RULEMAKING
AFFIRMATION

SECY-00-0118

May 31, 2000

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: FINAL RULES - 10 CFR PART 35, "MEDICAL USE OF BYPRODUCT MATERIAL" and 10 CFR PART 20, "STANDARDS FOR PROTECTION AGAINST RADIATION"

PURPOSE:

To request Commission approval of: (1) a final rule that revises 10 CFR Part 35 to make it risk-informed and more performance-based, and to codify requirements for certain therapeutic devices; and (2) a final rule that revises 10 CFR Part 20 in response to a Petition for Rulemaking (PRM) from the University of Cincinnati.

SUMMARY:

In its Staff Requirements Memorandum (SRM) - COMSECY-96-057, "Materials/Medical Oversight (DSI 7)," dated March 20, 1997 (Attachment 1), the Commission directed the restructuring of Part 35 into a risk-informed, more performance-based regulation. The program for revising Part 35 and the associated guidance document has provided more opportunity for input from potentially affected parties than is provided by the typical notice and comment rulemaking process. The final rule, that is attached for Commission approval to publish in the Federal Register, is consistent with a risk-informed, performance-based approach to regulation. Also provided, for Commission approval is a draft notice that will revise the Enforcement Policy to make it consistent with the rule.

BACKGROUND:

In its SRM COMSECY-96-057, the Commission directed the revision and restructuring of Part 35. During the rulemaking process, the staff forwarded several Commission Papers that either provided information on the major issues addressed during the rulemaking or requested direction on specific issues. A chronological list of these papers and associated SRMs is provided in Attachment 2.

Members of the public, stakeholders, Agreement States, non-Agreement States, and the Advisory Committee on the Medical Uses of Isotopes (ACMUI) provided input and discussed the proposed requirements for medical use licensees on numerous occasions. Since August 1997, the staff held seven facilitated public workshops with stakeholders and made formal presentations at approximately 20 professional society meetings. We also discussed key rulemaking issues three times with the full ACMUI and four times with ACMUI subcommittees. In addition, staff discussed the rulemaking at the 1997, 1998, and 1999 annual "All Agreement States" meetings.

In SECY-99-201, "Draft Final Rule - 10 CFR Part 35, 'Medical Use of Byproduct Material," staff provided the Commission with: (1) draft final regulatory text for the revision of Parts 20 and 35; (2) a summary of the public comments received on the proposed rule, the staff's draft responses to the comments, and resulting changes made in the proposed rule; and (3) a comparison of the requirements in the current Part 35, as codified in 10 CFR Chapter I, and the draft final rule. In its SRM on SECY 99-201, dated February 16, 2000 (Attachment 3), the Commission approved the staff's draft final rule language and responses to public comments subject to the comments and changes provided in the SRM and its attachment. The Commission directed that the staff incorporate the changes and submit the final Part 35 rulemaking package, including the guidance document, to the Commission. The SRM also directed the staff to consider several issues when finalizing the rulemaking package. These issues and their resolution are discussed in Attachment 4.

The final rule grants, in part, a PRM filed by the University of Cincinnati, dated April 7, 1996 (PRM 20-24), because the request pertains to the medical use of byproduct material (Attachment 5). The petition requests that the U.S. Nuclear Regulatory Commission (NRC) amend 10 CFR 20.1301, "Dose limits for individual members of the public," to allow visitors to individuals confined pursuant to 10 CFR 35.75, to receive up to 5 milliSievert (mSv) (0.5 rem) while visiting. Detailed information on the petition is provided in Section II of the attached final rule (Attachment 6).

DISCUSSION:

Attachment 6 is the draft Federal Register notice (FRN) for the final rule. As stated above, the final rule resolves the PRM filed by the University of Cincinnati. Attachment 7 is the guidance document associated with the revision to Part 35, NUREG 1556, Volume 9. The guidance document reflects a risk-informed, more performance-based approach to medical use licensing. This document provides guidance on preparing a byproduct material medical use license application as well as NRC criteria for evaluating such an application. There is also a reduction in the amount of detailed information that must be submitted by applicants to support an application for medical use of byproduct material. In addition, the document provides model procedures that are acceptable to NRC to meet the regulatory requirements. Applicants may choose to either adopt the model procedures or develop their own procedures.

In preparing the final rulemaking package, staff carefully reviewed the draft final FRN that was provided to the Commission in SECY-99-201. During this review we identified areas that needed to be revised to make the Statements of Consideration and rule text more consistent. In April 2000, the Office of Nuclear Material Safety and Safeguards (NMSS) forwarded the revised draft final FRN and supporting rulemaking documents to other NRC offices for their final review and concurrence. During that review, various minor changes were recommended. These changes were identified as a result of the complete review of the supporting documents that was conducted by various NRC staff members. This review has made the rule, Statements of Consideration, and all supporting documents more consistent. In addition, as a result of this review, two major issues were raised that had not been previously identified for consideration. These issues are discussed below.

The first issue relates to the paperwork reduction review that the Office of Management and Budget (OMB) will undertake of the recordkeeping and reporting requirements in 10 CFR 35.2045, 35.2047, 35.3045 and 35.3047. In particular, 10 CFR 35.2045 and 35.2047 require licensees to maintain information, in a record that is virtually identical to the information licensees are to report to the NRC under 10 CFR 35.3045 and 35.3047. This is of concern since OMB, as a general rule, does not approve information collections that require both the submittal and retention of the same information by a respondent. OMB's position is that if the information is reported, the agency has the information that it needs for its purposes, and therefore, there is no reason for the agency to require that respondents also maintain the records absent substantial justification for doing so.

We have developed alternative rule text (Attachment 8) for addressing OMB's possible concern. The alternative rule text would require that information on medical events and exposures to an embryo/fetus or a nursing child be reported in writing to the NRC and the referring physician. Under the alternative rule language, the recordkeeping requirements, 10 CFR 35.2045 and 35.2047, would be deleted in their entirety. The reporting sections, 10 CFR 35.3045 and 35.3047, would be revised to add a requirement for the licensee to annotate a copy of the report that is required to be submitted to the NRC with: (1) the names of the individuals involved; and (2) the social security number, or other identification number, of the individual who is the subject of the medical event, or the pregnant individual and nursing child, as applicable. This annotated report would then be provided to the referring physician. Licensees would presumably retain a copy of the report to respond to potential requests for a written description of the event. Upon Commission approval of the alternative rule text, staff will incorporate this text into the FRN and will revise the supporting documents.

The second issue relates to reporting requirements associated with the release of individuals, pursuant to 10 CFR 35.75. In the draft final rule forwarded to the Commission on August 3, 1999 (SECY-99-201), 10 CFR 20.1301 was modified to further clarify the Commission's long-standing view that patient release is governed by 10 CFR 35.75, not 10 CFR 20.1301. The Commission reiterated this position in the rulemaking entitled, "Criteria for the Release of Individuals Administered Radioactive Material" (62 FR 4120, January 29, 1997). The exclusion for patient release in 10 CFR 20.1301 has been revised to read ". . . exclusive of the dose contributions from . . . exposure to individuals administered radioactive material and released, which is governed by 10 CFR 35.75." This clarification has brought to our attention the fact that the reporting requirements in Part 20 do not apply if an individual receives an exposure in excess of 5 mSv (0.5 rem) from an individual released pursuant to 10 CFR 35.75. This reporting requirement is an issue regardless of whether Part 20 is clarified as noted above.

In most scenarios, licensees are required to report to NRC exposures in excess of the dose limits. The Statements of Consideration for the 1997 revision to 10 CFR 35.75 did not discuss whether reporting was required if the licensee (1) failed to comply with 10 CFR 35.75 and an individual received a dose in excess of 5 mSv (0.5 rem) or (2) if the licensee complied with 10 CFR 35.75 but, learned, after the fact, that another individual (including a nursing child) received a dose in excess of 5 mSv (0.5 rem). Since this issue was identified during final preparation of the rulemaking package, the staff has not had sufficient time to fully evaluate whether a reporting requirement is needed, and if so, at what level. In addition, this issue has not been discussed with the Agreement States, ACMUI, members of the public and other external stakeholders. We recommend that the issue be further explored with all stakeholders. Staff will then prepare a rulemaking plan that discusses options and alternatives, including a "no-action" option if the staff believes rulemaking is not necessary.

The Commission will also note that the "Supplementary Information" section of the FRN (Attachment 6) includes a statement on, "Assessment of Federal Regulations and Policies on Families." The revision of Parts 20 and 35 is the first rulemaking for which the Agency has assessed the impact of the rule on family well-being, pursuant to Section 654 of the Treasury and General Government Appropriations Act of 1999 (Act), Pub. L. No. 105-277, 112 Stat. 2681, 528-529 (1998), to be codified at 5 U.S.C. 601 note. For each rule that may affect family well-being, the agency is to conduct a seven-factor assessment that is contained in the statute. The head of each agency also is to certify to the OMB and to Congress that an assessment has been conducted for those policies and regulations having a potential effect on family well-being. Such certification must also provide an adequate rationale for implementing those policies and regulations that may negatively affect family well-being. If the Agency determines that its rule or policy has no impact on family well-being, no further action or notification is required. In this case, there was a potential for an impact, so an assessment was performed. The assessment

(Attachment 9) finds that the Part 20 and 35 rulemaking will not negatively affect family well-being. Letters will be forwarded to the OMB and Congress certifying that the required assessment has been performed and reflecting the assessment's finding.

SECY-99-201 indicated that the staff would submit an inspection plan with the final rulemaking package. We are in the process of implementing the Medical Pilot Inspection Program that was approved by the Commission in SRM-SECY-00-0001, "Pilot Program for NMSS Initiative on Streamlining Inspection and Enforcement." The year-long pilot program focuses inspection on risk-informed outcomes and licensee performance. It is limited to inspection of medical use licensees using unsealed byproduct material (10 CFR 35.100, 35.200, and 35.300). We plan to use the experience gained from this program to revise all medical inspection procedures. This will help to ensure that the medical inspection procedures incorporate the risk-informed, more performance-based approach in the rulemaking.

As part of our continuing efforts in Strategic Planning, the staff plans to disseminate information on this rulemaking to our internal and external stakeholders. These efforts will include continued interaction with professional societies and training for NRC staff involved in the implementation of the rule (e.g., inspectors, license reviewers, enforcement specialists, NMSS staff, etc.).

As a result of this rulemaking, we will also need to revise the examples in Supplement VI, NUREG-1600, "General Statement of Policy and Procedure for NRC Enforcement Actions." This revision to Supplement VI is provided in Attachment 11. This revision modifies the examples in the existing Enforcement Policy to remove the terms "quality management program" and "misadministration," and to use the new terms, "written procedures for administrations requiring a written directive," and "medical event."

As part of our review of NUREG-1600, we evaluated whether the term "programmatic" should be retained in Supplement VI. This evaluation was conducted to complete action on a commitment made by staff in SECY 99-219, "Proposed Revision of the Enforcement Policy to Address the Process for Assessing the Significance of Violations." We believe it is appropriate to maintain the term "programmatic." In 1993, this term was added to the medical examples in the Enforcement Policy to reflect a reduced severity level for isolated mistakes, recognizing that there is some baseline probability of medical error that is very difficult to further reduce. The term "programmatic" is used to contrast with "isolated." Programmatic deficiencies have, as their root cause, a correctable weakness in some part of the licensee's program for preventing medical events, such as a failure to train personnel. The staff will assure that the distinction between isolated and programmatic is not used as an alternate means of aggregating lesser violations to a higher severity level.

COORDINATION:

The Office of the General Counsel has no legal objection to this paper. The Office of the Chief Financial Officer has reviewed this paper for resource implications and potential impact on license fee and annual fee schedules and has no objections. Resources needed to prepare the final rulemaking package in Fiscal Year (FY) 2000 were reprogrammed from lower-priority rulemaking activities within NMSS. Resources needed to implement this rule are contained in the FY 2001 budget. The Office of the Chief Information Officer has reviewed the rule for information technology and information management and recommends that the alternative rule text in Attachment 8 be incorporated into the rulemaking.

RECOMMENDATIONS:

That the Commission:

1. Approve incorporation of the alternative rule text (Attachment 8) into the draft final Federal Register notice for Part 35 (Attachment 6 );

2. Approve the "Final Rule" (Attachment 6 ), with alternative rule text incorporated, for publication in the Federal Register;

3. Approve the "Notice of Change to Enforcement Policy" for publication in the Federal Register (Attachment 11);

4. Certify that this rule, if promulgated, will not have a negative economic impact on a substantial number of small entities, to satisfy requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b);

5. Certify that this rulemaking will not negatively affect family well-being (Attachment 10); and

6. Approve development of a rulemaking plan that provides the Commission with options, including the "no-action" option, for revising Parts 20 or 35 to add a requirement for a licensee to report events where an individual received an exposure in excess of 5 mSv (0.5 rem) from an individual released in accordance with 10 CFR 35.75.

7. Note:

   a. Staff will request that the Office of the Federal Register publish the Notice of Final Rulemaking and Notice of Change to the Enforcement Policy the same day in the Federal Register;

   b. 

The petitioner will be informed of the Commission's decision to grant, in part, its petition (Attachment 12);

c. The rulemaking and changes to the Enforcement Policy will become effective six months after publication in the Federal Register;

d. A regulatory analysis and environmental assessment will be placed in the NRC's Public Electronic Reading Room (Attachments 13 and 14);

e. The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification regarding economic impact on small entities and the reasons for it, as required by the Regulatory Flexibility Act (Attachment 15);

f. After the Commission approves the rule, it needs to be submitted to the OMB for approval under the Paperwork Reduction Act (44 U.S.C. 3501, et seq.) Any OMB comments must be considered before publication of the final rule in the Federal Register. The supporting statement for the rule is provided in Attachment 16;

g. The appropriate Congressional committees will be informed of this rulemaking;

h. The NRC has determined that this action is not a major rule under the Small Business Regulatory Enforcement Fairness Act of 1966, and has confirmed this determination with the Office of Management and Budget. The appropriate Congressional and General Accounting Office contacts will be informed (Attachment 17);

i. A press release will be issued; and

j. Copies of the Federal Register notice of the final rulemaking and the revision to the enforcement policy will be distributed to all affected Commission licensees, Agreement States, and potential Agreement States, and to other interested parties, upon request.

/RA by Carl J. Paperiello Acting For/

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Attachments:

1. SRM-COMSECY-96-057, dtd 3/20/97
2. Chronological List of Part 35 Commission Papers and SRMs
3. SRM-SECY-99-201, dtd 2/16/00
4. Closeout of Items in SRM-SECY-99-201
5. Letter from V. Morris, RSO, University of Cincinnati, dtd, 4/7/96
6. Draft Final Federal Register Notice for Part 35
7. NUREG 1556, Volume 9 *
8. Alternative Rule Text for 10 CFR 35.3045 and 35.3047
9. Assessment of Federal Regulations and Policies on Family
10. Draft Final Federal Register Notice for Enforcement Policy
11. Letter to University of Cincinnati
12. Draft Final Regulatory Analysis
13. Draft Final Environmental Assessment
14. Regulatory Flexibility Analysis
15. Supporting Statement for Submittal to OMB
16. Small Business Regulatory Enforcement Fairness Act Forms

* [Attachment 7 is unavailable for download due to size, please see ADAMS accession number **ML 003717096** for the electronic copy or contact the Public Document Room for a hardcopy]

ATTACHMENT 2

CHRONOLOGICAL LIST OF PART 35 COMMISSION PAPERS AND SRMS

February 16, 2000	Staff Requirements: SECY-99-201-Draft Final Rule-10 CFR Part 35, "Medical Use of Byproduct Material"
August 3, 1999	SECY-99-201: Draft Final Rule: 10 CFR Part 35, "Medical Use of Byproduct Material"
April 23, 1999	Staff Requirements: Briefing on Part 35 Rulemaking, March 25, 1999
November 13, 1998	Staff Requirements: SECY-98-263- Proposed Rule: Revision of 10 CFR Part 35, Medical Use of Byproduct Material
November 9, 1998	SECY-98-263: Proposed Rule: Revision of 10 CFR Part 35, Medical Use of Byproduct Material
July 21, 1998	Staff Requirements: SECY-98-128- Proposed Rule: Revision of 10 CFR Part 35, Medical Use of Byproduct Material
July 9, 1998	Staff Requirements: SECY-98-127- Draft Proposed Policy Statement on the Medical Use of Byproduct Material
June 26, 1998	Memo from John C. Hoyle to L. Joseph Callan on SECY-98-054: Commission Resolution of Significant Issues Associated with the Revision of 10 CFR Part 35, Medical Uses of Byproduct Material
June 4, 1998	SECY-98-128: Proposed Rule: Revision of 10 CFR Part 35, Medical Use of Byproduct Material
June 4, 1998	SECY-98-127: Draft Proposed Policy Statement on the Medical Use of Byproduct Material
March 20, 1998	SECY-98-054: Commission Resolution of Significant Issues Associated with the Revision of 10 CFR Part 35, Medical Uses of Byproduct Material
June 30, 1997	Staff Requirements: SECY-97-115- Program for Revision of 10 CFR Part 35, Medical Uses of Byproduct Material and Associated Federal Register Notice
June 20, 1997	SECY-97-131: Supplemental Information on SECY-97-115, Program for Revision of 10 CFR Part 35, Medical Uses of Byproduct Material and Associated Federal Register Notice
June 5, 1997	SECY-97-115: Program for Revision of 10 CFR Part 35, Medical Uses of Byproduct Material and Associated Federal Register Notice
March 20, 1997	Staff Requirements: COMSECY-96-057- Materials/Medical Oversight (DSI 7)

ATTACHMENT 4

Closeout of items in SRM-SECY-99-201 Not Addressed in Final Register Notice

Staff Requirements - SECY 99-201, Draft Final Rule - 10 CFR Part 35, "Medical Use of Byproduct Material" directed staff to consider several issues when preparing the final Part 35 rulemaking package. The following discussion documents staff's consideration of these issues where staff's consideration would not be readily identifiable in the Federal Register notice for the final rule.

Items from the Body of the Staff Requirements Memorandum

Item 2 - The Commission directed that staff make specific changes to § 35.2045, "Records of medical events," and § 35.3045, "Report and notification of a medical event." As a result of these changes, the Commission stated that "The staff should consider: 1) making conforming changes to §§ 35.2047 and 35.3047 and 2) whether the rule should specify when the record required under § 35.2045 must be provided to the referring physician"

> Response: We made conforming changes between §§ 35.2047 and 35.3047 to make them as consistent as possible. This consistency benefits both NRC staff and licensees because it makes the rule easier to use. These conforming changes also reduce the regulatory burden on licensees had the proposed rule text not been modified.
>
> We revised the rule text (§ 35.3045(g)) to reflect that a copy of the record required under § 35.2045 shall be provided to the referring physician, if other than the licensee, within 15 days after the discovery of the medical event. We believe that this change is needed to ensure that the referring physician has all the available documented information about the medical event to support any decisions about remedial or prospective health

care of the patient. The 15-day time period to provide the referring physician with a copy of the record is based on § 35.3045 (d) which requires a licensee to submit a report to the NRC within 15 days. We have attempted to have consistency in the requirements in Subparts L and M, where possible, to simplify compliance with the recordkeeping and reporting requirements.

As noted in the Commission paper, we have also developed alternative rule text for Commission consideration (See Attachment 8) which deletes the recordkeeping requirements in §§ 35.2045 and 35.2047. This implements the Commission's direction that the referring physician be provided with documentation of the medical event and minimizes the recordkeeping burden on licensees.

Item 6 - "The staff should reconsider the need for [the draft final rule to require acceptance testing of therapy-related computer systems]. In doing so, the staff should consider whether these requirements are duplicative of FDA requirements and whether licensees should be able to rely on the product manufacturer's testing. The staff should also consider whether licensees should be able to rely on the manufacturer's relative helmet factors instead of determining the relative helmet factors before the first use of the unit § 35.635."

Response: We have maintained the requirement for licensees to perform acceptance testing of therapy-related computer systems. The FDA does not test the output of software-based treatment planning systems as part of their approval for marketing process, rather they verify that the developer/vendor documents that industry accepted standards were used to develop, test, and verify the software's function and accuracy. Licensees should not be allowed to rely on the product manufacturer's testing to meet this requirement. Most software-based treatment planning systems are designed for general purpose use and often require the correct input of various source parameters by the user in order to obtain accurate treatment plan results. User acceptance testing serves not only to verify that the underlying treatment planning system software is producing the correct results but also verifies the accuracy of the user entered source parameters. American Association of Physicists in Medicine (AAPM) Report of the Therapy Committee Task Group 56, "Code of Practice for Brachytherapy Physics," was used in developing the components of acceptance testing.

Regarding helmet factors, the measurement of the helmet factors is inherent in patient dosimetry. Therefore, for the same reasons cited above, we have included this requirement in the final rule. The performance objectives for the tests required in § 35.635 are based on recommendations in AAPM Report No. 54, "Stereotactic Radiosurgery." For example, AAPM Report No. 54 recommends that helmet factors be measured by the end user.

Item 7 - "The staff should provide a copy of the final SRM to the SR-6 committee, keep abreast of the Committee's efforts to finalize the SSR, and informally provide the Commission with updates on this issue."

Response: A copy of the final SRM was provided to the Agreement States under Agreement State Letter No. SP-00-18, March 3, 2000. In addition, the staff will keep knowledgeable of the SR-6 Committee's efforts to finalize the Suggested State Regulation and informally provide the Commission with updates on this issue.

Items from the Attachment to SECY-99-201

Item 27, "On page 565, the dosage record requirements contained in 10 CFR 35.2063(b) should be further reviewed to ensure that enough information is retained to determine if a medical event had actually occurred. As part of this review, the staff should consider the possible time lapse between dosage determination and dosage administration. As appropriate from this review, the staff should consider revising the record keeping requirements in the final rule."

Response: We reviewed the recordkeeping requirements in § 35.2063, "Records of dosages of unsealed byproduct material for medical use." We considered the possible time lapse between dosage determination and administration for diagnostic and therapeutic administration. In the case of diagnostic procedures (written directive is not required), it is extremely unlikely that this time difference would result in a situation where the dose difference would exceed the threshold for a medical event identified in 35.3045 because the byproduct material has a short half life and low activities are administered. Therefore, we do not believe that a prescriptive requirement to record the time of dose administration can be justified in a risk-informed, more performance based rule.

In the case of therapeutic administrations (written directive is required), it is possible that a significant time difference between dosage determination and administration could result in a medical event. We do not believe however, that a requirement for recording the time of administration should be added to the rule. Licensees are required by § 35.41 to develop implement, and maintain written procedures to provide high confidence that ". . . each administration is in accordance with the written directive." Compliance with this performance-based requirement should provide NRC with sufficient information to establish whether an administration was in accordance with a written directive and did not result in medical event.

ATTACHMENT 8

Alternative Rule Text for §§ 35.3045 and 35.3047

Report and Notification of a Medical Event

Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child

Pertinent regulatory text from §§ 35.3045 and 35.3047 is provided below to highlight the differences between the regulatory text in the draft Federal Register notice and the alternative regulatory text. Text from §§ 35.2045 and 35.2047 is presented in strikeout format for reference purposes since this text will be deleted if this alternative is adopted.

§ 35.3045 Report and notification of a medical event.

*

(e) The licensee shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event 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 judgement, telling the individual would 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. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall 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 shall provide such a written description if requested.

(f) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relative or guardians.

~~(g) A licensee shall retain a record of a medical event in accordance with § 35.2045. A copy of the record required under § 35.2045 shall be provided to the referring physician if other than the licensee, within 15 days after discovery of the medical event.~~

(g) A licensee shall:

(1) Annotate a copy of the report provided to the NRC with the:

(a) Name of the individual who is the subject of the event; and

(b) Social security number or other identification number, if one has been assigned, of the individual who is the subject of the event; and

(2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

§ 35.3047 Report and notification of a dose to an embryo/fetus or a nursing child.

*

(e) The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under paragraph (a) or (b) of this section, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgement, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with 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. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother, when appropriate. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

~~(f) A licensee shall retain a record of a dose to an embryo/fetus or a nursing child in accordance with § 35.2047. A copy of the record required under § 35.2047 shall be provided to the referring physician, if other than the licensee, within 15 days after discovery of the event.~~

(f) A licensee shall:

(1) Annotate a copy of the report provided to the NRC with the:

(a) Name of the pregnant individual or the nursing child who is the subject of the event; and

(b) Social security number or other identification number, if one has been

assigned, of the pregnant individual or the nursing child who is the subject of the event; and

(2) Provide a copy of the annotated report to the referring physician, if other than the

licensee, no later than 15 days after the discovery of the event.

~~**§ 35.2045 Records of medical events.**~~

~~(a) A licensee shall retain a record of medical events reported in accordance with~~

~~§ 35.3045 for 3 years.~~

~~(b) The record must include--~~

~~(1) The licensee's name;~~

~~(2) Names of the individuals involved;~~

~~(3) The social security number or other identification number, if one has been assigned, of the individual who is the subject of the medical event;~~

~~(4) A brief description of the event and why it occurred;~~

~~(5) The effect, if any, on the individual;~~

~~(6) The actions, if any, taken or planned to prevent recurrence; and~~

~~(7) Whether the licensee notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.~~

~~**§ 35.2047 Record of a dose to an embryo/fetus or a nursing child.**~~

~~(a) A licensee shall retain a record of a dose to an embryo/fetus or a nursing child reported in accordance with § 35.3047 for 3 years.~~

~~(b) The record must include--~~

~~(1) The licensee's name;~~

~~(2) Names of the individuals involved;~~

~~(3) The social security number or other identification number, if one has been assigned, of the embryo/fetus or nursing child who is the subject of the event;~~

~~(4) A brief description of the event and why it occurred;~~

~~(5) The effect, if any, on the embryo/fetus or nursing child;~~

~~(6) The actions, if any, taken or planned to prevent recurrence; and~~

~~(7) Whether the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.~~

Alternative SOC Text for §§ 35.3045 and 35.3047

If the alternative rule text is approved, the following changes would be made in the Statement of Considerations where we discussed providing a copy of the record to the referring physician.

§ 35.3045 Report and notification of a medical event.

Issue 9: Should licensees be required to notify the referring physician about a medical event?

Comment. Several commenters disagreed with the need for a regulation requiring licensees to notify referring physicians about a medical event. Nuclear medicine physicians and referring physicians have a professional relationship that would be negatively impacted if the nuclear medicine physician provided inaccurate information or withheld information from the referring physician. Therefore, the NRC does not need to mandate notification of the referring physician.

Response. It is important that a referring physician is aware of medical events involving individuals. The referring physician

knows the individual and his or her medical history and is likely to be in the best position to make a decision about whether informing the individual about the medical event would be harmful. That physician may also need to evaluate any follow-up actions relative to the individual's overall health history. Although notification of referring physicians may represent the "standard of care," that practice may not be uniformly followed. Therefore, the NRC retained the current requirement for a licensee to notify the referring physician about a medical event. In addition, the final rule includes a requirement in paragraph (g) that an annotated ~~a~~ copy of the report required by § 35.3045 ~~record required by § 35.2045~~ be provided to the referring physician, if other than the licensee, within 15 days after discovery of the medical event. The copy of the report is to be annotated with the name and social security number or other identification number, if one has been assigned, of the individual who is the subject of the event. We believe that it is important for the referring physician to have all the available documentation about the medical event to support any decision about remedial or prospective health care. The 15-day time period to provide the referring physician with a copy of the record is based on paragraph (d) which requires a licensee to submit a report to the NRC within 15 days. Consistency, where possible, between the requirements in Subparts L and M will simplify compliance with the recordkeeping and reporting requirements.

The issue of notifying the referring physician was addressed in the Statements of Consideration for the 1995 rulemaking that amended the medical misadministration requirements ("Medical Misadministration of Radiation and Radioactive Material," 60 FR 48623; September 20, 1995). The Commission noted that "If a misadministration occurs because the material was administered to the wrong individual, there may be no referring physician. If there is no referring physician, the licensee is relieved of the responsibility of notifying the referring physician, but must comply with all other requirements of § 35.33."

§ 35.3047 Report and notification of a dose to an embryo/fetus or a nursing child.

Issue 7: Were there any other changes made in this section between the proposed and final rules?

We added a new paragraph (f) to the final rule ~~because the reference to the associated recordkeeping requirements in § 35.2047 was inadvertently omitted in the proposed rule. These records are needed to document these events for licensee and Commission review. This new paragraph includes the requirement for~~ that requires the licensee to provide an annotated ~~a~~ copy of the report required by § 35.3047 ~~record required by § 35.2047~~ to the referring physician, if other than the licensee, within 15 days after discovery of the event. The copy of the report is to be annotated with the name and social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event. We believe that it is important for the referring physician to have all the available documentation about the event to support any decision about remedial or prospective health care. The 15-day time period to provide the referring physician with a copy of the record was based on paragraph (d) which requires a licensee to submit a report to the NRC in within 15 days. We have attempted to have consistency in the requirements in Subparts L and M, where possible, to simplify compliance with the recordkeeping and reporting requirements.

ATTACHMENT 9

ASSESSMENT OF FEDERAL REGULATIONS AND POLICIES ON FAMILY

AGENCY:	Nuclear Regulatory Commission
TITLE OF ACTION 10	CFR Parts 20, 32, and 35, Medical Use of Byproduct Material
UPCOMING ACTION	Final Rule
RIN:	3150-AF74
ESTIMATED DATE OF ISSUANCE:	September 2000
STATUTORY OR JUDICIAL DEADLINE:	None

DESCRIPTION OF ACTION:

This final rule is a comprehensive revision of 10 CFR Part 35, "Medical Use of Byproduct Material." It relaxes certain prescriptive requirements in the current 10 CFR Part 35 with respect to Radiation Safety Committees, quality management programs, training and experience, reporting and recordkeeping, and other requirements currently covered by both 10 CFR Part 35 and 10 CFR Part 20.

At the same time that it revises Part 35, the final rule also amends the regulations in 10 CFR Part 20, "Standards for protection against radiation," § 20.1301, in response to a Petition for Rulemaking (PRM-20-24) dated April 7, 1996, from the

University of Cincinnati. PRM-20-24 requests NRC to authorize "specified visitors" of hospitalized radiation therapy patients, as individual members of the public, to receive up to 5 mSv (0.5 rem) of radiation exposure per year, rather than the current limit of 1 mSV (0.1 rem) in 10 CFR 20.1301.

POTENTIAL EFFECT ON FAMILIES:

The majority of the regulations promulgated in this rule do not pertain to families and are not likely to result in any of the impacts outlined in the seven assessment factors below. However, the estimated cost savings to NRC licensees from the new requirements, as compared to the current requirements, is approximately eight million dollars annually. This cost savings provides a general societal benefit, and may translate into lower costs for families that purchase health care insurance, or who have a member in need of medical services that use NRC-licensed material. In addition, the final rule contains three provisions that can benefit families in certain case-specific instances, as discussed below.

ASSESSMENT:

1. The action strengthens or erodes the stability of the family and, particularly, the marital commitment.

   The final rule can strengthen the stability of the family by expanding the circumstances and the time allowed for family members and others to visit a patient confined to a medical institution while undergoing radiation therapy using NRC-licensed material. Previously, visitors were subject to the dose limit for members of the general public, which is 1 mSv (0.1 rem). The final rule amends 10 CFR 20.1301 to permit visitors to receive up to 5 mSv (0.5 rem) if permitted by the physician authorized user.

   The final rule can strengthen the stability of the family by permitting a patient with a temporary implant containing byproduct material to return to the family rather than remain hospitalized. Release from the medical institution is subject to certain radiation dose limitations for family members and others. The provision that allows a medical institution to release a patient with a temporary implant is 10 CFR 35.75, "Release of individuals containing unsealed byproduct material or implants containing byproduct material." Before this final rule, § 35.75 was entitled, "Release of individuals containing radiopharmaceuticals or permanent implants." It did not permit the release of a patient with a temporary implant.

2. The action strengthens or erodes the authority and rights of parents in the education, nurture, and supervision of their children.

   See comments under Assessment Factor No. 1. Because the final rule expands the circumstances and the time allowed for visits to a child confined to a medical institution while undergoing radiation therapy using NRC-licensed material, the final rule can strengthen parental ability to nurture a child in this case-specific instance.

   In addition, the final rule may allow a child with a temporary implant containing byproduct material to be released from the medical institution and return to the family, in which case the ability of the family to nurture the child is strengthened.

3. The action helps the family perform its functions, or substitutes government activity for the function.

   Section 35.3047, "Report and notification of a dose to an embryo/fetus or a nursing child," establishes the criteria for reporting the radiation dose received by an embryo/fetus or nursing child incidental to the diagnosis or treatment of the mother. If a report is required, the licensee must notify the referring physician and pregnant individual or mother unless the referring physician informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. In addition, the licensee must provide the referring physician with a copy of the record of the event and have a written description of the event available for the mother, or the mother's or child's responsible relative or guardian. This provision will provide both the referring physician and the mother with information needed to make health care decisions in this sensitive area.

4. The action increases or decreases disposable income or poverty of families and children.

   See second comment under Assessment Factor No. 1. The final rule can result in shorter hospital stays for patients being treated with a temporary implant containing byproduct material. Under this case-specific instance, healthcare costs would be lower, and there may be less travel and meal expense for family members who would otherwise have to make visits to the patient at the medical institution.

   Additionally, as noted above, there is an estimated cost savings of approximately eight million dollars annually to NRC licensees from the final rule, as compared to the current requirements. This cost savings provides a general societal benefit, and could lower costs incrementally for families that purchase health care insurance, or who have a member in need of medical services that use NRC-licensed material.

5. The proposed benefits of the action justify the financial impact on the family.

   This action will not have a negative financial impact on the family.

6. The action may be carried out by State or local government or by the family.

   This assessment factor is not relevant to the final rule.

7. The action establishes an implicit or explicit policy concerning the relationship between the behavior and personal responsibility of youth, and the norms of society.

   This assessment factor is not relevant to the final rule.

NEGATIVE EFFECTS:

The NRC has determined that this action will not negatively affect family well-being.

RECORD OF COMPLIANCE WITH "ASSESSMENT OF FEDERAL REGULATION AND POLICIES ON FAMILIES"

TITLE OF ACTION: 10 CFR Parts 20, 32, and 35, Medical Use of Byproduct Material

RIN NUMBER: 3150-AF74

The requirements of the Act apply to this action because the action may affect family well-being.

Signed_____ Dated:_____

ATTACHMENT 10

7590-01-P

NUCLEAR REGULATORY COMMISSION
[NUREG - 1600]

NRC Enforcement Policy; Modification, Medical Use

AGENCY: Nuclear Regulatory Commission.

ACTION: Policy Statement: Modification.

SUMMARY: In conjunction with a major revision of 10 CFR Part 35, published in today's *Federal Register*, the Nuclear Regulatory Commission is amending its "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600 (Enforcement Policy). This change to the Enforcement Policy revises the examples of severity levels for violations associated with the requirements to use written directives for certain medical uses of byproduct material; and to develop, implement, and maintain certain procedures for medical uses that require a written directive (10 CFR 35.40 and 35.41). These examples are used in the enforcement process to provide guidance for determining the significance or a particular violation.

DATES: Consistent with the rulemaking to revise 10 CFR Part 35, this action is effective [insert date 6 months after publication in the Federal Register]. Comments on this change to the NRC's Enforcement Policy should be submitted not later than 30 days following the effective date and will be considered by the NRC before the next revision of the Enforcement Policy.

ADDRESSES: Submit written comments to: David L. Meyer, Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, Mail Stop: T6D59, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001. Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:30 a.m. and 4:15 p.m., Federal workdays. Copies of comments received may be examined at the NRC Public Document Room, 2120 L Street, N.W. (Lower Level), Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Bill Borchardt, Director, Office of Enforcement, (301) 415-2741.

SUPPLEMENTARY INFORMATION:

Background

In a separate action published in today's *Federal Register*, the NRC is revising its regulations in 10 CFR Part 35 governing the medical use of byproduct material to make the requirements risk informed and more performance based. Before this revision, 10 CFR 35.32 required a quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the physician who is the authorized user of the material under the NRC license. Among other things, the quality management program had to assure that, for certain medical uses, a written directive was prepared and signed by the authorized user. The term "written directive" is defined in 10 CFR 35.2. Before this revision to the regulations, the term "misadministration" was used to denote certain errors in administering byproduct material, or the radiation from byproduct material, to humans. It was defined in 10 CFR 35.2.

In the revision of 10 CFR Part 35 published today, the requirement to use written directives has been moved to § 35.40. The terms "quality management program" and "misadministration" are no longer used. The term "medical event" is used to denote certain errors in administering byproduct material, or the radiation from byproduct material, to humans. This term is now defined in 10 CFR 35.2. The new § 35.41 requires that the licensee develop, implement, and maintain written procedures for medical uses that require a written directive. Among other things, the written procedures must provide high confidence that each administration of byproduct material, or radiation from byproduct material, is in accordance with the written directive.

Minor conforming changes are being made to the examples in the NRC Enforcement Policy that formerly referred to the terms "quality management program" and "misadministration." The examples are being changed to reflect the new terms "written procedures for administrations requiring a written directive" and "medical event."

The last substantive change to the examples in the NRC Enforcement Policy that relate to errors in medical uses was published at 58 FR 17321 (April 2, 1993). At that time, the examples were changed to provide greater emphasis, and attach greater importance, to violations that are indicative of, or flow from, deficiencies of a programmatic nature. Programmatic deficiencies have, as their root cause, an underlying weakness in some part of the licensee's program for preventing medical events, such as failure to develop and implement adequate written procedures for administrations that require a written directive, failure to train personnel on the procedures, or failure to follow procedures that is more widespread than simple occasional human error. Programmatic deficiencies are correctable, and pose the risk of additional occurrence if effective corrective action is not taken.

Conversely, the 1993 changes reflected a reduced severity level for individual violations that represent isolated mistakes involving human error made in the diagnosis or treatment of individual patients with byproduct material. The Commission continues to believe that the examples established in 1993 are appropriate, with minor modifications to conform to the terminology used in the newly revised 10 CFR Part 35.

The examples use the terms "substantial programmatic failure" and "programmatic weakness." To differentiate between these two terms, "substantial programmatic failure" applies in cases where the licensee fails to establish or effectively implement one or more of the requirements in 10 CFR 35.40 or 35.41. The failure could be due to a serious omission in the procedures required under 10 CFR 35.41 or to a failure to train employees to follow procedures. "Programmatic weakness" indicates that the failure is more widespread than simple occasional human error. For example, the term "programmatic weakness" would apply in a situation where licensee employees are trained to check the calculation of radiation dose to be administered for a certain treatment and normally do so; however, there have been failures to meet this requirement on a number of occasions because of staffing shortages, and one of those occasions results in a medical event.

Paperwork Reduction Act

This final change to the NRC Enforcement Policy does not contain new or amended information collection requirements subject to the Paperwork Reduction Act fo 1995 (44 U.S.C. 3501 *et seq.*).

Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a "major" rule and has verified this determination with the Office of Information and Regulatory Affairs, Office of Management and Budget.

Accordingly, the NRC Enforcement Policy is amended to read as follows:

GENERAL STATEMENT OF POLICY AND PROCEDURE FOR NRC ENFORCEMENT ACTIONS

* * * * *

SUPPLEMENT VI--FUEL CYCLE AND MATERIALS OPERATIONS

* * * * *

A. Severity Level I - Violations involving for example:

* * * * *

4. Failure to use a properly prepared written directive as required by 10 CFR 35.40; or failure to develop, implement, or maintain procedures for administrations requiring a written directive as required by 10 CFR 35.41; that results in a death or serious injury (*e.g.*, substantial organ impairment).

B. Severity Level II - Violations involving for example:

* * * * *

3. A substantial programmatic failure to implement written directives or procedures for administrations requiring a written directive, such as a failure of the licensee's procedures to address one or more of the elements in 10 CFR 35.40 or 35.41, or a failure to train personnel in those procedures, that results in a medical event.

C. Severity Level III - Violations involving for example:

* * * * *

5. A substantial programmatic failure to implement written directives or procedures for administrations requiring a written directive, such as a failure of the licensee's procedures to address one or more of the elements in 10 CFR 35.40 or 35.41, or a failure to train personnel in those procedures, that does not result in a medical event. Failure to report a medical event. A programmatic weakness in the implementation of written directives or procedures for administrations requiring a written directive, whether or not a medical event occurs.

D. Severity Level IV - Violations involving for example:

* * * * *

3. Failure to use a properly prepared written directive as required by 10 CFR 35.40 or failure to follow procedures for administrations requiring a written directive as required by 10 CFR 35.41, whether or not a medical event occurs, provided that the failures: (1) are isolated; (2) do not demonstrate programmatic weakness in implementation; and (3) have limited consequences if a medical event is involved.

Dated at Rockville, Maryland, this day of 2000.

For the Nuclear Regulatory Commission

Annette Vietti-Cook,
Secretary of the Commission

ATTACHMENT 11

Victoria Morris, M.S., CHP
Radiation Safety Officer
University of Cincinnati
PO Box 670591
Cincinnati, Ohio 45267-0591

Dear Ms. Morris:

I am responding to the petition for rulemaking (PRM 20-24), dated April 7, 1996, that you submitted to the U.S. Nuclear Regulatory Commission (NRC). The petition requests that the NRC amend 10 CFR 20.1301, "Dose limits for individual members of the public," to allow specified visitors of radiation patients, as members of the public, to receive up to 5 milliSievert (mSv) (0.5 rem) per year.

On June 21, 1996 (61 FR 31874), the NRC published a notice of receipt of the PRM and requested comments by November 30, 1998. Because the petition pertained to the medical use of byproduct material, a decision was made to address the final resolution of the PRM as part of the major rulemaking action to revise 10 CFR Part 35, "Medical Use of Byproduct Material."

For the reasons specified in the enclosed Federal Register notice, we believe there is merit in granting your petition, in part. In our view, your petition was overly restrictive and we did not agree with your limitations to only allow non-pregnant adult (age 18 or older) visitors, to require documentation of radiation exposures from the patient to visitors, and to require licensees to instruct visitors.

In summary, you requested that the NRC:

(1) provide medical use licensees with the discretion to permit those visitors determined by the physician to be necessary for the emotional or physical support of the patient to receive up to 5 mSv (0.5 rem) (e.g., parents of very young radiation therapy patients, close family members of elderly patients, or other persons who could provide emotional support to the patient);

(2) exclude pregnant women and individuals younger than 18 years of age from receiving a dose in excess of 1 mSv (0.1 rem);

(3) document compliance by issuing a radiation dose monitoring device (i.e., pocket dosimeter, film badge, TLD, or electronic dosimeter) to each specified visitor; and

(4) require licensees to instruct visitors about radiation safety.

We agree with the first request, but disagree with the second, third, and fourth requests for the reasons set forth below. Although we agree in principle with your second, third, and fourth requests, we believe NRC regulations should be less prescriptive and more performance-based on these points.

We amended 10 CFR 20.1301 to allow a licensee the discretion to permit visitors to receive up to 5 mSv (0.5 rem) in a year from individuals who are not to be released pursuant to 10 CFR 35.75 (e.g., hospitalized radiation patients containing unsealed byproduct material, or permanent or temporary implants of byproduct material). We believe the emotional benefit to the patient or the visitor outweighs any increase in radiation risk to the visitor.

In addition, we believe that the authorized user (AU) would be the appropriate individual to evaluate, on a case-by-case basis, the merits of allowing a visitor (regardless of age) to potentially receive this additional dose, and would do so only when it is warranted. AUs have the primary responsibility for the health and safety of their patients and for determining, depending on the patient's condition, whether individuals can visit patients and if any limitations are appropriate. Therefore, we believe the AU should determine whether a visitor is allowed to receive a dose up to 5 mSv (0.5 rem).

We did not grant the request in the petition (2) that NRC prohibit pregnant women and individuals younger than 18 years of age from receiving a dose in excess of 1 mSv (0.1 rem). Pregnant visitors are not excluded automatically from visiting individuals who cannot be released pursuant to 10 CFR 35.75. The pregnant visitor is subject to the same exposure limits that are applied to any other adult member of the public. The reasons for not excluding pregnant visitors are two-fold.

First, as noted in National Council on Radiation Protection and Measurements (NCRP) Commentary No. 11 ("Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients, 1995"), members of a radionuclide therapy patient's family are likely to perceive that visitors will benefit from providing emotional and physical support to the patient during treatment, and these visitors are likely to be willing to bear greater risk to provide that benefit.

Second, a prospective visitor's declaration of pregnancy is strictly voluntary. If a prospective visitor does not voluntarily declare her pregnant status, the AU is not expected to demand confirmation of the visitor's nonpregnant status.

We also did not grant request (3) of the petition (that compliance be demonstrated by issuing a radiation dose monitoring device such as a pocket dosimeter, film badge, TLD, or electronic dosimeter to each specified visitor). The revised rule does not specifically require monitoring and recording of individual doses to visitors of hospitalized radiation patients however, licensees will need to ensure that doses to approved visitors are less than 5 mSv (0.5 rem).

We did not grant request (4) because safety instructions are addressed in 10 CFR 35.310 and 35.410. These sections require medical use licensees to instruct their personnel who care for patients that cannot be released in accordance with 10 CFR 35.75. One of the safety instruction topics listed in these sections is visitor control to the dose limits in 10 CFR 20.1301. As the licensee's personnel work to this performance-based objective they will instruct the specified visitors about the radiation safety precautions that you stated in your petition.

In addition, the safety precautions in 10 CFR 35.315 and 35.415 require the licensee to note on the door or in the patient's chart the location and stay time for visitors. These sections reinforce the ability of the licensee's personnel to instruct the

specified visitors about time, distance, and shielding factors that will effectively limit radiation exposure from the patient to levels that are as low as are reasonably achievable.

Sincerely,

William D. Travers
Executive Director for Operations

Enclosure: Federal Register notice for Part 35 and Part 20 rulemaking

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ATTACHMENT 13

ENVIRONMENTAL ASSESSMENT FOR AMENDMENTS TO 10 CFR PART 35 "MEDICAL USE OF BYPRODUCT MATERIAL" AND PETITION FOR RULEMAKING "REVISION OF DOSE LIMIT FOR MEMBERS OF THE PUBLIC EXPOSED TO HOSPITALIZED PATIENTS" (PRM-20-24) FINDING OF NO SIGNIFICANT IMPACT

1. Background

The Nuclear Regulatory Commission (NRC) is amending its regulations for the medical use of byproduct material. The NRC has examined the issues surrounding its medical use program, and has undertaken a comprehensive revision of Part 35. The revision is one component of the Commission's overall program for revising its regulatory framework for medical use. The overall goals of this program are to focus NRC regulation of medical uses of byproduct material on those medical procedures that pose the highest risk, to make the regulatory requirements more risk-informed and performance-based, and to reduce the prescriptive nature of some of the current requirements. The rule is intended to provide greater flexibility to licensees in providing high confidence that the byproduct material or radiation from byproduct material will be administered as directed by an authorized user physician, while also providing for protection of patients and the public. In addition, as a result of the development of new medical uses involving byproduct material, certain portions of the existing regulations in Part 35 need to be updated or expanded.

NRC's Medical Use Program includes uses of byproduct material in medical diagnosis, therapy, and research. Currently, there are approximately 1,700 NRC licenses authorizing the medical use of byproduct material under 10 CFR Part 35. In addition, there are approximately 4,200 State licenses in Agreement States authorizing the medical use of byproduct material. The Commission recognizes that physicians have the primary responsibility for the diagnosis and treatment of their patients, and recognizes that nuclear pharmacists have the primary responsibility for the preparation of radioactive drugs. The Commission's regulations are predicated on the assumption that properly trained and adequately informed physicians and pharmacists will make decisions that are in the best interests of their patients.

The major features of the amendments address: (1) restructuring of Part 35 to incorporate all of the requirements that are specific for a modality into the same subpart; (2) revisions to the requirement for a Radiation Safety Committee to require only licensees 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 to establish a Radiation Safety Committee, and to provide licensees more flexibility in carrying out the responsibilities for the radiation safety program; (3) requirements for written directives to provide high confidence that the physician's prescription is administered in accordance with the physician's directions and to focus on those requirements that are essential for patient safety; (4) reporting of medical events; (5) reduction of requirements in Part 35 that are in other parts of 10 CFR, particularly Part 20; (6) reduction in the number and type of licensing actions required under Part 35; (7) revision of the training and experience requirements for authorized users, Radiation Safety Officers, authorized nuclear pharmacists, and authorized medical physicists to focus more on radiation safety; (8) reductions in recordkeeping and/or reporting requirements when there would be no health and safety impact; and (9) revisions to the decay-in-storage provisions of Part 35.

2. Need for the Amendment

The rulemaking action addressed the following issues concerning 10 CFR Part 35:

First, amendments to Subpart B - General Administrative Requirements, Subpart C - General Technical Requirements, and to Subparts D through H are needed to reduce the prescriptive nature of certain requirements of Part 35, which result in costs to licensees without commensurate health and safety benefits. Although licensees currently can seek to adopt exemptions or alternatives to some prescriptive requirements through license amendment, such licensing amendment actions are costly both to the licensee and to NRC.

Second, amendments to Subparts D through H are needed for certain established medical uses, such as high dose-rate brachytherapy, low dose-rate brachytherapy, pulsed dose-rate brachytherapy, and gamma stereotactic radiosurgery. Regulation of these technologies currently is primarily through license conditions.

Third, amendments to Part 35 are needed to provide for the licensing of new medical uses in a timely manner. Currently, new medical uses must be licensed through case-by-case reviews in which the applicant or licensee must submit a request for an exemption for medical uses that are not specifically addressed in Part 35.

Fourth, the regulations in 10 CFR 35.2 regarding thresholds for "misadministrations" are not entirely dose based. Also, new medical uses are not addressed under the current criteria, and the current requirements do not address "patient intervention" or provide a threshold for wrong treatment site. Further, the Commission directed the staff to consider changing the nomenclature from "misadministration" to "medical event."

Fifth, regarding training and experience, Subpart J includes requirements for clinical experience in all modalities, even though diagnostic procedures present a lower overall risk than that presented by therapeutic procedures. Therefore, NRC requirements for clinical experience may not be necessary for most diagnostic procedures.

Sixth, the regulations permit medical use licensees to hold byproduct material with a physical half-life less than 65 days for decay-in-storage, if it holds the byproduct material for decay before disposal in ordinary trash for a minimum of ten half-lives. Licensees now must obtain a license amendment exempting them from the requirements of § 35.92 for materials with longer half-lives or to hold material for less than ten half-lives.

Finally, a Petition for Rulemaking (PRM-20-24) received by the Commission requests a revision from 1mSv (0.1 rem) to 5mSv (0.5 rem) of the public dose limit for specified visitors of radiation therapy patients who are not released in accordance with §35.75.

In its Staff Requirements Memorandum (SRM)-COMSECY-96-057, "Materials/Medical Oversight (SDI 7)," dated March 20, 1997, the Commission directed the NRC staff to revise 10 CFR Part 35, the NRC's regulations for the use of byproduct materials in medicine; associated guidance documents; and, if necessary, the Commission's 1979 Medical Policy Statement. The Commission's SRM specifically directed the restructuring of Part 35 into a risk-informed, more performance-based regulation. During development of the rule and associated guidance, the Commission directed the NRC staff to consider the following:

(1) Focusing Part 35 on those procedures that pose the highest risk;

(2) Regulatory oversight alternatives, for diagnostic procedures, that are consistent with the lower overall risk of these procedures;

(3) The best way to capture not only medical events, but also precursor events that could lead to a medical event;

(4) The need to change from the term "misadministration" to "medical event" or other comparable terminology;

(5) Redesigning Part 35 so that regulatory requirements for new treatment modalities can be incorporated in a timely manner;

(6) Revising the requirement for a quality management program (10 CFR 35.32) to focus on those requirements that are essential for patient safety; and

(7) The viability of using or referencing available industry guidance and standards, within Part 35 and related guidance, to the extent that they meet NRC's needs.

The staff identified the following issues that also needed to be addressed:

(1) Radiation Safety Committee (RSC) requirements;

(2) Threshold for reportable events; and

(3) Training and experience requirements for authorized users, Radiation Safety Officers, authorized nuclear pharmacists, and authorized medical physicists.

3. Alternatives

The following alternatives were considered in this rulemaking:

Alternative One: Status quo.

Continue 10 CFR Part 35 without revision. Deny PRM-20-24 and retain the 1mSv (0.1 rem) public dose limit for visitors of radiation therapy patients on the basis that there are sufficient provisions within 10 CFR 20.1301(c) to allow case-by-case use of the 5mSv (0.5 rem) annual dose limit for visitors of radiation patients.

Alternative Two: Comprehensive revision of Part 35.

Promulgate comprehensive amendments that focus NRC regulation of medical uses of byproduct material on those medical procedures that pose the highest risk, restructure the regulatory requirements into more risk-informed, performance-based standards, and relax or eliminate certain prescriptive requirements currently contained in Part 35. Promulgate new requirements pertaining to low dose-rate, pulsed dose-rate, and high dose-rate remote afterloaders, gamma stereotactic radiosurgery units, and mobile remote afterloaders. Promulgate a new dose limit of 5mSv (0.5 rem) for visitors of radiation patients, as requested under PRM-20-24.

The no-action alternative is not favored because, based on the information presented to it, the Commission believes that its current regulations may be unnecessarily prescriptive and are not sufficiently risk-informed and performance-based. The Commission believes that greater flexibility can be provided, while continuing adequate protection of public health and safety.

4. Impact on the Public and the Environment

The amendments would have no significant impact on the public and the environment.

The amendments to the general administrative requirements and general technical requirements, and to Subparts D through H of Part 35, reducing the prescriptive nature of certain sections of Part 35, and deleting requirements that are covered in other parts of NRC's regulations will have no significant impact on public health and safety, occupational health and safety, or the environment. First, 10 CFR Part 20 continues to require medical licensees to develop ALARA programs; possess, use, calibrate, and check instruments; conduct surveys for contamination and ambient radiation exposure; and ensure the control of volatiles and gases. Reliance on 10 CFR Part 20 is expected to have no significant impact on public health and safety, occupational health and safety, or the environment. Second, the amendments to Part 35, reducing the overly prescriptive nature of certain requirements and making them more risk-informed and performance-based, will allow licensees greater flexibility in the development and implementation of their radiation safety programs associated with the use of byproduct materials in medicine, but the amendments are expected to result in no significant impact on public health and safety, occupational health and safety, or the environment.

The amendments to Subparts D through H that place the basis for regulation of high dose-rate brachytherapy, low dose-rate brachytherapy, pulsed dose-rate brachytherapy, and gamma stereotactic radiosurgery units into the requirements in Part 35 will codify existing license conditions. This is expected to have no significant impact on public health and safety, occupational health and safety, or the environment.

The amendments to Part 35 regarding new medical uses provide information that is needed for submission of a license application, which should result in expedited licensing for new medical uses. This is expected to have no significant impact on public health and safety, occupational health and safety, or the environment.

The amendments to the requirements for reporting medical events would have a positive impact on public health and safety and the environment by helping to ensure that affected persons and the NRC are informed about conditions or incidents that have caused, or could cause, a medical event involving a patient or human research subject, dose to an embryo/fetus or a nursing child, worker or member of the public.

The amendments to the training and experience requirements in Part 35 focus on knowledge and experience that is integral to radiation safety. These changes are expected to have no significant impact on public health and safety, occupational health and safety, and the environment.

The amendment of § 35.92, pertaining to decay-in-storage, provides that byproduct material with a physical half-life of less than 120 days may be held for decay-in-storage before disposal without regard to its radioactivity and eliminates the requirement that such material be held for a minimum of ten half-lives. Licensees will be required to monitor the material at the surface before disposal to verify that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set at its most sensitive scale and with no interposed shielding, and to remove or obliterate all radiation labels except for material that will be handled as biomedical waste after it has been released from the licensee. These changes are expected to have no significant impact on public health and safety, occupational health and safety, or the environment.

The amendment in 10 CFR 20.1301 to permit, on a case-by-case basis, consenting adult, nonpregnant visitors to receive up to 5mSv (0.5 rem) in a year from exposure to radiation therapy patients, is expected to result in an increase in radiation exposure to the public. However, this alternative is considered acceptable, according to generally accepted radiation protection principles, such as those expressed by NRC, the National Council on Radiation Protection (NCRP), the International Atomic Energy Agency (IAEA), and the International Commission on Radiological Protection (ICRP).

Therefore, with the exception of the amendment to 10 CFR 20.1301, the rulemaking action will not lead to any increase in radiation exposure to the public, health care workers, or the environment. Revisions to the regulatory specifications to reduce the prescriptiveness of the requirements are not expected to lead to any increase in radiation exposure to the public, health care workers, or the environment, beyond the exposures currently resulting from the administration of byproduct material or radiation from byproduct material. Revisions to the requirements to focus on those requirements that are essential for patient safety will not lead to any increase in radiation exposure to the public, health care workers, or to the environment. These revisions would not increase radiation exposure because the performance-based regulations would provide for adequate protection. Reduction or elimination of duplication or overlaps between Part 35 and other parts of 10 CFR, particularly Part 20, will not lead to any increase in radiation exposure to the public, health care workers, or to the environment.

5. List of Agencies and Persons Consulted and Identification of Sources Used

The program for revising Part 35 and the associated guidance documents has involved more interactions and consultations with potentially affected parties (the medical community and the public) than is provided by the typical notice and comment rulemaking process. The NRC published an announcement of its proposed revision of Part 35 and a request for public input on NRC's medical use program in a Federal Register notice on August 6, 1997 (62 FR 42219). In response, NRC received numerous written comments, which were reflected in the proposed rule, published on August 14, 1998 (63 FR 43516). The NRC received numerous public comments on the proposed rule, which are reflected in the final rule.

To ensure that the interests affected by the medical use rulemaking were given an early opportunity to comment on the rulemaking alternatives, the Commission convened or participated in a number of public workshops to discuss the fundamental approaches and issues to be addressed in the rulemaking. NRC participated in a Part 35 workshop held during the Organization of Agreement States' All Agreement State meetings in October 1997 and October 1998. The All Agreement States workshops were attended not only by representatives of the 30 Agreement States, but also by the public. NRC convened two facilitated public workshops, in Philadelphia, Pennsylvania on October 28, 29, and 30, 1997, and in Chicago, Illinois on November 12, 13, and 14, 1997. (See 62 FR 53249; October 14, 1997) These workshops were attended by nuclear medicine physicians; radiation oncologists; other specialists (e.g., cardiologists, radiologists); radiation safety officers; medical physicists; medical technologists; nurses; medical education and certification organizations; radiopharmaceutical interests; hospital administrators; patients' rights advocates; Agreement States; Federal agencies; and members of the public. In addition, the Advisory Committee on the Medical Uses of Isotopes (ACMUI), an NRC advisory committee, discussed the issues raised by the proposed rulemaking in its semiannual meetings in 1997, 1998, and 1999. The ACMUI meetings were open to the public. Finally, NRC staff participated in meetings with numerous groups representing physicians, pharmacists, medical physicists, technicians, and other stakeholders.

Public input also was obtained by holding open meetings of the government groups developing the revised rule language; putting background documents, options for the more significant regulatory issues associated with the rulemaking, a "strawman" draft proposed rule, and the draft proposed rule on the Internet; and convening public workshops.

In addition, the rulemaking process used a working group, steering group, and guidance consolidation team that included not only members from the NRC Headquarters offices, but also members from the regional licensing and inspection staff who are in frequent contact with NRC's medical licensees. Representatives of two Agreement States and a non-Agreement State were members of the groups developing the rule and guidance. The Agreement State representative on the working group also is a member of the Conference of Radiation Control Directors' Suggested State Regulation Committee on Medical Regulation, which is working toward parallel development of suggested State regulations. State participation in the process was intended to enhance development of corresponding rules in State regulations and provide an early opportunity for State input. In addition, it allowed the State staff to assess the potential impacts of NRC draft language on the regulation of non-Atomic Energy Act materials used in medical diagnosis, treatment, or research in the States. The meetings of the groups developing the rule text and the associated guidance were noted in the NRC meeting announcements and were open to the public. The NRC also held public workshops during the public comment period on the rulemaking, and extended the public comment period to allow additional responses to be prepared and submitted..

6. Finding of No Significant Impact

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that the amendments, if adopted, would be a major Federal action but would not significantly affect the quality of the human environment, and therefore an environmental impact statement is not required. The amendments would relax certain requirements and eliminate other procedural restrictions associated with the medical use of byproduct material. The Commission believes these amendments would provide greater flexibility in the medical use of byproduct material while continuing to adequately protect public health and safety. It is expected that this rule, if adopted, would not cause any significant increase in radiation exposure to the public or radiation release to the environment beyond the exposures or releases currently resulting from the medical use of byproduct material.

Regulatory Flexibility Analysis

The NRC is required by the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) to consider the impact of its rulemakings on small entities and evaluate alternatives that would accomplish regulatory objectives without unduly burdening small entities or erecting barriers to competition. This paper describes the assessment of the small entity impacts expected to be incurred by 10 CFR Part 35 licensees as a result of the comprehensive revisions to Part 35.

This analysis describes (1) the NRC's definition of "small entities," including "small businesses," "small governmental jurisdictions," and "small organizations;" (2) what number constitutes a "substantial number" of these entities; (3) whether "significant impacts" will be incurred by licensees under the rule; and (4) the measures that NRC has adopted in the rule to mitigate impacts on small entities.

1.1 Defining "Small Entities" Affected by the Rule

The NRC has established size standards that it uses to determine which NRC licensees qualify as small entities (60 FR 18344; April 11, 1995). These size standards are codified in 10 CFR 2.810. The size standards pertinent to Part 35 licensees include the following:

Under 10 CFR 2.810 (a)(1), a small business is a for-profit concern and is a concern that provides a service or a concern not engaged in manufacturing with average annual gross receipts of $5 million or less over its last 3 completed fiscal years. (The Small Business Administration size standards for the "health services" category, including "offices and clinics of doctors of medicine" and all other health services subcategories also establish $5 million as the cut off point for "small entities.")

Under 10 CFR 2.810 (b), a small organization is a not-for-profit organization which is independently owned and operated and has annual gross receipts of $5 million or less.

Under 10 CFR 2.810(c), a small governmental jurisdiction is a government or a city, county, town, township, village, school district or special district with a population of fewer than 50,000 persons.

Under 10 CFR 2.810(d), a small educational institution is one that is (1) supported by a qualifying small governmental institution; or (2) not State or publicly supported and has 500 or fewer employees.

For purposes of this analysis, therefore, "small entity" refers to any specific medical licensee under 10 CFR Part 35 with annual gross receipts of $5 million or less, or a government medical institution licensee serving a population of less than 50,000.

The rule would affect about 1688 NRC licensees. These licenses are issued principally to medical institutions, with at least 1015 of the Part 35 licensees classified as medical institutions (codes 2110, 2120, and 2121 in NRC's licensee tracking system).

In 1998, NRC performed an analysis that indicated that, at most, eight of these medical institutions had operating revenues of less than $5 million in 1996 (the most recent year for which all necessary data were available). First, all hospitals in States in which Part 35 licensees are regulated by NRC first were screened for revenues (because annual gross receipts data were not available), using data obtained from Profiles of U.S. Hospitals, 1996, HCIA Inc. HCIA collects, analyzes, and publishes data on hospitals, based on financial submissions to the Health Care Financing Administration (HCFA). Revenues were measured as operating revenue, which is the sum of net patient revenue and other operating revenue, such as revenue from sources such as cafeterias and parking facilities, but which does not include revenue from non-operating sources such as investment income or donations. Operating revenue therefore is a less inclusive measure of revenues than gross revenues or annual gross receipts. All hospitals identified as having operating revenues less than $5 million then were checked against the NRC License Tracking System to identify those medical institutions that both had operating revenues less than $5 million and were regulated by NRC under Part 35. Of the eight institutions that were identified as meeting both criteria, three had operating revenues above $4.4 million, and therefore may have annual gross receipts above $5 million. They were, however, included in the group of institutions with less than $5 million in revenues for this analysis. Available data indicate substantial growth in annual receipts for hospitals between 1996 and 1997 (U.S. Census Bureau, Statistical Abstract of the United States, 1999, Table 192. Annual Receipts/Revenue for the Health Service Industries: 1990 to 1997), suggesting that this result overstates the number of NRC licensed medical institutions with annual gross receipts below $5 million.

Because NRC licensees that are government organizations serving populations of less than 50,000 pay reduced fees (64 FR 31448, June 10, 1999), the NRC has data on the number of Part 35 licensees who certified that they qualified as small entities for reduced fee purposes between 5/01/99 and 4/30/00. Based on self-certification by such entities, a substantially higher estimate was obtained of medical institutions that can be classified as small government entities on the basis of the population that they serve. Sixty-seven such licensees were identified.

The balance of the licenses, approximately 673 licenses, are issued principally to physicians in private practice. Information on annual gross receipts is not available, but information is available on annual revenues for such physicians.

First, data from the AMA's Socioeconomic Monitoring System, provided in Physician Socioeconomic Statistics 1999-2000 Edition: Profiles for Detailed Specialties, Selected States and Practice Arrangements, Center for Health Policy Research, American Medical Association, provides data from the AMA's Socioeconomic Monitoring System. Table 45, "Practice Revenue per Self-employed Physician, 1997 (in thousands of dollars)" indicates that at the 75th percentile only one physician specialty (Cardiovascular Diseases), and no geographic area, or practice arrangement exceeded $1 million in annual revenues. These results were based on a survey of 1,189 physicians, including physicians from over 20 different specialties. Therefore, a relatively small part of the sample is likely to be representative of Part 35 licensees. Data from the Physician Compensation and Production Survey: 1996 Report Based on 1995 Data, Medical Group Management Association, are similar. The median for "production," defined as gross charges, for all physicians was $422,937 in 1995 (p. 10). Although "production" generally is larger for specialists than all physicians, the difference is too small to place specialists above the $5 million criterion.

Because NRC licensees with annual gross receipts below $5 million pay reduced fees (64 FR 31448, June 10, 1999), NRC has data on the number of Part 35 licensees who certified that they qualified as small entities for reduced fee purposes between 5/01/99 and 4/30/00. A total of 334 Part 35 licensees reported that their annual gross receipts were below $5 million (236 below $5 million plus 97 below $350,000).

In total, therefore, the proportion of all NRC Part 35 licensees that are small entities could be as high as 44 percent (67 licensees in categories 2110, 2120, and 2131 and 673 in the remaining Part 35 categories, for a total of 740 out of 1688) or as low as 20 percent (334 out of 1688, based on self-reported data).

1.2 Determining What Number Constitutes a Substantial Number

NRC has not established a quantitative definition of the number or proportion of licensees that constitutes a substantial number. Even relying on the low estimate, however, it appears that over 300 licensees or 20 percent of all licensees constitutes a "substantial number" of small entities likely to be impacted by this rule. A substantial number of both of the two categories of licensees considered, medical institutions and individual private medical practitioners, are impacted by the rule.

1.3 Measuring "Significant Impacts"

To evaluate the impact that a small entity is expected to incur as a result of the rule, the ratio of annualized compliance costs was calculated as a percentage of gross receipts. Although NRC has not established a quantitative cutoff for "significant impact," entities were classified as facing potentially "significant" impacts if the ratio of annualized compliance costs to annual gross receipts exceeds one percent.

Determining annual compliance costs for this rule is complicated by the fact that the Part 35 rule comprehensively addresses a wide variety of uses of byproduct materials in medicine. The entities likely to be most affected by the rule are broad scope medical institutions with a large number of different modalities and conducting a large number of medical procedures involving byproduct material or radiation therefrom. However, the preceding analysis indicated that, at most, very few broad scope licensees are small entities. The costs attributable to Part 35 compliance for such broad scope licensees will be substantially greater than the annual compliance costs likely to be incurred by those licensees most likely to be small entities (i.e., single private practice physicians performing diagnostic procedures).

An additional complicating factor in calculating annual compliance costs likely to be incurred by licensees is that the Part 35 rule addresses contingent actions as well as actions that must be carried out by all licensees. In particular, the lower risk posed by diagnostic procedures reduces the likelihood that private practice physicians performing diagnostic procedures will experience medical events involving costs of reporting and followup. Licensees using unsealed byproduct material for uptake, dilution, and excretion studies or for imaging and localization studies are not required to prepare a written directive if they meet the criteria of Subpart D. Certain licensees may rely on a decay correction to determine the dosage of unsealed byproduct material for medical use, based on the activity or activity concentration determined by a manufacturer or preparer or an NRC or Agreement State licensee. Other contingencies include whether a licensee is 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. Only such licensees are required to establish a Radiation Safety Committee.

All licensees will incur annual compliance costs for general administrative and technical requirements established by Part 35, although the level of such compliance costs will vary significantly depending on the activities being performed by the licensee and other contingencies, such as those described above. Annual compliance costs for licensees are expected, in all cases, to involve compliance with requirements to establish and maintain a radiation safety program and compliance with those requirements pertinent to the modality or modalities used by the licensee. NRC estimates that annual compliance costs for a licensee will in all cases exceed 80 hours annually at $100 per hour, or $8,000.

Assuming annual revenues of $244,000 for a single private practitioner subject to Part 35,[(1)] or alternatively average annual "production" of $422,000, annual compliance costs as low as $8,000 per year exceed the one percent criterion for "significant impacts." Therefore, the proposed rule appears to affect a substantial number of licensees that are small entities, and to have a significant economic impact on those small entities.

1.4 Steps taken to Mitigate Economic Impacts on Small Entities

NRC has taken a number of actions in this rule to ensure that the selected alternative is the least costly alternative that adequately protects workers and patients from radiation exposure. As the Regulatory Analysis prepared for this rule demonstrates, the total annual cost to licensees (of both NRC and Agreement States) of compliance with the amended rule would be over $10.7 million less than the cost of compliance with the current rule. This is equivalent to savings of approximately $1,800 per licensee. (NRC notes that such savings will not necessarily be reflected in lower fees to licensees, because they are derived from lower costs of compliance due to the less prescriptive nature of the revised Part 35 regulations.) Although savings to small licensees can be expected to be proportionately less than savings to licensees with more extensive operations, smaller licensees also can be expected to incur smaller compliance costs.

In order to assist small licensees, the NRC has sought to eliminate prescriptive requirements wherever possible, and to allow for much greater flexibility in compliance. Such flexibility is particularly helpful to small licensees in reducing their cost of compliance, because it will enable them to avoid the costs of radiation safety measures, such as the detailed requirements for Radiation Safety Committees, that were especially oriented toward larger licensees with numerous modalities and activities in the same institution. NRC has reduced the training and experience requirements applicable to the diagnostic use of byproduct material by focusing those requirements on radiation safety and by reducing the number of hours of training required. NRC also has sought to reduce the prescriptive nature of requirements for testing and calibration, and to reduce reporting and recordkeeping burdens, which can have an especially strong impact on small entities.

Finally, the program for revising Part 35 and the associated guidance documents has involved numerous interactions and consultations with potentially affected parties (the medical community and the public, including representatives of small licensees) than is provided by the typical notice and comment rulemaking process. Early public input was solicited through several different mechanisms: requesting public comment through documents published in the Federal Register; holding open meetings of the government groups developing the revised rule language; meeting with medical professional societies and boards; putting background documents, options for the more significant regulatory issues associated with the rulemaking, and a "strawman" draft proposed rule on the Internet; convening public workshops, both before and after the publication of the proposed rule; and extending the public comment period on the proposed rule.

ATTACHMENT 15

5/12/00

SUPPORTING STATEMENT
FOR
10 CFR PART 35
MEDICAL USE OF BYPRODUCT MATERIAL
(3150-0010)
AND
NRC FORM 313
APPLICATION FOR MATERIAL LICENSE, AND
SUPPLEMENTAL FORMS
NRC FORM 313A, TRAINING AND EXPERIENCE AND
NRC FORM 313B, PRECEPTOR STATEMENT
(3150-0120)
AND
10 CFR PART 20
STANDARDS FOR PROTECTION AGAINST RADIATION
(3150-0014)
COMPLETE REVISION OF PART 35

- § 35.51 Training for an authorized medical physicist
- § 35.55 Training for an authorized nuclear pharmacist
- § 35.60 Possession, use, and calibration of instruments used to measure the activity of byrpoduct 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
- § 35.70 Surveys for ambient radiation exposure rate
- § 35.75 Release of individuals containing unsealed byproduct material or implants containing byproduct material
- § 35.80 Provision of mobile service

- § 35.92 Decay-in-storage
- § 35.190 Training for uptake, dilution, and excretion studies
  - § 35.204 Permissible molybdenum-99 concentration
- § 35.290 Training for imaging and localization studies
  - § 35.310 Safety instruction
- § 35.315 Safety precautions
  - § 35.390 Training for use of unsealed byproduct material for which a written directive is required
- § 35.392 Training for oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries)
  - § 35.394 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicurioes)
- § 35.404 Surveys after source implant and removal
- § 35.406 Brachytherapy sources accountability
  - § 35.410 Safety instruction
  - § 35.415 Safety precautions
  - § 35.432 Calibration measurements of brachytherapy sealed sources
  - § 35.433 Decay of strontium-90 sources for ophthalmic treatments
  - § 35.490 Training for use of manual brachytherapy sources
  - § 35.491 Training for opthalmic use of strontium-90
  - § 35.590 Training for use of sealed sources for diagnosis
  - § 35.604 Surveys of patients and human research subjects treated with a remote afterloader unit
  - § 35.605 Installation, maintenance, adjustment, and repair
  - § 35.610 Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units
  - § 35.615 Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units
  - § 35.630 Dosimetry equipment
  - § 35.632 Full calibration measurements on teletherapy units
  - § 35.633 Full calibration measurements on remote afterloader units
  - § 35.635 Full calibration measurements on gamma stereotactic radiosurgery units
  - § 35.642 Periodic spot-checks for teletherapy units
  - § 35.643 Periodic spot-checks for remote afterloader units
  - § 35.645 Periodic spot-checks for gamma stereotactic radiosurgery units
  - § 35.647 Additional technical requirements for mobile remote afterloaders
  - § 35.652 Radiation surveys
  - § 35.655 Five-year inspection for teletherapy and gamma stereotactic radiosurgery units
  - § 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units
  - § 35.1000 Other medical uses of byproduct material or radiation from byproduct material
  - § 35.2024 Records of authority and responsibilities for radiation protection programs
  - § 35.2026 Records of radiation protection program changes
  - § 35.2040 Records of written directives
  - § 35.2045 Records of medical events
  - § 35.2047 Record of a dose to an embryo/fetus or a nursing child
  - § 35.2060 Records of calibrations of instruments to measure the activity of unsealed byproduct materials
  - § 35.2061 Records of radiation survey instrument calibrations
  - § 35.2063 Records of dosages of unsealed byproduct material for medical use
  - § 35.2067 Records of possession of sealed sources and brachytherapy sources
  - § 35.2070 Records of surveys for ambient radiation exposure rate
  - § 35.2075 Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material
  - § 35.2080 Records of administrative and technical requirements that apply to the provision of mobile medical services
  - § 35.2092 Records of decay-in-storage
  - § 35.2204 Records of molybdenum-99 concentration
  - § 35.2310 Records of safety instruction
  - § 35.2404 Records of surveys after source implant and removal
  - § 35.2406 Records of brachytherapy source accountability
  - § 35.2432 Records of calibration measurements of brachytherapy sealed sources

Part 35 of Title 10 of the Code of Federal Regulations contains the Nuclear Regulatory Commission's requirements and provisions for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material.

This clearance package covers the requirements for all sections of Part 35, including the "Quality Management Program and Misadministrations," currently cleared under OMB Clearance No. 3150-0171. The current requirements in 10 CFR 35.32 to submit and maintain a Quality Management Program are being eliminated. However, the requirements in § 35.32 associated with written directives are being retained to provide high confidence that byproduct material will be administered as directed by the authorized user. These requirements are included in § 35.40 of the rule. The current requirements in 10 CFR 35.32 and 35.33 defining misadministrations and requiring notifications, reports, and records of misadministrations are being modified to refer instead to "medical events," to address patient intervention and wrong treatment site, and to make the reporting threshold dose-based where possible. These requirements are included in § 35.3045 of the rule. New requirements are being promulgated concerning reporting and notification of a dose to an embryo/fetus or a nursing child. These requirements are included in § 35.3047 of the rule. The recordkeeping and reporting requirements of Part 35 have been centralized into two Subparts: Subpart L - Records (§§ 35.2024-2655) and Subpart M - Reports (§§ 35.3045-3067). Cross references to the recordkeeping requirements appear in other related portions of the Part 35 rule, but these cross references do not constitute additional recordkeeping requirements.

This clearance package covers the requirements of new training and experience requirements in Subparts B and D-H of the rule. The current Subpart J, "Training and experience requirements," which is §§ 35.900 - 35.981 of the current Part 35, has been eliminated.

The burden for the new training and experience requirements in Subparts B and D-H of the rule are related as appropriate to the clearance for NRC Form 313, "Application for Material License," OMB Clearance No. 3150-0120, or to this clearance package for Part 35 requirements. Additional burdens not captured in the current clearance for NRC Form 313 are identified in this submittal. This submittal also includes the supplemental forms NRC Form 313A, "Training and Experience," and NRC Form 313B, "Preceptor Statement," which allow applicants to more easily present information required to be included in the NRC Form 313 submittal. The burden for this collection of information is already included in the current clearance for NRC Form 313 (OMB Clearance No. 3150-0120). However, the supplemental forms have never been submitted to OMB for review. Subsequent references to "NRC Form 313" are intended to refer to NRC Form 313, including the supplemental forms NRC Form 313A and NRC Form 313B.

This clearance package also covers the application for recognition by NRC or an Agreement State of an organization whose certification process constitutes recognized training. Submission of a letter by a medical speciality board to be recognized by NRC is expected to be a one-time burden.

The new total hour burden basis for the revised Part 35 rule information collections is provided in this submittal.

General requirements for radiation protection that are applicable to all NRC licensees are contained in 10 CFR Part 20. There are no burden changes to 10 CFR Part 20.

A. Justification

Part of the NRC's function is to license and regulate the medical use of byproduct materials, as provided by the Atomic Energy Act (AEA) as amended, in order to provide for the radiation safety of workers, the general public, and patients. Licensees must perform certain tasks, maintain records, and prepare reports to demonstrate their fulfillment of regulatory requirements. The records required by Part 35 are the least burdensome way for licensees to demonstrate compliance with the NRC's requirements. However, certain safety matters are of such significance that they must be reported to the NRC, to patients or human research subjects, and to referring physicians. Collection of this information enables the NRC to determine whether such events have been investigated by the licensee, whether required notifications have been made, and whether corrective actions have been taken. In addition, NRC has the responsibility to inform Congress of those events constituting "abnormal occurrences" and to inform medical use licensees of generic issues identified by the NRC review of medical events. In such cases, reports to NRC, patients or human research subjects, and referring physicians are required.

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

§ 35.6 Provisions for the protection of human research subjects

This section requires a licensee whose research is conducted, funded, supported, or regulated by another Federal agency that has implemented the Federal Policy for the Protection of Human Subjects, prior to conducting research, to obtain review and approval of the research from an "Institutional Review Board (IRB)," as defined and described in the Federal Policy and obtain "informed consent" from the human research subject. This review and approval is needed to evaluate the licensee's compliance with the requirements for the protection of human subjects. Informed consent is needed to ensure that the human research subject is informed of any potential risks and voluntarily agrees to them.

This section also requires a licensee whose research is not conducted, funded, supported, or regulated by another Federal Agency which has implemented the Federal Policy for the Protection of Human Subjects to apply for and receive approval of a specific amendment to its NRC medical use license before conducting such research. The amendment request must include a written commitment that the licensee will, prior to conducting research: (1) obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and (2) obtain "informed consent," as defined and described in the Federal Policy, from the human research subject. This information is needed to enable the Commission to evaluate the licensee's compliance with the requirements for the protection of human subjects.

§ 35.12 Application for license, amendment, or renewal

Paragraphs 35.12 (b) and (c) require that an application for a license for medical use of byproduct material as described in §§ 35.100, 35.200, 35.300, 35.400, 35.500, 35.600, and 35.1000 must be made by filing an original and one copy of either NRC Form 313, "Application for Material License," or a letter requesting the amendment or renewal that includes the facility diagram, equipment, and training and experience qualifications of the Radiation Safety Officer, authorized user(s), authorized medical physicist(s), and authorized nuclear pharmacist(s); and submitting procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable. The form elicits a description of the applicant's complete radiation safety program. An application must be signed by the applicant's or licensee's management.

Paragraph 35.12(c) also requires that a request for a license amendment or renewal must be made by submitting an original and one copy in letter format, and submitting procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable.

The burden for Paragraphs 35.12 (b) and (c) is cleared under OMB Clearance No. 3150-0120, which should be referred to for additional supporting information, burden and cost data.

Paragraph 35.12(d), in addition to the requirements in paragraphs (b) and (c) of this section, requires that an application for a

license or amendment for medical use of byproduct material as described in § 35.1000 must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in the requirements of Subparts A through C of this part. The applicant also is required to provide specific information on (1) radiation safety precautions and instructions, (2) methodology for measurement of dosages or doses to be administered to patients or human research subjects, and (3) calibration, maintenance, and repair of instruments and equipment necessary for radiation safety. The applicant or licensee also is required to provide any other information requested by the Commission in its review of the application. This information is needed to enable the Commission to evaluate the merits of a license application for a new medical use of byproduct material.

The new burden for new modalities to be submitted on the NRC Form 313 (OMB Clearance No. 3150-0120) is included in Table 6 for NRC licensees and Table 8 for Agreement State licensees..

§ 35.13 License amendments

This section requires that licensees apply for and receive a license amendment before receiving, preparing, or using material for medical uses that are permitted under Part 35, but are not authorized by the licensee's current license under this part; before permitting anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license; before changing Radiation Safety Officers (RSO), except as provided in § 35.24(c); before receiving byproduct material in excess of the amount or in a different form than is authorized on the license, or receiving a different radionuclide than is authorized on the license; before adding or otherwise changing the area of use identified in the application or on the license, except for areas where byproduct material is used in accordance with §§ 35.100 and 35.200; before changing the address(es) of use identified in the application or on the license, and before revising procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable, where such revision reduces radiation safety. The information is necessary to determine the licensee's ability to control radiation dose to workers and the public, and for NRC to contact the licensee or conduct an inspection of the licensee's program. The information also is required so that the NRC can determine whether the licensee has individuals with adequate training and experience to use radioactive material safely, and has the facilities and equipment necessary to ensure protection of public health and safety.

The burden for Section 35.13 is included in the information collection burden for NRC Form 313 (OMB Clearance No. 3150-0120).

§ 35.14 Notifications

Paragraph 35.14(a) requires that licensees provide to the Commission a copy of the board certification, the Commission or Agreement State license, the permit issued by an NRC master materials license, or the permit issued by a licensee of broad scope for each individual no later than 30 days after the date the licensee permits the individual to work as an authorized user (AU), as an authorized nuclear pharmacist (ANP), or as an authorized medical physicist (AMP). The information is required so that the NRC can determine whether the licensee has individuals with adequate training and experience to safely use radioactive material, and has the facilities and equipment necessary to assure protection of public health and safety.

Paragraph 35.14(b) requires that licensees notify the NRC by letter no later than 30 days after an ANP, AU, AMP, or RSO permanently discontinues performance of duties under the license or has a name change; when the licensee's mailing address changes; when the licensee has a name change that is not a transfer of control of the license; or when licensees authorized for use of byproduct material under §§ 35.100 and 35.200 have added to or changed the areas of use identified in the application or on the license. The report for AU and ANP is required in order to maintain the licensee's file with a current record of individuals authorized to use or prepare radioactive material. The report for changes in "key" workers is required because, if the licensee no longer has a complete staff, the collective training and experience of the remaining staff may no longer be sufficient to ensure the safety of all licensed users. This report will trigger a check of the licensee's file to determine whether the licensee's remaining users are qualified to receive and use radioactive material safely. The NRC needs to be aware of name and mailing address changes to ensure that the licensee continues receiving correspondence such as information notices, bulletins, and other safety related documents. The NRC needs to be aware of changes of areas of use so that NRC can determine if the facilities are adequate to assure protection of public health and safety.

§ 35.19 Specific exemptions

Section 35.19 provides that upon application or any interested person or upon its own initiative, the Commission may grant exemptions from the regulations in Part 35 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. Applications for and granting of specific exemptions will allow NRC to make provision for special circumstances outside the normal purview of the regulations.

§ 35.24 Authority and responsibilities for the radiation protection program

Paragraph 35.24(a) requires a licensee's management to approve requests for license application, renewal, or amendment prior to submittal; any individual, prior to allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and radiation protection program changes that do not require an amendment and are permitted under § 35.26. Management approval is necessary to ensure that actions affecting the radiation protection program have been reviewed by responsible licensee officials.

Paragraph 35.24(b) requires a licensee's management to appoint a Radiation Safety Officer, who agrees in writing to be responsible for implementing the radiation protection program. A licensee may permit an authorized user or an individual qualified to be a Radiation Safety Officer to function as a temporary Radiation Safety Officer, and a licensee may simultaneously appoint more than one temporary Radiation Safety Officer. The written agreement from the Radiation Safety Officer (including temporary Radiation Safety Officers) is needed to record the acceptance by the Radiation Safety Officer of all of the obligations of the post

Paragraph 35.24(c) requires a licensee that appoints a temporary Radiation Safety Officer to notify the Commission in accordance with § 35.14(b). The report of temporary Radiation Safety Officers is required because a licensee may permit an authorized user or an individual qualified to be a Radiation Safety Officer to function as a temporary Radiation Safety Officer only for up to 60 days each year.

Paragraph 35.24(e) requires a licensee to establish in writing the authority, duties, and responsibilities of the Radiation Safety Officer, so that the duties and responsibilities of the Radiation Safety Officer are clearly defined, and the Radiation Safety Officer is provided sufficient authority to assure that the licensee's radiation safety activities are being performed in accordance with regulatory requirements.

Paragraph 35.24(f) requires licensees who are 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, to establish a Radiation Safety Committee to oversee all uses of byproduct material permitted by the license. The requirement to establish a Radiation Safety Committee to oversee the radiation protection program provides assurance both to the licensees and to NRC that all of the different departments and diverse professional staff are aware of changes, needs, and issues related to the licensee's radiation protection program.

Paragraph 35.24(h) requires that a record of actions taken pursuant to paragraphs (a), (b) and (e) be retained in accordance with § 35.2024. A description of the contents of the record and the need for the record is provided under § 35.2024.

§ 35.26 Radiation protection program changes

Paragraphs 35.26(a) allows a licensee to revise its radiation protection program without Commission approval if the revision does not require an amendment under § 35.13; the revision is in compliance with the regulations and the license; the revision has been reviewed and approved by the Radiation Safety Officer and licensee management; and the affected individuals are instructed on the revised program before the changes are implemented. Review and approval by licensee management will allow a licensee to make some changes in their radiation safety program, provided that the changes do not reduce radiation safety.

Paragraph 35.26(b) requires a record of each change to be retained in accordance with § 35.2026. A description of the contents of the record and the need for the record is provided under § 35.2026.

§ 35.27 Supervision

Paragraph 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 as allowed by § 35.11(b) to instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, 10 CFR Part 35 regulations, and license conditions with respect to the use of byproduct material. This instruction is necessary to provide high confidence that the supervised individual knows and follows all necessary radiation protection procedures.

Paragraph 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 § 35.11(b)(2) to instruct the supervised individual in the preparation of byproduct material for medical use and requires 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, radiation protection procedures, Part 35 regulations, and license conditions.. This instruction is necessary to provide high confidence that the supervised individual properly prepares byproduct material for medical use.

§ 35.40 Written directives

Paragraph 35.40(a) requires licensees, prior to certain specified medical administrations or procedures involving I-131 sodium iodide greater than 1.11 Megabequerels (Mbq), administrations of a therapeutic dosage of unsealed byproduct material other than sodium iodide I-131, gamma stereotactic radiosurgery, teletherapy, high dose-rate remote afterloading brachytherapy, and all other brachytherapy, to have prepared a written directive containing the patient or human research subject's name, dose, and certain specified information pertaining to the administration or procedure, as specified in § 35.40(b). If an oral directive is used because of the emergent nature of the patient's condition, subsection 35.40(a)(1) requires the information in the oral directive to be documented as soon as possible in writing in the patient's record and a written directive must be prepared within 48 hours of the oral directive. Documenting an oral directive is needed to ensure that complete record is made of the administration or procedure.

Paragraph 35.40(c) requires that a written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration. If an oral directive is used because of the emergent nature of the

patient's condition, an oral revision to an existing written directive must be documented as soon as possible in the patient's record and a revised written directive must be signed by the authorized user within 48 hours of the oral revision. Documenting an oral directive is needed to ensure that complete record is made of the administration or procedure.

Paragraph 35.40 (d) requires the licensee to retain the written directive in accordance with § 35.2040. A description of the record and the need for the record is provided under § 35.2040. Preparation of a written directive is necessary to provide high confidence that byproduct material will be administered as directed by the authorized user physician.

§ 35.41 Procedures for administrations requiring a written directive

Paragraph 35.41(a) requires licensees to develop, maintain, and implement written procedures for any administration requiring a written directive to provide high confidence that the patient or human research subject's identity is verified prior to each administration and that each administration is in accordance with the written directive. These procedures are necessary to ensure that administrations that require a written directive are given as directed by the authorized user physician.

§ 35.50 Training for Radiation Safety Officer

Paragraph 35.50(a) requires a Radiation Safety Officer (RSO) to be certified by a specialty board whose certification process satisfies the requirements of § 35.50(b) and whose certification has been recognized by the Commission or an Agreement State. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an RSO.

The certification information required by § 35.50(a) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

Paragraph 35.50(b)(2) requires that an individual obtain a written certification, signed by a preceptor Radiation Safety Officer, that the educational requirements in paragraph 35.50 (b)(1) have been satisfactorily completed and that the individual has achieved a level of competency sufficient to function independently as a Radiation Safety Officer for a medical use licensee. This written certification is necessary to ensure that an individual fulfilling the responsibilities of an RSO has met the necessary training and experience requirements in § 35.50.

The certification information required by § 35.50(b)(2) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120. The burden under § 35.50(b)(2) for an individual to obtain the signed certification from a preceptor has not previously been included and, therefore, is included in Tables 2a (NRC licensees) and 4a (Agreement State licensees) as a revision to the clearance for NRC Form 313 (OMB Clearance No. 3150-0120).

§ 35.51 Training for an authorized medical physicist

Paragraph 35.51(a) requires the licensee to require the authorized medical physicist to be an individual who is certified by a specialty board whose certification process includes all of the requirements of § 35.51(b) and whose certification has been recognized by the Commission or an Agreement State. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized medical physicist.

The certification information required by § 35.51(a) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

Paragraph 35.51(b)(2) requires than an individual obtain a written certification, signed by a preceptor authorized medical physicist, that the individual has achieved a level of competency sufficient to independently function as an authorized medical physicist. This written certification is necessary to ensure that an individual fulfilling the responsibilities of an authorized medical physicist has met the training and experience requirements in § 35.51(b)(1).

The certification information required by § 35.51(b)(2) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120. The burden under § 35.51(b)(2) for an individual to obtain the signed certification from a preceptor has not previously been included and, therefore, is included in Table 2a (NRC licensees) and 4a (Agreement State licensees) as a revision to the clearance for NRC Form 313 (OMB Clearance No. 3150-0120).

§ 35.55 Training for an authorized nuclear pharmacist

Paragraph 35.55(a) requires the licensee to require the authorized nuclear pharmacist to be certified as a nuclear pharmacist by a specialty board whose certification process satisfies the requirements of § 35.55(b) and whose certification has been recognized by the Commission or an Agreement State. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

The certification information required by § 35.55(a) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

Paragraph 35.55(b)(2) requires the nuclear pharmacist to obtain a written certification, signed by a preceptor authorized nuclear pharmacist, that the educational requirements in paragraph 35.55 (b)(1) have been satisfactorily completed and that the individual has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist. This written certification is necessary to ensure that an individual fulfilling the responsibilities of an authorized nuclear pharmacist has met the necessary training and experience requirements in § 35.55 (b).

The certification information required by § 35.55(b)(2) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120. The burden under § 35.55(b)(2) for an individual to obtain the signed certification from a preceptor has not previously been included and, therefore, is included in Table 2a (NRC licensees) and 4a (Agreement State licensees) as a revision to the clearance for NRC Form 313 (OMB Clearance No. 3150-0120).

§ 35.60 Possession, use, and calibration of instruments used to measure the activity of byrpoduct material

Paragraph 35.60(b) requires licensees to calibrate the instrumentation required in paragraph 35.60(a) to measure the activity of unsealed byproduct material before it is administered.

Paragraph 35.60(c) requires licensees to retain a record of each instrument calibration required by § 35.60(b) in accordance with § 35.2060. A description of the contents of the record and the need for the record is provided under § 35.2060.

§ 35.61 Calibration of survey instruments

Paragraph 35.61(a) requires that the licensee conspicuously note on a survey instrument the date that the instrument was calibrated. This information is necessary to show that survey instruments were calibrated and operational.

Paragraph 35.61(c) requires that licensees retain a record of the survey instrument calibrations in accordance with § 35.2061. A description of the contents of the record and the need for the record is provided under § 35.2061.

§ 35.63 Determination of dosages of unsealed byproduct material for medical use

Paragraph 35.63(a) requires licensees to determine and record the activity of each dosage before medical use. Paragraph 35.63(e) requires licensees to retain a record of each radiopharmaceutical dosage determination in accordance with § 35.2063. A description of the contents of the record and the need for the record is provided under § 35.2063.

§ 35.67 Requirements for possession of sealed sources and brachytherapy sources

Paragraph 35.67(b) requires licensees in possession of sealed sources to test the sources for leakage. Paragraph 35.67(d) requires licensees to retain a record of sealed source leak tests in accordance with § 35.2067. A description of the contents of the record and the need for the record is provided under § 35.2067(a).

Paragraph 35.67(e)(2) requires licensees to file a report with the NRC within 5 days in accordance with § 35.3067 if leakage of a sealed source is detected. A description of the contents and need for the report is provided under § 35.3067.

Paragraph 35.67(g) requires licensees in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, to conduct a semi-annual physical inventory of all such sources in its possession and retain the inventory record in accordance with § 35.2067. A description of the contents and need for the record is provided under § 35.2067(b).

§ 35.69 Labeling of vials and syringes

Paragraph 35.69 requires that each syringe and vial that contains unsealed byproduct material must be labeled, and that each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded. Labeling is needed because review of misadministration/medical event reports has indicated that in many cases misadministrations/medical events are caused by inadvertent transposition of syringes or by drawing a dosage from the wrong vial of radioactive material.

§ 35.70 Surveys for ambient radiation exposure rate

This section requires licensees to survey with a radiation detection survey instrument at the end of each day of use all areas where unsealed byproduct material requiring a written directive was prepared for use or administered. Licensees are required to retain a record of each survey in accordance with § 35.2070. A description of the contents of the record and the need for the record is provided under § 35.2070.

§ 35.75 Release of individuals containing unsealed byproduct material or implants containing byproduct material

Paragraph 35.75(b) requires licensees to provide an individual who has been administered unsealed byproduct material or implants containing byproduct material and who is being released from the licensee's control in accordance with § 35.75(a) with instructions on actions recommended to maintain doses to other individuals as low as is reasonable achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). The licensee must provide special instructions to the released individual if the effective dose equivalent to a nursing infant or child could exceed 1 mSv (0.1 rem), assuming there is no interruption of breast feeding. These instructions are needed to ensure that the released individual is aware of the actions recommended to maintain doses to other persons as low as reasonably achievable (ALARA).

Paragraph 35.75(c) requires licensees to maintain a record of the basis for authorizing the release of an individual, in accordance with § 35.2075(a). A description of the contents of the records and a statement of need for the records is provided under § 35.2075.

Paragraph 35.75(d) requires licensees to maintain a record of the instructions that were provided to breast-feeding women in accordance with § 35.2075(b). A description of the contents of the record and a statement of need for the record is provided under § 35.2075.

§ 35.80 Provision of mobile service

Paragraph 35.80(a)(1) requires a licensee providing mobile service to obtain a letter signed by the management of each client that permits the use of byproduct material at the client's address and delineates the authority and responsibility of the licensee and the client. This record is necessary to show that the client's management has permitted this work and to clearly delineate the authority and responsibilities of each entity.

Paragraph 35.80(a)(4) requires a licensee to survey all areas of use to ensure compliance with the requirements of Part 20.

Paragraph 35.80(c) requires that the letter required in § 35.80(a)(1) and a record of the surveys required in § 35.80(a)(4) be retained in accordance with § 35.2080. A description of the contents of the record and the need for the record is provided under § 35.2080.

§ 35.92 Decay-in-storage

Paragraph 35.92(b) requires licensees to retain a record of disposal of waste that was decayed in storage and retain the record in accordance with § 35.2092. A description of the contents of the record and the need for the record is provided under § 35.2092.

§ 35.190 Training for uptake, dilution, and excretion studies

Paragraph 35.190(a) requires the licensee to require the authorized user of unsealed byproduct material for the uses authorized under § 35.100 to be a physician who is certified by a medical specialty board whose certification process includes all of the requirements of § 35.190 (c) and whose certification has been recognized by the Commission or an Agreement State. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user for uptake, dilution, and excretion studies. The certification information required by § 35.190(a) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

Paragraph 35.190 (c)(2) requires than an individual obtain a written certification, signed by a preceptor authorized user, that the individual has achieved a level of competency sufficient to independently function as an authorized user for the medical uses authorized under § 35.100. This written certification is necessary to ensure that an individual fulfilling the responsibilities of an authorized user has met the training and experience requirements in § 35.190(c)(1).

The certification information required by § 35.190 (c)(2) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120. The burden under § 35.190(c)(2) for an individual to obtain the signed certification from a preceptor has not previously been included and, therefore, is included in Table 2a (NRC licensees) and 4a (Agreement State licensees) as a revision to the clearance for NRC Form 313 (OMB Clearance No. 3150-0120).

§ 35.204 Permissible molybdenum-99 concentration

Paragraph 35.204(c) requires that if licensees are required to measure the molybdenum-99 concentrations in eluates from a molybdenum-99/technetium-99m generator the licensee shall retain the record in accordance with § 35.2204. A description of the contents of the record and the need for the record is provided under § 35.2204.

§ 35.290 Training for imaging and localization studies

Paragraph 35.290(a) requires the licensee to require an authorized user of unsealed byproduct material for the uses authorized under § 35.200 to be a physician who has been certified by a specialty board whose certification process satisfies the requirements of § 35.290 (c) and whose certification has been recognized by the Commission or an Agreement State. This

certification is necessary to ensure that the physician has achieved a level of competency sufficient to function independently as an authorized user of unsealed byproduct material for the uses authorized under § 35.200. The certification information required by § 35.290(a) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

Paragraph 35.290(c)(2) requires an authorized user to obtain a written certification, signed by a preceptor authorized user, that the individual has sucessfully completed the requirements in § 35.290 (c)(1) and that the individual has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under §§ 35.100 and 35.200. This written certification is necessary to ensure that an individual fulfilling the responsibilities of an authorized user has met the training and experience requirements in § 35.290.

The certification information required by § 35.290(c)(2) is submitted as part of a licensee's application, as required under §§ 35.12 and 35.13, and is cleared under OMB Clearance No. 3150-0120. The burden under § 35.290(c)(2) for an individual to obtain the signed certification from a preceptor has not previously been included and, therefore, is included in Table 2a (NRC licensees) and 4a (Agreement State licensees) as a revision to the clearance for NRC Form 313 (OMB Clearance No. 3150-0120).

§ 35.310 Safety instruction

Paragraph 35.310(a) requires that licensees provide safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that have received therapy with unsealed byproduct material and cannot be released in accordance with § 35.75. This instruction is needed to ensure that personnel receive instruction in (1) limiting radiation exposure to the public and workers, and (2) the actions to be taken in the event of death or medical emergency.

Paragraph 35.310(b) requires licensees to retain a record of individuals receiving instruction required by § 35.310(a) in accordance with § 35.2310. A description of the contents of the record and the need for the record are provided under § 35.2310.

§ 35.315 Safety precautions

Paragraph 35.315(a)(2) requires that the licensee post the room of a patient or human research subject who cannot be released in accordance with § 35.75 with a "Radioactive Materials" sign. Paragraph 35.315(a)(3) requires a note on the door or in the patient's chart where and how long visitors may stay in the patient's room. This posting and note is required so that employees and visitors receive information necessary for radiation safety.

Paragraph 35.315(b) requires that the licensee promptly notify the Radiation Safety Officer, or his or her designee and the authorized user, as soon as possible, if the patient has a medical emergency or dies. This notification is required so that the Radiation Safety Officer or his or her designee can take whatever actions are necessary for radiation safety.

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

Paragraph 35.390(a) requires an individual to be certified by a medical specialty board whose certification process satisfies the requirements of § 35.390(b) and whose certification has been recognized by the Commission or an Agreement State. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user of unsealed byproduct material for which a written directive is required.

The certification information required by § 35.390(a) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

Paragraph 35.390(b)(2) requires an authorized user to obtain a written certification, signed by a preceptor authorized user, that the individual has satisfactorily completed the requirements in § 35.390(b)(1) and that the individual has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.300, as appropriate. This written certification is necessary to ensure that an individual fulfilling the responsibilities of an authorized user for use of unsealed byproduct material for the medical uses authorized under § 35.300(a) or § 35.390(b)(1)(ii)(G)(1), (2), (3), or (4) has met the training and experience requirements in § 35.390 (b)(1).

The certification information required by § 35.390(b)(2) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120. The burden under § 35.390(b)(2) for an individual to obtain the signed certification from a preceptor has not previously been included and, therefore, is included in Table 2a (NRC licensees) and 4a (Agreement State licensees) as a revision to the clearance for NRC Form 313 (OMB Clearance No. 3150-0120).

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

Paragraph 35.392(a) requires licensees to require an authorized user to be certified by a medical specialty board whose certification process satisfies the requirements of § 35.392(c) and whose certification has been recognized by the Commission or an Agreement State. This certification is necessary to ensure that the individual has achieved a level of competency

sufficient to function independently as an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries).

The certification information required by § 35.392(a) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

Paragraph 35.392(c)(3) requires an authorized user to obtain a written certification, signed by a preceptor authorized user, that the individual has satisfactorily completed the requirements in

§ 35.392(c)(1) and (c)(2) and that the individual has achieved a level of competency sufficient to function independently as an authorized user for medical uses of unsealed byproduct material using sodium iodide I-131. This written certification is necessary to ensure that an individual fulfilling the responsibilities of an authorized user for use of unsealed byproduct material using sodium iodide I-131 and has met the requirements in § 35.392 (c)(1) and (c)(2).

The certification information required by § 35.392(c)(3) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120. The burden under § 35.392(c) for an individual to obtain the signed certification from a preceptor has not previously been included and, therefore, is included in Table 2a (NRC licensees) and 4a (Agreement State licensees) as a revision to the clearance for NRC Form 313 (OMB Clearance No. 3150-0120).

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

Paragraph 35.394(a) requires an individual to be certified by a medical specialty board whose certification process satisfies the requirements of § 35.394(c) and whose certification has been recognized by the Commission or an Agreement State. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries).

The certification information required by § 35.394(a) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

Paragraph 35.394(c)(3) requires an authorized user to obtain a written certification, signed by a preceptor authorized user, that the individual has satisfactorily completed the requirements in § 35.394(c)(1) and and (c)(2) and that the individual has achieved a level of competency sufficient to function independently as an authorized user for medical uses of unsealed byproduct material using sodium iodide I-131.

This written certification is necessary to ensure that an individual fulfilling the responsibilities of an authorized user for use of unsealed byproduct material using sodium iodide I-131 has met the training and experience requirements in § 35.394 (c)(1) and (c)(2).

The certification information required by § 35.394(c)(3) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120. The burden under § 35.394 (c)(3) for an individual to obtain the signed certification from a preceptor has not previously been included and, therefore, is included in Table 2a (NRC licensees) and 4a (Agreement State licensees) as a revision to the clearance for NRC Form 313 (OMB Clearance No. 3150-0120).

§ 35.404 Surveys after source implant and removal

Paragraph 35.404(c) requires a licensee to retain a record of surveys to locate and account for all sources that have not been implanted and, after implant removal, to confirm that all sources have been removed as required by §§ 35.404(a) and (b) in accordance with § 35.2404. A description of the contents of the record and the need for the record is provided under § 35.2404.

§ 35.406 Brachytherapy sources accountability

Paragraph 35.406(c) requires licensees to make a record of brachytherapy source accountability in accordance with § 35.2406. A description of the contents of the record and the need for the record is provided under § 35.2406.

§ 35.410 Safety instruction

Paragraph 35.410(a) requires licensees to provide safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that are undergoing implant therapy and cannot be released in accordance with § 35.75. This instruction is needed to ensure that personnel receive instruction in (1) limiting radiation exposure to the public and workers and (2) the actions to be taken in the event of death or medical emergency.

Paragraph 35.410(b) requires licensees to retain a record of radiation safety instruction for personnel who care for patients or human research subjects who are undergoing implant therapy, in accordance with § 35.2310. A description of the contents of the record and the need for the record is provided under § 35.2310.

§ 35.415 Safety precautions

Paragraph 35.415(a) requires that the licensee post the patient's or human research subject's room with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the room. This posting provides notice to control radiation exposures to hospital workers and the public.

Paragraph 35.415(c) requires that the licensee promptly notify the Radiation Safety Officer, or his or her designee, and authorized user as soon as possible if the patient or human research subject has a medical emergency or dies. This notification is required so that the Radiation Safety Officer, or his or her designee, or authorized user can take whatever actions are necessary for radiation safety.

§ 35.432 Calibration measurements of brachytherapy sealed sources

Paragraph 35.432(d) requires licensees to retain a record of calibration measurements made on brachytherapy sealed sources in accordance with § 35.2432. A description of the contents of the record and the need for the record is provided under § 35.2432.

§ 35.433 Decay of strontium-90 sources for ophthalmic treatments

Paragraph 35.433 (b) requires licensees to retain a record of the activity of each strontium-90 source in accordance with § 35.2433. A description of the contents of the record and the need for the record is provided under § 35.2433.

§ 35.490 Training for use of manual brachytherapy sources

Paragraph 35.490(a) requires licensees to require the authorized user of a manual brachytherapy source for the uses listed in § 35.400 to be a physician certified by a medical specialty board whose certification process includes all the requirements of § 35.490(b) and whose certification has been recognized by the Commission or an Agreement State. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.400.

The certification information required by § 35.490(a) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

Paragraph 35.490(b)(3) requires an authorized user to obtain a written certification, signed by a preceptor authorized user, that the educational and experience requirements in § 35.490(b)(1) and (2) have been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently function as an authorized user of manual brachytherapy sources for the medical uses authorized under § 35.400. This written certification is necessary to ensure that an individual fulfilling the responsibilities of an authorized user of brachytherapy sources has met the training and experience requirements in § 35.490.

The certification information required by § 35.490(b)(3) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120. The burden under § 35.490(b)(3) for an individual to obtain the signed certification from a preceptor has not previously been included and, therefore, is included in Table 2a (NRC licensees) and 4a (Agreement State licensees) as a revision to the clearance for NRC Form 313 (OMB Clearance No. 3150-0120).

§ 35.491 Training for opthalmic use of strontium-90

Paragraph 35.491(c) requires an authorized user to obtain a written certification, signed by a preceptor authorized user, that the educational and experience requirements in § 35.491 (a) and (b) have been satisfactorily completed and that the individual has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for opthalmic use.

This written certification is necessary to ensure that an individual fulfilling the responsibilities of an authorized user of strontium-90 for opthalmic use has met the training and experience requirements in § 35.491.

The certification information required by § 35.491(c) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120. The burden under § 35.491(c) for an individual to obtain the signed certification from a preceptor has not previously been included and, therefore, is included in Table 2a (NRC licensees) and 4a (Agreement State licensees) as a revision to the clearance for NRC Form 313 (OMB Clearance No. 3150-0120).

§ 35.590 Training for use of sealed sources for diagnosis

Paragraph 35.590(a) requires the licensee to require the authorized user of a diagnostic sealed source for use in a device listed in § 35.500 to be a physician, dentist, or podiatrist who has been certified by a medical specialty board whose

certification process satisfies the requirements of § 35.590(b) and whose certification has been recognized by the Commission or an Agreement State. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user of sealed sources for diagnosis.

The certification information is submitted as part of a licensee's application required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

§ 35.604 Surveys of patients and human research subjects treated with a remote afterloader unit

Paragraph 35.604(a) requires licensees who use sealed sources in remote afterloader units, before releasing a patient or human research subject from licensee control, to make a survey of the patient or human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe shielded position. Paragraph 35.604 (b) requires the licensee to retain a record of the survey required by paragraph 35.604(a) in accordance with § 35.2404. A description of the contents of the record and the need for the record is provided under § 35.2404.

§ 35.605 Installation, maintenance, adjustment, and repair

Paragraph 35.605(d) requires licensees to retain a record of each installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with § 35.2605. A description of the contents of the record and the need for the record is provided under § 35.2605.

§ 35.610 Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units

Paragraph 35.610(a)(4) requires licensees to develop, maintain, and implement written procedures for responding to an abnormal situation. These procedures are necessary because of the complexity and higher radiation risk associated with these units.

Paragraph 35.610(b) requires licensees to physically locate a copy of the procedures at the unit console. These safety procedures are necessary to ensure that workers at the console have physical access to the procedures.

Paragraph 35.610(c) requires licensees to post instructions for individuals who operate the devices at the device console providing the location of the procedures and emergency names and telephone numbers. These instructions are necessary to inform workers of the procedures and to serve as a quick reference in case of emergencies or equipment malfunction.

Paragraph 35.610(d) requires licensees to provide initial instruction and annual refresher instruction to all individuals who operate the unit in the procedures identified in § 35.610(a) and the operating procedures for the unit. The initial instruction and refresher instruction are necessary due to the complexity of therapeutic treatment devices.

Paragraph 35.61(e) requires licensees to ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually. The drills are necessary due to the complexity of therapeutic treatment devices.

Paragraph 35.610(f) requires licensees to make a record of initial instruction and refresher training for individuals who operate the units and to retain the record in accordance with § 35.2310. A description of the contents of the record and the need for the record is provided under § 35.2310.

§ 35.615 Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units

Paragraph 35.615(f)(4) requires a licensee to notify the Radiation Safety Officer, or his/her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies. This notification is required so that the Radiation Safety Officer, or his/her designee, or authorized user can take whatever actions are necessary for radiation safety.

§ 35.630 Dosimetry equipment

Paragraph 35.630(c) requires licensees to retain a record of each calibration, intercomparison, and comparison of calibrated dosimetry equipment in accordance with § 35.2630. A description of the contents of the record and the need for the record is provided under § 35.2630.

§ 35.632 Full calibration measurements on teletherapy units

Paragraph 35.632(g) requires licensees to retain a record of each calibration in accordance with § 35.2632. A description of the contents of the record and the need for the record is provided under § 35.2632.

§ 35.633 Full calibration measurements on remote afterloader units

Paragraph 35.633(i) requires licensees to retain a record of each calibration in accordance with § 35.2632. A description of the contents of the record and the need for the record is provided under §35.2632.

§ 35.635 Full calibration measurements on gamma stereotactic radiosurgery units

Paragraph 35.635(g) requires licensees to retain a record of each calibration in accordance with § 35.2632. A description of the contents of the record and the need for the record is provided under § 35.2632.

§ 35.642 Periodic spot-checks for teletherapy units

Paragraph 35.642(b) requires licensees to perform measurements in accordance with written procedures established by the authorized medical physicist. Written procedures are necessary to ensure that the spot-checks are performed correctly and consistently.

Paragraph 35.642(c) requires that the authorized medical physicist review the results of each spot-check and notify the licensee in writing of the results of each spot check. This record is needed to assure the licensee that the results of each spot-check have been reviewed by an expert.

Paragraph 35.642(f) requires licensees to retain a record of each spot-check required by § 35.642(a) and (d) in accordance with § 35.2642. A description of the contents of the record and the need for the record is provided under § 35.2642.

§ 35.643 Periodic spot-checks for remote afterloader units

Paragraph 35.643(b) requires licensees to have the authorized medical physicist establish written procedures for performing periodic spot-checks on remote afterloader units. These procedures are necessary to document the licensee's radiation protection program and to ensure that the dose limits in 10 CFR Part 20 are not exceeded.

Paragraph 35.643(c) requires licensees to have the authorized medical physicist review the results of each spot-check required by paragraph (a)(1) within 15 days of the check and to notify the licensee as soon as possible in writing of the results of each spot check. This record is necessary to ensure that the procedures are being followed accurately and that the dose limits in 10 CFR Part 20 are not exceeded.

Paragraph 35.643(f) requires licensees to retain a record of each check required by § 35.643(d) in accordance with § 35.2643. A description of the contents of the record and the need for the record is provided under § 35.2643.

§ 35.645 Periodic spot-checks for gamma stereotactic radiosurgery units

Paragraph 35.645(b)(1) requires licensees to have the authorized medical physicist establish written procedures for performing spot-checks on gamma stereotactic radiosurgery units. The authorized medical physicist is the most qualified individual to ensure that the procedures are performed in accordance with published recommendations of nationally recognized bodies. These procedures are necessary to document the licensee's radiation protection program and to ensure that the dose limits in 10 CFR Part 20 are not exceeded.

Paragraph 35.645(b)(2) requires licensees to have the authorized medical physicist review the results of each spot-check of a gamma stereotactic radiosurgery unit within fifteen days of each spot-check. This review is necessary to ensure that the dose limits in 10 CFR Part 20 are not exceeded.

Paragraph 35.645(g) requires licensees to retain a record of each spot-check required by § 35.645(c) and (d) in accordance with § 35.2645. A description of the contents of the record and the need for the record is provided under § 35.2645.

§ 35.647 Additional technical requirements for mobile remote afterloaders

Paragraph 35.647(e) requires licensees to retain a record of each check of mobile remote afterloaders before use at each address of use, as required by § 35.647(b), in accordance with § 35.2547. A description of the contents of the record and the need for the record is provided under § 35.2647.

§ 35.652 Radiation surveys

Paragraph 35.652(c) requires licensees to make radiation surveys to ensure radiation levels do not exceed levels stated in the Sealed Source and Device Registry, as required by§ 35.652 (a) and to retain a record of the radiation surveys in accordance with §35.2652. A description of the contents of the record and the need for the record is provided under § 35.2652.

§ 35.655 Five-year inspection for teletherapy and gamma stereotactic radiosurgery units

Paragraph 35.655(c) requires licensees to keep a record of the teletherapy unit and gamma stereotactic radiosurgery unit 5-year inspection and servicing required by § 35.655(a) in accordance with § 35.2655. A description of the contents of the record and the need for the record is provided under § 35.2655.

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

Paragraph 35.690(a) requires an individual to be certified by a medical specialty board whose certification process satisfies the requirements of § 35.690(b) and whose certification has been recognized by the Commission or an Agreement State. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The certification information is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120.

Paragraph 35.690(b)(3) requires an authorized user to obtain a written certification, signed by a preceptor authorized user, that the educational and experience requirements in § 35.690(b)(1) and (2) have been satisfactorily completed and that the individual has achieved a level of competency sufficient to function independently as an authorized user of the therapeutic medical unit for which the individual is requesting authorized user status. This written certification is necessary to ensure that an individual fulfilling the responsibilities of an authorized user of therapeutic medical unit(s) has met the training and experience requirements in § 35.690.

The certification information required by § 35.690(b)(3) is submitted as part of a licensee's application as required under §§ 35.12 and 35.13 and is cleared under OMB Clearance No. 3150-0120. The burden under § 35.690(b)(3) for an individual to obtain the signed certification from a preceptor has not previously been included and, therefore, is included in Table 2a (NRC licensees) and 4a (Agreement State licensees) as a revision to the clearance for NRC Form 313 (OMB Clearance No. 3150-0120).

§ 35.1000 Other medical uses of byproduct material or radiation from byproduct material

Paragraph 35.1000(a) provides that a licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of Part 35 if the applicant or licensee has submitted the information required by § 35.12(b) through (d) and has received written approval from the Commission.

The burden for Paragraphs 35.12 (b) through (d) is cleared under OMB Clearance No. 3150-0120, which should be referred to for additional supporting information, burden, and cost data.

§ 35.2024 Records of authority and responsibilities for radiation protection programs

Paragraph 35.2024(a) requires licensees to retain a record of actions taken by the licensee's management in accordance with § 35.24(a) for five years. This record must include a summary of actions taken and the signature of licensee management for requests for license application, renewal, or amendment; approvals or disapprovals of requests to allow an individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and approval or disapproval of radiation protection program changes that do not require an amendment. This record is needed to document these actions and the basis for them because they are important to the licensee's radiation safety program.

Paragraph 35.2024(b) requires licensees to retain a current copy of the authority, duties, and responsibilities of the Radiation Safety Officer as required by § 35.24(e) and a signed copy of the Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by § 34.24(b). The records must include the signature of the Radiation Safety Officer and licensee management. This record is important to show that the RSO has sufficient authority, time, resources, and management prerogative to ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

§ 35.2026 Records of radiation protection program changes

This section requires licensees to retain a record of each radiation protection program change made in accordance with § 35.26(a) for five years. The record must include a copy of the old and new procedure, the effective date of the change, and the signature of the licensee management that reviewed and approved the change. This record is needed to document what radiation safety factors were considered before implementing the minor change. This record facilitates the Commission's evaluation of the nature and appropriateness of the minor changes during inspections prior to renewal, and provides the licensee with a complete record of the radiation safety program changes until the changes are incorporated into the license when renewed.

§ 35.2040 Records of written directives

This section requires licensees to retain a copy of each written directive as required by

§ 35.40 for three years. Retention of the written directives and records of each administration for three years after the date of the administration will allow NRC to ensure that administrations were in accordance with the written directives by reviewing a sample of written directives and records of administrations during an NRC inspection.

§ 35.2045 Records of medical events

This section requires licensees to retain a record of medical events reported in accordance with § 35.3045 for three years. The record must include: the licensee's name; names of the individuals involved; the social security number or other identification number if one has been assigned of the individual who is the subject of the medical event; a brief description of the event and why it occurred; the effect, if any, on the individual; the actions, if any, taken or planned to prevent recurrence, and whether the licensee notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician. This record is needed to document medical events for licensee and Commission review, so that the Commission can ascertain whether medical events have been investigated by the licensee and that corrective actions have been taken.

§ 35.2047 Record of a dose to an embryo/fetus or a nursing child

This section requires licensees to retain a record of a dose to an embryo/fetus or a nursing child reported in accordance with § 35.3047 for three years. The record must include: the licensee's name; names of all the individuals involved; the social security number or other identification number if one has been assigned to the pregnant individual or nursing child who is the subject of the event; a brief description of the event and why it occurred; the effect, if any, on the embryo/fetus or nursing child; the actions, if any, taken or planned to prevent recurrence; and whether the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician. This record of a dose to an embryo/fetus or a nursing child is required to document such events for licensee and Commission review, so that the Commission can ascertain whether events involving a dose to an embryo/fetus or nursing child have been investigated by the licensee and that corrective actions have been taken.

§ 35.2060 Records of calibrations of instruments to measure the activity of unsealed byproduct materials

This section requires licensees to maintain a record of instrument calibrations required by § 35.60 for three years. The records must include the model and serial number of the instrument, the date of calibration, the results of the calibration, and the name of the individual who performed the calibration. The records of the checks and tests in § 35.60 are necessary to demonstrate that the instruments used to measure the activity of alpha-, beta-, and photon-emitting radionuclides are functioning correctly and are capable of accurately measuring dosages; to establish trends in equipment performance; and to show compliance with regulatory requirements.

§ 35.2061 Records of radiation survey instrument calibrations

This section requires licensees to maintain a record of radiation survey instrument calibrations required by § 35.61 for three years. The record must include the model and serial number of the instrument, the date of calibration, the results of the calibration, and the name of the individual who performed the calibration. This survey instrument calibration record is required to show that survey instruments were calibrated and are functioning correctly.

§ 35.2063 Records of dosages of unsealed byproduct material for medical use

This section requires licensees to maintain a record of dosage determinations required by § 35.63 for three years. The record must contain: the radiopharmaceutical; the patient's or human research subject's name, or identification number if one has been assigned; the prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.1 megabecquerels (30 microcuries); the date and time of the dosage determination; and the name of the individual who determined the dosage. This record is required to demonstrate that licensees are maintaining control of the use of radiopharmaceuticals.

§ 35.2067 Records of possession of sealed sources and brachytherapy sources

Paragraph 35.2067(a) requires licensees to retain records of leak tests required by § 35.67(b) for three years. The records must include the model number and serial number, if one has been assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the results of the test, the date of the test, and the name of the individual who performed the test. This record is required to demonstrate that the leak test was done as required, and that the source was not leaking.

Paragraph 35.2067(b) requires that licensees retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by § 35.67(g) for three years. The inventory records must contain the model number of each source, and serial number, if one has been assigned; the identity of each source radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the survey. This inventory record is needed to show that possession of sealed sources did not exceed the amount authorized by the license.

§ 35.2070 Records of surveys for ambient radiation exposure rate

This section requires a licensee to retain a record of each survey required by § 35.70 for three years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey. The records are needed to document that the surveys were performed, and that the ambient radiation exposure rates are below the limits set for protection of workers and the public.

§ 35.2075 Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material

Paragraph 35.2075(a) requires licensees to retain a record of the basis for authorizing the release of an individual in accordance with § 35.75, if the total effective dose equivalent is calculated by: using the retained activity rather than the activity administered; using an occupancy factor less than 0.25 at 1 meter; using the biological or effective half-life; or considering the shielding by tissue. These records are necessary to document the basis for releasing individuals containing radiopharmaceuticals or implants from the control of licensees, and into situations where they could expose members of the general public.

Paragraph 35.2075(b) requires licensees to retain a record that the instructions required by § 35.75(b) were provided to a breast-feeding female if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 millisieverts (0.5 rem). This record is necessary to show that nursing mothers have been provided with necessary information for the protection of an infant or child.

Paragraph 35.2075(c) requires licensees to retain the records required by paragraphs (a) and (b) of this section for three years after the date of release of the individual. Retention of the release records for three years after the date of the release will allow NRC to ensure that releases were in accordance with the criteria for release by reviewing a sample of the records during an NRC inspection.

§ 35.2080 Records of administrative and technical requirements that apply to the provision of mobile medical services

Paragraph 35.2080(a) requires licensees providing mobile medical services to retain a copy of each letter that permits the use of byproduct material at a client's address, as required by § 35.80(a)(1). The letter must clearly delineate the authority and responsibility of the licensee and the client and must be retained for three years after the last provision of service. These records are necessary to show that the licensees had permission to use byproduct material at the client's address of use.

Paragraph 35.2080(b) requires licensees to maintain a record of each survey required by § 35.80(a)(4) for three years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey. These records are needed to show that the required surveys were made to ensure compliance with the radiation protection requirements of 10 CFR Part 20.

§ 35.2092 Records of decay-in-storage

This section requires licensees to retain records of the disposal of licensed materials, as required by § 35.92 for three years. The record must include the date of 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. These records are needed to show that materials were decayed for the required length of time, that their radioactivity cannot be distinguished from background radiation levels, and that a proper survey of each waste container was made prior to disposal. These records are also needed to show that radioactive material is not disposed of as ordinary waste.

§ 35.2204 Records of molybdenum-99 concentration

This section requires licensees to maintain records of molybdenum-99 concentration tests required by § 35.204(b) for three years. The record must include, for each measured elution of technetium-99m, the ratio of the measures expressed as kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m, the time and date of the measurement, and the name of the individual who made the measurement. This record is needed to show that the concentration measurement was made and that the maximum molybdenum-99 concentration level was not exceeded.

§ 35.2310 Records of safety instruction

This section requires licensees to maintain records of safety instructions training required by §§ 35.310, 35.410, and 35.610 for three years. The record must include a list of the topics covered, the date of instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction. This record is needed to show that the required initial and refresher training was given and that the drills were performed so that individuals are aware of the safety procedures to be used in caring for patients and human research subjects treated with byproduct material or radiation therefrom.

§ 35.2404 Records of surveys after source implant and removal

This section requires licensees to maintain a record of the surveys required by §§ 35.404 and 35.604 for three years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey. This record is used to show that all sources were removed from the patient or human research subject, and that no sources have been misplaced.

§ 35.2406 Records of brachytherapy source accountability

This section requires licensees to maintain records of brachytherapy source accountability required by § 35.406 for three years. For temporary implants, the record must include: the number and activity of sources removed from and returned to storage; the time and dates they were removed from and returned to storage, the name of the individual(s) who removed them from and returned them to storage, and the location of use. For permanent implants, the record must include: the number and activity of sources removed from and returned to storage, the dates they were removed from and returned to storage, and the name of the individual(s) who removed them from and returned them to storage; the number and activity of sources not implanted; and the number and activity of sources permanently implanted in the patient or human research subject. This record is required so that, if a brachytherapy source is misplaced or missing, the licensee is immediately alerted and can take appropriate action.

§ 35.2432 Records of calibration measurements of brachytherapy sealed sources

This section requires licensees to maintain a record of calibrations of brachytherapy sources required by § 35.432 for three years after the last use of the source. The record must include: the date of calibration; the manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source; the source output or activity; the source positioning accuracy within the applicators; and the signature of the authorized medical physicist. These records are needed to document that the brachytherapy sources have been calibrated.

§ 35.2433 Records of decay of strontium-90 sources for ophthalmic treatments

This section requires licensees to maintain a record of the activity of a strontium-90 source required by § 35.433 for the life of the source. The record must include: the initial activity of the source and date; and for each decay calculation, the date and source activity as determined under § 35.433. These records are needed to document that the activity of the strontium-90 sources have been calculated to ensure that adequate radiation safety is maintained.

§ 35.2605 Records of installation, maintenance, adjustment, and repair

This section requires licensees to retain records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by § 35.605 for three years. For each installation, maintenance, adjustment, and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work. This record is necessary to show that the devices are properly installed, maintained, and repaired, to establish trends in device performance, and to establish a service history that may be used in evaluation of generic equipment problems.

§ 35.2630 Records of dosimetry equipment

This section requires licensees to retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with § 35.630 for the duration of the license. For each calibration, intercomparison, or comparison, the record must include: the date; the manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by paragraphs (a) and (b) of § 35.630; the correction factor that was determined from the calibration or the apparent correction factor that was determined from an intercomparison; and the names of the individuals who performed the calibration, intercomparison, or comparison. This record is needed to show that calibrations of medical devices were made with properly calibrated instruments.

§ 35.2632 Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations

This section requires licensees to maintain records of the teletherapy unit, remote afterloader unit, and gamma stereotactic radiosurgery unit full calibrations required by §§ 35.632, 35.633, and 35.635 for three years. The record must include: the date of the calibration; the manufacturer's name, model number, and serial number of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and the instruments used to calibrate the unit(s); the results and an assessment of the full calibrations; the results of the autoradiograph required for low dose-rate remote afterloader units; and the signature of the authorized medical physicist who performed the full calibration. This record is needed to show that the calibrations were done so that licensees did not inadvertently administer incorrect radiation doses to patients from the teletherapy unit.

§ 35.2642 Records of periodic spot-checks for teletherapy units

This section requires licensees to retain a record of each periodic spot-check for teletherapy units required by § 35.642 for three years. The record must include: the date of the spot-check; the manufacturer's name, model number, and serial number of the teletherapy unit, source, and instrument used to measure the output of the teletherapy unit; an assessment of timer linearity and constancy; the calculated on-off error; a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device; the determined accuracy of each distance measuring and localization device; the difference between the anticipated output and the measured output; notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and the name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot check. This record is needed to show that the spot-checks were performed and that the units are operating correctly.

§ 35.2643 Records of periodic spot-checks for remote afterloader units

This section requires licensees to retain records of each spot-check for remote afterloader units required by §§ 35.643 for three years. The record must include, as applicable: the date of the spot-check; the manufacturer's name, model number, and serial number for the remote afterloader unit and source; an assessment of timer accuracy; notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and the name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot check. This record is necessary to show that the spot-checks were performed and that the units are operating correctly.

§ 35.2645 Records of periodic spot-checks for gamma stereotactic radiosurgery units

This section requires licensees to retain records of each spot-check for gamma stereotactic radiosurgery units required by § 35.645 for three years. The record must include: the date of the spot-check; the manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit; an assessment of timer linearity and accuracy; the calculated on-off error; a determination of trunnion centricity; the difference between the anticipated output and the measured output; an assessment of source output against computer calculations; notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizaing devices (trunnions); and the name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot check. This record is necessary to show that the spot-checks were performed and that the units are operating correctly.

§ 35.2647 Records of additional technical requirements for mobile remote afterloaders

This section requires licensees to retain records of each check for mobile remote afterloader units required by § 35.647 for three years. The record must include: the date of the check; the manufacturer's name, model number, and serial number of the remote afterloader unit; notations accounting for all sources before the licensee departs from a facility; notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes and transfer tube applicator interfaces, and source positioning accuracy; and the signature of the individual who performed the check. This record is necessary to show that the checks were performed and that the units are operating correctly.

§ 35.2652 Records of surveys of therapeutic treatment units

This section requires licensees to maintain records of radiation surveys of treatment units made in accordance with § 35.652 for the duration of use of the unit. The record must include: the date of the measurements; the manufacturer's name, model number, and serial number of the treatment unit, source, and instrument used to measure radiation levels; each dose rate measured around the source while the unit is in the off position and the average of all measurements; and the signature of the person who performed the test. This record is necessary to show that the surveys were performed and that the units do not exceed occupational dose levels with the sources in the shielded position.

§ 35.2655 Records of five-year inspection for teletherapy and gamma stereotactic radiosurgery units

This section requires licensees to maintain a record of the five-year inspections for teletherapy and gamma stereotactic radiosurgery units required by § 35.655 for the duration of use of the unit. The record must contain: the inspector's radioactive materials license number; the date of inspection; the manufacturer's name and model number and serial number of both the treatment unit and source; a list of components inspected and serviced, and the type of service; and the signature of the inspector. This record is needed to document the type of service that was performed and that any required work was done.

§ 35.3045 Reports and notification of a medical event

Paragraph 35.3045(a) requires licensees 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 or dosage meeting or exceeding specified criteria. The burden associated with this paragraph is addressed under paragraphs (c) and (d) of this section.

Paragraph 35.3045(b) requires licensees 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. The burden associated with this paragraph is addressed under paragraphs (c) and (d) of this section.

Paragraph 35.3045(c) requires licensees to notify NRC by telephone no later than the next calendar day after discovery of the medical event. This reporting requirement is needed to ensure that NRC is aware of medical events and be able promptly to take any necessary actions based on the circumstances.

Paragraph 35.3045(d) requires licensees to submit a written report to NRC within 15 days of 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); 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 precipitating event might be generic.

Paragraph 35.3045(e) requires the licensee to notify the referring physician and the individual who is the subject of the medical event, or that individual's responsible relative or guardian when appropriate, no later than 24 hours after its discovery, or as soon as possible, if the patient or the referring physician can not be reached within 24 hours. Patients and their referring physician(s) need this information to make timely decisions regarding possible health care needs. If an oral notification is made, the licensee is required to inform the individual, responsible relative, or guardian that he may request a written description of the event and shall provide such a written description, if requested.

Paragraph 35.3045(g) requires the licensee to retain a record of a medical event in accordance with § 35.2045, and to provide a copy of the record required under § 35.2045 to the referring physician if other than the licensee within fifteen days after discovery of the medical event.

§ 35.3047 Report and notification of a dose to an embryo/fetus or a nursing child

Paragraph 35.3047(a) requires the licensee to report any dose to an embryo/fetus that is greater than 50 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 the embryo/fetus was specifically approved, in advance, by the authorized user. The burden for this requirement is addressed under paragraphs (c) and (d) of this section. This report is needed so that NRC can comply with the legislative intent of Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438) as amended, which requires NRC to submit reports to Congress of unintended radiation exposure.

Paragraph 35.3047(b) requires the licensee to report any dose to a nursing child 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 that is a result of an administration of byproduct material to a breast-feeding individual. The burden for this requirement is addressed under paragraphs (c) and (d) of this section. This report is needed so that NRC can comply with the legislative intent of Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438) as amended, which requires NRC to submit to Congress reports of unintended radiation exposure.

Paragraph 35.3047(c) requires the licensee to notify by telephone the NRC Operation 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 § 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.

Paragraph 35.3047(d) requires the licensee to submit a written report to the appropriate NRC Regional Office no later than 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report under § 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 the 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.

Paragraph 35.3047(e) requires the licensee to notify the referring physician and also notify the pregnant individual or mother (both hereafter referred to as the mother) no later than 24 hours after discovery of an event that would require reporting under paragraph (a) or (b) of this section, 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 would be harmful. If the referring physician or mother cannot be reached within 24 hours, the licensee is required to make the appropriate notifications as soon as possible thereafter. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible

relative or guardian instead of the mother, when appropriate. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such written description if requested. This reporting requirement is needed to provide information about the event to the referring physician and the pregnant individual or mother, or the mother's or child's responsible relative or guardian, for appropriate medical care, if needed.

Paragraph 35.3047(f) requires the licensee to retain a record of a dose to an embryo/fetus or a nursing child in accordance with § 35.2047. A copy of the record required under § 35.2047 shall be provided to the referring physician, if other than the licensee, within fifteen days after discovery of the event. This record is needed to ensure that the licensee can, if necessary, later refer to the record of the dose. This report is needed to ensure that patients can obtain a written report as a record of the information furnished to them orally.

§ 35.3067 Report of a leaking source

This section requires licensees to report detection of a leaking source by submitting a written report within 5 days after a leakage test required by § 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 NRC. The report must include the model 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 will enable NRC to promptly determine if the necessary follow-up actions were taken following discovery of the leaking source.

§ 35.50 Training for Radiation Safety Officer,

§ 35.51 Training for an authorized medical physicist,

§ 35.55 Training for an authorized nuclear pharmacist,

§ 35.190 Training for uptake, dilution, and excretion studies,

§ 35.290 Training for imaging and localization studies,

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

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

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

§ 35.490 Training for use of manual brachytherapy sources,

§ 35.491 Training for ophthalmic use of strontium-90,

§ 35.590 Training fo use of sealed sources for diagnosis, and

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

Each of these sections implicitly requires a medical specialty certifying board or similar organization providing training to prepare and submit a letter demonstrating to NRC that the board's certification process includes all of the requirements for training and experience specified for an authorized user for the medical use of byproduct material addressed in that section. Based on the contents of the letter, NRC will or will not recognize the certification process of that medical board. A licensee may, under these sections, require an authorized user under the particular section to be an individual certified by a medical board whose certification process has been recognized by NRC (or an Agreement State). Medical certification boards are expected in many, but not necessarily all, cases to seek recognition under more than one of these sections by means of the same letter. This is expected to be a one-time submission. The reporting requirements for this one-time submission are estimated in Table 1b. This submission is necessary to ensure that NRC can ascertain that an individual certified by a particular medical specialty certifying board for a particular medical use of byproduct material has achieved a level of competency sufficient to function independently as an authorized user.

2. Agency Use of Information

The NRC uses the records and reports required in this part to ascertain that licensees' medical use programs are adequate to

protect public health and minimize danger to life and property and that licensees' personnel are aware of the information needed to perform licensed activities in a safe manner. The staff makes use of the records and reports to determine whether the licensee has individuals with adequate training and experience to safely use radioactive material administered to patients or human research subjects, and has the facilities and equipment necessary to assure protection of public health and safety. NRC also uses the information to develop reports to inform Congress and the public about the measures taken to provide for the radiation safety of workers, the general public, and patients, and to alert licensees to issues of general concern. Reports of medical events are required to ensure that NRC is notified of significant events. These reports also allow NRC to determine whether to take actions, such as to conduct inspections, or to alert other medical use licensees, to prevent similar events that may have generic implications. In addition, collection of this information enables the NRC to ascertain whether such events are investigated by the licensee, reported to patients or human research subjects, and referring physicians, and that corrective action is taken.

3. Reduction of Burden Through Information Technology

There are no legal obstacles to reducing the burden associated with this information collection. However, because of the types of information, the applications and reports do not lend themselves readily to the use of automated information technology for submission. Section 35.5 of the rule provides that records under Part 35 may be stored in electronic media.

4. Effort to Identify Duplication and Use Similar Information

The Information Requirements Control Automated System was searched to determine duplication. None was found. In general, information required by the NRC in applications, reports, or records concerning the transfer, receipt, possession, or use of byproduct material does not duplicate other Federal information collection requirements and is not available from any source other than applicants or licensees. Portions of the needed information might also be contained in other information submittals to the NRC or other Federal agencies. However, duplication, if any, is slight, and the collection of this information by use of specified forms and other required reports and records is the most effective and least burdensome means of obtaining the information.

5. Effort to Reduce Small Business Burden

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

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

If the information is not collected, NRC will not be in a position to assess whether this category of licensee is operating within the specific radiation safety requirements applicable to the medical use, possession, or transfer of byproduct material. In addition, NRC will not be able to report to Congress and evaluate those medical events constituting "abnormal occurrences" or to ensure that patients, human research subjects, and referring physicians are informed of "medical events."

Applications are required to be submitted for the initial license, for amendments, and for renewals. The application process requires that applicants and licensees perform a comprehensive review of their entire radiation safety program to assure that all licensed activities will be or are being conducted safely and in accordance with NRC regulations. The review and submission of the information required for the application is essential to NRC's determination of whether the applicant has adequate training, experience, equipment, and facilities to protect public health and safety. Other reporting and recordkeeping requirements are occasioned by specific actions or events (i.e., inventories of licensed material, calibrations and checks of medical devices and medical events). Collection of specific information at the required frequency from licensees that administer byproduct material to patients or human research subjects is essential to protect the health and safety of workers, patients and human research subjects, and the public.

7. Circumstances Which Justify Variation from OMB Guidelines

Section 35.41(a) requires that written procedures for any administration requiring a written directive be maintained for the life of the license, or until superseded by new or revised procedures, to ensure that they remain available for reference and to enable the NRC to evaluate the nature and appropriateness of the procedures during inspections.

Section 35.67(e)(2) requires that licensees file a report within five days of the leakage test so that NRC may determine if any immediate follow-up actions are necessary.

Section 35.610(a) requires that the licensee maintain safety procedures and instructions for remote afterloaders, teletherapy units, and gamma stereotactic radiosurgery units for the life of the license or the devices, or until superseded by new or revised procedures, to ensure that they remain available for reference and to enable the NRC to evaluate the nature and appropriateness of the procedures during inspections.

Section 35.643(b) requires that procedures for performing periodic spot-checks on remote afterloader units be retained for the life of the license or the devices, or until superseded by new or revised procedures, to ensure that they remain available for reference and to enable the NRC to evaluate the nature and appropriateness of the procedures during inspections.

Section 35.643(c) requires that an authorized medical physicist shall review the results of each periodic spot-check of a remote afterloader unit and notify the licensee as soon as possible in writing of the results of each spot check, to ensure that the results of the spot check are available to the licensee for reference and to enable the NRC to evaluate the nature and appropriateness of the spot-checks during inspections..

Section 35.645(b)(1) requires that procedures for performing spot-checks on gamma stereotactic radiosurgery units be retained for the life of the license or the devices, or until superseded by new or revised procedures, to ensure that they remain available for reference and to allow the NRC to evaluate the nature and appropriateness of such procedures during inspections.

Section 35.2024(a) requires that a record of actions taken by licensee's management in accordance with § 35.24(a) be retained for five years to allow the NRC to evaluate the nature and appropriateness of such actions during inspections.

Section 35.2024(b) requires that a current copy of the authorities, duties, and responsibilities of the Radiation Safety Officer in accordance with § 35.24(d) be maintained to ensure that they remain available for reference and to allow the NRC to evaluate the nature and appropriateness of such actions during inspections.

Section 35.2026 requires that a record of radiation safety program changes in accordance with § 35.26 be retained for five years to allow the NRC to evaluate the nature and appropriateness of such changes during inspections.

Section 35.2433 requires that records of the activity of a strontium-90 source in accordance with § 35.433 be retained for the life of the source to ensure that they remain available for reference.
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Section 35.2630 requires that a record of each calibration, intercomparison, and comparison of dosimetry equipment done in accordance with § 35.630 be retained for the duration of the license to show throughout the period of use of the equipment that calibrations of medical devices were made with properly calibrated equipment.

Section 35.2652 requires that a record of radiation surveys of treatment units made in accordance with § 35.652 be retained for the duration of use of the unit to provide assurance that the source was properly installed or repaired and that the unit did not exceed occupational dose levels with the sources in the shielded position. These records also would be necessary in reconstruction following an incident involving the unit.

Section 35.2655 requires that a record of five-year inspections for teletherapy and gamma stereotactic radiosurgery units required by § 35.655 be retained for the duration of use of the unit. This record is required throughout the period of use of the unit to show that the required work was done and to establish a service history that may be used in incident investigations and evaluation of generic equipment problems.

Section 35.3045(d) requires that licensees submit a written report to the appropriate NRC Regional Office listed in § 30.6 within 15 calendar days after discovery of a medical event. This is the maximum time allowable to ensure that NRC can act, as necessary, to address the medical event.

Section 35.3045(e) requires that if an individual affected by a medical event has been notified orally of the medical event, the licensee must furnish a written report of the medical event to the individual upon request. This requirement ensures that complete written information will be furnished to an individual upon request so that adequate follow-up to the medical event can be provided, if needed.

Section 35.3045(g) requires a licensee to retain a record of a medical event in accordance with § 35.2045 and to provide a copy of the record to the referring physician if other than the licensee within 15 days after discovery of the medical event. This is the minimum period of time so that adequate follow-up to the medical event can be provided, if needed.

Section 35.3047(c) requires that the licensee 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 in in accordance with paragraphs (a) or (b) of § 3047. This is the maximum time allowable to ensure that NRC can act, as necessary, to address the event.

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 (both hereafter referred to as the mother) no later than 24 hours after discovery of an event that would require reporting under paragraph (a) or (b) of § 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 would be harmful. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. This requirement is the maximum time period to ensure that a verbal notice is supplied to the referring physician and the pregnant individual or mother so that adequate followup to the medical event can be provided, if necessary.

Section 35.3047(f) requires a licensee to provide a copy of the record of a dose to an embryo/fetus or a nursing child to the referring physician if other than the licensee within 15 days after discovery of the event. This is the minimum period of time so that adequate follow-up to the medical event can be provided, if needed.

Section 35.3067 requires licensees to file a report with the NRC within 5 days if a leakage test required by § 35.67 reveals the presence of 185 Bq (0.005 microcuries) or more of removable contamination. This report is necessary so that the NRC can make a determination as to whether other licensees who have similar sealed sources should take special precautions and to promptly notify other licensees if it appears there may be a generic problem. NRC allows the licensee up to five days to submit the report so that the licensee can review and analyze the source and the leak test result.

8. Consultations Outside the Agency

The program for revising Part 35 and the associated guidance documents has involved more extensive interactions and consultations with potentially affected parties (the medical community and the public) than is provided by the typical notice and comment rulemaking process. Early public input was solicited through several different mechanisms: requesting public input through Federal Register notices; holding open meetings of the government groups developing the revised rule language; meeting with numerous medical professional societies and boards; putting background documents, options for the more significant regulatory issues associated with the rulemaking, and a "strawman" draft proposed rule on the Internet; and convening public workshops. In addition, the Commission made public the staff's proposed rule text provided to the Commission for its approval. Participants from the broad spectrum of interests that may be affected by the rulemaking were invited to attend the public workshops in Philadelphia, PA and Chicago, IL, held in October and November 1997. The public was also welcome to attend these workshops, as well as the Part 35 Workshop that was held in conjunction with the All Agreement States Meeting in October 1997 and meetings of the NRC's Advisory Committee on the Medical Uses of Isotopes. NRC received numerous comments on the proposed rule (63 FR 43516, August 13, 1998), and extended the public comment period on the proposed rule to accomodate additional public comments. NRC's responses to comments made on the information collection requirements in the proposed rule are found on pages 46, 55-58, 62-63, 79-80, 83-85, 115-116, 124-128, 130, 140-142, 149, 152-153, 155-158, 160, 166-170, 179, 190, 203, 228-229, 264-265, 272-273, 275, 282, and 319-384 of the Statement of Considerations. Numerous changes were made in response to the comments on the proposed rule.

The rulemaking process used a working group, steering group, and guidance consolidation team that included not only members from the NRC headquarters offices, but also members from the regional licensing and inspection staff who are in frequent contact with NRC's medical licensees. Representatives of two Agreement States and a non-Agreement State were members of the groups that developed the rule and guidance. The Agreement State representative on the working group is also a member of the Conference of Radiation Control Directors' Suggested State Regulation Committee on Medical Regulation, which is working toward parallel development of suggested State regulations. State participation in the process enhanced development of corresponding rules in State regulations and provided an early opportunity for State input. In addition, it allowed the State staff to assess the potential impacts of NRC draft language on the regulation of non-Atomic Energy Act materials used in medical diagnosis, treatment, or research in the States. The meetings of the groups developing the rule text and the associated guidance were noted in the NRC meeting announcements and were open to the public.

9. Payment or Gift to Respondents

Not Applicable

10. Confidentiality of the Information

This information is usually not confidential. If it were, the information would be handled as proprietary in accordance with 10 CFR 2.790 of the NRC regulations.

11. Justification for Sensitive Questions

No sensitive information is requested under these regulations.

12. Estimated Burden and Burden Hour Cost

Clearance No 3150-0010

NRC LICENSEES

The revisions to the Part 35 requirements will become effective at the effective date of the regulation. The full annualized burden is shown for these requirements. Table 1 shows the reporting burden and Table 2 shows the recordkeeping burden.

Organizations and entities seeking to become recognized by NRC to certify authorized users will have one-time burdens associated with the preparation of letters to be submitted to NRC. This burden of 368 hours is shown in Table 3.

AGREEMENT STATE LICENSEES

The burden has been calculated on the basis of Agreement States having similar regulations for medical use programs and adopting those regulations at the effective date of the Part 35 revisions. The reporting burden is shown in Table 4 and the recordkeeping burden is shown in Table 5.

Clearance No. 3150-0120

NRC LICENSEES

The new burden for NRC license applications for licenses for other medical uses, included under OMB Clearance No. 3150-0120, for license applications under § 35.12 is shown in Table 6 and the new burden for NRC licensees for preceptor certifications is shown in Table 7..

AGREEMENT STATE LICENSEES

The new burden for Agreement State license applications for licenses for other medical uses, included under OMB Clearance No. 3150-0120, is shown for Agreement States in Table 8 and the new burden for Agreement State licensees for preceptor certifications is shown in Table 9.

BURDEN ESTIMATES FOR NRC LICENSEES:

Part 35:
Clearance No 3150-0010

The total annual burden for the 1,688 NRC licensees covered by 10 CFR Part 35 is estimated to be 236,213 hours, (28,697 hours reporting plus 207,516 hours recordkeeping) or an average of 140 hours per licensee. The details are shown in Tables 1 and 2. The total cost for NRC licensees is estimated at $33,778,459 (236,213 hours x $143.00 per hour).

Clearance No. 3150-0120

The total added burden under OMB Clearance No. 3150-0120 is estimated to be about 183 hours. (Burden total for NRC licensees for other medical uses shown in Table 6 of 8 hours plus burden total for NRC applicant preceptor certifications shown in Table 7 of 175 hours.) The total added burden under OMB Clearance No. 3150-0120 is estimated to be about 183 hours. The total cost for the NRC licensees is estimated at $26,169 (183 hours x $143.00 per hour).

BURDEN ESTIMATES FOR AGREEMENT STATE LICENSEES:

Part 35
Clearance No 3150-0010

This rule has several compatibility categories. Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997 (62 FR 46517), specific requirements within this rule should be adopted by Agreement States for purposes of compatibility or because of their health and safety requirement. The burden for Agreement State licensees has been calculated on the basis of Agreement States having similar regulations for medical use programs.

The total annual burden for Agreement States licensees, if all requirements are enacted, is estimated to be about 591,469 hours per year (70,727 hours reporting shown in Table 4 plus 520,742 hours recordkeeping shown in Table 5) or an average of 140 hours per licensee for the estimated 4,222 licensees covered by equivalent regulations. The details are shown in Tables 4 and 5. The total cost for the Agreement State licensees is estimated at $84,580,067 (591,469 hours x $143.00 per hour).

Clearance No. 3150-0120

The total added burden under OMB Clearance No. 3150-0120 is estimated to be about 480 hours. (Burden total for Agreement State applicant certifications shown in Table 8 of 20 hours plus burden total for Agreement State applicant preceptor certifications shown in Table 9 of 460 hours). The total cost for the Agreement State licensees is estimated at $68,640 (480 hours x $143.00 per hour).

SUMMARY BURDEN ESTIMATE

Clearance No. 3150-0010:

The total annual recurring burden for Part 35 under Clearance No. 3150-0010 is 827,682 hours (236,213 hours for NRC licensees plus 591,469 hours for Agreement State licensees).

Clearance No. 3150-0120:

The total additional recurring burden for Part 35 under Clearance No. 3150-0120 is 663 hours (183 hours for NRC licensees plus 480 hours for Agreement State licensees)
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Source of Burden and Cost Data and Method of Estimating and Cost

The burden estimates are based on the staff's best estimate of the time required to perform information collection activities. NRC received input on information collection activities during the public workshops and meetings described above. Cost estimates are based on the rate used in NRC's license fee rule.

13. Estimate of Other Additional Costs

For licensees under 10 CFR Part 35, it is most likely that purchases of equipment and services were already acquired as part of customary and usual business or private practices. Under § 35.432, however, an estimated 58 licensees would be required to purchase a source calibrating unit, at an estimated cost of $6,400 per unit, to satisfy the requirement to perform calibration measurements of brachytherapy sealed sources, if they do not rely in the alternative on measurements provided by the sealed source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine. Total one-time costs to the 58 licensees would be $371,000.

14. Estimated Annualized Cost to the Federal Government

For the requested clearance period the annualized burden and cost to NRC staff for review of submittals made under Part 35 is estimated to be 317 hours and $45,331 ($143 per hour x 317 hours). This estimate includes the recurring burden to review event reports (235 hours), and an annualized one-time burden of 82 hours for review of applications for certifying organizations (23 requests for recognition x 4 hours per request, as described in Table 3). This cost is fully recovered through fee assessments to NRC licensees pursuant to 10 CFR Parts 170 and 171.

There is no change in government burden for review of applications for other medical uses of byproduct material or radiation from the byproduct material that are not addressed in Part 35. NRC already reviews such applications. Part 35 merely incorporates reference to these uses in the rule.

15. Reasons for Changes in Burden and Cost

The revision is a net downward adjustment in burden under Clearance 3150-0010 of 543,414 hours (1,336,353 hours for the currently cleared Part 35 plus 34,743 hours for the quality management rule minus the 827,682 hours for the revised Part 35) as a result of a comprehensive revision of the Part 35 requirements to eliminate prescriptive requirements, including substantial components of the quality management rule requirements. Requirements for quality management programs have been eliminated. Prescriptive requirements for radiation safety committees have been eliminated, and requirements for radiation safety committees are now required only for licensees with multiple modalities or multiple users. Modified requirements for written directives are retained. Licensees are now allowed to revise their radiation protection program without Commission approval under specified circumstances. In addition, prescriptive general technical requirements also have been eliminated.

The revision is a new upward adjustment in annual burden under Clearance OMB 3150-0120 of 663 hours for applicant preceptor certifications.

16. Publication for Statistical Use

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

17. Reason for Not Displaying the Expiration Date

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

18. Exceptions to the Certification Statement

Not Applicable

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Not applicable

Table 1 - Annual Reporting Requirements
NRC Licensees

Section	Number of NRC Licensees	Number of Responses Per NRC Licensee	Total Number of NRC Licensee Responses	NRC Licensee Burden per Response (Hours)	Total Annual NRC Licensee Burden (Hours)
35.6(b)	164	1	164	4	656

35.6(c)	41	1	164	4	164
35.12(b), (c), & (d)	OMB Clearance 3150-0120				
35.13	OMB Clearance 3150-0120				
35.14(a) & (b)	47	1	47	0.25	12
35.19	2	1	2	1	2
35.24(c)	336	1	336	1	336
35.67(e)(2)	Burden covered in 35.3067				
35.75(b)	1,066	24	25,584	0.17	4,349
35.315(a)	1,015	varies	1,328	0.5	664
35.315(b)	16	1	16	1	16
35.415(c)	47	1	47	1	47
35.615(f)(4)	34,286	1	34,286	0.25	8,572
35.642(c)	41	12	492	0.25	123
35.643(c)	147	365	53,655	0.25	13,414
35.3045(a) & (b)	Burden covered in 35.3045(c) & (d)				
35.3045(c)	30	1	30	0.5	15
35.3045(d)	30	1	30	8	240
35.3045(e)	15	1	15	2	30
35.3045(g)	30	1	30	0.5	15
35.3047(a) & (b)	Burden covered in 35.3047(c) & (d)				
35.3047(c)	3	1	3	0.5	1.5
35.3047(d)	3	1	3	8	24
35.3047(e)	3	1	3	2	6
35.3047(f)	3	1	3	0.5	2
35.3067	2	2	4	2	8
Training and Experience Requirements: See Table 3	One-time burden for application for recognition of certifying groups				
Total:			116,242		28,697

Table 2 - Recordkeeping Requirements
NRC Licensees

Section	No. of NRC Recordkeepers	Number of Records per Licensee Year	Hours per Record	Total Record-keeping Hours	Record Retention Period
35.24(a)	1,070	5	0.5	2,675	5 years
35.24(b)	1,658	1	0.08	133	Duration of license
35.24(e)	1,658	1	0.5	829	Duration of license
35.24(f)	967	1	0.5	484	Duration of license
35.24(h)	Burden covered in 35.2024				
35.26(a)(3)&(4)	1,688	1	0.5	844	5 years
35.26(b)	Burden covered in 35.2026				
35.27(a)	1,688	1	1	1,688	
35.27(b)	1,210	1	1	1,210	
35.40(a)(1)	1,688	7	0.25	2,954	3 years
35.40(c)(1)	1,688	10	0.25	4,220	3 years
35.40(d)	Burden covered in 35.2040				
35.41(a)	1,400	1	0.5	700	Duration of license

35.50(a)	OMB Clearance 3150-0120				
35.50(b)(2)	OMB Clearance 3150-0120				
35.51(a)	OMB Clearance 3150-0120				
35.51(b)(2)	OMB Clearance 3150-0120				
35.55(a)	OMB Clearance 3150-0120				
35.55(b)(2)	OMB Clearance 3150-0120				
35.60(c)	Burden covered in 35.2060				
35.61(a)(3)	1,688	1	0.03	51	Equipment duration
35.61(c)	Burden covered in 35.2061				
35.63(e)	Burden covered in 35.2063				
35.67(d)	Burden covered in 35.2067				
35.67(g)	Burden covered in 35.2067				
35.69	1,476	1	0.25	369	Duration of license
35.70(c)	Burden covered in 35.2070				
35.75(c)	Burden covered in 35.2075(a)				
35.75(d)	Burden covered in 35.2075(b)				
35.80(a)(1)	40	20	1	800	3 years after last service
35.80(c)	Burden covered in 35.2080				
35.92(b)	Burden covered in 35.2092				
35.190(a)	OMB Clearance 3150-0120				
35.190(c)(2)	OMB Clearance 3150-0120				
35.204(c)	Burden covered in 35.2204				
35.290(a)	OMB Clearance 3150-0120				
35.290(c)(2)	OMB Clearance 3150-0120				
35.310(a)	1,015	1	1	1,015	Annual
35.310(b)	Burden covered in 35.2310				
35.315(a)(3)	1,328	3	0.2	797	Duration of treatment
35.390(a)	OMB Clearance 3150-0120				
35.390(b)(2)	OMB Clearance 3150-0120				
35.392(a)	OMB Clearance 3150-0120				
35.392 (c)(3)	OMB Clearance 3150-0120				
35.394(a)	OMB Clearance 3150-0120				
35.394(c)(3)	OMB Clearance 3150-0120				
35.404(c)	Burden covered in 35.2404				
35.406(c)	Burden covered in 35.2406				
35.410(a)	1,328	1	1	1,328	
35.410(b)	Burden covered in 35.2310				
35.415(a)(3)	454	18	0.2	1,634	Duration of treatment
35.432(d)	Burden covered in 35.2432				
35.433(b)	Burden covered in 35.2433				
35.490(a)	OMB Clearance 3150-0120				
35.490(b)(3)	OMB Clearance 3150-0120				
35.491 (c)	OMB Clearance 3150-0120				
35.590(a)	OMB Clearance 3150-0120				
35.604(b)	Burden covered in 35.2404				
35.605(d)	Burden covered in 35.2605				
35.610(a)(4)	190	1	0.5	95	Duration of use of unit
35.610(b)	190	1	0.03	6	Duration of use of unit
35.610(c)	190	1	0.5	95	Duration of use of unit

35.610(d)	190	1	1	190	Duration of use of unit
35.610(e)	190	1	0.5	95	
35.610(f)	Burden covered in 35.2310				
35.630(c)	Burden covered in 35.2630				
35.632(g)	Burden covered in 35.2632				
35.633(i)	Burden covered in 35.2632				
36.635(g)	Burden covered in 35.2632				
35.642(b)	41	1	4	164	Duration of use of unit
35.642(c)	41	12	0.25	123	Duration of use of unit
35.642(f)	Burden covered in 35.2642				
35.643(b)	114	1	0.25	29	Duration of use of unit
65.643(c)	114	260	0.25	7,410	3 years
35.643(f)	Burden covered in 35.2643				
35.645(b)(1)	9	1	0.5	5	Duration of use of unit
35.645(b)(2)	9	260	0.25	585	Duration of use of unit
35.645(g)	Burden covered in 35.2645				
35.647(e)	Burden covered in 35.2647				
35.652(c)	Burden covered in 35.2652				
35.655(c)	Burden covered in 35.2655				
35.690(a)	OMB Clearance 3150-0120				
35.690(b)(3)	OMB Clearance 3150-0120				
35.2024(a)	1,070	5	0.25	1,338	5 years
35.2024(b)	1,658	1	0.08	133	Duration of license
35.2026	1,688	1	0.25	422	5 years
35.2040	1,688	43	0.17	12,339	3 years
35.2045	30	1	1	30	3 years
35.2047	5	1	1	5	3 years
35.2060	1,688	400	0.02	13,504	3 years
35.2061	1,688	1.5	0.25	633	3 years
35.2063	1,150	290	0.17	56,695	3 years
35.2067(a)	538	2	0.17	183	3 years
35.2067(b)	538	2	0.5	538	3 years
35.2070	1,688	31	0.15	7,849	3 years
35.2075(a)	1,066	27	0.24	6,908	3 years
35.2075(b)	1,066	3	0.17	544	3 years
35.2080(a)	40	20	0.03	24	3 years after last service
35.2080(b)	40	260	0.1	1,040	3 years
35.2092	1,688	52	0.17	14,922	3 years
35.2204	674	52	0.08	2,804	3 years
35.2310	1,066	1	0.25	267	3 years
35.2404	621	29	0.17	3,062	3 years
35.2406	454	25	0.25	2,838	3 years
35.2432	454	25	0.2	2,270	3 years
35.2433	23	857	0.5	429	Life of source
35.2605	521	5	2	5,210	3 years
35.2630	521	1	0.5	261	3 years
35.2632	63	1.5	4	378	3 years
35.2642	63	12	0.5	378	3 years
35.2643	143	260	1	37,180	3 years
35.2645	9	260	2	4,680	3 years

35.2647	0	260	1	0	3 years
35.2652	195	1	0.5	98	Duration of use of unit
35.2655	65	0.2	2	26	Duration of use of unit
		3,544		207,516	
			Annualized Total:	207,516	

Table 3 - Total NRC Burden for Recognition of Certifying Boards and Total Burden for Medical Speciality Certifying Boards to Prepare Requests for Recognition

Section	Number of medical boards seeking recognition by NRC	NRC Burden Per Recognition Request (Hours)	Total NRC Recognition Burden (Hours)
35.50(a)	5	4	10
35.51(a)	2	4	8
35.55(a)	2	4	8
35.190(a)	5	4	20
35.290(a)	Same as 35.190	-	0
35.390(a)	1	4	4
35.392(a)	2	4	8
35.394(a)	Same as 35.392	-	0
35.490(a)	3	4	12
35.491	None	-	0
35.590(a)	Counted under other section	-	0
35.690(a)	3	4	12
Total Board Applications:	23	4	82
Calculation of One-Time Burden to Certifying Boards to Prepare Requests for Recognition:	23 Board Requests x 16 Hours per Request = 368 Hours		

Table 4 - Annual Reporting Requirements Agreement State Licensees

Section	Number of Agreement State Licensees	Number of Responses Per Agreement State Licensee	Total Number of Agreement State Licensee Responses	Agreement State Licensee Burden per Response (Hours)	Total Annual Agreement State Licensee Burden (Hours)
35.6(b)	410	1	410	4	820
35.6(c)	103	1	103	4	206
35.12(b), (c), & (d)	OMB Clearance 3150-0120				
35.13	OMB Clearance 3150-0120				
35.14(a) & (b)	118	1	118	0.25	0
35.19	3	1	3	1	3
35.24(c)	840	1	840	1	840
35.67(e)(2)	Burden covered				

	in 35.3067				
35.75(b)	2,665	24	63,960	0.17	10,873
35.315(a)	2,537	varies	3,322	0.50	1,661
35.315(b)	40	1	40	1	40
35.415(c)	118	1	118	1	118
35.615(f)(4)	85,715	1	85,715	0.25	21,429
35.642(c)	103	12	1,230	0.25	308
35.643(c)	368	365	134,320	0.25	33,580
35.3045(a) & (b)	Burden covered in 35.3045(c) & (d)				
35.3045(c)	75	1	75	0.5	38
35.3045(d)	75	1	75	8	600
35.3045(e)	38	1	38	2	75
35.3045(g)	75	1	75	0.5	38
35.3047(a) & (b)	Burden covered in 35.3047(c) & (d)				
35.3047(c)	7	1	7	0.5	4
35.3047(d)	7	1	7	8	56
35.3047(e)	7	1	7	2	14
35.3047(f)	7	1	7	0.5	4
35.3067	5	2	10	2	20
Total:			290,480		70,727

Table 5 - Recordkeeping Requirements
Agreement State Licensees

Section	No. of Agreement State Recordkeepers	Number of Records per Licencee Year	Hours per Record	Total Recordkeeping Hours	Record Retention Period
35.24(a)	2,675	5	0.5	6,687	5 years
35.24(b)	4,145	1	0.08	332	
35.24(e)	4,145	1	0.5	2,073	Duration of license
35.24(f)	2,418	1	0.5	1,209	Duration of license
35.24(h)	Burden covered in 35.2024				
35.26(a)(3)&(4)	4,220	1	0.5	2,110	5 years
35.26(b)	Burden covered in 35.2026				
35.27(a)	4,220	1	1	4,220	
35.27(b)	4,220	1	1	4,220	
35.40(a)(1)	4,220	7	0.25	7,385	3 years
35.40(c)(1)	4,220	10	0.25	10,550	
35.40(d)	Burden covered in 34.2040				
35.41(a)	3,500	1	0.5	1,750	Duration of license
35.50(a)	OMB Clearance 3150-0120				
35.50(b)(2)	OMB Clearance 3150-0120				
35.51(a)	OMB Clearance 3150-0120				
35.51(b)(2)	OMB Clearance 3150-0120				

35.55(a)	OMB Clearance 3150-0120				
35.55(b)(2)	OMB Clearance 3150-0120				
35.60(b)	4,220	1	0.25	1,055	Equipment duration
35.60(c)	Burden covered in 35.2061				
35.61(a)(3)	4,220	1	0.03	127	Equipment duration
35.61(c)	Burden covered in 35.2061				
35.63(e)	Burden covered in 35.2063				
35.67(d)	Burden covered in 35.2067				
35.67(g)	Burden covered in 35.2067				
35.69	3,690	1	0.25	923	Duration of license
35.70(c)	Burden covered in 35.2070				
35.75(c)	Burden covered in 35.2075(a)				
35.75(d)	Burden covered in 35.2075(b)				
35.80(a)(1)	100	20	1	2,000	3 years after last service
35.80(c)	Burden covered in 35.2080				
35.92(b)	Burden covered in 35.2092				
35.190(a)	OMB Clearance 3150-0120				
35.190(c)(2)	OMB Clearance 3150-0120				
35.204(c)	Burden covered in 35.2204				
35.290(a)	OMB Clearance 3150-0120				
35.290(c)(2)	OMB Clearance 3150-0120				
35.310 (a)	2,537	1	1	2,537	Annual
35.310(b)	Burden covered in 35.2310				
35.315(a)(3)	3,320	3	0.2	199	Duration of treatment
35.390(a)	OMB Clearance 3150-0120				
35.390(b)(2)	OMB Clearance 3150-0120				
35.392(a)	OMB Clearance 3150-0120				
35.392(c)(3)	OMB Clearance 3150-0120				
35.394(a)	OMB Clearance 3150-0120				
35.394(c)(3)	Burden covered in 35.392(b)(2)				
35.404(c)	Burden covered in 35.2404				
35.406(c)	Burden covered in 35.2406				
35.410(a)	3,320	1	1	3,320	
35.410(b)	Burden covered in 35.2310				
35.415(a)(3)	1,135	18	0.2	4,086	Duration of treatment
35.432(d)	Burden covered in 35.2432				
35.433(b)	Burden covered in 35.2433				
35.490(a)	OMB Clearance 3150-0120				
35.490(b)(3)	OMB Clearance 3150-0120				
35.491(c)	OMB Clearance 3150-0120				
35.590(a)	OMB Clearance 3150-0120				
35.604(b)	Burden covered in 35.2404				
35.605(d)	Burden covered in 35.2605				
35.610(a)(4)	475	1	0.5	238	Duration of use

					of unit
35.610(b)	475	1	0.03	14	Duration of use of unit
35.610(c)	475	1	0.5	238	Duration of use of unit
35.610(d)	475	1	1	475	Duration of use of unit
35.610(e)	475	1	0.5	238	
35.610(f)	Burden covered in 35.2310	1	0.5	238	
35.630(c)	Burden covered in 35.2630				
35.632(g)	Burden covered in 35.2632				
35.633(i)	Burden covered in 35.2633				
35.635(g)	Burden covered in 35.2635				
35.642(b)	103	1	4	412	
35.642(c)	103	12	0.25	308	Duration of use of unit
35.642(f)	Burden covered in 35.2642				
35.643(b)	285	1	0.25	71	Duration of use of unit
65.643(c)	285	260	0.25	18,525	3 years
35.643(f)	Burden covered in 35.2643				
35.645(b)(1)	23	1	0.5	11	Duration of use of unit
35.645(b)(2)	23	260	0.25	1,495	Duration of use of unit
35.645(g)	Burden covered in 35.2645				
35.647(e)	Burden covered in 35.2647				
35.652(c)	Burden covered in 35.2652				
35.655(c)	Burden covered in 35.2655				
35.690(a)	OMB Clearance 3150-0120				
35.690(b)(3)	OMB Clearance 3150-0120				
35.2024(a)	2,675	5	0.25	3,344	5 years
35.2024(b)	4,145	1	0.08	332	Duration of license
35.2026	4,220	1	0.25	1,055	5 years
35.2040	4,220	43	0.17	30,848	3 years
35.2045	75	1	1	75	3 years
35.2047	13	1	5	63	3 year
35.2060	4,220	400	0.02	33,760	3 years
35.2061	4,220	1.5	0.25	1,583	3 years
35.2063	2,875	290	0.17	141,738	3 years
35.2067(a)	1,345	2	0.17	457	3 years
35.2067(b)	1,345	2	0.5	1,345	3 years
35.2070	4,220	31	0.15	19,623	3 years
35.2075(a)	2,665	27	0.24	17,269	3 years
35.2075(b)	2,665	3	0.17	1,359	3 years
35.2080(a)	100	20	0.03	60	3 years after last service
35.2080(b)	100	260	0.1	2,600	3 years
35.2092	4,220	52	0.17	37,305	3 years
35.2204	1,685	52	0.08	7,010	3 years
35.2310	2,665	1	0.25	666	3 years
35.2404	1,553	29	0.17	7,656	3 years

35.2406	1,135	25	0.25	7,094	3 years
35.2432	1,135	25	0.2	5,675	3 years
35.2433	77	2,143	0.5	1,072	Life of source
35.2605	1,303	5	2	13,030	3 years
35.2630	1,303	1	0.5	652	3 years
35.2632	158	1.5	4	948	3 years
35.2642	158	12	0.5	948	3 years
35.2643	358	260	1	93,080	3 years
35.2645	23	260	2	11,960	3 years
35.2647	3	260	1	780	3 years
35.2652	488	1	0.5	244	Duration of use of unit
35.2655	163	0.2	2	65	Duration of use of unit
Total:		4,832		520,742	

Table 6 - Reporting Requirements - NRC Licensees New Application Burden for Licensees for Other Medical Uses (OMB Clearance No. 3150-0120)

Section	Number of NRC Licensees	Number of NRC Licensee Responses Annually	NRC Licensee Burden Per Response (Hours)	Total Annual NRC Licensee Burden (Hours)
35.12(d)	2	1	4	8
Total:	2	1	4	8

Table 7 - Recordkeeping Requirements for Individual Preceptor Certifications - NRC Licensees (OMB Clearance No. 3150-0120)

Section	Number of Applicants	Number of Records per Applicant	Hours per Record	Total Recordkeeping Hours
35.50(b)(2)	19	1	1	19
35.51(b)(2)	10	1	1	10
35.55(b)(2)	1	1	1	1
35.190(c)(2)	11	1	1	11
35.290(c)(2)	11	1	1	1
35.390(b)(2)	4	1	1	4
35.392(b)(2)	100	-	1	100
35.394(c)(3)	Burden in 35.392(b)(2)	-	-	-
35.490(b)(3)	7	1	1	7
35.491(c)	15		1	15
35.690(b)(3)	7	1	1	7
		8	-	175
			Annualized Total:	175

Table 8 - Reporting Requirements - Agreement State Licensees New Application Burden for Licensees for Other Medical Uses (OMB Clearance No. 3150-0120)

Section	Number of AS Licensees	Number of AS Licensee Responses Annually	AS Licensee Burden Per Response (Hours)	Total Annual AS Licensee Burden (Hours)
35.12(d)	5	1	4	20
Total:	5	1	4	20

Table 9 - Recordkeeping Requirements for Individual Preceptor Certifications - Agreement State Licensees (OMB Clearance No. 3150-0120)

Section	Number of Applicants	Number of Records per Applicant	Hours per Record	Total Recordkeeping (Hours)
35.50(b)(2)	48	1	1	48
35.51(b)(2)	25	1	1	25
35.55(b)(2)	3	1	1	3
35.190(c)(2)	28	1	1	28
35.290(c)(2)	28	1	1	28
35.390(b)(2)	4	1	1	4
35.392(b)(2)	250	-	1	250
35.394(c)(3)	Burden in 35.392(b)(2)	-	-	-
35.490(b)(3)	18	1	1	18
35.491(c)	38		1	38
35.690(b)(3)	18	1	1	18
		8	-	460
			Annualized Total:	460

1. Socioeconomic Characteristics of Medical Practice, 1997, American Medical Association, Center for Health Policy Research, Table 43."Mean Physician Net Income (in thousands of dollars) after Expenses before Taxes, 1995," indicates $244.4 thousand as the net income for "all physicians-rad." This is a very conservative surrogate for gross revenues, however.