): $1000

Benefits: Cost savings to licensees.

Section 35.13, “License amendments”

This section currently specifies the circumstances under which a licensee must apply for and receive a license amendment. If a physician or pharmacist is not already authorized by an NRC or Agreement State license or broad-scope licensee permit or certified by a specialty board indicated in Subpart J–Training and Experience Requirements,” then his/her individual credentials must be approved by the licensee’s radiation safety committee and/or management and by NRC. Currently a licensee must obtain a license amendment before it changes Radiation Safety Officers.

The final rule requires a licensee to obtain a license amendment before it permits anyone to work as an authorized nuclear pharmacist or authorized user, unless the individual meets specified conditions that are similar to those described in the preceding paragraph. The final rule continues to require a licensee to obtain a license amendment before it changes Radiation Safety Officers, except as provided in 10 CFR 35.24(c). The final rule also amends 10 CFR 35.13(e), which requires a licensee to obtain a license amendment before adding to or changing the areas of use. Specifically, 10 CFR 35.13(e) of the final rule does not require licensees to submit a license amendment for changes of area of use for medical uses permitted under 10 CFR 35.100 and 35.200, for diagnostic nuclear medicine.

Cost Impacts: NRC anticipates cost savings to licensees and NRC from a reduction in the number of license amendments that will be submitted to NRC to add areas of use where byproduct material is used in accordance with 10 CFR 35.100 or 35.200, for diagnostic nuclear medicine.

Total Annual Cost Savings for licensees for areas of use for diagnostic nuclear medicine: $82,000

Benefits: Cost savings to licensees, NRC, and Agreement States.

Section 35.14, "Notifications"

This section currently requires licensees to provide the Commission with a copy of the board certification or the permit issued by a licensee of broad scope for each individual who is allowed to work as an authorized user or as an authorized nuclear pharmacist, and requires the licensee to notify the Commission by letter when an authorized user, authorized nuclear pharmacist, or Radiation Safety Officer permanently discontinues performance of duties under the license, or has a name change.

The final rule adds permits issued by a Commission master material license broad-scope permittee, and clarifies the requirement concerning notice when the licensee's name changes; and adds the notification when the licensee has added to or changed the areas of use identified in the application or on the license, and permitted under 10 CFR 35.100 or 35.200 for diagnostic nuclear medicine.

Cost Impacts: NRC anticipates a small cost increase as a result of requiring licensees to report changes in the area of use. However, NRC estimates only a small number of total annual applications will be caused by changes in licensee area of use (12.5 percent of 4080 annual license notifications).

Total Annual Cost Increase for licensees for 10 CFR 35.14(b)(4): $8,000

Benefits: Increased flexibility and reduced regulatory burden for licensees are anticipated.

Section 35.15, "Exemptions regarding Type A specific licenses of broad scope"

This section currently exempts a licensee possessing a Type A specific license of broad scope for medical use from the notification requirements for an authorized user or an authorized nuclear pharmacist.

The final rule exempts a licensee possessing a Type A specific license of broad scope for medical use, issued under 10 CFR Part 33, from filing an application for an amendment to the license for medical uses of byproduct material, as described in 10 CFR 35.1000, or to add new authorized user physicians or authorized nuclear pharmacists who desire to use byproduct material for medical uses in diagnostic nuclear medicine. Such a licensee is also exempt from the notification requirements in 10 CFR 35.14 for new or discontinued authorized users and authorized nuclear pharmacists, or for additions to or changes in the areas of use identified in the application or on the license where byproduct material is used for diagnostic nuclear medicine.

Cost Impacts: None anticipated.

Benefits: Conforming change.

Section 35.18, "License issuance"

This section currently specifies the requirements for license issuance for use of byproduct material. Section 35.29 currently specifies the requirements for licensing mobile nuclear medicine services.

The final rule adds a new 10 CFR 35.18(b) providing that the Commission will issue a license for mobile services if: (1) the applicant meets the requirements specified in 10 CFR 35.18(a); and

(2) assures that individuals or human research subjects to whom byproduct material or radiation from implants containing byproduct material will be administered may be released following treatment, in accordance with 10 CFR 35.75.

Cost Impacts: No cost impacts are anticipated for licensees. Section 35.29 has been eliminated and replaced with requirements in final 10 CFR 35.18(b) and 35.80. The final rule promulgates, in 10 CFR 35.18(b), a criterion currently being implemented through licensing.

Benefits: If the amendment leads to an increase in the availability of mobile services, patients could experience benefits as a result of lessened travel to reach medical care.

Section 35.19, "Specific exemptions"

This section currently provides that the Commission may grant exemptions from the Part 35 requirements. It states that the Commission will review requests for exemptions from the training and experience requirements with the assistance of the Advisory Committee on the Medical Uses of Isotopes (ACMUI).

The final rule eliminates the reference to assistance from the ACMUI. NRC anticipates, however, that the Commission will continue to review such exemption requests with the assistance of ACMUI.

Cost Impacts: No cost impacts are anticipated because the only change is the elimination of the reference to assistance from the ACMUI.

Benefits: The current text regarding the ACMUI is a Commission policy position and is not a regulatory requirement. Therefore, this text was removed for improved clarity.

SUBPART B--GENERAL ADMINISTRATIVE REQUIREMENTS

Section 35.20, "ALARA program"

This section currently requires that licensees develop and implement a written radiation protection program that includes provisions for keeping doses as low as is reasonably achievable (ALARA) and specifies program content and implementation.

The final rule eliminates 10 CFR 35.20.

Cost Impacts: None anticipated. NRC considers the requirements of 10 CFR Part 20, particularly 10 CFR 20.1101, to be commensurate with the scope and extent of Part 35 ALARA requirements. Specifically, 10 CFR 20.1101 requires licensees to develop, document, and implement a radiation protection program and includes ALARA requirements. This is comparable to 10 CFR Part 35, where licensees are required to develop an ALARA program for activities conducted under Part 35.

In the final rule, the current ALARA requirements in 10 CFR 35.20 are unnecessary, given a performance-based approach, because ALARA is already required under Section 20.1101. However, no costs will be avoided in the final rule because licensees are still required, by Part 20 to keep doses ALARA.

Benefits: Eliminates the prescriptive requirements in 10 CFR 35.20 and provides licensees with greater flexibility regarding ALARA programs.

Section 35.21, "Radiation Safety Officer"

This section currently requires that each licensee appoint a Radiation Safety Officer (RSO) who is responsible for implementing the radiation safety program. This section specifies the duties and responsibilities of the RSO.

The final rule eliminates 10 CFR 35.21 and replaces it with a new section, 10 CFR 35.24, which addresses the authority and responsibilities for the radiation protection program, including specific requirements regarding the RSOs.

Cost Impacts: Cost impacts are evaluated under 10 CFR 35.24.

Benefits: Conforming change to restructuring of Part 35 to be more performance-based.

Section 35.22, "Radiation Safety Committee"

This section currently requires that each medical institution licensee establish a Radiation Safety Committee (RSC) to oversee the use of byproduct material. This section specifies the required membership of the RSC, meeting frequency, criteria for a quorum, content of minutes, distribution of minutes and the required retention period of minutes. This section requires the RSC to perform specific reviews.

The final rule eliminates 10 CFR 35.22, and replaces it with a new 10 CFR 35.24, which addresses the authority and responsibilities for the radiation protection program, including a requirement [10 CFR 35.24(f)] that licensees authorized for two or more different types of uses of byproduct material under Subparts E, F, and H, or two or more types of units under Subpart H, must establish an RSC to oversee all uses of byproduct material permitted by the license.

The RSC must include an authorized user of each type of use permitted by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an authorized user nor an RSO. The RSC may include other members whom the licensee considers appropriate.

Cost Impacts: The elimination of 10 CFR 35.22 results in significant cost savings for certain categories of licensees because of the deletion of the requirement to hold quarterly RSC meetings. The impacts of the elimination of 10 CFR 35.22 and its replacement by 10 CFR 35.24 are described under 10 CFR 35.24.

Benefits: Significant cost savings to licensees as well as greater flexibility to licensees in coordinating radiation safety activities.

Section 35.23, "Statements of authority and responsibility"

This section currently requires that each licensee provide RSOs and RSCs sufficient authority to fulfill their duties and responsibilities and to establish, in writing, those authorities, duties, and responsibilities, and to retain the current edition as a record, until the Commission terminates the license.

The final rule eliminates 10 CFR 35.23, and replaces it with a new section, 10 CFR 35.24, which specifies requirements for the radiation protection program, including written authorities, duties, and responsibilities of the RSO.

Cost Impacts: Cost impacts are evaluated under 10 CFR 35.24.

Benefits: Conforming change to restructuring of Part 35 to be more performance-based.

Section 35.24, "Authority and responsibilities for the radiation protection program"

The final rule contains a new section, 10 CFR 35.24, specifying authority and responsibility for the radiation protection program. In addition to the radiation protection program requirements of 10 CFR 20.1101, a licensee's management must approve: (1) requests for license application, renewal, or amendment before submittal; (2) any individual, before allowing that individual to work as an authorized user or authorized nuclear pharmacist; and (3) radiation protection program changes, permitted under 10 CFR 35.26 that do not require a license amendment.

A licensee's management is required to appoint an RSO who agrees in writing to be responsible for implementing the radiation protection program. The licensee, through the RSO, shall ensure that the licensee's radiation safety activities are being performed in accordance with the licensee-approved procedures and regulatory requirements. A licensee is authorized to permit, for up to 60 days each year, an authorized user or an individual qualified to be an RSO, to function as a temporary RSO, and to perform the functions of a RSO. A licensee is allowed to simultaneously appoint more than one temporary RSO, if needed to ensure that the licensee has a temporary RSO who satisfies the requirements to be a RSO for each of the different uses of byproduct material permitted by the license. A licensee is required to establish, in writing, the authority, duty, and responsibilities of the RSO. Licensees are required to provide the RSO with sufficient authority, organizational freedom, time, resources, and management prerogative to fulfill their duties to identify radiation safety problems; initiate, recommend, or provide corrective actions; stop unsafe operations; and verify implementation of corrective actions. Recordkeeping is required in the new 10 CFR 35.2024.

There would be no RSC to oversee diagnostic nuclear medicine, unless a licensee is authorized for two or more types of byproduct material under Subparts E, F, and H or two or more units under Subpart H. The RSC must include an authorized user of each type of use permitted by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an authorized user nor a RSO. The RSC may include other members whom the licensee considers appropriate.

Cost Impacts: No cost impacts are anticipated from 10 CFR 35.24(a), because licensees continue to be allowed to make changes to their radiation protection program, as currently allowed by 10 CFR 35.31.

Minimal cost impacts are anticipated from the requirement in 10 CFR 35.24(b) that the RSO must agree in writing to perform the duties of RSO. The RSO is required to perform a prescriptive list of duties in the current rule, 10 CFR 35.21. This change will allow greater flexibility.

Minimal cost savings are anticipated from the provisions in 10 CFR 35.24(c) and (d) that a licensee may appoint multiple temporary RSOs. Greater flexibility will be provided to licensees.

There are no cost impacts from the requirement in 10 CFR 35.24(e) that a licensee establish the authority, duties, and responsibilities of the RSO in writing because this requirement is carried over from the current rule, 10 CFR 35.23.

Cost savings to licensees are anticipated from the provision, in 10 CFR 35.24(f), that only licensees that are licensed for two or more different uses of byproduct material, under Subparts E, F, and H, or two or more types of units under Subpart H, must establish an RSC. Licensees under Subparts D and G that use only unsealed byproduct material for which a written directive is not required are not required to have a RSC. In addition, 10 CFR 35.24(f) eliminates prescriptive requirements, in 10 CFR 35.22(a)(2) and (3) of the current rule, requiring meetings to be held at least quarterly, specifying what constitutes a quorum, specifying the contents of minutes, and specifying in detail the required activities of the RSC.

NRC estimates that about 20 percent of medical institutions will not be required to have an RSC. In addition, NRC estimates that the costs of RSCs to those licensees that are required to maintain them will be reduced by 10 percent, under the final rule.

Licensees not required to set up RSCs:
Total Annual Cost Savings from meetings eliminated: $1,806,000

Licensees required to set up RSCs:
Total Annual Cost Savings from reduced requirements: $361,000

Total Annual Cost Savings from elimination
of 10 CFR 35.22 by 10 CFR 35.24(f): $2,167,000

No cost impacts are anticipated from the new 10 CFR 35.24(c), (d), and (e), because they continue to specify duties and responsibilities of RSOs.

Benefits: Provides greater flexibility to licensees.

Section 35.26, “Radiation protection program changes”

Section 35.31(a) currently allows licensees to make minor changes to their radiation safety procedures that do not impact safety, and lists examples of such changes. Section 35.31(b) requires records of such changes to be kept until the license is renewed or terminated, and specifies that changes must be signed by the RSO, the affected authorized user(s), and the licensee's management or in medical institutions, the chairman of the RSC and the management representative.

The final rule renumbers 10 CFR 35.31 as 10 CFR 35.26 and makes the following changes:

Section 35.26(a) allows licensees to revise their radiation protection program without Commission approval, provided the change: (1) does not require an amendment under 10 CFR 35.13; (2) is in compliance with the regulations and the license; and (3) has been reviewed and approved by the RSO and licensee management, and provided that affected individuals are instructed on the revised program before the changes are implemented. Also, 10 CFR 35.26(a) eliminates the examples of ministerial changes previously listed in 10 CFR 35.31(a).

Section 35.26(b) requires the licensee to maintain a record of each change in accordance with 10 CFR 35.2026.

Cost Impacts: On balance, cost savings are anticipated from the final rule.

Total Annual Cost Savings for licensees from 10 CFR 35.26: $14,000

Benefits: Cost savings to licensees.

Section 35.27, “Supervision”

Section 35.25 currently requires that each licensee permitting an individual to use byproduct material under the supervision of an authorized user must: (1) instruct the supervised individual in radiation safety; (2) require the supervised individual to follow the instructions of the authorized user and comply with regulations and license conditions; and (3) periodically review the supervised individual's use of byproduct material and records kept to reflect that use.

Currently, each licensee permitting preparation of byproduct material for medical use by an individual under the supervision of an authorized nuclear pharmacist or a physician who is an authorized user, must: (1) instruct the supervised individual in preparation of byproduct material for medical use and radiation safety; (2) require the supervised individual to follow certain instructions, and to comply with the regulations and license conditions; and (3) periodically review the work of the supervised individual and the records kept to reflect that work.

The final rule renumbers 10 CFR 35.25 as 10 CFR 35.27 and makes the following changes:

Section 35.27(a) requires a licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user or as allowed by 10 CFR 35.11(b)(1), in addition to the requirements in 10 CFR 19.12, to instruct the supervised individual in the licensee's written radiation protection procedures, regulations of this chapter, and license conditions with respect to the use of byproduct material; and to require the supervised individual to follow the instructions of the supervising authorized user for medical uses of byproduct material, written radiation protection procedures established by the licensee,

regulations, and license conditions with respect to the medical use of byproduct material. The final rule eliminates the requirement to periodically review the supervised individual's use of byproduct material and records.

Section 35.27(b) requires a licensee that permits the preparation of byproduct material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by 10 CFR 35.11(b)(2), in addition to the requirements in 10 CFR 19.12, to instruct the supervised individual in the preparation of byproduct material for medical use, as appropriate to that individual's involvement with byproduct material; and to require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of byproduct material for medical use, the written radiation protection procedures established by the licensee and the regulations of this chapter, and license conditions. The final rule eliminates the requirement to periodically review the individual's work as it pertains to preparing byproduct material for medical use and records kept to reflect that work.

Section 35.27(c) requires a licensee that permits supervised activities, under 10 CFR 35.27 (a) and (b), to be responsible for the acts and omissions of the supervised individual.

Cost Impacts: Increased costs are anticipated by requiring licensees to instruct the supervised individual on the regulations and license conditions.

Total Cost Increase for 10 CFR 35.27(a)(1): $1,159,000

Decreased costs are anticipated by 10 CFR 35.27(b) no longer requiring licensees to conduct periodic reviews of supervised individuals' work and records.

Total Annual Cost Savings for 10 CFR 35.27(b): $2,317,000

Total Annual Cost Savings for licensees from 10 CFR 35.27: $1,158,000

Benefits: Cost savings and increased flexibility for licensees.

Section 35.29, "Administrative requirements that apply to the provision of mobile nuclear medicine service"

Section 35.29 currently specifies the requirements for licensing mobile nuclear medicine service licensees.

The final rule eliminates 10 CFR 35.29, and replaces it with requirements in final 10 CFR 35.18(b) and 35.80.

Cost Impacts: Cost impacts are addressed under 10 CFR 35.18(b) and 35.80 of the final rule.

Benefits: Conforming change to restructuring of Part 35.

Section 35.50, "Training for Radiation Safety Officer"

Currently, 10 CFR 35.900 specifies the training requirements for an RSO and lists nine specialist boards through which an individual may become certified to be an RSO. Alternatively, training and experience requirements may be met in lieu of certification by one of the nine listed speciality boards, by completing 200 hours of classroom and laboratory training in specified

subjects. In addition, it requires 1 year of full-time experience as a radiation safety technologist at a medical institution under the supervision of the RSO. An authorized user for diagnostic nuclear medicine who is identified on the licensee's license is qualified to be the licensee's RSO.

The final rule renumbers 10 CFR 35.900 as 10 CFR 35.50 and makes the following changes. The list of nine approved speciality boards is eliminated. Section 35.50(a) provides instead that the licensee shall require an individual fulfilling the responsibilities of the RSO to be certified by a speciality board whose certification process includes all of the requirements in 10 CF 35.50(b), and whose certification has been recognized by the Commission or an Agreement State. Alternatively, under10 CFR 35.50(b) the individual is required to have completed: (1) a structured educational program consisting of 200 hours of didactic training in specified areas; and (2) 1 year of full-time radiation safety experience under the supervision of an individual identified as the RSO on a Commission or Agreement State license that authorizes similar types of use(s) of byproduct material involving specified experience. Also, the individual must obtain written certification, signed by a preceptor RSO, that the individual has completed the required training and the individual has achieved a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use license. Alternatively, under 10 CFR 35.50(c), the individual is required to be an authorized user, an authorized medical physicist, or authorized nuclear pharmacist, identified on the licensee's license, and to have experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has RSO responsibilities.

Cost Impacts: The cost impacts associated with this section involve additional costs to NRC/Agreement States for recognition of certifying specialty boards, to certifying boards for preparing materials supporting their recognition, and to some licensees and individuals seeking to be RSO clarification for the cost of preceptor certification. NRC estimates that approximately 190 individuals will seek to become RSOs under 10 CFR 35.50, annually. Of these, 90 percent, or 171, will seek certification by a certifying board, under 10 CFR 35.50(a). No additional cost impacts will be created for them under the final rule. NRC estimates that the remainder, or approximately 19 individuals, will seek to become RSOs, under 10 CFR 35.50(b). New costs for securing a preceptor statement are created by the final rule.

Under 10 CFR 35.50(a), NRC/Agreement States incur costs for recognizing specialty boards for purposes of 10 CFR 35.50(a). NRC estimates that recognition by NRC/Agreement States of specialty boards for certification requires 4 hours per board, and that NRC/Agreement States will be required to review five boards for approval.

Total Cost Increase: $2000

Certifying boards incur costs for preparing a submission supporting their recognition.

Total Cost Increase for Certifying Boards for 10 CFR 35.50(a): $4000

Under 10 CFR 35.50(b), licensees and preceptors incur costs associated with securing a preceptor's certification for purposes of 10 CFR 35.50(b).

Total Cost Increase for 10 CFR 35.50(b): $1000

Total Cost Increase for 10 CFR 35.50: $5000

Benefits: Training and experience commensurate with risk and focused on radiation safety.

Section 35.55, "Training for an authorized nuclear pharmacist"

Currently, 10 CFR 35.980 specifies the training requirements for an authorized nuclear pharmacist and lists one specialist board through which an individual may become certified to perform these procedures. Alternatively, training and experience requirements may be met in lieu of certification, by the listed speciality board by completing 700 hours of classroom and laboratory training in specified subjects as well as supervised experience in specified tasks. The candidate pharmacist must obtain written certification, signed by a preceptor-authorized nuclear pharmacist, that the training has been completed and the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

The final rule renumbers 10 CFR 35.980 as 10 CFR 35.55 and makes the following changes. The listing of approved speciality boards is eliminated. Section 35.55(a) provides instead that the licensee shall require the authorized nuclear pharmacist to be a pharmacist who is certified as a nuclear pharmacist by a speciality board whose certification process includes all of the requirements in Section 35.55(b) and whose certification has been recognized by the Commission or an Agreement State. Alternatively, the pharmacist is required to have completed 700 hours in a structured educational program consisting of both didactic training in specified subjects and supervised practical experience in a nuclear pharmacy performing specified tasks, and to have obtained written certification, signed by a preceptor-authorized nuclear pharmacist, that the individual has satisfactorily completed the didactic training and supervised practical experience and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

Cost Impacts: The cost impacts associated with this section involve additional costs to NRC/Agreement States to recognize specialty boards, to certification boards for preparing materials supporting their recognition, and to some individuals seeking to be authorized nuclear pharmacist for the cost of a preceptor certification.

NRC estimates that approximately 20 pharmacists will seek to become authorized nuclear pharmacists under 10 CFR 35.55 or equivalent Agreement State regulations annually. Of these, 90 percent, or 19 pharmacists, will seek certification by a certifying board under 10 CFR 35.55(a). No additional cost impacts are created for them under the final rule. NRC estimates that the remainder, or approximately one pharmacist, will seek to become an authorized nuclear pharmacist under 10 CFR 35.55(b). New costs for securing a preceptor statement are created by the final rule.

Certifying boards incur costs for preparing submissions supporting their recognition.

Total Cost Increase for Certifying Boards for 10 CFR 35.55: $2000

Benefits: Training and experience commensurate with risk and focused on radiation safety.

Section 35.59, "Recentness of training"

Currently, 10 CFR 35.972 specifies that the training and experience required under Part 35 must have been obtained within the 7 years preceding the application date or have been met by continuing education and experience.

The final rule renumbers 10 CFR 35.972 as 10 CFR 35.59 and substitutes references to the appropriate Subparts B and D through H, of the final rule, for the citations to the training and experience requirements in the current rule.

Cost Impacts: None anticipated.

Benefits: Conforming change to restructuring of Part 35.

SUBPART C--GENERAL TECHNICAL REQUIREMENTS

Section 35.60, "Possession, use, and calibration of instruments to measure the activity of unsealed byproduct material"

Currently, 10 CFR 35.50 requires licensees to possess a dose calibrator and to check each dose calibrator for constancy and to test each dose calibrator for accuracy, linearity, and geometric dependence. It specifies when these checks and tests must occur, and how they are performed.

The final rule combines requirements for calibration of instruments used to measure the activity of unsealed byproduct materials into one section, and renumbers 10 CFR 35.50 as 10 CFR 35.60. Section 35.60(a) requires, for direct measurements performed in accordance with 10 CFR 35.63, that a licensee possess and use instrumentation to measure the activity of unsealed byproduct material before it is administered to each patient or human research subject. Section 35.60(b) requires a licensee to calibrate the instrumentation in accordance with nationally recognized standards or the manufacturer's instructions. Section 35.60(c) requires a record of each instrument calibration to be retained in accordance with 10 CFR 35.2060.

Cost Impacts: Cost savings are anticipated as a result of the requirements for instrument calibration becoming more flexible, more adaptable to new technology, and more performance-based. In addition, if a licensee administers only unit dosages from manufacturers or preparers and uses decay methods to determine the dosages, the licensee is not required to have a measurement instrument and, thus, is exempt from the calibration requirements of this section.

Total Annual Cost Savings from 10 CFR 35.60: $521,000

Benefits: Cost savings to licensees who use only unit doses from manufacturers and preparers and use decay methods to determine the dosages and therefore are not required to calibrate a measurement instrument, and cost savings to all licensees from increased flexibility in requirements for instrument calibration.

Section 35.61, "Calibration of survey instruments"

Currently, Section 35.51 requires licensees to calibrate each survey instrument before first use, annually, and after repair. The current rule also requires the licensee to check each survey instrument for proper operation with a dedicated check source each day of use.

The final rule renumbers 10 CFR 35.51 as 10 CFR 35.61 and requires licensees to calibrate the survey instruments used to show compliance with Part 35 and with Part 20 before first use, annually, and after repairs that affect the calibration. All scales must be calibrated with readings up to 10 millisieverts (1000 millirem) per hour with a radiation source, with two separated readings on each scale or decade that will be used to show compliance, and conspicuously note on the instrument the date of calibration. The licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20 percent.

The final rule eliminates the requirement that the survey instrument be checked for proper operation with a dedicated check source each day of use.

The licensee must retain a record of each survey instrument calibration, in accordance with Section 35.2061.

Cost Impacts: Cost savings are anticipated for licensees from the elimination of daily checks with a dedicated check source.

Total Annual Cost Savings from 10 CFR 35.61: $136,000

Benefits: Cost savings to licensees.

Section 35.63, "Determination of dosages of unsealed byproduct material for medical use"

Currently, 10 CFR 35.53 requires that licensees measure the activity of dosages of unsealed byproduct material for medical use. It requires activity of dosages of a photon-emitting radionuclide to be measured, and activity of dosages of alpha- and beta-emitting radionuclides to be measured by direct measurement or a combination of measurements and calculations, except for unit dosages obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or equivalent Agreement State requirements. Results are required to be kept for 3 years and 10 CFR 35.53 includes requirements for the contents of these records.

The final rule renumbers 10 CFR 35.53 as 10 CFR 35.63. Section 35.63(a) requires licensees to determine and record the activity of each dosage before medical use. Section 35.63(b) provides that for a unit dosage, this determination must be made by direct measurement of radioactivity or a decay correction, based on the activity or activity concentration determined by a manufacturer or preparer licensed under 10 CFR 32.72, or equivalent Agreement State requirements, or an NRC or Agreement State licensee, in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the FDA for use in research. Section 35.63(c) requires that for other than unit dosages, this determination must be made by direct measurement of radioactivity, a combination of measurement of radioactivity and mathematical calculations, or by a combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed under Section 32.72 or equivalent Agreement State requirements. Section 35.63(e) provides that the licensee must retain a record of the dosage determination in accordance 10 CFR 35.2063.

Cost Impacts: The time necessary to perform a decay correction to determine the dosage of a unit dosage that is not measured directly is not significantly different from the time necessary to re-measure a unit dosage in a dose calibrator.

Cost savings result only for licensees who use exclusively unit dosages, because they will not have to possess, use, and maintain a dose calibrator. However, most licensees are expected to retain possession of existing dose calibrators for use, if needed.

Benefits: NRC anticipates that licensees using only unit dosages will gain added flexibility under 10 CFR 35.63, to rely on decay correction rather than direct measurement to determine the activity of dosages. If those licensees who use only unit dosages have no other need for dose calibrators, they will not be required to obtain or replace dose calibrators for measurements of dosages.

Cost savings to licensees who use only unit dosages and do not possess dose calibrators.

Section 35.65, "Authorization for calibration, transmission, and reference sources"

Currently, Section 35.57 allows each authorized licensee to receive, possess, and use byproduct material for check, calibration, and reference use under specific requirements.

The final rule renumbers 10 CFR 35.57 as 10 CFR 35.65, and allows any person authorized, by 10 CFR 35.11 for medical use of byproduct material, to receive, possess, and use any of the byproduct material specified in 10 CFR 35.65 for check, calibration, transmission, and reference use, as specified in Section 35.65(a)-(d). Section 35.65(a) specifies sealed sources manufactured and distributed by a person licensed under 10 CFR 32.74 or equivalent Agreement State regulations and that do not exceed 1.11 GBq (30 millicuries) each. The final rule increases the maximum sealed source activity from 0.56 MBq (15 mCi) to 1.11 MBq (30 mCi). Section 35.65(b) specifies sealed sources redistributed by a person licensed under Section 32.74 or equivalent Agreement State regulations and that do not exceed 1.11 GBq (30 mCi) each. The final rule specifies these redistributed sealed sources must be in the original packaging and shielding and be accompanied by the manufacturer's approved instructions. The final rule also increases the maximum sealed source activity from 0.56 MBq (15 mCi) to 1.11 MBq (30 mCi). Section 35.65(c) specifies any byproduct material with a half-life not longer than 120 days in individual amounts not to exceed 0.56 GBq (15 millicuries). Section 35.65(d) specifies any byproduct material with a half-life longer than 120 days, in individual amounts not to exceed 7.4 MBq (200 microcuries) or 1000 times the quantities in Appendix B of 10 CFR Part 30. Section 35.65(e) specifies technetium-99m may be received, possessed, and used in amounts "as needed," rather than in amounts not to exceed Gbq equivalent (50mCi), as provided in the current rule.

Cost Impacts: Cost savings are anticipated with the final changes to 10 CFR 35.65, formerly 10 CFR 35.57. Licensees will not need to obtain license amendments to obtain higher-activity check sources. NRC estimates that up to 151 amendments per year will be avoided.

Total Annual Cost Savings for licensees: $5000

Benefits: Improved flexibility for licensees.

Section 35.67, "Requirements for possession of sealed sources and brachytherapy sources

Currently, Section 35.59 requires each licensee in possession of sealed or brachytherapy sources to follow the radiation safety and handling instructions supplied by the manufacturer as well as leak-test requirements specified in 10 CFR 35.59.

The final rule renumbers 10 CFR 35.59 as 10 CFR 35.67. Section 35.67(a) requires licensees in possession of any sealed or brachytherapy source to follow the radiation safety and handling instructions supplied by manufacturers. Section 35.67(b) requires a licensee in possession of a sealed source to test the source for leakage before its first use, unless the licensee has a certificate from the supplier indicating that the source was tested within 6 months before transfer to the licensee; and test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the Commission or an Agreement State in the Sealed Source and Device Registry. Section 35.67(c) requires that to satisfy leak test requirements, licensees must measure the sample so that the leak-test can detect the presence of 185 Bq (0.005 microcuries) of radioactive material in the sample. Section 35.67(d) requires licensees to retain leak test-records in accordance with 10 CFR 35.2067. Section 35.67(e) specifies that if the leak test reveals the presence of 185 Bq (0.005 microcuries) or more of removable contamination, the licensee shall immediately withdraw the source from use and store, dispose of, or cause it to be repaired in accordance with Parts 20 and 30. The licensee also is required

to file a report within 5 days of the leak test in accordance with 10 CFR 35.3067. Section 35.67(f) provides that a licensee need not perform a leak test on certain specified sources. Section 35.67(g) requires licensees in possession of sealed or brachytherapy sources to conduct a semi-annual physical inventory of all such sources in their possession. This section requires the licensee to retain each inventory record in accordance with 10 CFR 35.2067.

The final rule also eliminates paragraphs 10 CFR 35.59(h) and (i), in the current rule, which require quarterly measurement of ambient dose rates in areas where sealed sources or brachytherapy sources are stored and retention of records of surveys. Surveys continue to be required to be performed to demonstrate compliance with Part 20.

Cost Impacts: Cost savings, from reduction in frequency of required source inventory from quarterly to semiannually.

Total Annual Cost Savings for licensees from 10 CFR 35.67: $56,000

Benefits: Cost savings to licensees and increased flexibility for licensees.

Section 35.69, "Labeling of vials and syringes"

Currently, 10 CFR requires that licensees keep syringes containing byproduct material conspicuously labeled and in a radiation shield that is also conspicuously labeled. Use of a syringe radiation shield is required when preparing and administering the radiopharmaceutical.

Section 35.61 currently requires that licensees preparing or handling vials containing byproduct material keep them conspicuously labeled and in a vial radiation shield that is also conspicuously labeled.

The final rule deletes 10 CFR 35.60 and 35.61 and replaces them with a new 10 CFR 35.69. The final rule requires that each syringe and vial that contains unsealed byproduct material must be labeled to identify the radioactive drug. Each syringe shield and vial shield also must be labeled unless the label on the syringe or vial is visible when shielded.

Cost Impacts: None anticipated. Licensees are expected to rely on labeling of vials and syringes by suppliers or in-house nuclear pharmacies and to properly label shields for vials and syringes. Labeling under the final rule is expected to require approximately the same time as under the current rule.

Benefits: Increased flexibility for licensees.

Section 35.80, "Provision of mobile medical service"

Section 35.80 currently provides technical requirements for mobile medical service. Section 35.29 currently specifies the requirements for licensing mobile nuclear medicine services.

The final rule combines the current requirements into 10CFR 35.80(a), (b), and (c), as follows. Section 35.80(a) of the final rule includes a requirement, previously included in 10 CFR 35.29(b) of the current rule, that licensees providing mobile medical services must obtain letters from all client's management, permitting and agreeing to the services, including discussions of all entitie's responsibilities. The final rule eliminates the requirement, from Part 35, that a licensee transport, to each address of use, only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of

radiopharmaceutical kits; the requirement that the licensee bring, into each address of use, all byproduct material to be used and, before leaving, remove all unused byproduct material and all associated waste; the requirement that the licensee secure or keep under constant surveillance and immediate control all byproduct material when in transit or at an address of use; and the requirement that the licensee carry a radiation detection survey meter in each vehicle used to transport byproduct material. The final rule continues to require licensees to check instruments used to measure the activity of unsealed byproduct materials, specifying that such checks occur before medical use at each client's address or on each day of use, whichever is more frequent; requires survey instruments to be checked for proper operation with a dedicated check source before use at each client's address; and before leaving a client's address of use, to survey all areas of use, to ensure compliance with the requirements in 10 CFR Part 20.

Section 35.80(b) prohibits a mobile medical service from having byproduct material delivered from the manufacturer or the distributor to the client's address of use, unless the client has a license allowing possession of the byproduct material. This section requires that byproduct material delivered to the client's address of use shall be received and handled in conformance with the client's license. Section 35.80(c) requires the letter required 10 CFR 35.80(a)(1) to be retained and the record of each survey required in paragraph (a)(4) of 10 CFR 35.80 to be retained in accordance with 10 CFR 35.2080.

Cost Impacts: Section 35.29 has been eliminated and replaced with requirements in final 10 CFR§ 35.18(b) and 35.80. Under 10 CFR 35.80, licensees may be required to incur costs to obtain a dedicated check source, although in many cases such sources will be supplied with the survey instruments. Licensees also may already possess check sources, because the current rule requires instruments to be checked for proper operation. Therefore, minimal cost impacts (i.e., <$1000) are expected.

Benefits: Conforming change for restructuring of Part 35.

Section 35.90, "Storage of volatiles and gases"

Section 35.90 currently requires licensees to store: (1) volatile radiopharmaceuticals and radioactive gases in the shipper's radiation shield and container; and (2) multi-dose containers in a fume hood after drawing the first dosage from it.

The final rule eliminates 35.90.

Cost Impacts: None anticipated.

Benefits: Increased flexibility for licensees.

Section 35.92, "Decay-in-storage"

Section 35.92 currently allows licensees to hold byproduct material with a physical half-life of less than 65 days and dispose of it in ordinary trash, provided it follows specified handling procedures.

The final rule, in 10 CFR 35.92(a), increases the maximum allowable half-life for byproduct material that may be held for decay in storage from 65 days to 120 days and eliminates a requirement that byproduct material must be held for decay in storage a minimum of 10 half-lives. Section 35.92 of the final rule also eliminates the requirement to separate and

monitor each generator column individually, with all radiation shielding removed to ensure that it has decayed to background radiation level before disposal. The final rule amends the requirement to remove or obliterate all radiation labels to specify that the licensee must remove or obliterate all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste, after they have been released from the licensee. Section 35.92(b) of the final rule requires licensees to retain a record of each disposal permitted under paragraph 10 CFR 35.92(a) in accordance with 10 CFR 35.2092.

Cost Impacts: Costs are expected to be avoided by the amendment to 10 CFR 35.92(a) as a result of a reduced number of requests for license amendments to allow an exemption for 120-day half-life for holding material for a minimum of 10 half-lives. Numerous licensees have already obtained such amendments, although the precise number is not available. Therefore, relatively few are expected to be avoided annually in the future.

Total Annual Cost Savings for licensees: $1000

Benefits: Increased flexibility for licensees and reduced number of license amendments.

SUBPART D--UNSEALED BYPRODUCT MATERIAL - WRITTEN DIRECTIVE NOT REQUIRED

Section 35.100, "Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required"

The current rule, in 10 CFR 35.100, permits a licensee to use for uptake, dilution, or excretion studies any unsealed byproduct material that is obtained from a manufacturer or preparer licensed under 10 CFR 32.72 or equivalent Agreement States requirements, or prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in 10 CFR 35.920, or an individual under the supervision of either, as specified in 10 CFR 35.25.

The final rule amends 10 CFR 35.100 by limiting the use of unsealed byproduct material for uptake, dilution, and excretion studies to medical uses that do not require a written directive pursuant to Section 35.40(b)(1) or (2). It revises the references in 10 CFR 35.100(b) to conform to the final rule. It allows the use of unsealed byproduct material that is obtained from a manufacturer or preparer licensed under 10 CFR 32.72 or equivalent Agreement State requirements, or prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements under 10 CFR 35.290 or 35.390, or an individual under the supervision of either. The final rule adds a new section, 10 CFR 35.100(c), specifying that material may be used that is obtained from and prepared by an NRC or Agreement State licensee, in research, in accordance with a Radioactive Drug Research Committee-approved (RDRC-approved) protocol or an Investigational New Drug (IND) protocol accepted by the FDA. It also adds a new section, 10 CFR 35.100(d), specifying that material may be used that is prepared by the licensee for use in research in accordance with a RDRC-approved application or an IND protocol accepted by FDA.

Cost Impacts: None anticipated.

Benefits: The final rule allows: (1) a medical use licensee to receive radioactive drugs, for use in RDRC-approved or IND research protocols, prepared and distributed by NRC or Agreement State licensees that are not 10 CFR 32.72 licensees; and (2) any individual to prepare a radioactive drug in accordance with either an RDRC-approved protocol or an IND protocol.

Section 35.120, "Possession of survey instrument"

The current rule, in 10 CFR 35.120, requires each licensee to have in its possession a radiation detection survey instrument capable of detecting dose rates over the range of metric (0.1 millirem) per hour to metric (100 millirem) per hour.

The final rule eliminates 10 CFR 35.120.

Cost Impacts: None anticipated, because licensees are expected to continue to possess survey instruments.

Benefits: Increased flexibility for licensees.

Section 35.190, "Training for uptake, dilution, and excretion studies"

The current rule, in 10 CFR 35.910, specifies the training requirements for an authorized user of a radiopharmaceutical for uptake, dilution, and excretion studies. Section 35.910(a) lists five specialist boards through which an individual may become certified to perform these procedures. Alternatively, 10 CFR 35.910(b) specifies training and experience requirements that may be met in lieu of certification by one of the five listed speciality boards. It currently requires 40 hours of classroom and laboratory training in specified subjects. In addition, it requires 20 hours of supervised clinical experience. Alternatively, 10 CFR 35.910(c) specifies that the individual may complete a 6 month training program in nuclear medicine approved by the Accreditation Council for Graduate Medical Education, that includes the classroom, laboratory, and clinical requirements specified in paragraph (b) of 10 CFR 35.910.

The final rule, in 10 CFR 35.190, eliminated the list of five approved speciality boards. Section 35.190(a) provides instead that the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under 10 CFR 35.100 to be a physician who is certified by a medical specialty board whose certification process includes all of the requirements in 10 CFR 35.190(c) and whose certification has been recognized by the Commission or an Agreement State. Alternatively, 10 CFR 35.190(b) acknowledges physicians who are authorized users under 10 CFR 35.290 or 35.390, or equivalent Agreement State requirements, as meeting the requirements of 10 CFR 35.190. Alternatively, under 10 CFR 35.190(c), the physician must have completed 60 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies, including classroom and laboratory training in specified areas; must have work experience under the supervision of an authorized user who meets the requirements in 10 CFR 35.190, 35.290, or 35.390, or equivalent Agreement State requirements in specified areas; and must have obtained written certification, signed by a preceptor authorized user who meets the requirements in 10 CFR§ 35.190, 35.290, or 35.390, or equivalent Agreement State requirements, that the individual has satisfactorily completed the classroom and laboratory training and work experience requirements and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100. The final rule eliminates the alternative of completing a 6 month program approved by the Accreditation Council for Graduate Medical Education in 10 CFR35.971.

Cost Impacts: NRC anticipates incremental costs associated with this section involving additional costs to NRC/Agreement States for recognizing specialty boards, to certification boards for preparing materials supporting their recognition, and to the authorized user for the cost of obtaining preceptor certifications.

NRC estimates that approximately 110 physicians seek to become authorized users under 10 CFR 35.190 or equivalent Agreement State regulations annually. Of these, 90 percent, or 99 physicians, seek certification by a certifying board under Section CFR 35.190(a). No additional cost impacts are created for them under the final rule. NRC estimates that the remainder, or approximately 11 physicians, seek to become authorized users under 10 CFR 35.190(c). New costs for securing a preceptor statement are created by the final rule.

Certifying boards incur costs for preparing submissions supporting their recognition.

Total Cost Increase for Certifying Boards for 10 CFR 35.190(a): $4000

The costs to licensees associated with securing a preceptor's certification for purposes of 10 CFR 35.190(b) are estimated on the basis of 10 percent of candidates seeking authorization through 10 CFR 35.190(b).

Total Cost Increase for 10 CFR 35.190(b): $1000

Total Cost Increase for licensees for 10 CFR 35.190: $5000

Benefits: Training and experience commensurate with risk and focused on radiation safety.

Section 35.200, "Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required"

The current rule, in 10 CFR 35.200, permits a licensee to use, for imaging and localization studies, any unsealed byproduct material that is obtained from a manufacturer or preparer licensed under 10 CFR 32.72 or equivalent Agreement States requirements, or prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Section 35.920, or an individual under the supervision of either, as specified in 10 CFR 35.25.

The final rule amends 10 CFR 35.200 by limiting the use of unsealed byproduct material for imaging and localization studies to medical uses that do not require a written directive pursuant to Section 35.40(b). It revises the references in 10 CFR 35.200(b) to conform to the final rule. Section 35.200(b) allows the use of unsealed byproduct material that is obtained from a manufacturer or preparer licensed under 10 CFR 32.72 or equivalent Agreement State requirements, or prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements under 10 CFR§ 35.290 or 35.390, or an individual under the supervision of either, as specified in 10 CFR 35.27. The final rule adds a new section, 10 CFR 35.200(c), specifying that material may be used that is obtained from and prepared by an NRC or Agreement State licensee in research, in accordance with an RDRC-approved protocol or an IND protocol accepted by the FDA. The final rule also adds a new section, 10 CFR 35.200(d), specifying that material may be used that is prepared by the licensee for use in research in accordance with a RDRC-approved application or an IND protocol accepted by FDA.

Cost Impacts: None anticipated.

Benefits: The final rule allows: (1) a medical use licensee to receive radioactive drugs, for use in RDRC-approved or IND research protocols, prepared and distributed by NRC or Agreement State licensees that are not 10 CFR 32.72 licensees; and (2) any individual to prepare a radioactive drug in accordance with either an RDRC-approved protocol or an IND protocol.

Section 35.204, "Permissible molybdenum-99 concentration"

Section 35.204(a) of the current rule prohibits licensees from administering to humans a radiopharmaceutical containing more than metric (0.15 microcurie) of molybdenum-99 per millicurie of technetium-99m. Section 35.204(b) requires licensees using molybdenum-99/ technetium-99m generators for preparing a technetium-99m radiopharmaceutical to measure the molybdenum-99 concentration of each eluate or extract.

The final rule, in 10 CFR 35.204(a), changes the expression of the permissible concentration to provide that a licensee may not administer more than 0.15 kilobecquerel of molybdenum-99 per MBq of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m). Section 35.204(b) requires that instead of each eluate, a licensee that uses molybdenum-99/technetium-99m generators must measure the molybdenum-99 concentration of the first eluate, after receipt of a generator, to demonstrate compliance with 10 CFR 35.204(a). Licensees are required to retain records of each measurement, in accordance with the requirements specified in 10 CFR 35.2204.

Cost Impacts: Cost savings are anticipated from elimination of the requirement that licensees must measure the molybdenum-99 concentration of each eluate or extract.

NRC assumes that 591 NRC licensees and 1,478 Agreement States licensees use molybdenum-99/technetium-99m generators. Under the final rule, sale or transfer of a generator will require the new owner or user to measure the concentration of the first eluate. Assuming that generators are replaced weekly, this amendment is expected to reduce the frequency of measurements from approximately 1per day to about 1 per week.

Total Annual Cost Savings from amendment to 10 CFR 35.204: $993,000

Benefits: Cost savings to licensees.

Section 35.205, "Control of aerosols and gases"

The current rule, in 10 CFR 35.205(a), requires licensees to administer radioactive aerosols or gases in a room with a system that will keep airborne concentrations below the limits prescribed by 10 CFR 20.1201 and 20.1301. Section 35.205(c) requires that before receiving, using, or storing a gas, a licensee must calculate the amount of time needed after a spill to reduce the concentration to the limits specified in 10 CFR 20.1201, and 10 CFR 35.205(d) requires the licensee to make a record of the calculations required by 10 CFR 35.205(c) and retain that record for the duration of the use of the area.

The final rule eliminates 10 CFR 35.205.

Cost Impacts: None anticipated.

Benefits: Regulatory flexibility for licensees.

Section 35.220, "Possession of survey instruments"

The current rule, in 10 CFR 35.220, requires each licensee to have in its possession a radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem per hour to 100 millirem per hour.

The final rule eliminates 10 CFR 35.220.

Cost Impacts: None anticipated, because licensees are expected to continue to possess survey instruments.

Benefits: Increased flexibility for licensees.

Section 35.290, "Training for imaging and localization studies"

The current rule, in 10 CFR 35.920, specifies the training requirements for an authorized user of radiopharmaceuticals and generators for imaging and localization studies. Section 35.920(a) lists five specialist boards through which an individual may become certified to perform these procedures. Alternatively, 10 CFR 35.920(b) specifies training and experience requirements that may be met in lieu of certification by one of the five listed speciality boards. The regulations currently require 200 hours of classroom and laboratory work training [10 CFR35.920(b)(1)]; 500 hours of supervised work experience [10 CFR 35.920(b)(2)]; and 500 hours of supervised clinical experience [10 CFR 35.920(b)(3)]. Alternatively, 10 CFR 35.920(c) specifies that the individual may complete a 6 month training program in nuclear medicine approved by the Accreditation Council for Graduate Medical Education, that includes the classroom, laboratory, and clinical requirements specified in paragraph (b) of 10 CFR 35.920.

The final rule, in 10 CFR 35.290, eliminated the list of five approved speciality boards. Section 35.290 provides that except as provided in 10 CFR 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under 10 CFR 35.200 to be a physician certified by a medical specialty board whose certification process includes all of the requirements in Section 35.290(c) and whose certification has been recognized by the Commission or an Agreement State. Alternatively, 10 CFR 35.290(b) acknowledges physicians who are authorized users under Section 35.390 or equivalent Agreement State requirements as meeting the requirements of 10 CFR 35.290. Alternatively, under 10 CFR 35.290(c), the physician must have completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience must include classroom and laboratory training in specified areas and work experience, under the supervision of an authorized user who meets the requirements in 10 CFR 35.290 or 10 CFR 35.390, or equivalent Agreement State requirements, involving specified activities. The physician must have obtained written certification, signed by a preceptor-authorized user who meets the requirements in 10 CFR 35.290 or 35.390, or equivalent Agreement State requirements, that the individual has satisfactorily completed the classroom and laboratory training and work experience required under 10 CFR 35.290(c) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200. The final rule eliminates the alternative of completing a 6-month training program approved by the Accreditation Council for Graduate Medical Education (10 CFR 35.971).

Cost Impacts: Cost savings are associated with the final rule because of reduction in required training hours. NRC assumes that the reduction in required hours will not be reflected in the educational process of the certifying boards.

NRC estimates that approximately 110 physicians will seek to become authorized users under 10 CFR 35.290 or equivalent Agreement State regulations annually. Of these, 90 percent, or 99, will seek certification by a certifying board under 10 CFR 35.290(a). No additional cost impacts will be created for them under the final rule. NRC estimates that the remainder, or approximately 11 physicians, will seek to become authorized users under 10 CFR 35.290(c). New costs for securing a preceptor statement are created by the final rule. However, NRC assumes that individuals will seek certification under both 10 CFR 35.190 and 35.290, and that, therefore, no additional costs for preceptor certification will be incurred because these costs are reflected under 10 CFR 35.190.

Additional costs to NRC/Agreement States are associated with the recognition of specialty boards and preparing the specialty board submission. Because both Sections 35.910(a) and 35.920(a) contain identical lists of certifying organizations, NRC assumes one review of each organization to satisfy the requirements of Section 10 CFR 35.190(a) and 35.290(a). Therefore, the costs to NRC/Agreement States for recognizing specialty boards for the purposes of 10 CFR 35.290(a) are estimated under Section 35.190(a).

The cost savings that will be realized under this section due to the reduction in training hours required in 10 CFR 35.290(c) are estimated below:

Total Annual Cost Savings from 10 CFR 35.290: $238,000

Benefits: Training and experience commensurate with risk and focused on radiation safety.

SUBPART L–RECORDS

Section 35.2024, "Records of authority and responsibilities for radiation protection programs"

Section 35.2024(a) requires licensees to retain a record of actions taken by the licensee's management, in accordance with 10 CFR 35.24(a) for 5 years and specifies the contents of those records. Section 35.2024(b) requires licensees to retain a copy of both the authority, duties, and responsibilities of the RSO, as required by 10 CFR 35.24(e), and a signed copy of each RSO's written agreement, as required by 10 CFR 35.24(b), for the duration of the license. Section 35.2024 requires the records to include the signature of the RSO and licensee management.

Cost Impacts: The final rule reduces the record retention period for records of actions taken by licensee's management, under 10 CFR 35.24(a), which under the current rule, lasts until the Commission terminates the license, to 5 years. Therefore, small cost reductions occur with shorter record retention periods.

Total Annual Cost Savings for licensees from 10 CFR 35.2024: $9000

Benefits: Cost savings for licensees.

Section 35.2026, "Records of radiation protection program changes"

The final rule, in new 10 CFR 35.2026, provides that a licensee must retain a record of each radiation protection program change made in accordance with 10 CFR 35.26(a), for 5 years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of licensee management that reviewed and approved the change.

Section 35.31(b) currently requires that a licensee retain a record of each "radiation safety program" change until the license has been renewed or terminated. Under the current rule, the record must include "the effective date of the change, a copy of the old and new radiation safety procedures, the reason for the change, a summary of radiation safety matters that were considered before making the change, the signature of the Radiation Safety Officer, and the signatures of the affected authorized users and of management or, in a medical institution, the Radiation Safety Committee's chairman and the management representative."

Section 35.26 of the final rule amends 10 CFR 35.31(b) to eliminate the quoted requirements and provides that a licensee shall retain a record of each change, in accordance with 10 CFR 35.2026. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management who reviewed and approved the change.

Cost Impacts: Small cost reductions are expected, with shorter record-retention periods, as follows:

Total Annual Cost Savings from 10 CFR 35.2026: $17,000

Benefits: Cost savings for licensees.

Section 35.2060, "Records of calibrations of instruments used to measure the activity of unsealed byproduct material"

The final rule, in new 10 CFR 35.2060, requires a licensee to maintain a record of instrument calibrations required by 10 CFR 35.60, for 3 years, and specifies that the records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

The final rule uses the phrase "instrument calibrations." Therefore, the scope of the final rule potentially is increased, through the inclusion of records of calibrations of instruments, in addition to dose calibrators.

Cost Impacts: The final rule is anticipated to result in minimal (<$1000) increased recordkeeping costs.

Benefits: The calibration ensures that instruments are functioning correctly and establishes trends in equipment performance.

Section 35.2061, "Records of radiation survey instrument calibrations"

The final rule, in new 10 CFR 35.2061, requires a licensee to maintain a record of radiation survey instrument calibrations required by 10 CFR 35.61 for 3 years and specifies the contents of that record.

Cost Impacts: The final rule duplicates the recordkeeping requirements in 10 CFR 35.51(d) of the current rule. The record retention period remains 3 years. Therefore, no cost impacts are anticipated from the final rule.

Benefits: Conforming change.

Section 35.2063, "Records of dosages of unsealed byproduct material for medical use"

The final rule, in new 10 CFR 35.2063, requires a licensee to maintain a record of dosage determinations required by 10 CFR 35.63 for 3 years and specifies the records that must be maintained.

The recordkeeping requirements in the final rule parallel the recordkeeping requirements in 10 CFR 35.53 of the current rule. The record retention period remains 3 years. The final rule makes two changes: (1) eliminating the requirement that the record contain the expiration dates of the radiopharmaceutical; and (2) changing "measurements" to "determination" in Section 35.2063(b)(3) of the final rule.

Cost Impacts: None anticipated.

Benefits: Conforming change.

Section 35.2067, "Records of leak tests and inventory of sealed sources and brachytherapy sources"

The final rule, in new 10 CFR 35.2067(a), requires records of leak tests of sealed sources and brachytherapy sources required by 10 CFR 35.67(b) of the final rule to be retained for 3 years and specifies the contents of the records. Section 35.2067(b) requires records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by 10

CFR 35.67(g) of the final rule to be retained for 3 years and specifies the content of the inventory records.

Cost Impacts: The final rule duplicates, with one change, the recordkeeping requirements in 10 CFR 35.59(d) and (g) of the current rule. The final rule reduces the record-retention time from 3 years to 5 years. This reduction of the record retention period by 2 years is expected to result in small cost savings to licensees, as follows:

Total Annual Cost Savings from 10 CFR 35.2067: $3000

Benefits: Cost savings for licensees.

Section 35.2080, "Records of mobile medical services"

The final rule, in new 10 CFR 35.2080, requires licensees to retain a copy of the letter(s) that permit the use of byproduct material at a client's address of use, in accordance with 10 CFR 35.80(a)(l), for 3 years after the provision of last service. Section 35.2080(a) also requires the letter to clearly delineate the authority and responsibility of each entity. Section 35.2080(b) requires licensees to retain a record of each survey required by 10 CFR 35.80(a)(4) for 3 years and specifies the contents of the records.

Cost Impacts: None anticipated. The recordkeeping required in 10 CFR 35.2080 of the final rule is also required in 10 CFR 35.80(f) of the current rule. Therefore, no incremental costs nor cost savings are anticipated from the final rule.

Benefits: Conforming change.

Section 35.2092, "Records of decay-in-storage"

The final rule, in new 10 CFR 35.2092, requires a licensee to maintain records of the disposal of licensed materials by decay in storage, as permitted by 10 CFR 35.92 for 3 years. The record must include: the date of the disposal; the survey instrument used; the background radiation level; the radiation level measured at the surface of each waste container; and the name of the individual who performed the survey.

Cost Impacts: The final rule parallels, with one change, the recordkeeping requirements in Section 35.92 of the current rule. The final rule eliminates the requirement that the record include the date on which the byproduct material was placed in storage. Therefore, the final rule may create small cost savings (i.e., less than $1000) for licensees, as a result of the slight reduction in the scope of records that must be maintained.

Benefits: Small cost savings for licensees (less than $1000).

Section 35.2204, "Records of molybdenum-99 concentrations"

The final rule, in new 10 CFR 35.2204, requires licensees to maintain a record of the molybdenum-99 concentration tests required by 10 CFR 35.204(b) for 3 years and specifies the contents of the record.

Cost Impacts: The final rule parallels, with changes, the recordkeeping requirements in the current rule in 10 CFR 35.204(c). The changes in 10 CFR 35.204 reduce the number of required measurements, thus reducing the number of records that must be maintained.

Cost savings to licensees are estimated at:

Total Annual Cost Savings from 10 CFR 35.2204:	$12,000

Benefits: Cost savings for licensees.

SUBPART M

Section 35.3045, "Report and notification of a medical event"

Section 35.3045(a) requires a licensee to report any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material, results in a dose meeting or exceeding specified criteria in §§ 35.3045(a)(1), (2), or (3). This reporting requirement is needed to ensure that NRC is aware of medical events and to promptly take any necessary actions based on the circumstances.

Section 35.3045(b) requires a licensee to report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician

Section 35.3045(c) requires licensees to notify the NRC Operations Center by telephone no later than the next calendar day after discovery of the medical event.

Section 35.3045(d) requires licensees to submit a written report to the appropriate NRC Regional Office within 15 days after the discovery of the medical event. The report must include: the licensee's name; the name of the prescribing physician; a brief description of the event; why the event occurred; the effect, if any, on the individual(s) who received the administration; what actions, if any, have been taken or are planned to prevent recurrence; certification that the licensee notified the individual (or the individual's responsible relative or guardian); and if not, why not. The report must not contain the individual's name or any other information that could lead to identification of the individual. This reporting requirement is needed to provide NRC a synopsis of the event, its cause(s), and corrective actions taken, so that NRC can ensure that appropriate follow-up actions are taken after medical events, and so that NRC can promptly notify other licensees if it appears the event might be generic.

Section 35.3045(e) requires the licensee to provide notification of the event to the referring physician and the individual who is the subject of the medical event, or that individual's responsible relative or guardian, no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. If a verbal notification is made, the licensee is required to inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee then must provide such a written description if requested. Individuals and their referring physician(s) need this information to make timely decisions regarding possible health care needs.

Section 35.3045(f) specifies that aside from the notification requirement, nothing in 10 CFR 35.3045 affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individuals responsible relatives or guardians.

Section 35.3045(g) provides that a licensee shall annotate a copy of the report provided to the NRC with the name of the individual who is subject to the event, and their social security number or other identification number, if one has been assigned. The licensee shall provide a copy of the annotated report to the referring physician, if other than the licensee, within 15 days after discovery of the medical event.

Cost Impacts:

None anticipated. The changes in 10 CFR 35.3045 of the final rule are not expected to substantially change the number or type of medical events to be reported under 10 CFR 35.3045 from the number and type of misadministrations reported under the current rule. The deletion of the requirement to maintain a record of the misadministration (medical event) is not expected to have a significant cost impact because a report still needs to be prepared and sent to the NRC and to the referring physician.

Benefits:

Reduced prescriptiveness as to providing written report or description of the medical event to the individual verbally notified.

Section 35.3047, "Report and notification of a dose to an embryo/fetus or a nursing child"

Section 35.3047(a) requires the licensee to report to NRC any dose to an embryo/fetus that is greater than 50 milliseivert (mSv) (5 rem) dose equivalent that is the result of an administration of byproduct material or radiation from byproduct material to a pregnant individual unless, the dose to embryo/fetus was specifically approved, in advance, by the authorized user.

Section 35.3047(b) requires the licensee to report to NRC any dose to a nursing child that is the result of an administration of byproduct material to a breast-feeding individual that is greater than 50 mSv (5 rem) total effective dose equivalent or has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician. This report is needed so that NRC can comply with the legislative intent of Section 208 of the Energy Reorganization Act of 1974 (P.L.93-438) as amended, which requires NRC to submit reports of unintended radiation exposure to Congress.

Section 35.3047(c) requires the licensee to notify, by telephone, the NRC Operations Center, no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report under 10 CFR 35.3047(a) or (b). This reporting requirement is needed to ensure that NRC is aware of unintended radiation exposure to an embryo/fetus or nursing child and can promptly take any necessary actions based on the circumstances.

Section 35.3047(d) requires the licensee to submit a written report, to the appropriate NRC Regional Office, within 15 days after discovery of a dose, to the embryo/fetus or nursing child, that requires a report under 10 CFR 35.3047(a) or (b). The written report must include: the licensee's name; the name of the prescribing physician; a brief description of the event; why the event occurred; the effect, if any, on the embryo/fetus or nursing child; what actions, if any, have been taken or are planned to prevent recurrence; and certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not. The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child. This reporting requirement is needed to provide information to NRC about the causes of the unintended radiation exposure to an embryo/fetus or nursing child and methods to prevent recurrence.

Section 35.3047(e) requires the licensee to provide notification of the event to the referring physician, and also notify the pregnant individual or mother, no later than 24 hours after discovery of an event that requires reporting under paragraph (a) or (b) of 10 CFR 35.3047, unless the referring physician personally informs the licensee either that he or she will inform the mother, or that, based on medical judgment, telling the mother may be harmful. The licensee is not required to notify the mother without first consulting the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. The licensee can demonstrate compliance with this paragraph by notifying the mother's or child's responsible relative or guardian. If a verbal notification is made, the licensee is required to inform the mother, or the mother's or child's responsible relative or guardian, instead of the mother, that a written description of the event can be obtained from the licensee request. The licensee then must make such a written description available, if requested.

Section 35.3047(f) provides that a licensee shall annotate a copy of the report provided to the NRC with the name of the individual who is subject to the event, and his/her social security number or other identification number, if one has been assigned. The licensee shall provide a copy of the annotated report to the referring physician, if other than the licensee, within 15 days after discovery of the medical event.

Cost Impacts: Cost increases are anticipated, from requirements in 10 CFR 35.3047(a) that require licensees to report a dose to an embryo/fetus, and requirements in 10 CFR 35.3047(b), that require licensees to report a dose to a nursing child. NRC anticipates that 10 such administrations occur annually for NRC and Agreement States licensees. Costs are addressed under 10 CFR 35.3047(c) and (d).

Cost increases are anticipated, from requirements in 10 CFR 35.3047(c), that require licensees to notify, by phone, the NRC Operation Center, within 5 days after discovery of a dose to an embryo/fetus or nursing child. NRC anticipates that 10 such administrations occur annually for NRC and Agreement States licensees.

Total Annual Cost Increase for licensees from 10 CFR 35.3047(c):	less than$1000

Cost increases are anticipated, from requirements in 10 CFR 35.3047(d), that require licensees to submit a written report to the appropriate NRC Regional Office within 30 days after discovery of a dose to the embryo/fetus or nursing child. NRC anticipates that 10 such administrations occur annually for NRC and Agreement States licensees.

Total Annual Cost Increase for licensees: from 10 CFR 35.3047(d)	$2000

Cost increases are anticipated from requirements in 10 CFR§ 35.3047(e) and (f) that require notification to the referring physician and also to the mother. NRC anticipates that 10 such notifications occur annually for NRC and Agreement States licensees.

Total Annual Cost Increase for licensees from Sections 35.3047(e) and (f):	$1000
Total Annual Cost Increase for licensees from 10 CFR 35.3047:	$4000

Benefits: Provides NRC with information to comply with Section 208 of the Energy Reorganization Act and to determine the nature and frequency of such events.

Section 35.3067, "Report of a leaking source"

This section requires that licensees file a written report within 5 days if a leak test required by Section 35.67 reveals the presence of 185 Bq (0.005 microcurie) or more of removable contamination. The report must be filed with the appropriate NRC Regional Office, with a copy to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. The report must include the model number and serial number, if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken. This report enables NRC to promptly determine if the requisites follow-up actions are necessary following discovery of the leaking source.

Cost Impacts: None anticipated.

Benefits: Conforming change.