FINAL REGULATORY ANALYSIS
10 CFR PARTS 20, 32, and 35

COMPREHENSIVE REVISION OF
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)
AMENDING 10 CFR PART 20
"STANDARDS FOR PROTECTION AGAINST RADIATION"
AND
CONFORMING AMENDMENT TO
10 CFR PART 32
"SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL"

1. BACKGROUND

10 CFR Part 35

NRC's Medical Use Program includes uses of byproduct material in medical diagnosis, therapy, and research. There are approximately 1,688 NRC licenses authorizing the medical use of byproduct material under 10 CFR Part 35. There are approximately 4,222 State licenses in Agreement States authorizing the medical use of byproduct material. It's estimated more than twelve million patients annually have nuclear medicine procedures involving byproduct materials.[1] Use of teletherapy, brachytherapy, and gamma stereotactic radiosurgery for treatment involves more than half a million patients annually.[2]

[1] A survey performed for the Society of Nuclear Medicine in 1993 estimated that about 10.7 million procedures were performed annually. Clouse, J.C., Rogers, M., Carretta, R.F., et al., Future Nuclear Medicine Physician Requirements, J. Nucl. Med., May 1996 (37: 5), 14N - 18 N (Figures 2 and 3). A more recent estimate places the number of procedures in 1997 at about 12.9 million. (Communication with Dr. M. Polycove, September 1999)

[2] Estimate based on estimated number of new cancer cases treated with radiation provided by the (continued...)

During the last six years, the Nuclear Regulatory Commission (NRC) has examined the issues surrounding its regulations governing the medical use of byproduct material (10 CFR Part 35), and now is enacting a comprehensive revision of those regulations.

The NRC's reexamination of 10 CFR Part 35 began in 1993 with an internal senior management review report prepared by NRC. NRC then sponsored an external study, conducted between January 1994 and 1996, by the National Academy of Sciences, Institute of Medicine. 10 CFR Part 35 also was addressed in NRC's Strategic Assessment and Rebaselining Project (SA), culminating in the SA Direction-Setting Issue Paper Number 7 (DSI 7) released September 16, 1996. On March 20, 1997, the Commission issued a Staff Requirements Memorandum (SRM) ("COMSECY-96-057, Materials/Medical Oversight (DSI 7)") directing the staff to revise 10 CFR Part 35 to restructure it into a risk-informed, more performance-based regulation.

On August 13, 1998, NRC published proposed revisions to 10 CFR Part 35 in the Federal Register (63 FR 43516). The public comment period on this proposed rule expired on November 12, 1998. The NRC subsequently reopened the public comment period until December 16, 1998 (63 FR 64829). The NRC staff reviewed the public comments and evaluated possible changes to the proposed rule. On March 25, 1999, the staff and members of the Advisory Committee on Medical Uses of Isotopes briefed the Commission on the public comments and the proposed responses to the comments.

In a Staff Requirements Memorandum (SRM) dated April 23, 1999, the Commission requested that staff provide it with a paper providing draft final rule text and those portions of the statements of consideration that discuss resolution of public comments and provide enough information to allow comparison of the changes from the current rule to the proposed rule and the draft final rule. In a SRM dated February 16, 2000, the Commission requested the NRC staff incorporate specific changes to the draft final rule language and responses to public comments.

10 CFR Part 20

At the same time that it is revising Part 35, the NRC also is amending its regulations in 10 CFR Part 20, Standards for Protection Against Radiation, 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) per year, rather than the current limit of 1 mSv (0.1 rem) in 10 CFR 20.1301.

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[2] (...continued)
American Cancer Society to the National Academy of Sciences. Institute of Medicine, National Academy of Sciences, Radiation in Medicine, Washington, D.C. 1996, 65 - 67. Tabulations by the American College of Radiology of Medicare data (Part B Medicare Annual Data) for 1997 show approximately 33,000 brachytherapy procedures and approximately 75,000 cobalt teletherapy applications for Medicare patients. As a general rule, the total for all Americans is approximately 3 times the Medicare total or about 100,000 brachytherapy and approximately 225,000 teletherapy procedures. However, this 3 to 1 approximation is less accurate for quite specific procedures, as here, than it is for broad ranges of health care services.

The 1991 revision of 10 CFR Part 20 (56 FR 23398; May 21, 1991) established a public dose limit of one mSv (0.1 rem) per year (10 CFR 20.1301(a)). 10 CFR 20.1301(c) permits licensees to request NRC authorization to operate up to an annual dose limit for an individual member of the public of five mSv (0.5 rem) per year. However, fewer than 10 medical licensees have applied for such an NRC authorization for visitors since the 1991 revision. Under 10 CFR 35.75(a), a licensee who is an authorized user of byproduct materials for medical use may authorize the release from its control of any patient who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from the released patient is not likely to exceed five mSv (0.5 rem).

The petitioner in PRM-20-24 requested that the NRC amend 10 CFR 20.1301 to authorize "specified visitors" of hospitalized radiation therapy patients, as individual members of the public, to receive up to five mSv (0.5 rem) per year. The petitioner argued that the higher dose limit is appropriate for visitors determined by the physician to be necessary for the emotional or physical support of the patient (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).

The proposed revision to Part 20 was published in the Federal Register on August 13, 1998 (63 FR 43516). The public comment period on the proposed rule ended December 16, 1998.

10 CFR Part 32

References to certain sections of Part 35 contained in Part 32 are being revised to conform Part 32 to the revisions in Part 35.

1.1 Statement of the Problem

10 CFR Part 35

NRC has identified the following six problems that require revisions to 10 CFR Part 35:[3]

First, revisions are needed to address the unnecessarily overly prescriptive nature of specific sections of 10 CFR Part 35 that result in costs to licensees without commensurate health and safety benefits. Although licensees currently have the option of adopting alternative measures, this requires a license amendment. License amendments are costly both to the licensee and to NRC.

[3] The Commission, in its Staff Requirements Memorandum (SRM)-COMSECY-96-057 dated March 20, 1997, also directed the NRC staff to consider a seventh issue, the best way to capture not only relevant safety-related events, but also precursor events. After detailed consideration, including comments from a wide variety of stakeholders and the public, proposals for addressing precursor events were not adopted for the final rule.

Second, revisions are needed to place the basis for regulation of certain well-established technologies into 10 CFR Part 35. Specifically, the regulations in 10 CFR Part 35 currently do not address high dose-rate remote brachytherapy, low dose-rate remote brachytherapy, pulsed dose-rate remote brachytherapy, and gamma stereotactic radiosurgery. The regulatory basis for these technologies currently is established by license conditions rather than regulations.

Third, revisions are needed to provide for the incorporation of new technologies in a timely manner. Currently, new technologies must be licensed through case-by-case reviews in which the applicant or licensee must submit a request for an exemption for technologies not specifically addressed in 10 CFR Part 35.

Fourth, the regulations in § 35.2, regarding thresholds for misadministrations, are not entirely dose based. These regulations do not address new technologies or patient intervention, nor do they provide a threshold for wrong treatment site. Further, the Commission directed the staff to consider changing the nomenclature from "misadministration" to "medical event."

Fifth, the requirements in Subpart J, concerning training and experience, include requirements for clinical experience in all modalities. Because diagnostic procedures present a lower overall risk, as compared to therapeutic procedures, most of the supervised clinical experience currently required may not be necessary for most diagnostic uses.

Sixth, the regulations now permit medical use licensees to hold byproduct material with a half-life less than 65 days for decay-in-storage for a minimum of ten half-lives before disposal in ordinary trash. 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.

10 CFR Part 20

Revisions to 10 CFR Part 20 are required because the 100 mrem public dose limit in 10 CFR 20.1301(c) is overly restrictive with respect to visitors to patients undergoing therapy involving byproduct material. This is a problem because there are occasions when additional access to the radiation therapy patient by family or friends, as determined by the authorized user physician, is necessary to provide both physical and emotional support while the patient is under licensee control.

10 CFR Part 32

Revisions to 10 CFR Part 32 are required to conform references to Part 35 in Part 32 to the revised Part 35.

1.2 Earlier NRC Actions

10 CFR Part 35

The NRC published an announcement of its program for revision of 10 CFR Part 35 and a request for public input on the rule development in a document published in the Federal Register on

August 6, 1997 (62 FR 42219). The NRC staff adopted a modality approach to the 10 CFR Part 35 rule. The final rule addresses the following modalities: (1) unsealed byproduct material - written directive not required; (2) unsealed byproduct material - written directive required; (3) manual brachytherapy; (4) sealed sources for diagnosis; (5) photon emitting remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units; and (6) other medical uses of byproduct material or radiation from byproduct material.

Development of the text of the final rule as well as draft guidance documents was done by a governmental Working Group and a Steering Group. Representatives of the Organization of Agreement States and the Conference of Radiation Control Program Directors, Inc. were members of both the Working Group and the Steering Group.

The NRC convened or participated in a number of public workshops and meetings to discuss the fundamental approaches and issues to be addressed in the rulemaking. These workshops and meetings were intended to ensure that the interests affected by the medical use rulemaking were given an early opportunity to comment on the rulemaking issues and to discuss the rulemaking issues with one another and the NRC. NRC participated in a workshop held during the Organization of Agreement States' 1997 All Agreement States meeting on October 18, 1997 in Los Angeles, California. (See 62 FR 52513; October 8, 1997). The All Agreement States meeting was 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 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 and radiologists); 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 regarding the revision of 10 CFR Part 35 in its meetings on September 25 and 26, 1997 and March 1 and 2, 1998. Finally, NRC staff attended meetings with numerous groups representing physicians, pharmacists, medical physicists, technologists, and other stakeholders.

The two facilitated workshops sponsored by the NRC, as well as NRC's participation in other meetings, were intended to foster a clearer understanding of the positions and concerns of the affected interests, and were not intended to develop a consensus agreement of the participants on the rulemaking issues. However, the proposed rule was the evolutionary result of these numerous meetings, as well as the reasoned consideration of the Working Group and Steering Group.

Following the August 13, 1998, publication of the proposed rule, NRC convened three facilitated workshops during the public comment period on the proposed rule to provide an opportunity for the affected interests and other members of the public to discuss the proposed rule. (These meetings were held in San Francisco, California on August 19 and 20, 1998; in Kansas City, Missouri on September 16 and 17, 1998; and in Rockville, Maryland on October 21 and 22, 1998.) In addition, NRC staff attended a meeting of the Association of Agreement States held on October 31, 1998. NRC staff also met with members of medical specialties boards on February 17 - 18, 1999. A Diagnostic Subcommittee of the ACMUI met in Rockville, Maryland on

February 23 - 24, 1999, and a Therapeutic Subcommittee of the ACMUI met in Rockville, Maryland on February 25 - 26, 1999, to discuss issues raised by the Part 35 rulemaking. A meeting of the full ACMUI to discuss the Part 35 rulemaking was held on March 24 - 25, 1999.

10 CFR Part 20

The analysis of PRM-20-24 began on June 21, 1996 (61 FR 31874), when the NRC published a notice of receipt and a request for comment on the petition. All commenters agreed with the petitioner that it was unreasonable to require licensees to limit doses to specified visitors to the public dose limit of one mSv (0.1 rem). A draft rulemaking plan was prepared and provided to the Agreement States on May 1, 1997, for review and comment, and a final rulemaking plan was submitted to the Commission for approval on August 1, 1997. The NRC consolidated action on PRM-20-24 with the 10 CFR Part 35 rulemaking in January, 1998.

2. OBJECTIVES OF THE RULEMAKING

10 CFR Part 35

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

(1) Focusing 10 CFR 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 relevant safety-significant events, but also precursor events;

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

(5) Redesigning 10 CFR 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 (e.g., confirming patient identity requiring written directives, and verifying dose; and

(7) The viability of using or referencing available industry guidance and standards, within 10 CFR Part 35 and related guidance, to the extent that they meet NRC's needs.

In carrying out these objectives, the NRC also sought the following:

- Restructuring 10 CFR Part 35 to incorporate a modality-based approach;
- Reducing or eliminating duplication or overlaps between 10 CFR Part 35 and other Parts of 10 CFR, particularly 10 CFR Part 20; and
- Reducing recordkeeping and/or reporting requirements whenever possible.

10 CFR Part 20

The objective of the rulemaking to address PRM-20-24 is to permit authorized user physicians the discretion to permit specified visitors to receive doses in excess of the one mSv (0.1 rem) public dose limit in order to provide physical and emotional support to hospitalized individuals administered radioactive materials or radiation from byproduct materials.

3. ALTERNATIVES

The following alternatives were considered in this analysis:

Alternative One:

10 CFR Part 35: Continue 10 CFR Part 35 without revision.

10 CFR Part 20: Deny PRM-20-24 and retain the one mSv (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 five mSv (0.5 rem) annual dose limit for visitors of radiation patients.

10 CFR Part 32: Continue 10 CFR Part 32 without revision.

Alternative Two:

10 CFR Part 35: Promulgate comprehensive revisions to 10 CFR Part 35 that relax certain prescriptive requirements currently contained in 10 CFR Part 35 with respect to Radiation Safety Committees, quality management, training and experience, reporting and recordkeeping, and other requirements currently covered by both 10 CFR Part 35 and 10 CFR Part 20. Substitute new requirements with respect to training and experience. Incorporate new requirements for therapeutic uses of radionuclides, including requirements for remote afterloaders, and gamma stereotactic radiosurgery.

10 CFR Part 20: Promulgate a new dose limit of five mSv (0.5 rem), as requested under PRM-20-24, including a requirement to provide basic radiation safety instruction for specified visitors of radiation therapy patients, but no requirement for visitor badging or recordkeeping.

10 CFR Part 32: Promulgate conforming changes to reflect changes to 10 CFR Part 35.

The staff selected alternative two as the preferred option.

4. UNDERLYING DATA AND ASSUMPTIONS

The following data and assumptions were used to evaluate the values and impacts of the alternatives for revisions to 10 CFR Part 35 and response to PRM-20-24.

4.1 Number and Type of Licensees

Table 1 provides data from NRC's License Tracking System on the number of NRC 10 CFR Part 35 licensees, by category, as of July 1999. The number of Agreement States licensees is estimated at 2.5 times the number of NRC licensees, based on discussions with cognizant staff of the NRC Office of State Programs. Estimates throughout are based on the assumption that Agreement States will adopt all of the regulatory changes.

Table 1
Number and Type of Licenses

	Program Code[1]	NRC[2]	Agreement States[3]
Numbers and Types of Medical Licensees			
Medical Institution-Broad	2110	75	188
Medical Institution-QMP Req.	2120	821	2,053
Medical Institution-QMP Not Req.	2121	119	298
Medical Private Practice-QMP Req.	2200	152	380
Medical Private Practice-QMP Not Req.	2201	266	665
Eye Applicators Strontium-90	2210	22	55
Mobile Nuclear Medicine Service	2220	43	108
High Dose-Rate Remote Afterloader	2230	118	295
Medium and Low Dose-Rate Remote Afterloader		29[4]	71[4]
Pulse Dose-Rate Remote Afterloader		0	3[5]
Mobile HDR Remote Afterloader	2231	2	3[6]
Mobile Therapy	2240	0	0
Teletherapy	2300	41	103
		1,688	4,222

[1] NRC Material License Program Codes, July 1999.

[2] Data from NRC License Tracking System (LTS), July 29, 1999, adjusted by subtraction of Ohio licensees in each program code category. Data on Ohio supplied by Ohio Department of Health, August 1999. Adjustment performed to reflect transition of Ohio to Agreement State status as of 8/31/99.

[3] Estimated, based on 1 to 2.5 ratio of NRC licensees to Agreement States licensees.

[4] Not based on NRC License Tracking System; estimated based on information supplied by ACMUI, March 2, 1998. As of August 1999, these data constitute upper bound estimates, due to shifts from use of LDR to HDR when feasible.

[5] Estimated, based on information supplied by ACMUI, March 2, 1998.

[6] Estimated, based on information supplied by NRC Office of State Programs.

4.2 General Administrative Activities

Table 2 provides estimates of the numbers of activities or persons subject to the general administrative requirements of 10 CFR Part 35, such as Radiation Safety Officers, meetings of Radiation Safety Committees, and license amendments under 10 CFR Part 35. It also provides estimates of the number of individuals per year becoming authorized users, authorized nuclear pharmacists, Radiation Safety Officers, or medical physicists for the first time.

Table 2
General Administrative Activities

	NRC	**Agreement States**
Number of Radiation Safety Officers[1]	1,658	4,145
Number of Medical Institutions with Quality Management Plans[2]	1,207	2,112
Number of License Amendments Completed Annually[3]	1,688	3,377
Number of Radiation Safety Committee Meetings[4]	4,180	10,450
	NRC and Agreement States	
Number of individuals per year[5] seeking certification for:		
Uptake, Dilution, and Excretion Studies	110	
Imaging and Localization Studies	110	
Therapeutic Unsealed Sources	100	
Oral administration of sodium iodide I-131	100	
Ophthalmic use of Strontium-90	15	
Brachytherapy	150	
Sealed Sources for Diagnosis	80	
Therapeutic Medical Devices	150	
Nuclear Pharmacist	20	
Medical Physicist	100	

Footnotes to Table 2

[1] Estimated for current rule, based on regulatory requirement that all licensees must appoint an RSO, but adjusted to avoid double-counting, based on the assumption that for 85 percent of the teletherapy licensees (program code 2300) and 80 percent of the high dose-rate remote afterloader licensees (program code 2230) the RSO on the license will be the same as the RSO on the medical institution license because the activities take place entirely within the medical institution.

[2] Total of program codes 2110, 2120, 2200, 2210, 2230, and 2300 for NRC licensees. Agreement States estimate adjusted to reflect the proportion of Agreement States (9 of 30, according to data provided by the NRC Office of State Programs) that have not adopted a quality management rule.

[3] Estimated as one amendment per year per licensee for current rule for NRC licensees and one amendment per year for 80 percent of Agreement State licensees. This represents an upper bound estimate. According to NRC's final rule promulgating fee schedules for FY 1999, not all materials licensees request amendments during a given fiscal year. Over a five-year period, approximately 80 percent request at least one amendment, and approximately 40 percent request multiple amendments. (64 FR 31460; June 10, 1999)

[4] Estimated as number of medical institution licensees that are required to have a Radiation Safety Committee (estimated as the total for program codes 2110, 2120, and 2121, plus 20 percent of 2230 and 15 percent of 2300 to account for licensees not covered under medical institution licenses but working in such settings) times four (quarterly) meetings per year.

[5] Compiled from estimates (in some cases covering a period of five or more years of data) obtained from American Board of Radiology, American Board of Nuclear Medicine, American Board of Medical Physicists, Health Physics Society, Board of Pharmaceutical Specialities and from personal communications with Barry Siegel, M.D., Mr. Mark Rotman, and NRC staff. Published sources include American Board of Radiology, ABR Examiner, 2:1 (Examination Statistical Summary 1991-1996) and 4:1 (Examination Statistical Summary 1994-1998); Society of Nuclear Medicine, Journal of Nuclear Medicine, Newsline: The SNM Manpower Survey Report, 33:11 (November 1992), Newsline: Future Nuclear Medicine Physician Requirements, 37:5 (May 1996), and Newsline: Future of Nuclear Medicine, Part 3: Assessment of the U.S. Therapeutic Radiopharmaceuticals Market (2001-2020), 39:7 (July 1998): and The Official ABMS Directory of Board Certified Medical Specialists, 1997 and 1999.

4.3 Current Uses of Byproduct Materials

Since 1946, growth in the medical applications of radioisotopes has been very rapid as their usefulness has become more apparent in diagnosis, therapy, and medical research. Current medical procedures employ a number of radionuclides in a wide variety of chemical and physical forms. Nuclear medicine procedures for diagnostic and therapeutic applications involve the internal administration of radiolabeled tracers. Administration of the radiolabeled tracers, known as radiopharmaceuticals, may be performed by intravenous injection, inhalation, or oral ingestion. In most cases, diagnostic nuclear medicine involves imaging agents used for the delineation and localization of organ tissues by scintigraphy (e.g., technetium-99m hydroxymethylene diphosphonate used as a bone seeking radiopharmaceutical). Organ function may be determined by quantifying the accumulation of radiopharmaceuticals in organs of interest (e.g., iodine-131 uptake studies used to assess thyroid function). Therapeutic nuclear medicine may use various radiopharmaceuticals for the treatment of disease by selective absorption or concentration (e.g., iodine-131 used to treat thyroid cancer). Other therapeutic applications may involve the use of radiopharmaceuticals in colloidal suspensions for the treatment of malignant tumors (e.g., phosphate-32 infusion for treatment of peritoneal or pleural effusions associated with malignant tumors).

Since the early 1900s, radiation therapy has become one of the major modalities of treatment in the management of neoplastic disease, generally referred to as cancer. Radiation therapy may also be used as a palliative agent in the medical treatment process. The objective of conventional radiation therapy using a teletherapy sealed source is to deliver a precisely measured dose of radiation to a defined tumor volume. This is usually accomplished by delivering a dose in daily increments over several weeks. External beam radiation therapy has evolved using innovative technology that has led to the development of the gamma stereotactic radiosurgery device used for treatment of precisely defined intracranial targets (e.g., brain tumors and arteriovenous malformations).

Brachytherapy uses a variety of smaller sealed sources for localized treatment of cancer. Typically the sealed sources are either inserted in a cavity (e.g., cesium-137 sources used for intracavitary treatment of cervical cancer) or implanted in tissue (e.g., iodine-125 seeds used for interstitial treatment of prostate cancer). Various remote afterloading devices have been developed for low, medium, and high dose-rate brachytherapy treatments.

5.0 REVISIONS TO REGULATORY TEXT AND CONSEQUENCES

SUBPART A--GENERAL INFORMATION

5.1 Purpose and scope (§ 35.1).

Section 35.1 currently provides that 10 CFR Part 35 contains requirements for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of public health and safety.

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

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

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

5.2 Definitions (§ 35.2).

Section 35.2 sets out the applicable definitions for 10 CFR Part 35.

The final rule deletes the definitions of "ALARA," "Dental use," “Diagnostic clinical procedures manual,” “Mobile nuclear medical service,” "Ministerial change," "Misadministration," "Podiatric use," "Recordable event," and "Teletherapy physicist."

The final rule revises the definitions of “Area of use,” "Authorized nuclear pharmacist," “Authorized user,” “Brachytherapy source," “Management,” “Medical use,” “Output,” "Prescribed dosage," “Prescribed dose,” “Radiation Safety Officer,” and "Written directive."

The final rule adds definitions for "Authorized medical physicist," “Brachytherapy,” “Client’s address,” “High dose-rate remote afterloader,” “Low dose-rate remote afterloader,” “Manual brachytherapy,” “Medical event," “Medium dose-rate remote afterloader,” “Mobile Medical service,” “Patient intervention,” “Preceptor,” “Pulsed dose-rate remote afterloader,” "Sealed Source and Device Registry," "Stereotactic radiosurgery," "Structured educational program,"

“Teletherapy,” "Temporary jobsite," “Therapeutic dosage,” “Therapeutic dose,” "Treatment site," “Type of use,” and "Unit dosage."

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Provide improved clarity and precision.

5.3 Maintenance of records (§ 35.5).

Section 35.5 specifies that records required by Part 35 must be legible throughout the retention period. It specifies that the record may be the original, a reproduced copy, or a microform provided that the copy or microform is authenticated by authorized personnel and the microform is capable of providing a clear copy throughout the required retention period. It also specifies that the record may be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. The final rule revises the phrase "Records such as letters, drawings, specifications, must include all pertinent information . . . " to read "Records such as letters, drawings, and specifications . . . ."

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Improved clarity.

5.4 Provisions for the protection of human research subjects (§ 35.6).

Section 35.6 provides that a licensee may conduct research involving human subjects using byproduct material if requirements specified in the section are met.

Section 35.6(a) of the final rule provides that a licensee may conduct research involving human research subjects only if using the byproduct materials specified on its license for the uses authorized on its license.

Section 35.6(b) of the final rule requires that if the research is conducted, funded, supported, or regulated by another Federal agency that has implemented the Federal Policy for the Protection of Human Subjects (Federal Policy), the licensee shall, before conducting research, obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy and obtain "informed consent," as defined and described in the Federal Policy, from the human research subject.

Section 35.6(c) of the final rule requires that if the research is not conducted, funded, supported, or regulated by another Federal agency that has implemented the Federal Policy, the licensee shall, before conducting research, apply for and receive a specific amendment to its NRC medical use license. The amendment request must include a written commitment that the licensee will, before conducting research, obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy and obtain "informed consent," as defined and described in the Federal Policy, from the research subject.

Section 35.6(d) of the final rule clarifies that nothing in this section relieves licensees from complying with the other requirements in Part 35 and that all relevant radiation safety provisions of Part 35 are applicable to research involving human subjects.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Improved clarity.

5.5 FDA, other Federal, and State requirements (§ 35.7).

Section 35.7 provides that nothing in Part 35 relieves a licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs or devices.

The final rule amends the section to provide that licensees are required to comply with applicable FDA, other Federal, and State requirements governing radioactive drugs or devices.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Improved clarity.

5.6 Information collection requirements: OMB approval (§ 35.8).

Section 35.8(a) specifies the OMB-approved information collection requirements contained in 10 CFR Part 35, and specifies that OMB has approved the information collection requirements in this 10 CFR Part under control number 3150-0010.

The final rule changes section numbers in § 35.8(b) to conform with the final rule.

Section 35.8(c) of the final rule adds NRC Forms 313A and 313B to the information collection approved under control number 3150-0120 for § 35.12.

The final rule deletes § 35.8(d) referring to OMB control number 3150-0171, which covered the information collection requirements contained in §§ 35.32 and 35.33, which are eliminated in the final rule.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change for restructuring of 10 CFR Part 35.

5.7 Implementation (§ 35.10).

The final rule adds a new section, § 35.10, that provides implementation schedules.

Section 35.10(a) requires licensees to implement the provisions in 10 CFR Part 35 on or before six months from publication of the final rule.

Section 35.10(b) allows licensees currently exempted from a provision in the current 10 CFR Part 35 to continue to be exempt under the final regulations.

Section 35.10(c) provides that if a requirement in an existing license condition differs from a requirement in the current 10 CFR Part 35, the requirements in Part 35 govern.

Section 35.10(d) requires licensees to continue to comply with any license conditions that requires them to implement procedures required by §§ 35.610, 35.642, 35.643 and 35.645.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Provides licensees time to implement new requirements.

5.8 License required (§ 35.11).

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

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

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

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Improved clarity.

5.9 Application for license, amendment, or renewal (§ 35.12).

Section 35.12 of the current rule specifies the procedures for license application, amendment, or renewal.

Section 35.12(a) currently specifies that if the application is for medical use sited in a medical institution, only the institution's management may apply. If the application is for medical use not sited in a medical institution, any person may apply.

Sections 35.12(b) and (c) currently specify that an application for medical use of byproduct material as described in the pertinent sections of 10 CFR Part 35 must be made by filing Form NRC-313.

The final rule provides in § 35.12(a) that the application must be signed by the applicant's or licensee's management and eliminates the reference to application by "any person."

In § 35.12(b), the final rule adds a reference to § 35.600, which in the final rule addresses remote afterloader units and gamma stereotactic radiosurgery units, and § 35.1000, which in the final rule addresses medical uses not covered by §§ 35.100 through 35.600. Section 35.12(b)(2) of the final rule requires the submission of procedures mandated by §§ 35.610, 35.642, 35.643, and 35.645, as applicable.

Section 35.12(c) specifies 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 final rule adds a new § 35.12(d) that establishes requirements for license applications for other medical uses of byproduct material as described in § 35.1000. Specifically, § 35.12(d) requires that, in addition to the information currently required in Form NRC-313, "Application for a Materials License," the applicant must also supply the following:

-- Any information regarding any radiation safety aspects of the medical use of the material that is not addressed in Subparts A through C of 10 CFR Part 35;

-- Any specific information necessary for: (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.

-- Any other information requested by the Commission in its review of the application.

Cost Impacts:

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

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

Assumptions:	
Licensees:	
Total annual licensee applications:	2
Reduced application preparation time, hours:	4
Physician hourly rate:[4]	$100
Total Annual Cost Savings for licensees:	$1,000[5]
Total Annual Cost Savings from amendment to § 35.12(d):	$1,000

Health and Safety Impacts:

None anticipated.

Benefits:

Cost savings to licensees.

5.10 License amendments (§ 35.13).

Section 35.13 currently specifies the circumstances under which a licensee must apply for and receive a license amendment.

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[4] The regulatory analysis assumes the following hourly rates, by labor category, fully loaded:

RSO/Authorized User/Medical Physicist/Physician/ Administrator/Management:	$100
Scientific Staff:	$50
Technical Staff:	$30
Clerical Staff:	$18

[5] Costs below $500 rounded down; costs at or above $500 rounded up to nearest thousand.

Section 35.13(b) currently requires a licensee to obtain a license amendment before it permits anyone to work as an authorized user or authorized nuclear pharmacist under the license, unless

-- Under § 35.13(b)(1) the authorized user is certified by an organization specified in 10 CFR Part 35; or

-- Under § 35.13(b)(2) the authorized nuclear pharmacist is certified by an organization specified in 10 CFR Part 35; or

-- Under § 35.13(b)(3) the person is identified as an authorized user or authorized nuclear pharmacist on an NRC or Agreement States license; or

-- Under § 35.13(b)(4) the person is identified as an authorized user or authorized nuclear pharmacist on a permit issued by an NRC or Agreement States specific licensee of broad scope.

Section 35.13(c) currently requires a licensee to obtain a license amendment before it changes Radiation Safety Officers or Teletherapy Physicists.

The final rule, in § 35.13(b), requires a licensee to obtain a license amendment before it permits anyone to work as an authorized nuclear pharmacist, authorized user, or authorized medical physicist, unless the individual meets specified conditions described in paragraphs (b)(1) through (b)(4).

The final rule, in § 35.13(c), continues to require a licensee to obtain a license amendment before it changes Radiation Safety Officers, except as provided in § 35.24(c). The final rule also amends § 35.13(e), which requires a licensee to obtain a license amendment before adding to or changing the areas of use. Specifically, § 35.13(e) of the final rule does not require licensees to submit a license amendment for changes of area of use for medical uses permitted under §§ 35.100 and 35.200.

Cost Impacts:

NRC anticipates cost savings to licensees and NRC from a reduction in the number of license amendments that will be submitted to NRC to add teletherapy physicists (changed to medical physicists) to a license (§ 35.13(c)) and areas of use where byproduct material is used in accordance with §§ 35.100 or 35.200 (§ 35.13(e)).

Assumptions (§ 35.13(c)):
Licensees:

License amendment applications[6] (20 percent of 144 licensees need to apply for one amendment/year):[7]	29
Physician/management amendment preparation time, hours:	1
Physician/management hourly rate:	$100
Technical staff hours to prepare amendment:	4
Technical staff hourly rate:	$30
Total Annual Cost Savings for licensees:	$6,000
NRC/Agreement States:[8]	
Total amendments:	29
NRC/Agreement States amendment review time, hours:	4
NRC/Agreement States hourly rate:	$75
Total Annual Cost Savings for NRC and Agreement States:	$9,000
Total Annual Cost Savings from amendment to § 35.13(c):	$15,000

NRC also anticipates cost savings to licensees and NRC or Agreement States from a reduction in the number of license amendments that will be submitted for changes in areas of use.

Assumptions (§ 35.13(e)):	
Licensees:	
Total annual amendments for changes in areas of use:	18[9]
Physician amendment preparation time, hours:	1
Physician hourly rate:	$100
Technical staff amendment preparation time, hours:	4
Technical staff hourly rate:	$30
Total Annual Cost Savings for licensees:	$4,000
NRC/Agreement States:	
Total annual amendments for changes in areas of use:	18[5]
NRC/Agreement States amendment review time, hours:	4
NRC/Agreement States hourly rate:	$75
Total Annual Cost Savings for NRC and Agreement States:	$5,000

[6] The NRC license tracking system does not generate data on license amendments by type of action requested. In addition, one amendment application may include a request for several actions. The estimated number of amendment applications per year therefore may overstate the number of requests received. Estimates are based on discussions with NRC Regional Staff and State personnel on the regulatory working group.

[7] The labor turnover rate in the U.S. economy averages approximately 20 percent, as of March 2000. This rate may overstate slightly the turnover rate for medical physicists.

[8] NRC no longer charges a separate, per-amendment fee. The NRC has amended 10 CFR 170.31 to eliminate the flat amendment fee for materials licensees. (64 FR 31460; June 10, 1999) A labor rate of $75/hour is used for NRC labor costs, which represents a partially loaded blended rate of technical, clerical, and managerial staff. The $75/hour labor rate also is used for Agreement States labor costs.

[9] Assuming approximately 10-15 percent of 144 annual amendments involve changes in areas of use.

Total Annual Cost Savings for § 35.13(e):	$9,000
Total Annual Cost Savings from § 35.13:	$24,000

Health and Safety Impacts:

None anticipated.

Benefits:

Cost savings to licensees, NRC, and Agreement States.

5.11 Notifications (§ 35.14).

Section 35.14(a) currently requires licensees to provide the Commission with a copy of the board certification or the permit issued by a licensee of broad scope for each individual who is allowed to work as an authorized user or an authorized nuclear pharmacist. Section 35.14(b)(1) requires the licensee to notify the Commission by letter when an authorized user, authorized nuclear pharmacist, Radiation Safety Officer, or teletherapy physicist permanently discontinues performance of duties under the license or has a name change.

The final rule amends §§ 35.14(a) and (b)(1) to add authorized medical physicist to the list of persons about whom the licensee must notify the Commission while simultaneously deleting teletherapy physicist from the list. The final rule, in § 35.14(a), adds permits issued by an Commission master materials licensee. The final rule adds § 35.14(b)(3) to clarify the requirement concerning notice when the licensee's name changes; and adds § 35.14(b)(4) to require notification when the licensee has added to or changed the areas of use identified in the application or on the license and permitted under §§ 35.100 or 35.200.

Cost Impacts:

NRC anticipates a small cost increase as a result of an increase in the number of notices that licensees will be required to submit. Of those licensees employing a medical physicist (estimated at about 144 licensees), about 20 percent are estimated to notify NRC or Agreement States agencies at least one additional time per year.

Assumptions (§ 35.14(b)(1)):	
Licensees:	
NRC/Agreement States licensee notifications pertaining to medical physicists:	29
Annual licensee notification, hours:	0.5
Technical staff hourly rate:	$30
Total Annual Cost Increase for licensees:	<$1,000
NRC/Agreement States:	
NRC/Agreement States licensee notifications:	29
NRC/Agreement States review time:	0.25
NRC/Agreement States hourly rate:	$75

Total Annual Cost Increase for NRC and Agreement States:	$1,000
Total Annual Cost Increase for § 35.14(b)(1):	$1,000

NRC also anticipates a small cost increase as a result of requiring licensees to report changes in the area of use. However, NRC estimates only a small number of total annual applications will be due to changes in license area of use (12.5 percent of 144 annual license notifications).

Assumptions (§ 35.14(b)(4)):	
Licensees:	
Total annual notification of changes in licensee's areas of use:	18
Notification preparation time, hours:	0.5
Technical staff hourly rate:	$30
Total Annual Cost Increase for licensees:	<$1,000
NRC/Agreement States:	
Total annual notification of changes in licensee's areas of use:	18
NRC/Agreement States review time, hours:	0.25
NRC/Agreement States hourly rate:	$75
Total Annual Cost Increase for NRC and Agreement States:	<$1,000
Total Annual Cost Increase for § 35.14(b)(4):	<$1,000
Total Annual Cost Increase for § 35.14:	$2,000

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change with substitution of term "medical physicist" for "teletherapy physicist." Also, increased flexibility and reduced regulatory burden for licensees are anticipated.

5.12 Exemptions regarding Type A specific licenses of broad scope (§ 35.15).

Section 35.15(d) currently exempts a licensee possessing a Type A specific license of broad scope for medical use from the provisions of § 35.14(b)(1) for an authorized user or an authorized nuclear pharmacist.

The final rule amends §§ 35.15(a) and (b) to authorize the exemption of a licensee possessing a Type A specific license of broad scope for medical use, issued under Part 33, from the provisions of § 35.12(d) regarding the need to file an amendment to the license for medical uses of byproduct material, as described in § 35.1000, and the provisions of § 35.13(b), respectively. Section 35.15(c) exempts a licensee with Type A specific license of broad scope for medical use from the provisions of § 35.13(e) regarding additions to or changes in the areas of use only at the addresses specified in the application or on the license.

The final rule amends § 35.15(d) to exempt a licensee with Type A specific license of broad scope for medical use from the provisions of § 35.14(a).

The final rule adds new §§ 35.15(e)-(g) to exempt Type A license holders from the provisions of § 35.14(b)(1) for an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist; provisions of § 35.14(b)(4) regarding additions to or changes in the areas of use identified in the application or on the license where byproduct material is used in accordance with §§ 35.100 or 35.200; and the provisions of § 35.49(a).

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

5.13 License issuance (§ 35.18).

Section 35.18 currently specifies the requirements for license issuance for use of byproduct material.

The final rule adds a new § 35.18(b) providing that the Commission will issue a license for mobile services if: (1) the applicant meets the requirements specified in § 35.18(a); and (2) assures that individuals or human research subjects to whom byproduct material or radiation from implants containing byproduct material will be administered may be released following treatment in accordance with § 35.75.

Cost Impacts:

No cost impacts are anticipated for licensees. The final rule promulgates, as a regulatory requirement, a criterion currently being implemented through licensing.

Health and Safety Impacts:

None anticipated.

Benefits:

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

5.14 Specific exemptions (§ 35.19).

Section 35.19 currently provides that the Commission may grant exemptions from the 10 CFR Part 35 requirements. It states that the Commission will review requests for exemptions from the training and experience requirements with the assistance of the Advisory Committee on the Medical Uses of Isotopes (ACMUI).

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

Cost Impacts:

NRC anticipates small cost increases for licensees who choose to prepare and submit exemption requests to NRC. Small costs are also associated with the necessary NRC review of these submittals.

Assumptions:	
Licensees:	
Total annual exemption applications:	5
Physician/management exemption preparation time, hours:	1
Physician/management hourly rate:	$100
Technical staff hours to prepare exemption:	4
Technical staff hourly rate:	$30
Total Annual Cost Increase for licensees:	$1,000
NRC/Agreement States:	
Total annual exemption applications:	5
NRC/Agreement States exemption review time, hours:	24
NRC/Agreement States hourly rate:	$75
Total Annual Cost Increase for NRC and Agreement States:	$9,000
Total Annual Cost Increase for § 35.19:	$10,000

Health and Safety Impacts:

None anticipated.

Benefits:

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

SUBPART B--GENERAL ADMINISTRATIVE REQUIREMENTS

5.15 ALARA program (§ 35.20).

Section 35.20 currently requires that licensees develop and implement a written radiation protection program that includes provisions for keeping doses as low as reasonably achievable (ALARA) and specifies program content and participants.

The final rule eliminates § 35.20.

Cost Impacts:

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

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

Health and Safety Impacts:

None anticipated because 10 CFR Part 20 continues to require an ALARA program.

Benefits:

Eliminates the prescriptive requirements in § 35.20 and provides licensees with greater flexibility regarding ALARA programs.

5.16 Radiation Safety Officer (§ 35.21).

Section 35.21 currently requires that each licensee appoint a Radiation Safety Officer (RSO).

Section 35.21(a) requires each licensee to appoint an RSO who is responsible for implementing the radiation safety program. The licensee, through the RSO, ensures compliance with the radiation safety program.

Section 35.21(b) specifies the duties and responsibilities of the RSO.

The final rule eliminates § 35.21 and replaces it in 10 CFR Part 35 with § 35.24, which addresses the authority and responsibilities for the radiation protection program, including specific requirements regarding the RSOs.

Cost Impacts:

Cost impacts are evaluated under § 35.24.

Health and Safety Impacts:

No health and safety impacts are anticipated from elimination of § 35.21 because § 35.24 specifically addresses requirements regarding the RSO.

Benefits:

Conforming change to restructuring of 10 CFR Part 35 to be more performance based.

5.17 Elimination of § 35.22 of the Current Rule (Radiation Safety Committee).

Section 35.22 currently requires that each medical institution licensee establish a Radiation Safety Committee (RSC) to oversee the use of byproduct material. Section 35.22(a) specifies the required membership of the RSC, meeting frequency, criteria for a quorum, content of minutes, distribution of minutes and the required retention period of minutes. Section 35.32(b) requires the RSC to perform specific reviews.

The final rule eliminates § 35.22, and replaces it with a new § 35.24, which addresses the authority and responsibilities for the radiation protection program, including a requirement (§ 35.24(f)) that licensees that 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 must establish a Radiation Safety Committee to oversee all uses of byproduct material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. The Committee may include other members whom the licensee considers appropriate.

Cost Impacts:

The elimination of § 35.22 results in significant cost savings for certain categories of licensees because of the deletion of the requirement to hold quarterly Radiation Safety Committee meetings. The impacts of the elimination of § 35.22 and its replacement by § 35.24 are described under § 35.24.

Health and Safety Impacts:

No health and safety impacts are anticipated from elimination of § 35.22 because § 35.24 incorporates requirements for coordination of the radiation safety program.

Benefits:

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

5.18 Statements of authority and responsibility (§ 35.23).

Section 35.23(a) currently requires that each licensee provide Radiation Safety Officers and Radiation Safety Committees sufficient authority to fulfill their duties and responsibilities. Section 35.23(b) requires the licensee to establish those authorities, duties, and responsibilities in writing and to retain the current edition as a record until the Commission terminates the license.

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

Cost Impacts:

Cost impacts are evaluated under § 35.24.

Health and Safety Impacts:

No health and safety impacts are anticipated from elimination of § 35.23, because § 35.24 incorporates requirements for written statements of authorities, duties, and responsibilities of the RSO.

Benefits:

Conforming change to restructuring of 10 CFR Part 35 to be more performance based.

5.19 Authority and responsibilities for the radiation protection program (§ 35.24).

The final rule contains a new section, § 35.24, specifying authority and responsibility for the radiation protection program.

Section 35.24(a) provides that, in addition to the radiation protection program requirements of 10 CFR 20.1101, a licensee's management must approve: (1) requests for license application, renewal, or amendment before submittal; (2) any individual, before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and (3) radiation protection program changes that do not require a license amendment and are permitted under § 35.26.

Section 35.24(b) requires a licensee’s management to appoint an RSO who agrees in writing to be responsible for implementing the radiation protection program. The licensee, through the RSO, shall ensure that the licensee's radiation safety activities are being performed in accordance with the licensee-approved procedures and regulatory requirements.

Section 35.24(c) authorizes a licensee to permit, for up to 60 days each year, an authorized user or an individual qualified to be a Radiation Safety Officer to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in § 35.24(g), if the licensee takes the actions required in paragraphs (b), (e), (g), and (h) of § 35.24.

Section 35.24(d) allows a licensee to simultaneously appoint more than one temporary Radiation Safety Officer in accordance with paragraph (c), if needed to ensure that the licensee has a temporary Radiation Safety Officer that satisfies the requirements to be a Radiation Safety Officer for each of the different uses of byproduct material permitted by the license.

Section 35.24(e) requires licensees to establish in writing the authority, duty, and responsibilities of the RSO.

Section 35.24(f) requires licensees that are authorized for two or more types of byproduct material under Subparts E, F, and H or two or more units under Subpart H, to establish a Radiation Safety Committee to oversee all uses of byproduct material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. The Committee may include other members whom the licensee considers appropriate.

Section 35.24(g) requires licensees to provide the RSO sufficient authority, organizational freedom, time, resources, and management prerogative to fulfill their duties to identify radiation safety problems; initiate, recommend, or provide corrective actions; stop unsafe operations; and verify implementation of corrective actions.

Section 35.24(h) requires recordkeeping under paragraphs (a), (b) and (e) in accordance with new § 35.2024.

Cost Impacts:

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

Minimal cost impacts are anticipated from the requirement in § 35.24(b) that the RSO must agree in writing to perform the duties of RSO.

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

Cost savings to licensees are anticipated from the provision in § 35.24(f) that only licensees that are licensed for two or more different uses of byproduct material under Subparts E, F, and H or two or more types of units under Subpart H must establish a Radiation Safety Committee. Licensees under Subparts D and G that use only unsealed byproduct material for which a written directive is not required are not required to have a Radiation Safety Committee. In addition,

§ 35.24(f) eliminates prescriptive requirements in §§ 35.22(a)(2) and (3) of the current rule requiring meetings to be held at least quarterly, specifying what constitutes a quorum, specifying the contents of minutes, and specifying in detail the required activities of the Radiation Safety Committee.

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

The costs associated with § 35.24(f) are estimated as follows:

Assumptions:	
Licensees not required to set up RSCs:	
Total licensee meetings eliminated annually:	2,926
Persons responsible for coordination:	4
Time saved per meeting eliminated, hours:	2
Combined staff hourly rate (medical, scientific, technical):	$75
Total Annual Cost Savings from meetings eliminated by § 35.24(f):	$1,756,000
Licensees required to set up RSCs:	
Total licensee meetings annually:	11,704
Persons responsible for coordination:	4
Reduced time required per meeting, hours:	0.1
Combined staff hourly rate (medical, scientific, technical):	$75
Total Annual Cost Savings from reduced requirements under § 35.24(f):	$351,000
Total Annual Cost Savings from elimination of § 35.22 by § 35.24(f):	$2,107,000

No cost impacts are anticipated from the new §§ 35.24(c), (d), and (e), because they continue to specify duties and responsibilities of Radiation Safety Officers.

Health and Safety Impacts:

No health and safety impacts are anticipated from the new §§ 35.24(c), (d), and (e) because they continue to specify duties and responsibilities of Radiation Safety Officers. No health or safety impacts are anticipated under § 35.24(f) because Subpart E, F, and H licensees continue to be required to have Radiation Safety Committees.

Benefits:

Provides greater flexibility to licensees.

5.19 Radiation protection program changes (§ 35.26).

Section 35.31(a) currently allows licensees to make minor changes to their radiation safety procedures that do not impact safety, and lists examples of such changes. Section 35.31(b) requires records of such changes to be kept until the license is renewed or terminated, and

specifies that changes must be signed by the Radiation Safety Officer, the affected authorized user(s), and the licensee's management or in medical institutions, the chairman of the Radiation Safety Committee and the management representative.

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

Section 35.26(a) continues to allow licensees to revise their radiation protection program without Commission approval, provided the change: (1) does not require an amendment under § 35.13; (2) is in compliance with the regulations and the license; (3) has been reviewed and approved by the RSO and licensee management; and (4) affected individuals who are instructed on the revised program before the changes are implemented. Also, § 35.26(a) eliminates the examples of ministerial changes previously listed in § 35.31(a).

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

Cost Impacts:

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

Assumptions:	
Licensees:	
Total licensees:	5,910
Net reduction in time, hours:	0.08
Technical staff hourly rate:	$30
Total Annual Cost Savings from § 35.26:	$14,000

Health and Safety Impacts:

No health and safety impacts are anticipated from the changes to § 35.26.

Benefits:

Cost savings to licensees.

5.20 Supervision (§ 35.27).

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

Section 35.25(b) currently requires that each licensee permitting preparation of byproduct material for medical use by an individual under the supervision of an authorized nuclear

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

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

Section 35.27(a) requires a licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user or as allowed by § 35.11(b)(1), in addition to the requirements in § 19.12, to instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of this chapter, and license conditions with respect to the use of byproduct material; and to require the supervised individual to follow the instructions of the supervising authorized user for medical uses of byproduct material, written radiation protection procedures established by the licensee, regulations, and license conditions with respect to the medical use of byproduct material. The final rule deletes references to the licensee's quality management program. The final rule eliminates the requirement to instruct the supervised individual in the licensee's written quality management program and to periodically review the supervised individual's use of byproduct material and records.

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

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

Cost Impacts:

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

Assumptions:	
Licensees:	
Total NRC/Agreement States licensees:	5,910
Authorized user instruction time, hours:	2
Authorized user hourly rate:	$100

Total Cost Increase for § 35.27(a)(1):	$1,182,000

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

Assumptions (elimination of periodic reviews):	
Licensees:	
Total NRC/Agreement States licensees:	5,910
Authorized user periodic review time (quarterly reviews), hours:	4
Authorized user hourly rate:	$100
Total Annual Cost Savings for § 35.27(b):	$2,364,000
Total Annual Cost Savings from § 35.27:	$1,182,000

Health and Safety Impacts:

Increased radiation safety.

Benefits:

Cost savings and increased flexibility for licensees.

5.21 Administrative requirements that apply to the provision of mobile nuclear medicine service (§ 35.29).

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

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

Cost Impacts:

Cost impacts are addressed under §§ 35.18(b) and 35.80 of the final rule.

Health and Safety Impacts:

No health and safety impacts are anticipated from elimination of § 35.29 because administrative requirements for mobile nuclear medicine services continue to be addressed under the final §§ 35.18(b) and 35.80.

Benefits:

Conforming change to restructuring of 10 CFR Part 35.

5.22 Quality Management Program (§ 35.32).

Section 35.32 currently requires each licensee to establish and maintain a written quality management program (QMP).

Section 35.32(a) requires that the quality management program must include procedures for preparing written directives for teletherapy, gamma stereotactic radiosurgery, brachytherapy, administrations of sodium iodide I-125 or I-131 in quantities greater than 30 microcuries, and therapeutic administrations of a radiopharmaceutical other than sodium iodide I-125 or I-131; verifying the patient's identity by more than one method; ensuring that each administration is in accordance with the written directive and any unintended deviation from the written directive is identified and evaluated and appropriate action is taken.

Section 35.32(b) requires that the licensee must develop procedures for and conduct a review of the quality management program at least annually.

Section 35.32(c) requires evaluation and response to each recordable event.

Section 35.32(d) provides for retention of specified records.

Section 35.32(e) permits licensees to make certain modifications to the quality management program. These changes are required to be submitted to the NRC.

Section 35.32(f) requires each applicant for a new license to submit a quality management program.

The final rule eliminates § 35.32. The final regulations in §§ 35.40 and 35.41 establish requirements for written directives and procedures to be followed for administrations requiring a written directive. This change results in significant cost saving to medical use licensees as compared to the current § 35.32.

Cost Impacts:

The deletion of § 35.32 results in significant cost savings.

Assumptions (elimination of § 35.32(b)):	
Licensees:	
Total affected licensees:	3,319
Time to develop procedures, hours	2
Hours for annual licensee QMP review/recordkeeping:	12
Authorized user hourly rate:	$100
Total Annual Cost Savings for licensees:	$4,647,000
NRC/Agreement States (elimination of § 35.32(f)):	
NRC/Agreement States review of each licensee's QMP review:	8
NRC/Agreement States staff hourly rate:	$75
Total Annual Cost Savings for NRC and Agreement States:	$1,991,000

Each applicable licensee is currently required by § 35.32(c) to evaluate and respond to each recordable event, including retaining records of the event for three years. The analysis assumes 80 annual events for which technical staff address the provisions of § 35.32(c).

Assumptions (elimination of § 35.32(c)):	
Licensees:	
Annual number of recordable events:	80
Licensee response time, hours:	2
Technical staff hourly rate:	$30
Total Annual Cost Savings for licensees:	$5,000
Total Annual Cost Savings from elimination of § 35.32(c) for licensees and NRC and Agreement States:	$6,643,000

Health and Safety Impacts:

No health and safety impacts are anticipated from elimination of § 35.32 because § 35.40 retains requirements for written directives and § 35.41 retains requirements for procedures requiring a written directive.

Benefits:

Cost savings to licensees.

5.23 Notifications, reports, and records of misadministrations (§ 35.33).

Section 35.33 currently requires that each licensee notify NRC, by phone, no later than the next calendar day, when a “misadministration” occurs; notify the referring physician and also notify the individual receiving the misadministration within 24 hours (unless the referring physician personally informs the licensee that he will inform the individual or that, based on medical judgment, telling the individual be harmful); and submit a written report to NRC and the individual notified within 15 days. Section 35.33 requires records of misadministrations to be retained for five years.

The final rule eliminates § 35.33. Requirements for reporting "medical events" are established by the final rule under § 35.3045. Section 35.2 defines "medical event" as an event that meets the criteria of § 35.3045(a). Section 35.3045(a) of the final rule, a new section, revises the requirements in § 35.33 of the current rule. Section 35.3045(a) replaces the word "misadministration" with "medical event" and makes other changes defining the situations in which reports must be made. However, the changes in § 35.3045 are not expected to change the number or type of medical events that are reported under § 35.2045 substantially from the number and type of misadministrations reported under the current rule.

Cost Impacts:

Cost impacts are evaluated under § 35.3045.

Health and Safety Impacts:

No health and safety impacts are anticipated from elimination of § 35.33 because § 35.2045 essentially retains requirements for records of medical events and § 35.3045 essentially maintains reporting requirements for medical events.

Benefits:

Conforming change to restructuring of 10 CFR Part 35 to be more performance based.

5.24 Written directives (§ 35.40).

The final rule adds a new § 35.40(a) providing that a written directive must be dated and signed by the authorized user before the administration of I-131 sodium iodide greater than 1.11 Megabequerels (MBq), any therapeutic dosage of unsealed byproduct material, or any therapeutic dose of radiation from byproduct material.

Section 35.40(b) specifies that the written directive must contain the name of the patient or human research subject and the following information: for any administration of quantities greater than 1.11 MBq of sodium iodide I-131: the dosage; for an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration; for gamma stereotactic radiosurgery: the total dose, treatment site, and number of target coordinate settings per treatment for each anatomically distinct treatment site; for teletherapy: the total dose, dose per fraction, number of fractions, and treatment site; for high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; and for all other brachytherapy, including low, medium, and pulsed dose-rate remote afterloaders: before implantation: treatment site, the radionuclide, and dose, and after implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

Section 35.40(c) provides 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 of the dosage of unsealed byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose. If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

Section 35.40(d) specifies that the licensee must retain the written directive in accordance with § 35.2040 of the final rule.

Cost Impacts:

No costs are either avoided or increased for licensees, Agreement States, or NRC because § 35.40 essentially retains the requirements in the current § 35.32(a) regarding written directives.

Health and Safety Impacts:

None anticipated.

Benefits:

Reduced regulatory burden to licensees compared to the current § 35.32 Quality Management Program, while maintaining an adequate level of health and safety.

5.25 Procedures for administrations requiring a written directive (§ 35.41).

The final rule adds a new § 35.41. Section 35.41(a) requires for any administration requiring a written directive that the licensee must develop, implement, and maintain written procedures to provide high confidence that before each administration the patient's identity is verified and that each administration is in accordance with the written directive. Section 35.41(b) specifies that the contents of the procedures must include: (1) verifying the identity of the patient or human research subject; (2) verifying that the administration is in accordance with the treatment plan, if applicable, and written directive; (3) checking both manual and computer-generated dose calculations; and (4) verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by § 35.600.

Cost Impacts:

No costs are either avoided or increased for licensees, Agreement States, or NRC because § 35.41 essentially retains the requirements in the current § 35.32(a) for administrations requiring a written directive.

Health and Safety:

None anticipated.

Benefits:

Reduced regulatory burden to licensees compared to the current § 35.32 Quality Management Program (i.e., flexibility in program management), while maintaining an adequate level of health and safety.

5.26 Suppliers for sealed sources or devices for medical use (§ 35.49).

Section 35.49 currently provides that a licensee may use for medical use only: (a) sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to 10 CFR Part 30 and § 32.74 or the equivalent requirements of an Agreement State; or (b) teletherapy sources manufactured and distributed in accordance with a license issued pursuant to 10 CFR Part 30 or the equivalent requirements of an Agreement State.

The final rule amends the text of § 35.49(a) to provide that for medical use, a licensee may only use sealed sources or devices "initially" manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to 10 CFR Part 30 and 10 CFR 32.74 of this chapter or the equivalent requirements of an Agreement State. The final rule also specifies, in § 35.49(b), that sealed sources or devices noncommercially transferred from a Part 35 licensee and, in § 35.49(c), that teletherapy sources manufactured and distributed in accordance with a license.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Greater clarity concerning the sealed sources and devices that may be used for medical uses, and greater clarity that only initial manufacturing, labeling, packaging, and distribution of a sealed source or device is covered by this section.

5.27 Training for Radiation Safety Officer (§ 35.50).

The current rule, in § 35.900, specifies the training requirements for a Radiation Safety Officer.

Section 35.900(a) lists nine specialist boards through which an individual may become certified to be an RSO.

Alternatively, § 35.900(b) specifies training and experience requirements that may be met in lieu of certification by one of the nine listed speciality boards. It currently requires 200 hours of classroom and laboratory training in specified subjects. In addition, it requires one year of full time experience as a radiation safety technologist at a medical institution under the supervision of the RSO.

Alternatively, § 35.900(c) allows an individual to be the Radiation Safety Officer if the individual is an authorized user identified on the licensee's license.

The final rule renumbers § 35.900 as § 35.50 and makes the following changes:

The list of nine approved speciality boards is eliminated. Section 35.50(a) provides instead that the licensee shall require an individual fulfilling the responsibilities of the RSO to be certified by a speciality board whose certification process includes all of the requirements in § 35.50(b) and whose certification has been recognized by the Commission or an Agreement State.

Alternatively, under § 35.50(b) the individual is required to have completed: (1) a structured educational program consisting of 200 hours of didactic training in specified areas; and (2) one

year of full time radiation safety experience under the supervision of an individual identified as the RSO on a Commission or Agreement State license that authorizes similar types of use(s) of byproduct material involving specified experience. Also, the individual must obtain written certification, signed by a preceptor RSO, that the individual has completed the required training and the individual has achieved a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use license.

Alternatively, under § 35.50(c), the individual is required to be an authorized user, an authorized medical physicist or authorized nuclear pharmacist identified on the licensee's license and to have experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has RSO responsibilities.

Cost Impacts:

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

Under § 35.50(a), NRC incurs costs for recognizing specialty boards for purposes of § 35.50(a). NRC estimates that recognition by NRC of specialty boards for certification require four hours per board and that NRC will be required to review five boards for approval.[10]

Assumptions:

NRC/Agreement States:	
Number of boards reviewed:	5
NRC review time:	4 hours/board at $75 per hour
Total Cost Increase:	$2,000

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

Assumptions:

Certifying Boards:

[10] NRC will allow medical certifying boards to submit one application for recognition that addresses every training and experience section of the final rule for which they believe the board's diplomates should be deemed to meet the requirements. However, the number of boards that are estimated to seek recognition under each training and experience section in this analysis reflects the assumption that while some boards will submit one application for multiple sections, boards also may choose to prepare more than one application when the training and experience requirements for the different sections for which they are applying are significantly different.

Number of boards seeking recognition:	5
Preparation of submission:	12 hours/board for Technical Staff at $30/hour 4 hours/board for Management at $100/hour
Total Cost Increase for Certifying Boards:	$4,000
Total Cost Increase for § 35.50(a):	$6,000

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

Assumptions:

Licensees:

Number of candidates:	19
Cost of preceptor certification:	½ hour at $20 hour for candidate[11] plus ½ hour at $100/hour for preceptor
Total Cost Increase for § 35.50(b):	$1,000
Total Cost Increase for § 35.50:	$7,000

Health and Safety Impacts:

None anticipated.

Benefits:

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

5.28 Training for authorized medical physicist (§ 35.51).

The current rule, in § 35.961, specifies the training requirements for a teletherapy physicist.

Section 35.961(a) and (b) each list one specialist board through which an individual may become certified.

Alternatively, § 35.961(c) specifies training and experience requirements that may be met in lieu of certification by one of the listed speciality boards. It currently requires holding a master's or doctor's degree in one of four areas. In addition, one year of full time training in therapeutic radiological physics followed by one year of full time work experience under the supervision of a teletherapy physicist at a medical institution that includes performing specified tasks is required.

[11] Candidate's time measured at $20 per hour based on an individual’s estimated annual salary of $30,000 to $40,000.

The final rule renumbers § 35.961 as § 35.51, changes "teletherapy physicist" to "authorized medical physicist," and makes the following additional changes:

The list of two approved speciality boards is eliminated. Section 35.51(a) provides that the licensee shall require the authorized medical physicist to be an individual who is certified by a specialty board whose certification process includes all of the training and experience requirements in § 35.51(b) and whose certification has been recognized by the Commission or an Agreement State.

Alternatively, 35.51(b)(1) adds "medical physics" to the list of degrees approved by NRC. Section 35.51(b)(1) continues to require one year of full time training in therapeutic radiological physics followed by one year of full time work experience but adds to the list of specified tasks that must be performed under supervision of an individual who meets the requirements for an authorized medical physicist at a medical institution that includes the tasks listed in §§ 35.67, 35.433, 35.632, 35.633, 35.635, 35.642, 35.643, 35.645, and 35.652, as applicable.

Section 35.51(b)(2) adds a requirement that the candidate medical physicist must obtain written certification, signed by a preceptor authorized medical physicist, that the training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to function independently as an authorized medical physicist.

Cost Impacts:

The cost impacts associated with this section involve additional costs to NRC to recognize certifying specialty boards, to certification boards for preparing materials supporting their recognition, and to some licensees and individuals seeking to be an authorized medical physicist for the cost of preceptor certification.

NRC estimates that approximately 100 physicists will seek to become authorized medical physicists under § 35.51 annually. Of these, 90 percent, or 90, will seek certification by a certifying board under § 35.51(a). No additional cost impacts will be created for them under the final rule. NRC estimates that the remainder, or approximately 10 physicists, will seek to become authorized medical physicists under § 35.51(b). New costs for securing a preceptor statement are created by the final rule.

NRC estimates that approval by NRC of specialty boards for certification for purposes of § 35.51(a) will require four hours per board and that NRC will be required to review two boards for recognition. The costs to NRC for certifying specialty boards are estimated below.

Assumptions:	
NRC/Agreement States:	
Number of boards reviewed:	2
NRC review time:	4 hours/board at $75 per hour
Total Cost Increase:	$1,000

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

Assumptions:

Certifying Boards:

Number of boards reviewed:	2
Preparation of submission:	12 hours/board for Technical Staff at $30/hour 4 hours/board for Management at $100/hour
Total Cost Increase for Certifying Boards:	$2,000
Total Cost Increase for § 35.51(a):	$3,000

The costs to licensees and preceptors associated with securing a preceptor's certification for purposes of § 35.51(b) are estimated below.

Assumptions:

Licensees:

Number of candidates:	10
Cost of preceptor certification:	½ hour at $20/hour for candidate plus ½ hour at $100/hour for preceptor
Total Cost Increase for § 35.51(b):	<$1,000
Total Cost Increase for § 35.51:	$3,000

Health and Safety Impacts:

None anticipated.

Benefits:

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

5.29 Training for an authorized nuclear pharmacist (§ 35.55).

The current rule, in § 35.980, specifies the training requirements for an authorized nuclear pharmacist.

Section 35.980(a) lists one specialist board through which an individual may become certified to perform these procedures.

Alternatively, § 35.980(b)(1) specifies training and experience requirements that may be met in lieu of certification by the listed speciality board. It currently requires 700 hours of classroom and laboratory training in specified subjects as well as supervised experience in specified tasks.

Section 35.980(b)(2) requires that the candidate pharmacist must obtain written certification, signed by a preceptor authorized nuclear pharmacist, that the training has been completed and the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

The final rule renumbers § 35.980 as § 35.55 and makes the following changes:

The listing of approved speciality boards is eliminated. Section 35.55(a) provides instead that the licensee shall require the authorized nuclear pharmacist to be a pharmacist who is certified as a nuclear pharmacist by a speciality board whose certification process includes all of the requirements in § 35.55(b) and whose certification has been recognized by the Commission or an Agreement State.

Alternatively, § 35.55(b) requires: (1) the pharmacist to have completed 700 hours in a structured educational program consisting of both didactic training in specified subjects and supervised practical experience in a nuclear pharmacy performing specified tasks; and (2) to have obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the didactic training and supervised practical experience and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

Cost Impacts:

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

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

Under § 35.55(a), NRC estimates that approval by NRC of specialty boards for certification will require four hours per board and that NRC will be required to review two boards for approval.

Assumptions:	
NRC/Agreement States:	
Number of boards reviewed:	2
NRC review time:	4 hours/board at $75 per hour
Total Cost Increase:	$1,000

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

Assumptions:	
Certifying Boards:	
Number of boards reviewed:	2
Preparation of submission:	12 hours/board for Technical Staff at $30/hour 4 hours/board for Management

	at $100/hour
Total Cost Increase for Certifying Boards:	$2,000
Total Cost Increase for § 35.55(a):	$3,000

Under § 35.55(b), the costs to licensees associated with obtaining a preceptor's certification are estimated below.

Assumptions:	
Licensees:	
Number of candidates:	1
Cost of preceptor certification:	½ hour at $20/hour for candidate plus ½ hour at $100/hour for preceptor
Total Cost Increase for § 35.55(b):	<$1,000
Total Cost Increase for § 35.55:	$3,000

Health and Safety Impacts:

None anticipated.

Benefits:

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

5.30 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist (§ 35.57).

Three sections of the current rule, §§ 35.901, 35.970, and 35.981, address training requirements for experienced Radiation Safety Officers, experienced authorized users, and experienced nuclear pharmacists. (The current § 35.57 addresses authorization for calibration and reference sources. That topic is addressed in the final rule in § 35.65.)

The current rule, in § 35.901, provides that an individual identified as a Radiation Safety Officer on Commission or Agreement States license before October 1, 1986, need not comply with § 35.900.

The current rule, in § 35.970, provides that physicians, dentists, or podiatrists identified as authorized users for the medical, dental, or podiatric use of byproduct material on Commission or Agreement States licenses before April 1, 1987, performing only those methods of use for which they were originally licensed, need not comply with the training requirements and Subpart J.

The current rule, in § 35.981, requires licensees to apply for and receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before the individual can begin work as an authorized nuclear pharmacist. It allows pharmacists who completed a structured educational program, as specified in § 35.980(b)(1) before December 2, 1994, to qualify as an "experienced nuclear pharmacist" and need not comply with the requirements for a preceptor statement (§ 35.980(b)(2)) or recentness of training (§ 35.972).

The final rule renumbers and merges §§ 35.901, 35.970, and 35.981 as § 35.57 and makes the following changes:

Section 35.57(a) provides that an individual identified as a Radiation Safety Officer, teletherapy or medical physicist, or a nuclear pharmacist by the Commission or Agreement State license, a permit issued by a Commission master material licensee, a permit issued by a Commission or Agreement State licensee, or a permit issued by a Commission master material license broad scope permittee before a specified date who perform only those medical uses for which they were authorized on that data need not comply with training requirements of Subpart D-H.

Section 35.57(b) replaces the April 1, 1987, threshold date associated with physicians, dentists, or podiatrists identified as authorized users for the medical, dental, or podiatric use of byproduct material with a date to be later specified. It also changes the training and experience citation from Subpart J to include Subparts D through H.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change to restructuring of 10 CFR Part 35.

5.31 Recentness of training (§ 35.59).

The current rule, in § 35.972, specifies that the training and experience required under 10 CFR Part 35 must have been obtained within the seven years preceding the application date or been met by continuing education and experience. (The current § 35.59 addresses requirements for possession of sealed sources and brachytherapy sources. That topic is addressed in the final rule in § 35.67.)

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

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change to restructuring of 10 CFR Part 35.

SUBPART C--GENERAL TECHNICAL REQUIREMENTS

5.32 Possession, use, and calibration of instruments to measure the activity of unsealed byproduct material (§ 35.60).

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

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

Cost Impacts:

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

Assumptions:	
Licensees:	
Total licensees:	5,910
Reduced annual testing, hours:	3
Technical staff hourly rate:	$30
Total Annual Cost Savings from § 35.60:	$532,000

Health and Safety Impacts:

No health and safety impacts are anticipated from this amendment.

Benefits:

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

5.33 Calibration of survey instruments (§ 35.61).

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

The final rule renumbers § 35.51 as § 35.61 and makes the following changes:

The final rule, in § 35.61(a), requires licensees to calibrate the survey instruments used to show compliance with 10 CFR Part 35 and with 10 CFR Part 20 before first use, annually, and following repairs that affect the calibrations.

The final rule, in § 35.61(a), specifies that the licensee must calibrate all scales with readings up to 10 mSv (1000 mrem) per hour with a radiation source; calibrate two separated readings on each scale or decade that will be used to show compliance; and requires the calibration date to be conspicuously noted on the instrument.

Section 35.61(b) provides that the licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20 percent.

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

Section 35.61(c) requires the licensee to retain a record of each survey instrument calibration in accordance with § 35.2061.

Cost Impacts:

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

Assumptions:	
Licensees:	
Total licensees:	5,910
Annual days survey instruments checked:	260
Time to test survey instruments daily, hours:	0.003
Technical staff hourly rate:	$30
Total Annual Cost Savings from § 35.61:	$138,000

Health and Safety Impacts:

None anticipated. Under 10 CFR 20.1501(b), licensees continue to be required to ensure that instruments and equipment are calibrated periodically.

Benefits:

Cost savings to licensees.

5.34 Determination of dosages of unsealed byproduct material for medical use (§ 35.63).

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

The final rule renumbers § 35.53 as § 35.63. Section 35.63(a) requires licensees to determine and record the activity of each dosage before medical use.

Section 35.63(b) provides that for a unit dosage this determination must be made by direct measurement of radioactivity or a decay correction, based on the activity or activity concentration determined by a manufacturer or preparer licensed under § 32.72 or equivalent Agreement State requirements or an NRC or Agreement State licensee in accordance with a Radioactive Drug Research Committee approved protocol or an Investigational New Drug (IND) protocol accepted by the FDA for use in research.

Section 35.63(c) requires that for other than unit dosages, this determination must be made by direct measurement of radioactivity, a combination of measurement of radioactivity and mathematical calculations, or by a combination of volumetric measurements and mathematical calculations based on the measurement made by a manufacturer or preparer licensed under § 32.72 or equivalent Agreement State requirements.

Section 35.63(d) provides that the licensee must retain a record of the dosage determination in accordance with new § 35.2063.

Cost Impacts:

The time necessary to perform a decay correction to determine the dosage of a unit dosage that is not measured directly is not significant different from the time necessary to remeasure a unit dosage in a dose calibrator. Cost savings result only for licensees who use only unit dosages, because they will not have to possess, use, and maintain a dose calibrator. However, most licensees are expected to retain possession of existing dose calibrators for use if needed.

Health and Safety Impacts:

No health and safety impacts are anticipated from the changes to § 35.63 because unit dosages will be measured by the manufacturer or commercial nuclear pharmacy.

Benefits:

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

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

5.35 Authorization for calibration, transmission, and reference sources (§ 35.65).

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

The final rule renumbers § 35.57 as § 35.65 and allows any person authorized by § 35.11 for medical use of byproduct material to receive, possess, and use any of the byproduct material specified in § 35.65 for check, calibration, transmission, and reference use as specified in §§ 35.65(a)-(d).

Section 35.65(a) specifies sealed sources manufactured and distributed by a person licensed under §§ 32.74 or equivalent Agreement State regulations and that do not exceed 1.11 Gbq (30 mCi) each. The final rule increases the maximum sealed source activity from 0.555 MBq (15 mCi) to 1.11 MBq (30 mCi).

Section 35.65(b) specifies sealed sources redistributed by a person licensed under §§ 32.74 or equivalent Agreement State regulations and that do not exceed 1.11 Gbq (30 mCi) each. The final rule specifies these redistributed sealed sources must be in the original packaging and shielding and be accompanied by the manufacturer’s approved instructions. The final rule also increases the maximum sealed source activity from 0.555 MBq (15 mCi) to 1.11 MBq (30 mCi).

Section 35.65(c) specifies any byproduct material with a half-life longer than 120 days in individual amounts not to exceed 7.4 MBq (200 µCi) or 1000 times the quantities in Appendix B of 10 CFR Part 30.

Section 35.65(d) specifies technicium-99m may be received, possessed, and used in amounts "as needed," rather than in amounts not to exceed 50 millicuries, as provided in the current rule.

Cost Impacts:

Cost savings are anticipated with the final changes to § 35.65, formerly § 35.57. Licensees will not need to obtain license amendments to obtain higher activity check sources. NRC estimates that up to151 amendments per year will be avoided.

Assumptions:

Licensees:

Total NRC/Agreement States amendments avoided (estimated):	151
Technical staff preparation time, hours:	1
Technical staff hourly rate:	$30

Total Annual Cost Savings for licensees:	$5,000
NRC/Agreement States:	
NRC/Agreement States amendments avoided:	151
NRC/Agreement States amendment review:	4 hours/amendment at $75
Total Annual Cost Savings for NRC and Agreement States:	$45,000
Total Annual Cost Savings from § 35.65:	$50,000

Health and Safety Impacts:

None anticipated.

Benefits:

Improved flexibility for licensees.

5.36 Requirements for possession of sealed sources and brachytherapy sources (§ 35.67).

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

The final rule renumbers § 35.59 as § 35.67.

Section 35.67(a) requires licensees in possession of any sealed or brachytherapy source to follow the radiation safety and handling instructions supplied by manufacturers.

Section 35.67(b) requires a licensee in possession of a sealed source to test the source for leakage before its first use, unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and test the source for leakage at intervals not to exceed six months or at other intervals approved by the Commission or an Agreement State in the Sealed Source and Device Registry.

Section 35.67(c) requires that to satisfy leak test requirements, licensees must measure the sample so that the leak test can detect the presence of 185 Bq (0.005 µCi) of radioactive material in the sample.

Section 35.67(d) requires licensees to retain leak test records in accordance with § 35.2067.

Section 35.67(e) specifies that if the leak test reveals the presence of 185 Bq (0.005 µCi) or more of removable contamination the licensee shall immediately withdraw the source from use and store, dispose, or cause it to be repaired in accordance with 10 CFR Parts 20 and 30. The licensee also is required to file a report within five days of the leak test in accordance with § 35.3067.

Section 35.67(f) provides that a licensee need not perform a leak test on certain specified sources.

Section 35.67(g) requires licensees in possession of sealed or brachytherapy sources, except for gamma stereotactic radiosurgery sources, to conduct a semi-annual physical inventory of all such sources in their possession. This section requires the licensee to retain each inventory record in accordance with § 35.2067.

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

Cost Impacts:

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

Assumptions:	
Licensees:	
Total affected licensees:	1,885
Reduction in frequency of required source inventory, hours:	1
Technical staff hourly rate:	$30
Total Annual Cost Savings from § 35.67:	$57,000

Health and Safety Impacts:

None anticipated. The source inventory requirements of § 35.67(g) of the final rule, the requirements of 10 CFR 20.1501(a)(2)(iii), as well as the occupational dose and ALARA requirements of 10 CFR Part 20, adequately address ambient dose rate measurements in areas where sealed sources are stored.

Benefits:

Cost savings to licensees and increased flexibility for licensees.

5.37 Labeling of vials and syringes (§ 35.69).

Section 35.60 currently requires that licensees keep syringes containing byproduct material conspicuously labeled and in a radiation shield that is also conspicuously labeled. Use of a syringe radiation shield is required when preparing and administering the radiopharmaceutical.

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

The final rule deletes §§ 35.60 and 35.61 and replaces them with a new § 35.69. The final rule requires that each syringe and vial that contains unsealed byproduct material must be labeled to

identify the radioactive drug. Each syringe shield and vial shield also must be labeled unless the label on the syringe or vial is visible when shielded.

Cost Impacts:

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

Health and Safety Impacts:

None anticipated.

Benefits:

Increased flexibility for licensees.

5.38 Surveys of ambient radiation exposure rate (§ 35.70).

Section 35.70 currently provides specific requirements for licensees to conduct daily and weekly surveys.

Section 35.70(a) of the final rule requires, in addition to the surveys required by Part 20, that a licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where unsealed byproduct materials requiring a written directive were prepared for use or administered.

Section 35.70(b) provides that a licensee does not need to perform the surveys required by § 35.70(a) in an area(s) where patients or human research subjects are confined when they cannot be released under § 35.75.

Section 35.70(c) requires licensees to retain a record of each survey in accordance with § 35.2070.

The final rule also eliminates in their entirety paragraphs §§ 35.70(b)-(g) in the current rule.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

No health or safety impact is anticipated from this amendment. NRC assumes most 10 CFR Part 35 licensees will continue to conduct adequate surveys as part of their radiation protection program.

Benefits:

Increased flexibility for licensees.

5.39 Release of individuals containing unsealed byproduct material or implants containing byproduct materials (§ 35.75).

Section 35.75 currently requires the following:

(a) The licensees may authorize the release from its control of any individual who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed five millisieverts (0.5 rem).

(b) The licensee shall provide the released individual with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed one millisievert (0.1 rem). If the dose to a breast-feeding infant or child could exceed one millisievert (0.1 rem) assuming there were not interruption of breast-feeding, the instructions shall also include:

(1) Guidance on the interruption or discontinuation of breast-feeding and

(2) Information on the consequences of failure to follow the guidance.

(c) The licensee shall maintain a record of the basis for authorizing the release of an individual, for three years after the date of release, if the total effective dose equivalent is calculated by:

(1) Using the retained activity rather than the activity administered,

(2) Using an occupancy factor less than 0.25 at one meter,

(3) Using the biological or effective half-life, or

(4) Considering the shielding by tissue.

(d) The licensee shall maintain a record, for three years after the date of release, that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding five millisieverts (0.5 rem).

The final rule essentially retains § 35.75 and provides that records of the release of individuals containing unsealed byproduct material or implants containing byproduct material are to be maintained in accordance with §§ 35.2075(a) and (b). Section 35.75 also makes the following changes in the final rule: (1) eliminates “permanent” from the § 35.75(a); (2) adds “parent or

guardian" to § 35.75(b); (3) adds "potential" and "if any" to § 35.75(b)(2); (4) revises the record requirements in § 35.75(c); and (5) adds references to the recordkeeping requirements in §§ 35.2075(a) and (b) to §§ 35.75(c) and (d), respectively.

Cost Impacts:

No incremental costs or cost savings are anticipated with § 35.75 for licensees, Agreement States, or NRC.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change to restructuring of 10 CFR Part 35.

5.40 Provision of mobile medical service (§ 35.80).

Section 35.80 currently provides technical requirements for mobile medical service.

The final rule is revised as follows:

Sections 35.80(a), (b), and (c) of the current rule are eliminated.

Section 35.80(a) of the final rule includes a requirement previously included in § 35.29(b) of the current rule that licensees providing mobile medical services must obtain a letter from each client's management permitting and agreeing to the services, including a discussion of each entity's responsibilities. The final rule eliminates the requirement from Part 35 that a licensee transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits; the requirement that the licensee bring into each address of use all byproduct material to be used and, before leaving, remove all unused byproduct material and all associated waste; the requirement that the licensee secure or keep under constant surveillance and immediate control all byproduct material when in transit or at an address of use; and the requirement that the licensee carry a radiation detection survey meter in each vehicle used to transport byproduct material. The final rule continues to require licensees to check instruments used to measure the activity of unsealed byproduct materials, specifying that such checks occur before medical use at each client's address or on each day of use, whichever is more frequent; requires survey instruments to be checked for proper operation with a dedicated check source before use at each client's address; and before leaving a client's address of use, to survey all areas of use, to ensure compliance with the requirements in 10 CFR Part 20.

Section 35.80(b) prohibits a mobile medical service from having byproduct material delivered from the manufacturer or the distributor to the client's address of use, unless the client has a license allowing possession of the byproduct material. This section requires that byproduct

material delivered to the client's address of use shall be received and handled in conformance with the client's license.

Section 35.80(c) requires the letter required in paragraph § 35.80(a)(1) to be retained and the record of each survey required in paragraph (a)(4) to be retained in accordance with § 35.2080.

Cost Impacts:

Licensees may be required to incur costs to obtain a dedicated check source, although in many cases such sources will be supplied with the survey instruments. Licensees also may already possess check sources, because the current rule requires instruments to be checked for proper operation. Therefore, minimal cost impacts (i.e., <$1,000) are expected.

Health and Safety Impacts:

Elimination of the requirements currently in §§ 35.80(1)(a) through (c) is not expected to result in impacts to health or safety.

Benefits:

Conforming change for restructuring of 10 CFR Part 35.

5.41 Storage of volatiles and gases (§ 35.90).

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

The final rule eliminates § 35.90.

Cost Impacts:

None anticipated.

Health and Safety:

None anticipated. Section 10 CFR 20.1701 currently requires licensees to use, to the extent practical, process or other engineering controls, such as containment or ventilation, to control the concentration of radioactive material in air, and 10 CFR 20.1702 requires use of other controls, if necessary, to control concentrations to values below those that define an airborne radioactivity area. Elimination of § 35.90 provides licensees with flexibility to determine the most effective method of storage. NRC anticipates that in general licensees continue to store volatile radiopharmaceuticals and radioactive gases in the shipper's radiation shield and container and to store multi-dose containers in a fume hood.

Benefits:

Increased flexibility for licensees.

5.42 Decay-in-storage (§ 35.92).

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

The final rule, in § 35.92(a), increases the maximum allowable half-life for byproduct material that may be held for decay in storage from 65 days to 120 days and eliminates a requirement that byproduct material must be held for decay in storage a minimum of ten half-lives. Section 35.92 of the final rule also eliminates the requirement to separate and monitor each generator column individually with all radiation shielding removed to ensure that it has decayed to background radiation level before disposal. The final rule amends the requirement to remove or obliterate all radiation labels to specify that the licensee must remove or obliterate all radiation labels, except for radiation labels on materials that are within containers and that will be handled as biomedical waste, after it has been released from the licensee.

Section 35.92(b) of the final rule requires licensees to retain a record of each disposal permitted under paragraph § 35.92(a) in accordance with § 35.2092.

Cost Impacts:

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

Assumptions:	
Licensees:	
Total annual amendments avoided:	17
Technical staff preparation time, hours:	1
Technical staff hourly rate:	$30
Total Annual Cost Savings for licensees:	$1,000
NRC/Agreement States:	
NRC/Agreement States amendment review time, hours:	0.5
NRC/Agreement States staff hourly rate:	$75
Total Annual Cost Savings for NRC and Agreement States:	$1,000
Total Annual Cost Savings from § 35.92:	$2,000

Health and Safety Impacts:

None anticipated because licensees are expected to continue to monitor waste to ensure it has decayed to background radiation levels before disposal.

Benefits:

Increased flexibility for licensees and reduced number of license amendments.

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

5.43 Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required (§ 35.100).

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

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

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None Anticipated.

Benefits:

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

5.44 Possession of survey instrument (§ 35.120).

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

The final rule eliminates § 35.120.

Cost Impacts:

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

Health and Safety Impacts:

None anticipated because licensees must continue to meet the requirements in 10 CFR 20.1501 and 20.1502 and 10 CFR 30.33 requiring surveys and monitoring.

Benefits:

Increased flexibility for licensees.

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

The current rule, in § 35.910, specifies the training requirements for an authorized user of a radiopharmaceutical for uptake, dilution, and excretion studies.

Section 35.910(a) lists five specialist boards through which an individual may become certified to perform these procedures.

Alternatively, § 35.910(b) specifies training and experience requirements that may be met in lieu of certification by one of the five listed speciality boards. It currently requires 40 hours of classroom and laboratory training in specified subjects. In addition, it requires 20 hours of supervised clinical experience.

Alternatively, § 35.910(c) specifies that the individual may complete a six month training program in nuclear medicine approved by the Accreditation Council for Graduate Medical Education that includes the classroom, laboratory, and clinical requirements specified in paragraph (b).

The final rule, in § 35.190, provides the following:

The list of five approved speciality boards is eliminated. Section 35.190(a) provides instead that the licensee shall require an 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 in § 35.190(c) and whose certification has been recognized by the Commission or an Agreement State.

Alternatively, § 35.190(b) acknowledges physicians who are authorized users under §§ 35.290 or 35.390 or equivalent Agreement State requirements as meeting the requirements of § 35.190.

Alternatively, under § 35.190(c), the physician must have completed 60 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies, including classroom and laboratory

training in specified areas; work experience under the supervision of an authorized user who meets the requirements in §§ 35.190, 35.290, or 35.390 or equivalent Agreement State requirements in specified areas; and who must have obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.190, 35.290, or 35.390 or equivalent Agreement State requirements, that the individual has satisfactorily completed the classroom and laboratory training and work experience requirements and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.100.

The final rule eliminates the alternative of completing a six-month program approved by the Accreditation Council for Graduate Medical Education (§ 35.971).

Cost Impacts:

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

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

The costs to NRC for recognizing specialty boards for purposes of § 35.190(a) are estimated below.

Assumptions:	
NRC/Agreement States:	
Number of boards reviewed:	5
NRC review time:	4 hours/board at $75 per hour
Total Cost Increase:	$2,000

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

Assumptions:	
Certifying Boards:	
Number of boards seeking recognition	5
Preparation of submission:	12 hours/board for Technical Staff at $30/hour 4 hours/board for Management at $100/hour
Total Cost Increase for Certifying Boards:	$4,000
Total Cost Increase for § 35.190(a):	$6,000

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

Assumptions:

Licensees:

Number of candidates:	11
Cost of preceptor certification:	½ hour at $20 hour for candidate[12] plus ½ hour at $100/hour for preceptor
Total Cost Increase for § 35.190(b):	$1,000
Total Cost Increase for § 35.190:	$7,000

Health and Safety Impacts:

None anticipated.

Benefits:

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

5.46 Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required (§ 35.200).

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

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

[12] Candidate's time measured at $20 per hour based on a resident physician's estimated annual salary of $30,000 to $40,000.

in research in accordance with a RDRC-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

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

5.47 Permissible molybdenum-99 concentration (§ 35.204).

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

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

Cost Impacts:

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

NRC assumes that 674 NRC licensees and 1,685 Agreement States licensees use molybdenum-99/ technetium-99m generators. Under the final rule, sale or transfer of a generator will require the new owner or user to measure the concentration of the first eluate. Assuming that generators are replaced weekly, this amendment is expected to reduce the frequency of measurements from approximately one per day to about one per week.

Assumptions:	
Licensees:	
Number of licensees:	2,359
Number of avoided eluate tests per licensee:	200
Time required to measure concentration of eluate, hours:	0.08
Technical staff hourly rate:	$30
Total Annual Cost Savings from amendment to § 35.204:	$1,132,000

Health and Safety Impacts:

None anticipated.

Benefits:

Cost savings to licensees.

5.48 Control of aerosols and gases (§ 35.205).

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

The final rule eliminates § 35.205.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated. Licensees will continue to be required to meet the requirements for occupational dose limits for adults and dose limits for individual members of the public, as specified in 10 CFR 20.1201 and 20.1301, respectively.

Benefits:

Regulatory flexibility for licensees.

5.49 Possession of survey instruments (Current § 35.220).

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

The final rule eliminates § 35.220.

Cost Impacts:

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

Health and Safety Impacts:

None anticipated because licensees must continue to meet the requirements in 10 CFR 20.1501 and 20.1502 and 10 CFR 30.33 requiring surveys and monitoring.

Benefits:

Increased flexibility for licensees.

5.50 Training for imaging and localization studies (§ 35.290).

The current rule, in § 35.920, specifies the training requirements for an authorized user of radiopharmaceuticals and generators for imaging and localization studies.

Section 35.920(a) lists five specialist boards through which an individual may become certified to perform these procedures.

Alternatively, § 35.920(b) specifies training and experience requirements that may be met in lieu of certification by one of the five listed speciality boards. The regulations currently require 200 hours of classroom and laboratory work training (§ 35.920(b)(1)); 500 hours of supervised work experience (§ 35.920(b)(2)); and 500 hours of supervised clinical experience (§ 35.920(b)(3)).

Alternatively, § 35.920(c) specifies that the individual may complete a six month training program in nuclear medicine approved by the Accreditation Council for Graduate Medical Education that includes the classroom, laboratory, and clinical requirements specified in paragraph (b).

The final rule, in § 35.290, provides the following:

The list of five approved speciality boards is eliminated. Section 35.290 provides that except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.200 to be a physician certified by a medical specialty board whose certification process includes all of the requirements in § 35.290(c) and whose certification has been recognized by the Commission or an Agreement State.

Alternatively, § 35.290(b) acknowledges physicians who are authorized users under § 35.390 or equivalent Agreement State requirements as meeting the requirements of § 35.290.

Alternatively, under § 35.290(c), the physician must have completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience must include

classroom and laboratory training in specified areas and work experience, under the supervision of an authorized user who meets the requirements in § 35.290 or § 35.390 or equivalent Agreement State requirements, involving specified activities. The physician must have obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.290 or 35.390 or equivalent Agreement State requirements, that the individual has satisfactorily completed the classroom and laboratory training and work experience required under § 35.290(c) and 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.

The final rule eliminates the alternative of completing a six-month training program approved by the Accreditation Council for Graduate Medical Education (§ 35.971).

Cost Impacts:

Cost savings are associated with the final rule due to the reduction in required training hours. NRC assumes that the reduction in required hours will not be reflected in the educational process of the certifying boards. NRC expects that 90 percent of physicians seeking approval for medical use for imaging and localization studies will obtain certification through a certification board, as specified by § 35.290(a). Ten percent of the candidates are expected to seek to qualify under § 35.290(c). NRC estimates that approximately 110 physicians will seek to become authorized users under § 35.290 annually. Of these, 90 percent, or 99, will seek certification by a certifying board under § 35.290(a). No additional cost impacts be created for them under the final rule. NRC estimates that the remainder, or approximately 11 physicians, will seek to become authorized users under § 35.290(c). New costs for securing a preceptor statement are created by the final rule. However, NRC assumes that individuals will seek certification under both §§ 35.190 and 35.290, and that, therefore, no additional costs for preceptor certification will be incurred because these costs are reflected under § 35.190.

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

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

Assumptions:	
Licensees:	
Number of candidates seeking certification through § 35.290(c):	11
Training hours required under current rule:	1,200 at $20/hour
Training hours required under rule:	700 at $20/hour
Total Annual Cost Savings from § 35.290:	$238,000

Health and Safety Impacts:

None anticipated.

Benefits:

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

5.51 Elimination of § 35.971 of the current rule (Physician training in a three month program).

Section 35.971 of the current rule provides that a physician who began a three month nuclear medicine training program approved by the Accreditation Council for Graduate Medical Education before July 1, 1984, and successfully completed the program was not required to comply with the requirements of §§ 35.910 or 35.920.

The final rule deletes § 35.971.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Consistency with the revised training and experience requirements.

SUBPART E--UNSEALED BYPRODUCT MATERIAL - WRITTEN DIRECTIVE REQUIRED

5.52 Use of unsealed byproduct material for which a written directive is required (§ 35.300).

The current rule, in § 35.300, provides that a licensee may use unsealed byproduct material prepared for medical use for therapeutic administration that is either obtained from a manufacturer or preparer licensed under § 32.72 or equivalent Agreement State requirements, or prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in § 35.920, or an individual under the supervision of either as specified in § 35.25.

Section 35.300 of the final rule is revised to indicate that it applies to any medical use of unsealed byproduct material for which a written directive is required. The final rule also changes the reference to the training and experience requirements for authorized users to §§ 35.290 or 35.390 and the reference to the regulatory requirements for supervision (§ 35.27). It adds two additional subsections indicating that it also applies to use of unsealed byproduct material obtained from NRC or an Agreement State licensee in accordance with an Investigational New Drug (IND) application accepted by FDA or prepared by the licensee for use in accordance with an IND protocol accepted by FDA for use in research.

Cost Impacts:

None anticipated.

Health and Safety:

None anticipated.

Benefits:

Provides clarification that any medical use of unsealed byproduct material (e.g., diagnostic or therapeutic) requiring a written directive are included under this subpart. Also, the final rule allows specific licensees to obtain unsealed byproduct material prepared by other NRC or Agreement State licensees for use in medical research in accordance with an IND protocol accepted by the FDA.

5.53 Safety Instruction (§ 35.310).

Section 35.310(a) of the current rule requires safety instruction for all personnel caring for the patient or human research subject receiving radiopharmaceutical therapy and hospitalized under § 35.75. Instruction is required in the following areas: (1) patient or human research subject control; (2) visitor control; (3) contamination control; (4) waste control; and (5) notification of the Radiation Safety Officer in case of patient death or medical emergency. Section 35.310(b) requires that the licensee retain records of individuals receiving instruction for three years.

The final rule adds a provision specifying that the requirements of § 35.310 are in addition to the worker instruction requirements of 10 CFR 19.12. Section 35.310(a) provides that radiation safety instruction must be given initially and at least annually to personnel caring for patients or human research subjects who cannot be released in accordance with § 35.75. Section 35.310(a) also specifies that such training must be commensurate with the duties of the personnel and what such training must include. Section 35.310(b) of the final rule requires records of persons receiving instruction to be retained in accordance with § 35.2310.

Cost Impacts:

No cost impacts anticipated. The requirements are consistent with current license conditions.

Health and Safety Impacts:

None anticipated.

Benefits:

Increased radiation safety.

5.54 Safety Precautions (§ 35.315).

Section 35.315(a) currently specifies safety precautions that licensees must take for each patient receiving radiopharmaceutical therapy and hospitalized for compliance with § 35.75.

Section 35.315(a)(1) requires a private room with a private sanitary facility.

Section 35.315(a)(2) requires posting a “Radioactive Materials” sign on the patient’s door and indicating on the door or in the patient’s chart where and how long visitors may stay in the room.

Section 35.315(a)(3) authorizes visits by individuals under age 18 on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer.

Section 35.315(a)(4) requires the licensee to measure dose rates in contiguous areas promptly after administration of the dosage and retain for three years a record of each survey demonstrating compliance with 10 CFR Part 20.

Section 35.315(a)(5) requires the licensee to monitor items removed from the patient’s room to determine that their radioactivity is not greater than background radioactivity or handle them as radioactive waste.

Section 35.315(a)(6) is reserved.

Section 35.315(a)(7) requires the licensee to survey the patient’s room for removable contamination before assigning another patient the same room.

Section 35.315(a)(8) requires the licensee to measure the thyroid burden of each individual who helped prepare or administer a dosage of I-131 and retain a record of each measurement.

Section 35.315(b) requires a licensee to notify the Radiation Safety Officer if the patient has a medical emergency or dies.

The final rule makes the following changes to § 35.315:

Section 35.315(a) specifies licensee actions for each patient or human research subject who cannot be released in accordance with § 35.75.

Section 35.315(a)(1) requires the licensee to quarter the patient or human research subject in either: (1) a private room with a private sanitary facility or (2) a room with a private sanitary facility, with another individual who also has received therapy with unsealed byproduct material and who also cannot be released pursuant to § 35.75.

Section 35.315(a)(2) and (a)(3) require the patient's or the human research subject's room to be posted with a "Radioactive Materials" sign and a note on the door or in the patient's or human research subject's chart stating where and how long visitors may stay in the room.

Sections 35.315(a)(3) and (a)(4) in the current rule are eliminated.

Section 35.315(a)(5) in the current rule is renumbered as § 35.315(a)(4) in the final rule.

Sections 35.315(a)(6), (a)(7) and (a)(8) in the current rule are eliminated.

Section 35.315(b) clarifies that licensees shall notify the authorized user and the Radiation Safety Officer, or his or her designee, as soon as possible if the patient or human research subject has a medical emergency or dies.

Cost Impacts:

Cost savings may exist from § 35.315(a)(1)(ii) allowing two patients who cannot be released to be quartered in the same room. Cost savings may be possible if, when medical institutions elect to quarter two patients together, they are able to slightly increase occupancy rates.

No cost impacts are anticipated from elimination of §§ 35.315(a)(3), (4), and (6)-(8) of the current rule. Licensees will continue to be required to comply with 10 CFR Part 20.

Health and Safety Impacts:

None anticipated.

Benefits:

Improved flexibility for licensees.

5.55 Possession of survey instruments (§ 35.320).

The current rule, in § 35.320, requires each licensee to have in its possession portable radiation detection survey instruments.

The final rule eliminates § 35.320.

Cost Impacts:

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

Health and Safety Impacts:

None anticipated because licensees must continue to meet the requirements in 10 CFR 20.1501 and 20.1502 and 10 CFR 30.33 requiring surveys and monitoring.

Benefits:

Increased flexibility for licensees.

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

The current rule, in § 35.930, specifies the training requirements for an authorized user of radiopharmaceuticals for therapeutic administration of unsealed byproduct material.

Section 35.930(a) lists four specialist boards through which an individual may become certified.

Alternatively, § 35.930(b) specifies training and experience requirements that may be met in lieu of certification by one of the four listed speciality boards. It currently requires 80 hours of classroom and laboratory training in specified subjects. In addition, it requires supervised clinical experience, including use of I-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals and use of I-131 for treatment of thyroid carcinoma in three individuals.

The final rule renumbers § 35.930 as § 35.390 and makes the following changes:

The list of four approved speciality boards is eliminated. Section 35.390 provides that except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.300 to be a physician who is certified by a medical specialty board whose certification process includes all of the requirements in § 35.390(b) and whose certification has been recognized by the Commission or an Agreement State.

Alternatively, the licensee shall require an authorized user to have completed the training and experience specified in § 35.390(b) and to have obtained written certification signed by a preceptor authorized user meeting certain specified requirements.

Section 35.390(b)(1) requires completion of 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. It specifies the topics in which classroom and laboratory training must occur and the areas in which work experience, under the supervision of an authorized user meeting specified requirements, must occur. Section 35.390(b)(1)(ii)(G) specifies that experience must include administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the categories for which the individual is requesting authorized user status, and lists four categories of administration in §§ 35.390(b)(1)(ii)(G)(1) through (G)(4).

Section 35.390(b)(2) replaces the current § 35.930(b)(2). Section 35.390(b)(2) requires that the individual obtain written certification, signed by a preceptor authorized user who meets the requirements in § 35.390(a) or specified sections of § 35.390(b), or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in § 35.390(b) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.300.

Cost Impacts:

The cost impacts associated with this section involve additional costs to NRC for recognition of certifying specialty boards, and to certifying boards for preparing materials supporting their recognition. Some individuals seeking to be an authorized user will incur costs for additional training and for preceptor certification.

NRC estimates that approximately 80 physicians will seek to become authorized users under § 35.390 annually. Of these, 95 percent, or 76, will seek certification by a certifying board under § 35.390(a). Training currently accepted by the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association includes more than 700 hours of classroom and laboratory training and practical experience. Therefore, no additional costs will be incurred by these applicants to satisfy the new 700 hour training and experience requirement in § 35.390(b). The remaining five percent, an estimated four physicians, will seek to become authorized users by satisfying the training and experience requirements in § 35.390(b). They will incur costs for the additional 620 hours of training and experience required under the final rule and for obtaining a preceptor certification.

Costs to NRC for recognizing specialty boards for purposes of § 35.390(a) are estimated below.

Assumptions:

NRC/Agreement States:	
Number of boards reviewed:	1
NRC review time:	4 hours/board at $75 per hour
Total Cost Increase:	<$1,000

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

Assumptions:

Certifying Boards:	
Number of boards reviewed:	1
Preparation of submission:	12 hours/board for Technical Staff at $30/hour 4 hours/board for Management at $100/hour
Total Cost Increase for Certifying Boards:	$1,000
Total Cost Increase for § 35.390(a):	$1,000

NRC estimates that approximately four applicants, will seek to become authorized users under § 35.390(b). The costs to licensees associated with training and securing a preceptor's certification for purposes of § 35.390(b) are estimated below.

Costs to applicants for additional training and experience:	
Assumptions:	
Licensees:	
Total licensees:	4
Number of additional hours of training required:	620
Authorized user candidate hourly rate:	$20
Total Cost Increase from additional training requirements for § 35.390(b):	$50,000

New costs for securing a preceptor statement under § 35.390(b) are created by the final rule.

Assumptions:	
Licensees:	
Number of candidates:	4
Cost of preceptor certification (½ hour of preceptor's time at $100/hour plus ½ hour of candidate's time at $20/hour):	$60
Cost Increase for obtaining preceptor certification under § 35.390(b):	<$1,000
Total Cost Increase for § 35.390:	$51,000

Health and Safety Impacts:

None anticipated.

Benefits:

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

5.57 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) (§ 35.392).

The current rule, in § 35.930, specifies the training requirements for an authorized user of radiopharmaceuticals for therapeutic administration of unsealed byproduct material and in § 35.932 specifies the training requirements for an authorized user of iodine-131 for the treatment of hyperthyroidism.

Section 35.930(a) lists four specialist boards through which an individual may become certified.

Alternatively, § 35.930(b) specifies training and experience requirements that may be met in lieu of certification by one of the four listed speciality boards. It currently requires 80 hours of classroom and laboratory training in specified subjects. In addition, it requires supervised clinical experience, including use of I-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals and use of I-131 for treatment of thyroid carcinoma in three individuals.

Section 35.932 specifies that the licensee shall require the authorized user of only iodine-131 for the treatment of hyperthyroidism to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating hyperthyroidism and supervised clinical experience consisting of 80 hours of classroom and laboratory training that includes specified subjects, and also supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism in 10 individuals.

The final rule creates a new § 35.392 providing the following:

Section 35.392(a) provides that, except as provided in § 35.57, the licensee shall require 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) to be a physician who is certified by a medical specialty board whose certification process includes all of the requirements in § 35.392(c) and whose certification has been recognized by the Commission or an Agreement State.

Alternatively, § 35.392(b) provides that the licensee shall require an authorized user to be an authorized user under §§ 35.390(a), 35.390(b), for uses listed in §§ 35.390(b)(1)(ii)(G)(1) or (2), or 35.394 or equivalent Agreement State requirements.

Alternatively, § 35.392(c) provides that the licensee shall require an authorized user to have: (1) successfully completed 80 hours of classroom and laboratory training in specified subjects; (2) work experience under the supervision of an authorized user who meets specified requirements involving specified activities, including administering dosages to patients or human research subjects that includes at least 3 cases involving the oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and (3) obtained written certification, signed by a preceptor authorized user who meets specified requirements, that the individual has successfully completed the classroom and laboratory and work experience requirements and 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.

Cost Impacts:

NRC anticipates incremental costs associated with this section involving additional costs to NRC for certifying medical specialty boards. NRC anticipates costs to the physicians seeking authorized user status from obtaining the preceptor's certification.

Costs to NRC for recognizing specialty boards for purposes of § 35.392(a) are estimated below.

Assumptions:	
NRC/Agreement States:	
Number of boards reviewed:	2
NRC review time:	4 hour/board at $75 per hour
Total Cost Increase:	$1,000

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

Assumptions:	
Certifying Boards:	
Number of boards reviewed:	2
Preparation of submission:	12 hours/board for Technical Staff at $30/hour 4 hours/board for Management at $100/hour
Total Cost Increase for Certifying Boards:	$2,000
Total Cost Increase for § 35.392(a):	$3,000

New costs for securing a preceptor statement under § 35.392(c) are created by the final rule.

Assumptions:	
Licensees:	
Number of candidates:	100
Cost of preceptor certification (½ hour of preceptor's time at $100/hour plus ½ hour of candidate's time at $20/hour):	$60
Cost Increase for obtaining preceptor certification under § 35.392(c):	$6,000
Total Cost Increase for § 35.392:	$9,000

Health and Safety Impacts:

None anticipated.

Benefits:

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

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

The current rule, in § 35.930, specifies the training requirements for an authorized user of radiopharmaceuticals for therapeutic administration of unsealed byproduct material, and, in § 35.934, specifies the training requirements for use of iodine-131 for the treatment of thyroid carcinoma.

Section 35.930(a) lists four specialist boards through which an individual may become certified.

Alternatively, § 35.930(b) specifies training and experience requirements that may be met in lieu of certification by one of the four listed speciality boards. It currently requires 80 hours of classroom and laboratory training in specified subjects. In addition, it requires supervised clinical experience, including use of I-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals and use of I-131 for treatment of thyroid carcinoma in three individuals.

Section 35.934 specifies that the licensee shall require the authorized user of only iodine-131 for the treatment of thyroid carcinoma to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating thyroid carcinoma and supervised clinical experience consisting of 80 hours of classroom and laboratory training that includes specified subjects, and also supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for the treatment of thyroid carcinoma in five individuals.

The final rule creates a new section, § 35.394, providing the following:

Section 35.394(a) provides that, except as provided in § 35.57, the licensee shall require 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) to be a physician who is certified by a medical specialty board whose certification process includes all of the requirements in § 35.394(c) and whose certification has been recognized by the Commission or an Agreement State.

Alternatively, § 35.394(b) provides that the licensee shall require an authorized user to be an authorized user under §§ 35.390(a), 35.390(b), with work experience in administering dosages as stated in § 35.390(b)(1)(ii)(G)(2), or equivalent Agreement State requirements.

Alternatively, § 35.394(c) provides that the licensee shall require an authorized user to have: (1) successfully completed 80 hours of classroom and laboratory training in specified subjects; (2) have work experience under the supervision of an authorized user who meets specified requirements involving specified activities, including administering dosages to patients or human research subjects that includes at least three cases involving the oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and (3) have obtained written certification, signed by a preceptor authorized user who meets specified requirements, that the

individual has successfully completed the classroom and laboratory and work experience requirements and 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.

Cost Impacts:

NRC anticipates that the medical boards recognized under § 35.392 will also seek recognition under this section. Therefore, no incremental costs will be associated with this section involving costs to NRC for certifying medical specialty boards. NRC anticipates costs to the physicians seeking authorized user status under § 35.394(c) from obtaining the preceptor's certification.

New costs for securing a preceptor statement under § 35.394(c) are created by the final rule. However, NRC assumes that candidates under § 35.394 will also seek to qualify under § 35.392, and therefore the costs of preceptor certification are reflected under § 35.392.

Health and Safety Impacts:

None anticipated.

Benefits:

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

SUBPART F--MANUAL BRACHYTHERAPY

5.59 Use of sealed sources for manual brachytherapy (§ 35.400).

Section 35.400 currently requires a licensee to use specified sources for brachytherapy in accordance with the manufacturer's radiation safety and handling instructions. Section 35.400 approves the use of seven sealed sources for brachytherapy and specifies how they may be used (e.g., topically, interstitially).

The final rule amends § 35.400 to eliminate the listing of permissible sealed sources and therapeutic use specifications. It replaces the list with the provision that a licensee shall only use brachytherapy sealed sources for therapeutic medical uses as approved in the Sealed Source and Device Registry (SSDR) or in research in accordance with an effective Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 35.49(a) are met.

Cost Impacts:

Cost savings are associated with this section in the final rule. Use of a brachytherapy source or employment of a brachytherapy therapeutic treatment method not listed in § 35.400 currently requires a license amendment. The final rule eliminates the need for a licensee to obtain a license amendment to use a source or therapeutic method not listed in § 35.400. No longer requiring licensees to submit license amendments if they want to use a source or therapeutic method not listed in § 35.400 reduces both licensee costs and NRC and Agreement States costs.

Assumptions:	
Licensees:	
Total number of amendments (10 NRC and 25 Agreement States licensees):	35
Licensee amendment preparation time, hours:	2
Technical staff hourly rate:	$30
Total Annual Cost Savings for licensees:	$2,000
NRC/Agreement States:	
Total license amendment submittals (10 NRC and 25 Agreement States licensees):	35
NRC/Agreement States amendment review time, hours:	1
NRC/Agreement States staff hourly rate:	$75
Total Annual Cost Savings for NRC and Agreement States:	$2,000
Total Annual Cost Savings from changes to § 35.400:	$4,000

Health and Safety Impacts:

Physicians have a wider range of therapeutic options and the methods in which the sealed sources can be used will increase. Use of new or revised techniques no longer require a license amendment, if the manufacturer updates the SSDR.

Benefits:

Improved licensee flexibility and cost savings to licensees due to the elimination of license amendments.

5.60 Surveys after source implant and removal (§ 35.404).

Section 35.404(a) currently specifies that immediately after removing the last temporary implant source, the licensee must make a radiation survey of the patient or human research subject to confirm that all sources have been removed. The final rule provides that a licensee may not release a patient treated with temporary implants from confinement for medical care until all sources have been removed. Section 35.404(b) requires licensees to retain records of surveys.

Section 35.404(a) of the final rule specifies that immediately after implanting sources, the licensee must make a radiation survey of the patient or human research subject to locate and account for all sources that have not been implanted. The final rule in § 35.404(b) specifies that immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a radiation survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

The final rule also eliminates the requirement that patients with temporary implants cannot be released until all implants have been removed. In the final rule, all requirements regarding the release of patients with temporary implants are contained in § 35.75. Section 35.404(c) requires licensees to retain a record of patient or human research subject surveys in accordance with § 35.2404.

Cost Impacts:

Currently, a license amendment is required to allow for the release from hospital confinement of patients with temporary implants that have not been removed. The NRC anticipates cost savings for both licensees and NRC and Agreement States with the changes to § 35.404 in the final rule eliminating the requirement that the licensee may not release from confinement a patient or a human research subject treated by temporary implant until all sources have been removed. These cost savings result from no longer requiring the submission of license amendments to allow the release of patients with temporary implants that have not been removed.

Assumptions:	
Licensees:	
Total number of amendments (10 NRC and 25 Agreement States licensees):	35
Licensee amendment preparation time, hours:	2
Technical staff hourly rate:	$30
Total Annual Cost Savings for licensees:	$2,000
NRC and Agreement States:	
Total license amendment submittals (10 NRC and 25 Agreement States licensees):	35

NRC/Agreement States amendment review time, hours:	1
NRC/Agreement States staff hourly rate:	$75
Total Annual Cost Savings for NRC and Agreement States:	$3,000
Total Annual Cost Savings from changes to § 35.404:	$5,000

Health and Safety Impacts:

None anticipated.

Benefits:

Cost savings and reduced regulatory burden due to the elimination of license amendments.

5.61 Brachytherapy sources accountability (§ 35.406).

Section 35.406(a) currently requires a licensee to return brachytherapy sources to the storage area promptly after removal and to count the number of sealed sources to ensure all sources taken from the storage area have been returned. Sections 35.406(b)(1)-(3) describe the specific records that must be kept concerning the use of the source. Section 35.406(c) requires a radiation survey of the patient and area of use immediately following a source implantation and § 35.406(d) mandates that these inventory and survey records must be kept for three years.

The final rule, in §35.406, eliminates the requirement for a count of sources returned to the storage area. The final rule eliminates detailed specifications for the source inventory and survey requirements of the current rule. The final rule removes the requirement for a radiation survey immediately following a source implant from § 35.406(c) of the current rule and moves it to § 35.404(a) of the final rule.

Section 35.406(a) of the final rule requires licensees to maintain accountability at all times for all brachytherapy sources in storage or use.

Section 35.406(b) of the final rule requires licensees to return brachytherapy sources to a secure storage area, as soon as possible after removing sources from a patient or a human research subject.

Section 35.406(c) of the final rule requires that licensees make a record of brachytherapy source accountability in accordance with § 35.2406.

Cost Impacts:

None anticipated. Licensees continue to be required to maintain accountability for each brachytherapy source.

Health and Safety Impacts:

None anticipated. Licensees continue to be required to maintain records so that, if a brachytherapy source is misplaced or missing, the licensee is immediately alerted and can take appropriate action.

Benefits:

Improved flexibility for licensees.

5.62 Safety instruction (§ 35.410).

Section 35.410 currently requires that radiation safety instruction be given to all personnel caring for patients or human research subjects undergoing implant therapy. Sections 35.410(a)(1)-(5) specify the subjects that must be covered in the instruction. Section 35.410(b) requires that records of individuals receiving instruction must be retained for three years.

The final rule amends § 35.410(a) to specify that radiation safety instruction must be provided to all personnel caring for patients undergoing implant therapy and to require that the instruction be given "initially and at least annually." The instruction must be "commensurate with the duties of the personnel." Sections 35.410(a)(1)-(5) specifies the topics for instruction. Section 35.410(a)(5) adds a requirement that an authorized user, as well as the RSO or the RSO's designee, be notified if the patient or human research subject has a medical emergency or dies. Section 35.410(b) requires records to be maintained in accordance with § 35.2310.

Cost Impacts:

None anticipated. The requirements are consistent with current license conditions.

Health and Safety Impacts:

None anticipated.

Benefits:

Increased radiation safety.

5.63 Safety precautions (§ 35.415).

Currently, § 35.415(a)(1) requires that implant patients confined to medical care may not be quartered with other hospital patients not receiving radiation therapy. Section 35.415(a)(2) stipulates that a sign "Radioactive Materials" and a note must be posted on an implant patient's door or chart regarding visiting instructions. Section 35.415(a)(3) requires that requests by minors to visit implant patients must be reviewed on a case-by-case basis by the authorized user in consultation with the RSO. Radiation surveys immediately following the implantation of a brachytherapy source to demonstrate compliance with 10 CFR Part 20 are required by § 35.415(a)(4) and immediate notification of the RSO upon patient death or patient medical emergency is required by § 35.415(b).

The final rule, in § 35.415(a), requires for each patient or human research subject who is receiving brachytherapy and cannot be released in accordance with § 35.75, a licensee shall: (1) not quarter the patient or the human research subject in the same room as an individual who is not receiving brachytherapy; (2) visibly post the patient's or human research subject's room with a "Radioactive Materials" sign; and (3) note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room. Section 35.415(b) of the final rule requires licensees to have available, near each treatment room, emergency response equipment to respond to a source dislodged from the patient and lodged within the patient following removal of the source applicators. Section 35.415(c) provides that the licensee notify an authorized user and the RSO, or his or her designee, as soon as possible, if the patient or human research subject has a medical emergency or dies.

Cost Impacts:

None anticipated.

Health and Safety:

Safety will be enhanced by assuring that both the authorized user and the RSO must be notified.

Benefits:

Enhanced safety and increased flexibility for licensees.

5.64 Possession of survey instrument (§ 35.420).

The current rule, in § 35.420, requires each licensee to have in its possession a portable radiation detection survey instrument.

The final rule eliminates § 35.420.

Cost Impacts:

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

Health and Safety Impacts:

None anticipated because licensees will continue to meet the requirements in 10 CFR 20.1501 and 20.1502 and 10 CFR 30.33 requiring surveys and monitoring.

Benefits:

Increased flexibility for licensees.

5.65 Calibration measurements of brachytherapy sealed sources (§ 35.432).

The final rule adds a new section, § 35.432(a), that requires that before the first medical use of a brachytherapy sealed source a licensee shall determine the source output or activity using a dosimetry system that meets the requirements of § 35.630(a) and determine source positioning accuracy within applicators. Section 35.432(a)(3) requires these determinations to be made using published protocols accepted by nationally recognized bodies. Alternatively, § 35.432(b) of the final rule allows the licensee to use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with § 35.432(a). Section 35.432(c) requires the licensee to mathematically correct the outputs or activities determined under paragraph (a) for physical decay at intervals consistent with one percent physical decay. Section 35.432(d) requires that records of these calibration measurements be retained by licensees in accordance with § 35.2432.

NRC assumes that sources now provided by the manufacturer have been calibrated by the manufacturer in accordance with the requirements and licensees can rely on this calibration. Each licensee that chooses to calibrate its sources itself is estimated to spend approximately $1,000 annually to perform these calibrations and may need to purchase a new source calibration unit. Twenty percent of licensees are expected to calibrate sources currently in inventory or receive sources that require calibration.

Cost Impacts:

Cost increases are anticipated from requirements in § 35.432 that require licensees using long-lived radionuclides to calibrate their sources. Only a very few of the affected licensees are not expected to have access to such a device and will need to purchase a new source calibrating unit. Licensees under § 35.432 are also expected to be licensed under § 35.632. To avoid double-counting, the cost estimate for both sections is included under § 35.432.

Assumptions:	
Licensees:	
Licensees purchasing source calibration device[13]:	58
Average cost of new source calibration unit[14]:	$6,400
Total Cost Increase from Purchasing New Source Calibration Units:	$371,000

Cost increases are anticipated from requiring licensees using long-lived radionuclides to calibrate their sources.

[13] There were 581 NRC licensees estimated to need to own a dose calibrator. All High Dose-Rate Remote Afterloader (118), Medium Dose-Rate Remote Afterloader (29), Eye Applicators Strontium-90 (22), Mobile HDR Remote Afterloader (2) licensees plus half of Medical Institution-QMP Required (410). Of these 581 licensees, only 10 percent or 58 licensees were believed to not already own such a calibrating unit and would need to purchase a unit.

[14] Personal communications with several nuclear medicine manufacturers resulted in estimated prices for calibration units ranging from almost $6,000 to almost $7,000. An average rate of $6,400 per unit was used in this analysis.

Assumptions:

Licensees:

Licensees calibrating sources:	762
Annual source calibration cost:	$1,000
Total Annual Cost Increase from source calibration:	$762,000
Total Annual Cost Increase for § 35.432:	$1,133,000

Health and Safety Impacts:

Enhanced safety. A required calibration measurement of brachytherapy sealed sources is expected to help ensure that the sealed source dose that is administered matches the prescribed dose.

Benefits:

Enhanced safety.

5.66 Decay of strontium-90 sources for ophthalmic treatments (§ 35.433).

The final rule adds a new section, § 35.433, that provides that only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under § 35.432.

Section 35.433(b) provides that the licensee retain a record of the activity of each strontium-90 source in accordance with § 35.2433.

Cost Impacts:

Cost increases are anticipated from requiring that an authorized medical physicist must perform activity calculations.

Assumptions:

Licensees:

Licensees for Strontium-90 eye applicators:	77
Medical physicist services:	1 hour/week/licensee at $100 per hour
Total Cost Increase for § 35.433:	$400,000

Health and Safety Impacts:

Enhanced safety.

Benefits:

Enhanced safety.

5.67 Therapy-related computer systems (§ 35.457).

The final rule adds a new section, § 35.457, that provides that the licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. The section specifies that at a minimum the acceptance testing must include, as applicable: (1) verification of the source-specific input parameters required by the dose calculation algorithm; (2) the accuracy of dose, dwell time, and treatment time calculations at representative points; (3) the accuracy of isodose plots and graphic displays; and (4) the accuracy of the software used to determine radioactive source positions from radiographic images.

Cost Impacts:

Minimal cost increases are anticipated from this section of the final rule because licensees currently perform acceptance testing according to procedures established by software providers.

Health and Safety Impacts:

Enhanced safety.

Benefits:

Enhanced safety.

5.68 Training for use of manual brachytherapy sources (§ 35.490).

The current rule, in § 35.940, specifies the training requirements for an authorized user of brachytherapy sources.

Section 35.940(a) lists four specialist boards through which an individual may become certified to become an authorized user of brachytherapy sources.

Section 35.940(b) specifies training and experience requirements that may be met in lieu of certification by one of the five listed speciality boards. It currently requires 200 hours of classroom and laboratory training in specified subjects. In addition, it requires 500 hours of specific, supervised work experience. Finally, the current rule also requires three years of supervised clinical experience to include: (1) examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contradictions; (2) selecting the proper manual brachytherapy sources and dose and method of administration; (3) calculating the dose; and (4) post-administration follow up and review of case histories in collaboration with the authorized user.

The final rule creates a new § 35.490 providing the following:

The list of four approved speciality boards is eliminated. Section 35.490(a) provides that, except as provided in § 35.57, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under § 35.400 to be a physician who is certified by a medical specialty board whose certification process includes all of the requirements in § 35.490(b) and whose certification has been recognized by the Commission or an Agreement State.

Alternatively, § 35.490(b) provides that the licensee shall require an authorized user to have: (1) completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes 200 hours of classroom and laboratory training in specified subjects; (2) 500 hours of work experience under the supervision of an authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements at a medical institution involving specified activities; and (3) obtained three years of supervised clinical experience in radiation oncology under an authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience. In addition, the physician must obtain written certification, signed by a preceptor authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in §§ 35.490(b)(1) and (b)(2) and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under § 35.400.

Cost Impacts:

NRC anticipates incremental costs associated with recognizing specialty boards. NRC also anticipates costs to the physicians seeking authorized use status under §35.490(b) for obtaining a preceptor certification.

NRC estimates that approximately 150 physicians will seek to become authorized users under § 35.490 annually. Of these, 95 percent, or 143, will seek certification by a certifying board under § 35.490(a). No additional cost impacts will be created for them under the final rule. NRC estimates that the remainder, or approximately seven physicians, will seek to become authorized users under § 35.490(b). New costs for securing a preceptor statement will be created by the final rule.

Assumptions:

NRC/Agreement States:

Number of boards reviewed:	3
NRC review time:	4 hours/board at $75 per hour
Total Cost Increase for § 35.490(a):	$1,000

The costs to applicants associated with securing a preceptor's certification for purposes of § 35.490(b) are estimated below.

Assumptions:
Licensees:

Number of candidates:	7
Cost per preceptor statement (½ hour of preceptor's time plus ½ hour of candidate's time):	$60
Total Cost Increase for § 35.490(b):	<$1,000
Total Cost Increase for § 35.490:	$1,000

Health and Safety Impacts:

None anticipated.

Benefits:

Training and experience commensurate with risk and focused on radiation safety

5.69 Training for ophthalmic use of strontium-90 (§ 35.491).

The current rule, in § 35.941, specifies the training requirements for ophthalmic use of strontium-90.

Section 35.941 of the current rule provides that, except as provided in § 35.970, the licensee shall require the authorized user of only strontium-90 for ophthalmic radiography to be a physician who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and supervised clinical training in ophthalmic radiotherapy that includes: (1) 24 hours of classroom and laboratory training in specified subjects; and (2) supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals that includes examination of each individual to be treated, calculation of the dose to be administered, administration of the dose, and follow-up and review of each individual's case history.

The final rule creates a new § 35.491 providing the following:

Section 35.491 substitutes § 35.57 for §35.970 in the initial sentence, but otherwise incorporates the requirements in the current §§ 35.941(a) and (b) into the final rule's §§ 35.491 (a) and (b), respectively. A new paragraph, 35.491(b)(3) is added, requiring an individual to obtain written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.490, 35.491, or equivalent Agreement State requirements, that the individual has successfully completed the requirements in § 35.491 and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

Cost Impacts:

NRC anticipates incremental costs associated with recognizing specialty boards. NRC also anticipates costs to the physicists seeking authorized user status for obtaining a preceptor certification. NRC estimates that approximately 15 physicians will seek to become authorized users under § 35.491 annually. All will incur costs for securing a preceptor statement.

The costs to applicants associated with securing a preceptor's certification for purposes of § 35.491(c) are estimated below.

Assumptions:	
Licensees:	
Number of candidates:	15
Cost per preceptor statement (½ hour of preceptor's time plus ½ hour of candidate's time):	$60
Total Cost Increase for § 35.491(c):	$1,000
Total Cost Increase for § 35.491:	$1,000

Health and Safety Impacts:

None anticipated.

Benefits:

Training and experience commensurate with risk and focused on radiation safety

SUBPART G--SEALED SOURCES FOR DIAGNOSIS

5.70 Use of sealed sources for diagnosis (§ 35.500).

Section 35.500 currently requires a licensee to use specified sources for diagnosis in accordance with the manufacturer's radiation safety and handling instructions. Section 35.500 approves the use of four medical uses of sealed sources for diagnostic procedures and specifies how they may be used.

The final rule, in § 35.500, eliminates the listing of permissible sealed sources and specifies that a licensee may use only sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.

Cost Impacts:

The NRC anticipates cost savings with the changes to § 35.500. No longer requiring licensees to submit license amendments each time they want to use a source for a specific designated application not listed in § 35.500 will reduce both licensee costs and NRC and Agreement States costs.

Assumptions:	
Licensee:	
Total licensees seeking amendments (5 NRC and 13 Agreement States licensees):	18
Licensee amendment preparation time, hours:	2
Technical staff hourly rate:	$30
Total Annual Cost Savings for licensees:	$1,000
NRC/Agreement States:	
Total license amendment submittals (5 NRC and 13 Agreement States licensees):	18
NRC/Agreement States amendment review time, hours:	1
NRC/Agreement States staff hourly rate:	$75
Total Annual Cost Savings for NRC and Agreement States:	$1,000
Total Annual Cost Savings from changes to § 35.500:	$2,000

Health and Safety Impacts:

None anticipated.

Benefits:

Cost savings and increased licensee flexibility for licensees.

5.71 Availability of survey instrument (§ 35.520).

The current rule, in § 35.520, requires each licensee to have in its possession a portable radiation detection survey instrument.

The final rule eliminates § 35.520.

Cost Impacts:

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

Health and Safety Impacts:

None anticipated, because licensees must continue to meet the requirements in 10 CFR 20.1501 and 20.1502 and 10 CFR 30.33 requiring surveys and monitoring.

Benefits:

Increased flexibility for licensees.

5.72 Training for use of sealed sources for diagnosis (§ 35.590).

The current rule, in § 35.950, specifies the training requirements for an authorized user of sealed sources for diagnosis.

Section 35.950(a) lists four specialist boards through which an individual may become certified to use sealed sources for diagnosis.

Section 35.950(b) specifies training and experience requirements that may be met in lieu of certification by one of the four listed speciality boards. It currently requires eight hours of classroom and laboratory training in basic radioisotope handling techniques.

The final rule makes the following changes:

The specific list of four approved speciality boards is eliminated. Section 35.590(a) of the final rule provides instead that the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under § 35.500 to be a physician, dentist, or podiatrist who is certified by a speciality board whose certification process includes all of the requirements in § 35.590(b) and whose certification has been recognized by the Commission or an Agreement State.

Alternatively, § 35.590(b), requires eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device that include: (1) radiation physics and instrumentation; (2) radiation protection; (3) mathematics pertaining to the use and measurement of radioactivity; (4) radiation biology; and (5) training in the use of the device for the uses requested..

Cost Impacts:

No cost impacts are expected to be associated with this section. The medical specialty boards providing certification under this section are expected to have been recognized under other sections of the final rule.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

SUBPART H–PHOTON EMITTING REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS

5.73 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit (§ 35.600).

Section 35.600 currently regulates the use of teletherapy units for medical use that contain a sealed source of cobalt-60 or cesium-137.

The final rule amends the title and text of § 35.600 to include remote afterloader units and gamma stereotactic radiosurgery units, as well as teletherapy units, in Subpart H. The final rule eliminates the references to a sealed source of cobalt-60 or cesium-137 and specifies instead that a licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units: (1) as approved in the Sealed Source and Device Registry; or (2) in research in accordance with an effective Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 35.49(a) are met.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Improved flexibility for licensees.

5.74 Surveys of patients and human research subjects treated with a remote afterloader unit (§ 35.604).

The final rule adds a new § 35.604 pertaining to radiation surveys for remote afterloaders. Section 35.604(a) requires that before releasing a patient or human research subject from licensee control, a licensee shall survey the patient or the 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. Section 35.604(b) requires licensees to retain a record of these surveys in accordance with § 35.2404.

Cost Impacts:

None anticipated. Requirements are consistent with current license conditions.

Health and Safety Impacts:

None anticipated.

Benefits:

Improved regulatory efficiency and consistency.

5.75 Installation, maintenance, adjustment, and repair (§ 35.605).

Section 35.605 requires that only persons specifically licensed by the Commission or an Agreement State to perform teletherapy unit maintenance and repair can: (1) install, relocate, or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source; or (2) maintain, adjust, or repair the source drawer, shutter or other mechanism of a teletherapy unit that could expose the source, reduce the shielding around the source, or result in increased radiation levels.

The final rule adds remote afterloader units and gamma stereotactic radiosurgery units to the types of units covered by this section. Section 35.605(a) provides that only a person specifically licensed by the Commission or an Agreement State shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the device or the source(s).

Section 35.605(b) of the final rule provides that except for low dose-rate remote afterloader units, only a person specifically licensed by the Commission or an Agreement State shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic units.

A new § 35.605(c) is added to provide that only a person specifically licensed by NRC or an Agreement State or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in a low dose-rate remote afterloader unit.

A new § 35.605(d) provides that a record of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units must be retained in accordance with § 35.2605.

Cost Impacts:

None anticipated. Section 35.605(a) makes no change with respect to teletherapy. It adds requirements for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloaders and gamma stereotactic radiosurgery. However, these requirements are consistent with current license conditions.

Section 35.605(c) creates a new exemption for low dose-rate remote afterloaders from the requirement that maintenance and repair personnel must be specifically licensed, by providing that authorized medical physicists may install, replace, relocate, or remove sources contained in low

dose-rate remote afterloaders. This is anticipated to provide a small savings for licensees using a new source for every treatment.

Health and Safety Impacts:

No health or safety impacts are anticipated. Maintenance and repair will continue to be performed only by qualified personnel.

Benefits:

Improved flexibility and a small cost savings for licensees.

5.76 License amendments (§ 35.606).

The current § 35.606 requires a licensee to apply for and receive a license amendment before making any change in the treatment room shielding; making any change in the location of the teletherapy unit within the treatment room; using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room; relocating the teletherapy unit; or allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist.

The final rule eliminates § 35.606.

Cost Impacts:

No significant cost impacts are anticipated.

Health and Safety Impacts:

None anticipated. Occupational exposure and control of exposure and control of access continue to be covered by the requirements of 10 CFR Part 20.

Benefits:

Improved flexibility for licensees.

5.77 Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units (§ 35.610).

Section 35.610 currently establishes safety instruction requirements for teletherapy units. Section 35.610(a) requires that instructions regarding the proper operation of a teletherapy unit must be posted at the unit console. In addition, § 35.610(b) requires that operators of teletherapy units receive instruction. Section 35.610(c) requires that records of individuals receiving training must be kept for three years.

The final rule amends the title and text of § 35.610. Section 35.610(a) requires that licensees secure the unit, the console, the console keys, and the treatment room when not in use or unattended; permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s); prevent dual operation of more than one radiation producing device in a treatment room if applicable; and develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. New paragraphs (a)(4)(i) through (iii) specify what the procedures must include.

New § 35.610(b) provides that a copy of the procedures required by paragraph (a)(4) must be physically located at the unit console.

Section 35.610(c) requires licensees to post instructions at the unit console for individuals who operate the devices. These instructions inform the operator of the location of the procedures required by § 35.610(a)(4) and the names and telephone numbers of the authorized users, the authorized medical physicist, and the RSO to be contacted if the unit or console operates abnormally.

Section 35.610(d) requires licensees to provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in the procedures required by paragraph (a)(4) and the operating procedures for the unit.

Section 35.610(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.

Section 35.610(f) requires licensees to retain a record of individuals receiving instruction required by § 35.610(d), in accordance with § 35.2310.

Cost Impacts:

No incremental costs are associated with § 35.610. These requirements are consistent with current license conditions.

Health and Safety Impacts:

None anticipated.

Benefits:

Regulatory efficiency and consistency, as a result of codifying requirements previously used as license conditions.

5.78 Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units (§ 35.615).

Section 35.615 currently specifies detailed access controls and equipment requirements, including radiation monitoring equipment, for teletherapy rooms. In particular, § 35.615(a) requires access control to teletherapy rooms and § 35.615(b) requires an electrical interlock system. Section 35.615(c) requires licensees to equip each entrance to the teletherapy room with a beam condition indicator light and § 35.615(d) requires licensees to install in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status. Section 35.615(e) requires that each teletherapy room will be constructed or equipped to permit continuous observation of the patient or human research subject from the teletherapy unit console during irradiation.

The final rule amends the title of the section to specify that the section pertains to remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. It eliminates requirements for equipping each entrance with a beam condition indicator light, permanent radiation monitoring, and associated record keeping requirements. The final rule also adds requirements for viewing and intercom systems for all modalities except low dose-rate remote afterloaders.

Section 35.615(e) provides that for licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

Sections 35.615(f)(1)-(4) establish requirements pertaining to remote afterloaders and gamma stereotactic radiosurgery units. Section 35.615(f)(1) requires for medium dose-rate and pulsed dose-rate remote afterloader units that an authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and an authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

Section 35.615(f)(2) requires for high dose-rate remote afterloader units that an authorized user and an authorized medical physicist will be physically present during the initiation of all patient treatments involving the unit; and that an authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, will be physically present during continuation of all patient treatments involving the unit.

Section 35.615(f)(3) requires for gamma stereotactic radiosurgery units that an authorized user and an authorized medical physicist will be physically present throughout all patient treatments involving the unit.

Section 35.615(f)(4) requires the 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.

Section 35.615(g) requires applicable emergency response equipment to be available near each treatment room to respond to a source remaining in the unshielded position; and lodged within the patient following completion of the treatment.

Cost Impacts:

The elimination of requirements in §§ 35.615 (a)-(e) of the current rule for beam condition indicator lights and permanent radiation monitoring are expected to be offset by new requirements for viewing and intercom systems. Therefore, no incremental cost impacts are expected from revisions to these sections. In addition, 10 CFR 20.1601 continues to require control measures for high radiation areas.

Future cost savings are expected to be associated with § 35.615(f)(1). Under the final rule, an authorized user is allowed to leave a medium or pulsed dose-rate remote afterloader treatment following the treatment's initialization if a medical physicist and either an authorized user or an individual under the supervision of an authorized user who has been given specified training is immediately available during continuation of the patient treatment. Currently, the authorized user is required to remain for the duration of the procedure. Future cost savings will result from increased use of pulsed dose-rate and medium dose-rate remote afterloaders, which are used infrequently at present, and from the opportunity to rely on less expensive staff for immediate response availability.

Costs savings are expected to be associated with § 35.615(f)(2). Under the final rule, an authorized user will be allowed to leave a high dose-rate remote afterloader procedure following procedure initialization if a physician with remote afterloader emergency response training is available to observe the procedure. Currently, the authorized user is required to remain for the duration of the procedure. Other requirements are consistent with current license conditions. Cost savings will result from the opportunity to rely on less expensive staff to be present during continuation of treatments involving the HDR afterloader.

Assumptions:

Licensees:

Number of annual HDR treatment fractions (35,000 procedures with 4 fractions per procedure):	140,000
Time to complete fraction after initiation, hours:	0.0667
Net reduction in hourly rate:[15]	$20
Total Annual Cost Savings from § 35.615:	$187,000

Health and Safety Impacts:

None anticipated.

[15] Difference between authorized user physician at $100/hour and a non-authorized user physician at $80/hour.

Benefits:

Improved flexibility and cost savings for licensees.

5.79 Possession of survey instrument (§ 35.620).

The current rule, in § 35.620, requires a licensee authorized to use byproduct material in a teletherapy unit to have in its possession a portable radiation detection survey instrument.

The final rule eliminates § 35.620.

Cost Impacts:

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

Health and Safety Impacts:

None anticipated, because licensees are expected to continue to meet the requirements in 10 CFR 20.1501 and 20.1502 and 10 CFR 30.33 requiring surveys and monitoring.

Benefits:

Increased flexibility for licensees.

5.80 Dosimetry equipment (§ 35.630).

Section 35.630(a)(1) of the current rule specifies that dosimetry equipment must be calibrated after any servicing and every two years at a minimum by the NIST or any calibration laboratory accredited by the AAPM. Alternatively, § 35.630(a)(2) allows dosimetry equipment to be calibrated every four years and subsequently intercompared at an intercomparison meeting to dosimetry equipment calibrated within the past two years by NIST or any other calibration laboratory accredited by AAPM. In addition, the current rule requires that a dosimetry system be available for spot-check measurements. The spot-check system can be the same system used to meet the requirements in § 35.630(a). Finally, § 35.630(c) requires a record of each calibration, intercomparison, and comparison.

The final rule requires that, except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. Section 35.630(a) requires the system will be calibrated either: (1) using a system or source traceable to the National Institute of Standards and Technology (NIST) and published protocols accepted by nationally recognized bodies; or (2) by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous two years and after any servicing that may have affected system calibration. Alternatively, the system must have been calibrated within the previous four years. Eighteen to 30 months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the previous 24 months by the National

Institute of Standards and Technology (NIST) or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The final rule eliminates the requirement in the current rule that equipment comparison must take place during an intercomparison meeting.

Section 35.630(b) requires the licensee to have a dosimetry system available for use for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with § 35.630(a). This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirements of § 35.630(a).

Section 35.630(c) requires a record of each calibration, intercomparison, and comparison to be retained in accordance with § 35.2630.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Increased flexibility for licensees.

5.81 Full calibration measurements on teletherapy units (§ 35.632).

Section 35.632 currently requires licensees to perform full calibration measurements on each teletherapy unit, and provides specific requirements for such calibration measurements. Section 35.632(d) specifies that the calibration shall be performed according to certain protocols cited in the regulation.

The final rule amends § 35.632(d) to eliminate the citations to specific protocols and instead provides that the licensee shall make full calibration measurements in accordance with "published protocols approved by nationally recognized bodies."

A new § 35.632(b)(4) requires “timer accuracy” instead of “timer constancy.”

A new § 35.632(e) requires a licensee to mathematically correct the outputs determined in § 35.632(b)(1) for physical decay for intervals not exceeding one month for cobalt-60, six months for cesium-137, or at intervals consistent with one percent decay for all other nuclides.

A new § 35.632(f) requires full calibration measurements required by § 35.632(a) and physical decay corrections required by § 35.632(e) to be performed by the authorized medical physicist.

A new § 35.632(g) requires a licensee to retain a record of each calibration in accordance with § 35.2632.

Cost Impacts:

None anticipated. Cost to licensees to obtain calibration instruments are evaluated under § 35.432.

Health and Safety Impacts:

None anticipated.

Benefits:

The amendment provides greater flexibility to licensees to adopt calibration protocols and avoid the problem that protocols cited in 10 CFR Part 35 may become outdated over time. NRC will experience regulatory efficiencies as a result of not being required to periodically amend § 35.632.

5.82 Full calibration measurements on remote afterloader units (§ 35.633).

The final rule adds a new section, § 35.633, providing detailed specifications for calibration measurements on remote afterloaders.

Sections 35.633(a)(1) and (2) of the final rule require full calibration measurements on a remote afterloader before the first medical use of the device and before medical use following certain specified conditions.

Sections 35.633(a)(3) and (a)(4) of the final rule require an additional calibration at intervals not exceeding one quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloaders with sources whose half-life exceeds 75 days and at intervals not to exceed one year for low dose-rate remote afterloaders.

Section 35.633(b) specifies that full calibration measurements must include, as applicable, determination of output within specified limits, source positioning accuracy within specified limits, source retraction, length of source transfer tubes, timer accuracy and linearity, length of the applicators; and function of source transfer tubes, applicators, and transfer tube-applicator interfaces.

Section 35.633(c) requires the licensee to use the dosimetry system described in § 35.630(a) to measure the output.

Section 35.633(d) requires the licensee to make full calibration measurements required by § 35.630(a) in accordance with published protocols accepted by nationally recognized bodies.

Section 35.633(e) specifies that in addition to the requirements for full calibrations for low dose-rate remote afterloader units in § 35.633(b), a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding one quarter.

Section 35.633(f) specifies that for LDR afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with §§ 35.633(a)-(e).

Section 35.633(g) requires licensees to mathematically correct the output measurements determined in the full calibration for physical decay at intervals consistent with one percent physical decay.

Section 35.633(h) provides that the full calibration measurements and physical decay corrections must to be performed by the authorized medical physicist.

Section 35.633(i) requires that a record of each calibration must be kept in accordance with § 35.2632.

Cost Impacts:

None anticipated. Requirements are consistent with current license conditions.

Health and Safety Impacts:

None anticipated.

Benefits:

Regulatory clarity and efficiency from including in regulations requirements that previously had been applied as license conditions.

5.83 Full calibration measurements on gamma stereotactic radiosurgery units (§ 35.635).

The final rule adds a new section, § 35.635, that provides detailed specifications for calibration measurements on gamma stereotactic radiosurgery units.

Sections 35.635(a)(1) and (2) require full calibration measurements on a gamma stereotactic radiosurgery unit before the first medical use of the device and before medical use whenever spot-check measurements indicate the output differs by more than five percent from the output obtained at the last full calibration corrected mathematically for radioactive decay; following replacement of the sources or reinstallation of the unit in a new location; and following any repair of the unit that includes removal of the sources or major repair of the components associated with the source assembly. In addition, calibrations are required at intervals not exceeding one year, with the exception that relative helmet factors need only be determined before the first medical use of the helmet and following any damage to a helmet.

Section 35.635(b) specifies the measurements that need to take place in the full calibration.

Section 35.635(c) requires that a licensee use the dosimetry system described in § 35.630(a) to measure the output for one set of exposure conditions. The remaining measurements required in paragraph (b)(1) may be made using a dosimetry system that indicates relative dose rates.

Section 35.635(d) requires full calibration measurements to be in accordance with published protocols accepted by nationally recognized bodies.

Section 35.635(e) specifies requirements for mathematical correction of outputs.

Section 35.635(f) requires that full calibration measurements and physical decay corrections mandated by §§ 35.633(a) and (e), respectively, must be performed by the authorized medical physicist.

Section 35.635(g) requires that records of calibrations must be retained in accordance with § 35.2632.

Cost Impacts:

None anticipated. Requirements are consistent with current license conditions.

Health and Safety Impacts:

None anticipated.

Benefits:

Regulatory clarity and efficiency from including in regulations requirements that previously had been applied as license conditions.

5.85 Elimination of former § 35.636:

Section 35.636 of the current rule requires that licensees check all teletherapy operation systems listed in § 35.634(d) promptly following an installation of a source. A safety check is also required promptly following a teletherapy unit change pursuant to § 35.606. Section 35.636(b) stipulates that if a teletherapy unit malfunction is detected, the device console must be locked in the off position. Section 35.636(c) requires the retention of records of facility checks following an installation of a source for three years.

The final rule eliminates § 35.636.

Cost Impacts:

None anticipated. Requirements from this section are incorporated into §§ 35.642, 35.643, 35.644, and 35.645 of the final rule.

Health and Safety Impacts:

None anticipated.

Benefits:

Improved regulatory efficiency by reducing redundancy of requirements.

5.84 Radiation surveys for teletherapy facilities (§ 35.641).

The current rule, in § 35.641, specifies detailed requirements for radiation surveys for teletherapy facilities.

The final rule eliminates § 35.641.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Increased flexibility for licensees.

5.85 Periodic spot-checks for teletherapy units (§ 35.642).

Section 35.634 of the current rule requires periodic spot-checks of teletherapy units to determine proper unit operation.

The final rule replaces the term "teletherapy physicist"with "authorized medical physicist." Section 35.642(a) retains essentially the same requirements as § 35.634(a) of the current rule, except that § 35.642(a)(1) requires “timer accuracy” instead of “timer constancy.” Section 35.642(b) retains the same requirements as § 35.634(b), except that the final rule requires that the procedures established by the authorized medical physicist be in writing. The amended § 35.642(c) eliminates the requirement that the licensee must keep a record of the reports detailing the results of teletherapy unit periodic spot-checks for three years. Section 35.642(d) retains essentially the same requirements as § 35.634(d), except that the final rule, in § 35.642(d)(3), uses the term “source exposure” instead of “beam indicator” and § 35.642(d)(4) adds “intercom systems.” Section 35.642(d) adds a new requirement for safety spot-checks after each source installation. Section 35.642(d)(4) also requires the installation of intercom systems in teletherapy unit treatment rooms. The final rule provides in § 35.642(e) that if the results of the checks required in § 35.642(d) indicate the malfunction of any system, a licensee shall lock the console in the off position and not use the unit except as may be necessary to repair, replace, or

check the malfunctioning system. Section 35.642(f) requires records of each spot-check required by § 35.642(a) and § 35.642(d) to be kept in accordance with § 35.2642.

Cost Impacts:

No incremental costs are associated with § 35.642. The requirements are consistent with current license conditions.

Health and Safety Impacts:

None anticipated.

Benefits:

Regulatory clarity and efficiency from including in regulations requirements that previously had been applied as license conditions.

5.86 Periodic spot-checks for remote afterloader units (§ 35.643).

The final rule adds a new section, § 35.643, that provides detailed specifications for periodic spot-checks for remote afterloader units.

Section 35.643(a) requires a periodic spot-check for each remote afterloader facility and on each unit. Section 35.643(a)(1) requires a spot-check before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader on a given day. Section 35.643(a)(2) requires a periodic spot-check before each patient treatment with a low dose-rate remote afterloader. Section 35.643(a)(3) requires a periodic spot-check for each facility and unit after each source installation.

Section 35.643(b) requires a licensee to perform the measurements required by § 35.643(a) in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

Section 35.643(c) requires the licensee to have the authorized medical physicist review the results of each spot-check within 15 days of its completion.

Section 35.643(d) specifies the measurements and the systems that must be accounted for in a spot-check.

Section 35.643(e) requires that if the results of the checks required in § 35.643(d) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

Section 35.643(f) requires a record of spot-checks mandated by § 35.643(d) to be recorded and retained in accordance with § 35.2643.

Cost Impacts:

None anticipated. The requirements are consistent with current license conditions.

Health and Safety Impacts:

None anticipated.

Benefits:

Regulatory clarity and efficiency from including in regulations requirements that previously had been applied as license conditions.

5.89 Elimination of former § 35.643:

Section 35.643 of the current rule is eliminated in the final rule. Section 35.643 of the current rule stipulates that if a survey required under § 35.641 indicates that any individual member of the public is likely to receive a dose in excess of the limits specified in 10 CFR 20.1301, the licensee shall either equip the unit with stops or add additional shielding. Sections 35.643(a)(2) and (3) require the licensee to perform the survey required by § 35.641 again; and paragraph (3) includes in the report required by § 35.645, the results of the initial survey, a description of the modification made to comply with paragraph (a)(1) of § 35.643, and the results of the second survey.

Section 35.643(b) allows radiation levels to exceed those mandated by 10 CFR 20.1301 if a license amendment is applied for and issued.

The final rule eliminates the current § 35.643.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated, because 10 CFR Part 20, particularly Subparts C and D, establishing occupational and public dose limits will continue to apply.

Benefits:

Improved flexibility for licensees.

5.87 Periodic spot-checks for gamma stereotactic radiosurgery units (§ 35.645).

Section 35.645, "Reports of teletherapy surveys, checks, tests, and measurements," of the current rule is eliminated. The final rule includes a new § 35.645 that requires periodic spot-checks for gamma stereotactic radiosurgery units.

Section 35.645(a)(1) requires spot-checks of each gamma stereotactic radiosurgery facility and on each unit monthly.

Section 35.645(a)(2) requires a periodic spot-check for gamma stereotactic radiosurgery facilities and units before each day of use.

Section 35.645(a)(3) requires spot-checks for gamma stereotactic radiosurgery facilities and units after each source installation.

Sections 35.645(b)(1) and (b)(2) require an authorized medical physicist to establish written procedures for performing spot-checks and to review the results of each spot-check required by § 35.645(a)(1) within 15 days of its completion. The authorized medical physicist need not actually perform the spot-check measurements.

Section 35.645(c)and (d) describe the measurements and the systems that have to be accounted for in spot-checks. Section 35.645(c) specifies the requirements for spot-checks under §§ 35.645(a)(1) and §35.645(d) specifies the requirements for spot-checks under (a)(2) and (a)(3).

Section 35.645(e) requires the licensee to arrange for repair as soon as possible of any system identified under paragraph (c) that is not working properly.

Section 35.645(f) requires that if the results of the checks required in (d) indicate the malfunction of any system, the licensee must lock the control console in the off position and not use the unit, except as necessary to repair, replace, or check the malfunctioning system.

Section 35.645(g) requires a licensee to retain a record of each check required by paragraphs (c) and (d) of this section in accordance with § 35.2645.

Cost Impacts:

None anticipated. Requirements are consistent with current license conditions.

Health and Safety Impacts:

None anticipated.

Benefits:

Regulatory clarity and efficiency from including in regulations requirements that previously had been applied as license conditions.

5.91 Elimination of the former § 35.645:

Section 35.645 of the current rule requires that records required by §§ 35.363, 35.641, 35.643, and full calibration measurements required in § 35.632 must be mailed to the appropriate NRC Regional Office.

The final rule eliminates § 35.645.

Cost Impacts

The elimination of the forwarding requirement results in savings to licensees, estimated below:

Assumptions:	
Licensees (NRC):	
Number of mailings by NRC licensees avoided annually:	45
Estimated cost per mailing	$20
Total Annual Cost Savings for NRC licensees:	$1,000
Licensees (Agreement States):	
Number of mailings by Agreement States licensees avoided annually:	113
Estimated cost per mailing:	$20
Total Annual Cost Savings for Agreement State licensees:	$2,000
Total Annual Cost Savings from elimination of the former § 35.645:	$3,000

Health and Safety Impacts

None anticipated.

Benefits:

Cost savings to licensees.

5.88 Additional technical requirements for mobile remote afterloader units (§ 35.647).

Requirements in the current § 35.647, "five-year inspection," are moved to § 35.655.

The final rule adds a new section establishing technical requirements for mobile remote afterloader units. Section 35.647(a) in the final rule requires all survey instruments to be checked before medical use at each licensee address of use or on each day of use, whichever is more frequent, and that all sources be accounted for before leaving from a client's address of use. Section 35.647(b) requires checks of each remote afterloader unit before use at each address of use. Section 35.647(b) specifies the checks that must be made. Section 35.647(c) requires licensees to ensure overall proper operation by conducting a simulated cycle of treatment before use at each address of use. Section 35.647(d) requires that if the results of the checks required in (b) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use

the unit except as may be necessary to repair, replace, or check the malfunctioning system. Section 35.647(e) requires a record of each check required by § 35.647(b) be kept in accordance with § 35.2647.

Cost Impacts:

Minimal cost impacts (<$1,000) are anticipated because of a small number (5) of licensees.

Health and Safety Impacts:

None anticipated.

Benefits:

Regulatory clarity and efficiency from including in regulations requirements that previously had been applied as license conditions.

5.89 Radiation surveys (§ 35.652).

Currently, § 35.641 requires a radiation survey before medical use, after each installation of a source in a teletherapy unit, and after making other changes to a teletherapy unit. Section 35.641(a) describes the scope of the survey and what operational conditions need to be verified. Section 35.641(b) requires that the teletherapy unit control be locked in the off position if the survey indicates that radiation levels exceed the limit set in 10 CFR 20.1301.

The final rule amends § 35.641 and renumbers it as § 35.652. Section 35.652(a) of the final rule requires that in addition to the survey requirement in 10 CFR 20.1501, a person licensed under this subpart shall make such surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the sources in the shielded position do not exceed levels stated in the Sealed Source and Device Registry. Section 35.652(b) of the final rule requires that licensees make the surveys required in paragraph (a) at installation of a new source and following specified repairs. Section 35.652(c) requires licensees to retain records of radiation surveys in accordance with § 35.2652.

Cost Impacts:

None anticipated. Requirements are consistent with current license conditions.

Health and Safety Impacts:

None anticipated.

Benefits:

Regulatory clarity and efficiency from including in regulations requirements that previously had been applied as license conditions.

5.90 Five-year inspection for teletherapy and gamma stereotactic radiosurgery units (§ 35.655).

Section 35.647 of the current rule stipulates that teletherapy units must be inspected and serviced during teletherapy source replacement or every five years, whichever comes first. Section 35.647(b) of the current rule requires that this inspection and servicing may only be performed by a individual licensed by the Commission or Agreement States.

The final rule amends § 35.647 and renumbers it as § 35.655. The final rule adds a requirement for inspection and servicing of gamma stereotactic radiosurgery units during source replacement or every five years, whichever comes first. Section 35.655(b) requires that the servicing must be performed only by persons specifically licensed by NRC or an Agreement State.

Section 35.655(c) requires that licensees keep a record of inspection and servicing in accordance with new § 35.2655.

Cost Impacts:

None anticipated. Requirements are consistent with current licensee activities. Although the inspection cycle is currently seven years, inspections are being conducted more frequently as standard practice.

Health and Safety Impacts:

None anticipated.

Benefits:

Regulatory clarity and efficiency from including in regulations requirements that previously had been applied as license conditions.

5.91 Therapy-related computer systems (§ 35.657).

The final rule adds a new § 35.657 requiring licensees to perform acceptance testing in accordance with published protocols accepted by nationally recognized bodies. Sections 35.657(a) through (e) specify the activities that the acceptance testing must include.

Cost Impacts:

None anticipated. Licensees using computerized operating and planning systems currently verify their proper operation by conducting detailed acceptance testing.

Health and Safety Impacts:

Acceptance testing and verification of correct operation ensure safe operation of these systems.

Benefits:

Codifies existing practice.

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

The current rule, in § 35.960, specifies the training requirements for the authorized user of a sealed source in a teletherapy unit.

Section 35.960(a) lists four specialist boards through which an individual may become certified to use sealed sources in a teletherapy unit.

Section 35.960(b) specifies training and experience requirements that may be met in lieu of certification by one of the four listed speciality boards. It currently requires 200 hours of classroom and laboratory training in specified subjects. In addition, it requires 500 hours of specific, supervised work experience. The current rule also requires three years of supervised clinical experience.

The final rule makes the following changes:

The list of four specialist boards is eliminated. Section 35.690 requires that, except as provided in § 35.57, the licensee shall require the authorized user of a sealed source for a use listed in § 35.600 to be a physician who is certified by a medical speciality board whose certification process includes all of the requirements in § 35.690(b) and whose certification has been recognized by the Commission or by an Agreement State.

Alternatively, § 35.690(b) provides that the physician must have completed a structured educational program in basic radionuclide techniques, including specified areas of training, applicable to the use of a sealed source in a therapeutic medical unit and must have completed 200 hours of classroom and laboratory training in specified topics and 500 hours of work experience, including specified activities, under the supervision of an authorized user who meets the requirements in § 35.690 or equivalent Agreement State requirements at a medical institution; and has completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in § 35.690 or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience. The physician also must have obtained written certification that the individual has satisfactorily completed the requirements in §§ 35.690(b)(1) and (b)(2) and 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 written certification must be signed by a preceptor authorized user who meets the requirements in § 35.690 or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status.

Cost Impacts:

The cost impacts of the final rule apply to both NRC and licensees.

NRC estimates that approximately 150 physicians will seek to become authorized users under § 35.690 annually. Of these, 95 percent, or 143, seek certification by a certifying board under § 35.690(a). No additional cost impacts be created for them under the final rule. NRC estimates that the remainder, or approximately seven physicians, seek to become authorized users under § 35.690(b). New costs for securing a preceptor statement are created by the final rule.

The costs to NRC for recognizing specialty boards for purposes of § 35.690(a) are estimated below. Because of the complexity of training under this section, NRC has assumed that medical boards that have sought recognition under other sections may prepare a separate application under this section.

Assumptions:	
NRC/Agreement States:	
Number of boards:	3
NRC review time:	4 hours/board at $75 per hour
Total Cost Increase to NRC:	$1,000

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

Assumptions:	
Certifying Boards:	
Number of boards reviewed:	3
Preparation of submission:	12 hours/board for Technical Staff at $30/hour 4 hours/board for Management at $100/hour
Total Cost Increase for Certifying Boards:	$2,000
Total Cost Increase for § 35.690(a):	$3,000

The costs to applicants associated with securing a preceptor's certification for purposes of § 35.690(b) are estimated below.

Assumptions:	
Licensees:	
Number of candidates:	7
Cost per preceptor statement (½ hour of preceptor's time and ½ hour of candidate's time):	$60
Total Cost Increase for § 35.690(b):	<$1,000
Total Cost Increase for § 35.690:	$3,000

Health and Safety Impacts:

None anticipated.

Benefits:

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

SUBPART I -- [Reserved]

SUBPART J – [Reserved]

Subpart J of the current rule establishes training and experience requirements as follows: § 35.900 Radiation Safety Officer; § 35.901 Training for experienced Radiation Safety Officer; § 35.910 Training for uptake, dilution, and excretion studies; § 35.920 Training for imaging and localization studies; § 35.930 Training for therapeutic use of unsealed byproduct material; § 35.932 Training for treatment of hyperthyroidism; § 35.934 Training for treatment of thyroid carcinoma; § 35.940 Training for use of brachytherapy sources; § 35.941 Training for ophthalmic use of strontium-90; § 35.950 Training for use of sealed sources for diagnosis; § 35.960 Training for teletherapy; § 35.961 Training for teletherapy physicist; § 35.970 Training for experienced authorized users; § 35.971 Physician training in a three month program; § 35.972 Recentness of training; § 35.980 Training for authorized nuclear pharmacist; § 35.981 Training for experienced nuclear pharmacists.

The final rule eliminates Subpart J. Training and experience requirements in the final rule are in Subparts B and D through H of the final rule. The cost impacts, health and safety effects, and benefits of the training and experience requirements in the final rule are addressed under the relevant sections of the final rule.

SUBPART K--OTHER MEDICAL USES OF BYPRODUCT MATERIAL OR RADIATION FROM BYPRODUCT MATERIAL

5.93 Other medical uses of byproduct material or radiation from byproduct material (§ 35.1000).

The final rule, in new § 35.1000, provides that a licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in Subpart D through H of 10 CFR Part 35 if: (1) the applicant or licensee submits the required information pursuant to §§ 35.12 (b) through (d); and (2) the applicant or licensee receives written approval from the Commission and uses the material in accordance with the regulations and specific conditions deemed necessary by the Commission for the medical use of the material.

Cost Impacts:

Applicants for other medical uses will need to prepare and submit information as specified under §§ 35.12 (b) through (d). However, the requirements under § 35.12(d) are an alternative to the requirements for an exemption under § 35.19 and are anticipated to provide cost savings. The cost savings are estimated under § 35.12(d).

Health and Safety Impacts:

None anticipated.

Benefits:

Regulatory efficiency, as a result of specification of requirements in advance.

SUBPART L

5.98 Records of authority and responsibilities for radiation protection programs (§ 35.2024).

Section 35.2024(a) requires licensees to retain a record of actions taken by the licensee's management pursuant to § 35.24(a) for five years and specifies the contents of those records. Section 35.2024(b) requires licensees to retain a current copy of the authorities, duties, and responsibilities of the Radiation Safety Officer as required by § 35.24(e) and a signed copy of the RSO's written agreement, as required by § 35.24(b). Section 35.2024 requires the records to include the signature of the Radiation Safety Officer and licensee management.

Cost Impacts:

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

Assumptions:

Licensees:

Licensees:	3,554
Reduction in storage requirements:	1 cubic foot (about ½ file drawer)
Cost of storage:	$1.50 per cubic foot
Total Annual Cost Savings from § 35.2024:	$5,000

Health and Safety Impacts:

None anticipated.

Benefits:

Cost savings for licensees.

5.94 Records of radiation protection program changes (§ 35.2026).

The final rule, in new § 35.2026, provides that a licensee must retain a record of each radiation protection program change, as required by § 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 licensee management who reviewed and approved the change.

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

affected authorized users and of management or, in a medical institution, the Radiation Safety Committee's chairman and the management representative."

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

Cost Impacts:

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

Assumptions:	
Licensees:	
Total licensees:	5,910
Reduction in storage requirements:	2 cubic feet (about 1 file drawer)
Cost of storage:	$1.50 per cubic foot
Total Annual Cost Savings from § 35.2026:	$18,000

Health and Safety Impacts:

None anticipated.

Benefits:

Cost savings for licensees.

5.95 Records of written directives (§ 35.2040).

The final rule, in new § 35.2040, requires licensees to retain a copy of the written directive, as required by § 35.40, for three years.

Cost Impacts:

Because the number of procedures requiring written directives is not expected to change under the requirements of § 35.40 of the final rule, the scope of the recordkeeping requirements under § 35.2040 of the final rule is not expected to change. The final rule requires a three year record retention period, which corresponds to the record retention period for written directives under the current rule. Therefore, no cost impacts are anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

5.96 Records of medical events (§ 35.2045).

The current rule, in § 35.33(b), requires a licensee to retain records of misadministrations.

The final rule, in new § 35.2045, requires a licensee to retain a record of medical events reported under § 35.3045 for three years and specifies the contents of the records.

Section 35.2045 of the final rule changes the record retention period from five years, under § 35.33(b) of the current rule, to three years. Therefore, § 35.2045 is expected to create small cost savings for licensees maintaining records of medical events under this section of the final rule.

Cost Impacts:

The final rule is anticipated to result in minimal (<$1,000) decreased recordkeeping costs due to the reduced retention period for reports of medical events.

Health and Safety Impacts:

Prevention of occurrence of similar events.

Benefits:

Provides documentation for subsequent licensee and NRC review.

5.97 Record of a dose to an embryo/fetus or a nursing child (§ 35.2047).

The final rule, in new § 35.2047(a), requires a licensee to retain a record of a dose to an embryo/fetus or a nursing child, reported in accordance with § 35.3047, for three years. Section 35.2047(b) defines the required content of the record.

Cost Impacts:

The final rule is anticipated to result in minimal (<$1,000) increased recordkeeping costs.

Health and Safety Impacts:

Prevention of occurrence of similar events.

Benefits:

Provides documentation for subsequent licensee and NRC review.

5.98 Records of calibrations of instruments used to measure the activity of unsealed byproduct materials (§ 35.2060).

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

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

Cost Impacts:

The final rule is anticipated to result in minimal (<$1,000) increased recordkeeping costs.

Health and Safety Impacts:

None anticipated.

Benefits:

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

5.99 Records of radiation survey instrument calibrations (§ 35.2061).

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

Cost Impacts:

The final rule duplicates the recordkeeping requirements in § 35.51(d) of the current rule. The record retention period remains three years. Therefore, no cost impacts are anticipated from the final rule.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

5.100 Records of dosages of unsealed byproduct material for medical use (§ 35.2063).

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

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

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

5.101 Records of leak tests and inventory of sealed sources and brachytherapy sources (§ 35.2067).

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

Cost Impacts:

The final rule duplicates, with one change, the recordkeeping requirements in §§ 35.59(d) and (g) of the current rule. The final rule reduces the record retention time from five years to three years. This reduction of the record retention period by two years is expected to result in small cost savings to licensees, as follows:

Assumptions:	
Licensees:	
Licensees:	1,885
Reduction in storage requirements:	1 cubic foot (about ½ file drawer)
Cost of storage:	$1.50 per cubic foot
Total Annual Cost Savings from § 35.2067:	$3,000

Health and Safety Impacts:

None anticipated.

Benefits:

Cost savings for licensees.

5.102 Records of surveys for ambient radiation exposure rate (§ 35.2070).

The final rule, in new § 35.2070, requires licensees to retain a record of each survey required by § 35.70 for three years. The final rule parallels the recordkeeping requirements in § 35.70(h) of the current rule.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

5.103 Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material (§ 35.2075).

The final rule, in new § 35.2075(a), requires a licensee to retain a record of the basis for authorizing the release of an individual in accordance with § 35.75 ensuring that certain specified calculations were used. Section 35.2075(b) requires a record will be retained that the instructions required by § 35.75(b) were provided to a breast feeding woman. Section 35.2075(c) requires licensees to retain records of patient release required by §§ 35.75(a) and (b) for three years after the date of release of the individual.

Cost Impacts:

None anticipated. The recordkeeping requirements in the final rule parallel the recordkeeping requirements in §§ 35.75(c) and (d) of the current rule. Therefore, no incremental costs or cost savings are anticipated from the final rule.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

5.104 Records of mobile medical services (§ 35.2080).

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

Cost Impacts:

None anticipated. The recordkeeping requirements in the final rule duplicate the recordkeeping requirements in § 35.80(f) of the current rule. Therefore, no incremental costs or cost savings are anticipated from the final rule.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

5.105 Records of decay-in-storage (§ 35.2092).

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

Cost Impacts:

The final rule parallels, with one change, the recordkeeping requirements in § 35.92 of the current rule. The final rule eliminates the requirement that the record include the date on which the byproduct material was placed in storage. Therefore, the final rule may create small cost savings (i.e., <$1,000) for licensees, as a result of the slight reduction in the scope of records that must be maintained.

Health and Safety Impacts:

None anticipated.

Benefits:

Small cost savings for licensees (<$1,000).

5.106 Records of molybdenum-99 concentrations (§ 35.2204).

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

Cost Impacts:

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

Cost savings to licensees are estimated at:

Assumptions:	
Licensees:	
Total licensees:	2,359
Reduction in storage requirements:	4 cubic feet (about 2 file drawers)
Cost of storage:	$1.50 per cubic foot
Total Annual Cost Savings from § 35.2204:	$14,000

Health and Safety Impacts:

None anticipated.

Benefits:

Cost savings for licensees.

5.107 Records of safety instruction (§ 35.2310).

The final rule, in new § 35.2310, requires a licensee to maintain a record of safety instructions required by §§ 35.310, 35.410, and 35.610 for three years. The record must include: a list of topics covered; the date of the instruction; the name(s) of the attendee(s); and the name(s) of the individual(s) who provided the instruction.

The final rule parallels, with one change, the recordkeeping requirements in the current rule in §§ 35.310(b), 35.410(b), and 35.610(c). The final rule eliminates the requirement that the record include a description of the instruction. Therefore, the final rule creates small cost savings (i.e., <$1,000) for licensees using unsealed byproduct material for therapeutic administration, manual brachytherapy, and teletherapy. However, §§ 35.310, 35.410, and 35.610 are amended to require radiation safety instruction "initially and at least annually." Such annual training, and records of such training, previously has been required by license condition.

Cost Impacts:

Small cost savings are anticipated (<$1,000).

Health and Safety Impacts:

None anticipated.

Benefits:

Small cost savings to licensees.

5.108 Records of surveys after source implant and removal (§ 35.2404).

The final rule, in new § 35.2404, requires that a licensee maintain a record of the radiation surveys required by §§ 35.404 and 35.604 for three years and specifies that each record must contain the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

The final rule slightly reduces the scope of the records that must be maintained, because licensees for manual brachytherapy are not required to maintain a record of the dose rate from the patient or human research subject, as currently required by § 35.404(b).

Cost Impacts:

None anticipated. The requirements are consistent with current license conditions.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

5.109 Records of brachytherapy source accountability (§ 35.2406).

The final rule, in new § 35.2406, requires licensees to maintain a record of brachytherapy source accountability required by § 35.406 for three years and specifies the records that must be maintained.

The final rule reorganizes and reduces the recordkeeping requirements in § 35.406 of the current rule. The record retention period does not change.

Section 35.2406(b), which parallels the requirements in the current rule in § 35.406(b), with changes, specifies requirements for records of temporary implants. However, it eliminates the

requirement to maintain a record of the name of the individual permitted to handle the sources; the requirement to record the name and room number of the patient or human research subject; and the number and activity of sources in storage after the return of sources after removal from a patient or human research subject.

Section 35.2406(c), a new paragraph, specifies requirements for records of permanent implants. It requires the record to include the number and activity of sources removed from storage and the name of the individual who removed them from storage; the date they were removed from storage; the number and activity of sources not implanted; the date they were returned to storage and the name of the individual who returned them to storage; and the number and activity of sources permanently implanted in the patient or human research subject.

The final rule is not expected to increase the scope of the records that must be maintained, because records of inventory for brachytherapy sources used for permanent implants are covered, under the current rule. The final rule is expected to result in small cost savings (i.e., <$1,000) for licensees from the reduced scope of the inventory records that must be maintained.

Cost Impacts:

Small cost savings to licensees (<$1,000).

Health and Safety Impacts:

None anticipated.

Benefits:

Cost savings to licensees.

5.110 Records of calibration measurements of brachytherapy sealed sources (§ 35.2432).

The final rule, in new § 35.2432, requires a licensee to maintain a record of the calibrations on brachytherapy sources required by § 35.432 for three years after the last use of the source. The final rule specifies that the record must include: the date of the calibration; the manufacturer's name, the model number, and serial number for the source and instruments used to calibrate the source; the source output or activity; source positioning accuracy within applicators; and the signature of the authorized medical physicist.

Cost Impacts:

The current rule contains no requirements pertaining to records of full calibrations on brachytherapy sources. Therefore, this section of the final rule creates small (i.e., <$1,000), new cost impacts for licensees.

Health and Safety Impacts:

Increased safety.

Benefits:

Conforming change.

5.111 Records of decay of strontium-90 sources for ophthalmic treatments (§ 35.2433).

The final rule, in new § 35.2433, requires a licensee to maintain a record of the activity of a strontium-90 source required by § 35.433 for the life of source. The final rule specifies that the record must include the date and the initial activity of the source as determined under § 35.432; and for each decay calculation, the date and source activity as determined under § 35.433.

Cost Impacts:

The current rule contains no requirements pertaining to records of decay for strontium-90 sources used for ophthalmic treatments. Therefore, this section of the final rule creates small (i.e., <$1,000), new cost impacts for licensees.

Health and Safety Impacts:

Increased safety.

Benefits:

Conforming change.

5.112 Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units (§ 35.2605).

The final rule, in new § 35.2605, requires that a licensee retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by § 35.605 for three years and specifies that 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.

Cost Impacts:

None anticipated. The requirements are consistent with current license conditions.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change resulting from the restructuring of 10 CFR Part 35.

5.113 Records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units (§ 35.2630).

The final rule, in new § 35.2630, requires that a licensee 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 and specifies in detail what information must be included in each of these records.

Cost Impacts:

The final rule parallels the recordkeeping requirements in the current rule in § 35.630. However, the final rule eliminates the requirement for evidence to be provided that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by AAPM. Therefore, this section of the final rule creates no new cost impacts for licensees.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

5.114 Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations (§ 35.2632).

The final rule, in new § 35.2632, requires that a licensee maintain a record 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 and specifies in detail what information must be included in each of these records.

The final rule parallels, with three exceptions, the recordkeeping requirements in the current rule in § 35.632(g). The final rule changes the record retention period from the duration of use of the teletherapy source to three years after the last use of the source. It does not require maintenance of a record of the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit. It refers to the "authorized medical physicist" instead of the "teletherapy" physicist, to conform to the nomenclature of the final rule.

Cost Impacts:

This section of the final rule creates small incremental costs (i.e., <$1,000) for licensees as a result of the increase in the length of the record retention period.

Health and Safety Impacts:

None anticipated. Records already being retained.

Benefits:

Demonstrates that calibrations were done correctly and correct doses administered. Conforming change to restructuring of 10 CFR Part 35.

5.115 Records of periodic spot-checks for teletherapy units (§ 35.2642).

The final rule, in new § 35.2642, requires that a licensee retain a record of each periodic spot-check for teletherapy units required by § 35.642 for three years. The final rule also specifies in detail what information must be contained in each of these records.

The final rule parallels, with two minor changes, the recordkeeping requirements for periodic spot-checks for teletherapy units in the current rule in § 35.634(f).

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

5.116 Records of periodic spot-checks for remote afterloader units (§ 35.2643).

The final rule, in new § 35.2643, requires that a licensee retain a record of each spot-check for remote afterloaders required by § 35.643 for three years. The final rule also specifies in detail what information must be contained in each of these records.

Cost Impacts:

None anticipated. The requirements are consistent with current license conditions.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

5.117 Records of periodic spot-checks for gamma stereotactic radiosurgery units (§ 35.2645).

The final rule, in new § 35.2645, requires that a licensee retain a record of each spot-check for gamma stereotactic radiosurgery units required by § 35.645 for three years. The final rule also specifies in detail what information must be contained in each of these records.

Cost Impacts:

The current rule contains no section addressing records of periodic spot-checks for gamma stereotactic radiosurgery units. Therefore, this section of the final rule creates cost impacts for licensees, as follows:

Assumptions:	
Licensees:	
Total licensees:	30
Increase in storage requirements:	2 cubic feet (about 1 file drawer)
Cost of storage:	$1.50 per cubic foot
Total Annual Cost Increase from § 35.2645:	<$1,000

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

5.118 Records of additional technical requirements for mobile remote afterloader units (§ 35.2647).

The final rule, in new § 35.2647, requires that a licensee retain a record of each check for mobile remote afterloader units required by § 35.647 for three years. The final rule also specifies in detail what information must be contained in each of these records.

Cost Impacts:

None anticipated. The current rule contains no section addressing records of additional technical requirements for mobile remote afterloaders. Three mobile remote afterloaders currently are licensed by Agreement States but recordkeeping requirements are already established by the individual Agreement State.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

5.119 Records of surveys of therapeutic treatment units (§ 35.2652).

The final rule, in new § 35.2652, requires that a licensee maintain a record of radiation surveys of treatment units made in accordance with § 35.652 for the duration of use of the unit and specifies the records that must be maintained.

The final rule parallels, with changes, the requirements for records of radiation surveys for teletherapy facilities in § 35.641 of the current rule. The final rule requires records to be maintained for the duration of use of the unit, rather than for the duration of the license. It does not require a record to be maintained for why the survey is required; a plan of the areas surrounding the treatment room that will be surveyed; the measured dose rate at several points in each area, or the calculated maximum quantity of radiation over a period of one week for each restricted and unrestricted area. This section of the final rules reduce the cost impacts for licensees of teletherapy sources. The final rule also creates a new regulatory requirement for other therapy units. However, the net effect is anticipated to be small (i.e., <$1,000).

Cost Impacts:

None anticipated. The requirements are consistent with current license conditions.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change to restructuring of 10 CFR Part 35.

5.120 Records of five-year inspection for teletherapy and gamma stereotactic radiosurgery units (§ 35.2655).

The final rule, in new § 35.2655, requires that a licensee maintain a record of the 5-year inspection for teletherapy and gamma stereotactic radiosurgery units required by § 35.655 for the duration of use of the unit and specifies the records that must be maintained.

The final rule parallels, with changes, the requirements for 5-year inspections of teletherapy units in § 35.647 of the current rule. The costs of conducting the inspections are estimated under its replacement, § 35.655 of the final rule. The final rule requires records to be maintained for the duration of use of the unit, rather than for the duration of the license. It does not require a record

to be maintained of the list of components replaced, which lessens the cost impacts for licensees of teletherapy sources.

Cost Impacts:

The current rule does not contain requirements for records of five-year inspections for gamma stereotactic radiosurgery units. A cost increase is anticipated, as follows:

Assumptions:	
Licensees:	
Total licensees:	30
Increase in storage requirements:	2 cubic feet (about 1 file drawer)
Cost of storage:	$1.50 per cubic foot
Total Annual Cost Increase from § 35.2655:	<$1,000

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

SUBPART M

5.121 Report and notification of a medical event (§ 35.3045).

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

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

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

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

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

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

Section 35.3045(g) provides that a licensee shall retain a record of a medical event in accordance with § 35.2045. The licensee, as required under § 35.2045, will provide a copy of the record to the referring physician, if other than the licensee, within 15 days after discovery of the medical event.

Cost Impacts:

None anticipated. The changes in § 35.3045 of the final rule are not expected to substantially change the number or type of medical events to be reported under § 35.3045 from the number and type of misadministrations reported under the current rule.

Health and Safety Impacts:

None anticipated.

Benefits:

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

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

Section 35.3047(a) requires the licensee to report to NRC 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 embryo/fetus was specifically approved, in advance, by the authorized user. A main purpose of the report is to enable NRC to comply with Section 208 of the Energy Reorganization Act of 1974 (P.L.93-438) as amended, which requires NRC to submit reports of "Abnormal Occurrences" to Congress.

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

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

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

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

Section 35.3047(f) requires a licensee to retain a record of a dose to an embryo/fetus or a nursing child in accordance with § 35.2047.

Cost Impacts:

Cost increases are anticipated from requirements in § 35.3047(a) that require licensees to report a dose to an embryo/fetus and requirements in § 35.3047(b) that require licensees to report a dose to a nursing child. NRC anticipates that 10 such administrations occur annually for NRC and Agreement States licensees.

Assumptions:	
Licensees:	
Total annual reports:	10
Total report preparation time, hours:	10
Technical staff hourly rate:	$30
Total Annual Cost Increase for licensees from §§ 35.3047(a) and (b):	$3,000

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

Assumptions:	
Licensees:	
Total annual reports:	10
Total phone reporting time, hours:	0.5
Technical staff hourly rate:	$30
Total Annual Cost Increase for licensees from § 35.3047(c):	<$1,000

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

Assumptions:	
Licensees:	
Total annual licensee administrations:	10
Total report preparation time, hours:	8
Technical staff hourly rate:	$30
Total Annual Cost Increase for licensees from § 35.3047(d):	$2,000

Cost increases are anticipated from requirements in §§ 35.3047(e) and (f) that require notification to the referring physician and also the mother (or the responsible relative or guardian of the mother or child), if she requests such written notification. NRC anticipates that 10 such notifications occur annually for NRC and Agreement States licensees.

Assumptions:	
Licensees:	
Total annual licensee notifications:	10
Total notification time, hours:	0.5
Technical staff hourly rate:	$30
Total Annual Cost Increase for licensees from §§ 35.3047(e) and (f):	<$1,000

Cost increases are anticipated from requirements in § 35.3047(e) that require licensees to attempt to consult the referring physician before giving notice to the mother. NRC anticipates that 10 such consultations or attempts to consult occur annually for NRC and Agreement States licensees.

Assumptions:	
Licensees:	
Total annual licensee consultations:	10
Total consultation time, hours:	0.5
Technical staff hourly rate:	$30

Total Annual Cost Increase for licensees from § 35.3047(e):	<$1,000
Total Annual Cost Increase for licensees from § 35.3047:	$6,000

Health and Safety Impacts:

Provides notification of such events to individual and to referring physician.

Benefits:

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

5.123 Report of a leaking source (§ 35.3067).

This section requires that licensees file a written report within five days if a leak 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 Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. The report must include the model number and serial number, if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken. This report enables NRC to promptly determine if the necessary follow-up actions are necessary following discovery of the leaking source.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

No health and safety impacts are anticipated.

Benefits:

Conforming change.

SUBPART N--ENFORCEMENT

The final rule amends the former Subpart K and retitles it as Subpart N and makes the following changes:

5.124 Violations (§ 35.4001).

Section 35.990 of the current rule specifies that the Commission may obtain an injunction or other court order to prevent specified violations.

The final rule renumbers § 35.990 as new § 35.4001, without other changes.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change to restructuring of 10 CFR Part 35.

5.125 Criminal penalties (§ 35.4002).

Section 35.991(a) of the current rule specifies that the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, or attempted violation of, or conspiracy to violate, any regulation issued under specified sections of the Act. Section 35.991(b) lists the regulatory sections that are not covered by criminal sanctions.

The final rule renumbers § 35.991 as § 35.4002 and makes conforming changes to the section numbers in the final rule.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change to restructuring of 10 CFR Part 35.

5.126 Dose limits for individual members of the public (10 CFR 20.1301).

10 CFR 20.1301(a) of the current rule provides that each licensee shall conduct operations so that certain dose limits are maintained for members of the public.

The final rule amends 10 CFR 20.1301(a) to add a new paragraph, 20.1301(c), that provides that, notwithstanding the requirements in paragraph (a)(1), a licensee may permit visitors to individuals who are not released, which is governed by § 35.75, to receive a radiation dose greater than (1 mSv) 0.1 rem, but not to exceed (5 mSv) 0.5 rem, if the authorized user, as defined in 10 CFR Part 35, determines that it is appropriate .

The final rule addresses a Petition for Rulemaking (PRM-20-24) dated April 7, 1996, from the University of Cincinnati. On June 21, 1996 (61 FR 31874), the NRC published a notice of receipt and a request for comment on the petition (PRM-20-24). All commenters agreed with the petitioner that it was unreasonable to require licensees to limit doses to specified visitors to the public dose limit of one mSv (0.1 rem). A draft rulemaking plan was prepared and provided to the Agreement States on May 1, 1997, for review and comment, and a final rulemaking plan was submitted to the Commission for approval on August 1, 1997. The NRC determined that the following alternatives should be evaluated:

! Alternative 1: retain the 1 mSv (0.1 rem) public dose limit

This alternative evaluates the cost effectiveness of retaining the current dose limit of one mSv (0.1 rem) to an individual exposed to a hospitalized radiation patient. The petition would be denied on the basis that there are sufficient provisions within 10 CFR 20.1301(c) to allow case-by-case use of the five mSv (0.5 rem) annual dose limit for visitors of radiation patients.

! Alternative 2: 5 mSv (0.5 rem) public dose limit for specified visitors of radiation therapy patients

This alternative incorporates the provisions requested by the petitioner and evaluates the cost effectiveness of amending 10 CFR 20.1301 to permit, on a case-by-case basis, consenting adult, nonpregnant visitors to receive up to five mSv (0.5 rem) in a year from exposure to radiation therapy patients and to direct the authorized user to provide basic radiation safety instruction to visitors to minimize their doses while visiting the patient and require licensees to badge those visitors whose total effective dose equivalent exceed one mSv (0.1 rem).

! Alternative 3: 5 mSv (0.5 rem) public dose limit for visitors of radiation patients without badging or recordkeeping

This alternative evaluates the cost effectiveness of amending 10 CFR 20.1301 to permit visitors to individuals who are not released in accordance with § 35.75 to receive a radiation dose greater than one mSv (0.1 rem) but not to exceed five mSv (0.5 rem) if the authorized user determines that it is appropriate. No visitor badging or recordkeeping would be required in this alternative.

Cost Impacts:

Costs of safety instructions:

Alternatives 1 and 3 have no requirement for providing ALARA instructions to either the hospitalized patient or the visitor to the radiation patient and therefore have no related cost. However, the final rule associated with Alternative 2 would impose additional costs for providing basic radiation safety instruction to the 4,650 patients and 9,300 visitors. A cost of $22 per radiation patient or $102.3 thousand per year is the estimated total cost of providing instruction for Alternative 2. This estimate, obtained from NUREG-1492 (NRC 1997), assumes that the licensee spends 10 minutes providing instruction to the patient and visitors.

Costs of recordkeeping:

Alternatives 1 and 3 have no recordkeeping requirements and therefore have no related costs. However, the final rule associated with Alternative 2 would impose additional paperwork and recordkeeping requirements on the estimated 1,350 licensees (NRC- and Agreement States-licensed) that provide therapeutic administrations of radiopharmaceuticals to hospitalized patients. A record documenting the receipt of informed consent from the visitor to potentially receive up to the five mSv (0.5 rem) dose limit, receipt of basic safety instruction, and external radiation dosimetry records must be maintained for three years. It is estimated that approximately 4,650 procedures per year would be subject to these requirements. A cost of $17 per radiation patient or $79.1 thousand per year is the estimated total cost for record keeping. This estimate, obtained from NUREG-1492 (NRC 1997), assumes that the licensee spend eight minutes per patient documenting the provisions of instruction and dosimetric monitoring.

Costs of Providing Dosimetry:

Alternatives 1 and 3 have no dosimetry requirements, and therefore, have no related costs. However, the final rule associated with Alternative 2 would impose new dosimetry and paperwork requirements on the estimated 1,350 licensees (NRC- and Agreement States-licensed) that provide diagnostic and therapeutic administrations of radiopharmaceuticals to hospitalized patients. The cost of the dosimeter and dosimeter processing is estimated at $2.50 each. Labor associated with TLD or film badge issuance to and return from the visitor, and badge receipt from and shipment to a NVLAP accredited processing contractor is estimated at $14.00. A cost of $16.50 per visitor is estimated. This results in an annual estimated cost of approximately $153,400.

Qualitative Benefits:

Retention of patients in a hospital by design necessitates that the patient be "isolated" and that human contact, inclusive of family members, is either minimized or avoided. This isolation may bring about numerous changes and impositions in the lives of the patient and family members. The deterioration in the quality of life brought on by illness is frequently referred to as an "intangible cost." For thyroid cancer or thyroid dysfunction requiring therapeutic doses of I-131, for example, a deterioration in the quality of life may be precipitated by the loss of bodily function, a lifetime dependence on medication, hormonal instability, uncertainty of normal

life-expectancy, disruption of normal daily routines, and reduced financial security related to employment, lost earnings, and medical expenses.

While some of these elements of intangible costs are the result of the disease itself, others such as disruption of normal routines, social isolation, and enhanced financial strain are clearly elements of psychological costs that are directly related to patient retention. Allowing greater visitor access to the patient while they are under licensee control will provide an unquantifiable amount of physical and emotional benefit to the patient and the visitor alike. However, the conversion of this benefit into an equivalent dollar amount is complex, highly subjective, and dependent upon the individual situation. Instead, this analysis uses a qualitative and reasonable approach to scope the range of possible responses.

Health and Safety.

Selection of the five mSv (0.5 rem) total effective dose equivalent per year criterion is consistent with: (1) the Commission's provision in 10 CFR 20.1301(c) for authorizing a licensee to operate up to this limit; (2) the recommendations of the International Commission on Radiological Protection (ICRP) in ICRP Publication 60, "1990 Recommendations of the International Commission on Radiological Protection"; (3) the recommendations of the NCRP in NCRP Report No. 116, "Limitation of Exposure to Ionizing Radiation"; and (4) the International Atomic Energy Agency (IAEA) in Safety Series No. 115, “International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources.” Each of these documents provides a basis for allowing visitors to radiation patients to receive annual doses up to five mSv (0.5 rem).

The ICRP recommends that dose limits should not be applied to medical exposures, if the medical exposure is intended to provide a direct benefit to the exposed individual and the dose is kept as low as is compatible with the medical purposes. In this instance, medical exposure is defined to include “exposures incurred by individuals as part of their own medical diagnosis and treatment and to exposures (other than occupational) incurred knowingly and willingly by individuals helping in the support and comfort of patients undergoing diagnosis and treatment.”

Current NCRP guidance regarding radiation protection dose limits (NCRP Report No. 116) recommends that any activity which involves radiation exposure must be justified on the basis of the expected benefits to society exceeding the overall cost, the total societal detriment is maintained ALARA, economic and social factors are taken into account, and individual dose limits are applied to ensure that the procedures of ALARA and justification do not result in individuals exceeding levels of acceptable risk. Based upon this basic radiation protection philosophy, NCRP Commentary 11 (1995), “Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients,” noted that members of a radionuclide therapy patient’s family are likely to perceive that the visitors also will benefit from providing emotional and physical support to the patient during their treatment, and these visitors are likely to be willing to bear greater risk in order to achieve that benefit. Consequently, the NCRP Commentary No. 11

recommends that the dose limit for adult family members[16] "exposed to a radionuclide therapy patient should not exceed 50 mSv annually. When family members are likely to receive exposures in excess of 5 mSv annually, they should receive appropriate training and individual monitoring."

The IAEA description of dose limits for individual members of the general public is similar to the recommendations of the ICRP and NCRP. IAEA-115 specifies that:

> "II-9. The dose limits set out in this part shall not apply to comforters or patients, i.e., to individuals knowingly exposed while voluntarily helping (other than in their employment or occupation) in the care, support and comfort of patients undergoing medical diagnosis or treatment, or to visitors of such patients. However, the dose of any such comforter or visitor of patients shall be constrained so that it is unlikely that his or her dose will exceed 5 mSv during the period of the patient's diagnostic examination or treatment. The dose to children visiting patients who have ingested radioactive materials should be similarly constrained to less than 1 mSv."

Preferred Alternative:

To determine the preferred alternative, the costs and benefits that result when Alternatives 2 and 3 are each compared with Alternative 1 (the status quo) were analyzed. Both Alternatives 2 and 3 allow greater visitor access to the radiation patient, hence a larger collective dose is associated with these alternatives. Any potential detriment associated with this additional collective dose is offset by the qualitative benefit the patient and visitor receive under Alternatives 2 and 3. No monetary value was placed upon the qualitative benefit to either the patient or the specified visitor under each alternative. However, a net cost is associated with Alternative 2 to provide visitor badging, instruction and recordkeeping. No such requirements are associated with Alternative 3. The net cost of Alternative 2, compared to Alternatives 1 or 3, is anticipated to be $334,800. Evaluating the costs associated with monitoring individuals versus the benefits at these low doses, required monitoring is not considered to be justified, although the licensee is not precluded from monitoring and recording individual doses.

[16] NCRP Commentary No. 11 defines family member as "any person who spends a substantial amount of time in the company of the patient on a regular basis, providing support and comfort, and whom the patient considers a member of their "family," whether by birth, by marriage, or by virtue of a close, caring relationship."

6. COSTS AND BENEFITS FOR ALTERNATIVES FOR REVISIONS TO 10 CFR PART 35

6.1 Summary of Estimated Annual Costs of Rule

Table 6-1 presents a summary of the estimated values and impacts of the revisions to 10 CFR Part 35. For each regulatory change described above, Table 6-1 lists the estimated total costs avoided (-) or total costs added (+) (i.e., the change in costs from the current rule) for that section.

Table 6-1. Summary of the Rule's Cost Effects

Subpart	Section	Change in Licensee Costs (nominal $)	Change in NRC and Agreement States Costs (nominal $)	Total Change in Costs (nominal $)
A	**35.1**	0	0	0
	35.2	0	0	0
	35.5	0	0	0
	35.6	0	0	0
	35.7	0	0	0
	35.8	0	0	0
	35.10	0	0	0
	35.11	0	0	0
	35.12	-1,000	0	-1,000
	35.13	-10,000	-14,000	-24,000
	35.14	1,000	1,000	2,000
	35.15	0	0	0
	35.18	0	0	0
	35.19	1,000	9,000	10,000
B	**35.20**	0	0	0
	35.21	0	0	0
	35.22	0	0	0
	35.23	0	0	0
	35.24	-2,107,000	0	-2,107,000
	35.26	-14,000	0	-14,000
	35.27	-1,182,000	0	-1,182,000
	35.29	0	0	0
	35.32	-4,652,000	-1,991,000	-6,643,000
	35.33	0	0	0
	35.40	0	0	0
	35.41	0	0	0

Table 6-1. Summary of the Rule's Cost Effects (continued)

Subpart	Section	Change in Licensee Costs (nominal $)	Change in NRC and Agreement States Costs (nominal $)	Total Change in Costs (nominal $)
	35.49	0	0	0
	35.50	5,000	2,000	7,000
	35.51	2,000	1,000	3,000
	35.55	2,000	1,000	3,000
	35.57	0	0	0
	35.59	0	0	0
C	**35.60**	-532,000	0	-532,000
	35.61	-138,000	0	-138,000
	35.63	0	0	0
	35.65	-5,000	-45,000	-50,000
	35.67	-57,000	0	-57,000
	35.69	0	0	0
	35.70	0	0	0
	35.75	0	0	0
	35.80	0	0	0
	35.90	0	0	0
	35.92	-1,000	-1,000	-2,000
D	**35.100**	0	0	0
	35.120	0	0	0
	35.190	5,000	2,000	7,000
	35.200	0	0	0
	35.204	-1,132,000	0	-1,132,000
	35.205	0	0	0
	35.220	0	0	0
	35.290	-238,000	0	-238,000
E	**35.300**	0	0	0
	35.310	0	0	0
	35.315	0	0	0
	35.320	0	0	0
	35.390	51,000	0	51,000
	35.392	8,000	1,000	9,000
	35.394	0	0	0
F	**35.400**	-2,000	-2,000	-4,000
	35.404	-2,000	-3,000	-5,000
	35.406	0	0	0
	35.410	0	0	0
	35.415	0	0	0

Table 6-1. Summary of the Rule's Cost Effects (continued)

Subpart	Section	Change in Licensee Costs (nominal $)	Change in NRC and Agreement States Costs (nominal $)	Total Change in Costs (nominal $)
	35.420	0	0	0
	35.432	1,133,000	0	1,133,000
	35.433	400,000	0	400,000
	35.457	0	0	0
	35.490	0	1,000	1,000
	35.491	1,000	0	1,000
G	**35.500**	-1,000	-1,000	-2,000
	35.520	0	0	0
	35.590	0	0	0
H	**35.600**	0	0	0
	35.604	0	0	0
	35.605	0	0	0
	35.606	0	0	0
	35.610	0	0	0
	35.615	-187,000	0	-187,000
	35.620	0	0	0
	35.630	0	0	0
	35.632	0	0	0
	35.633	0	0	0
	35.635	0	0	0
	35.636	0	0	0
	35.641	0	0	0
	35.642	0	0	0
	35.643	0	0	0
	35.645	-3,000	0	-3,000
	35.647	0	0	0
	35.652	0	0	0
	35.655	0	0	0
	35.657	0	0	0
	35.690	2,000	1,000	3,000
J	**35.900**	0	0	0
	35.910	0	0	0
	35.920	0	0	0
	35.930	0	0	0
	35.932	0	0	0
	35.934	0	0	0
	35.940	0	0	0

Table 6-1. Summary of the Rule's Cost Effects (continued)

Subpart	Section	Change in Licensee Costs (nominal $)	Change in NRC and Agreement States Costs (nominal $)	Total Change in Costs (nominal $)
	35.941	0	0	0
	35.950	0	0	0
	35.960	0	0	0
	35.961	0	0	0
	35.980	0	0	0
K	**35.1000**	0	0	0
L	**35.2024**	-5,000	0	-5,000
	35.2026	-18,000	0	-18,000
	35.2040	0	0	0
	35.2045	0	0	0
	35.2047	0	0	0
	35.2060	0	0	0
	35.2061	0	0	0
	35.2063	0	0	0
	35.2067	-3,000	0	-3,000
	35.2070	0	0	0
	35.2075	0	0	0
	35.2080	0	0	0
	35.2092	0	0	0
	35.2204	-14,000	0	-14,000
	35.2310	0	0	0
	35.2404	0	0	0
	35.2406	0	0	0
	35.2432	0	0	0
	35.2433	0	0	0
	35.2605	0	0	0
	35.2630	0	0	0
	35.2632	0	0	0
	35.2642	0	0	0
	35.2643	0	0	0
	35.2645	0	0	0
	35.2647	0	0	0
	35.2652	0	0	0
	35.2655	0	0	0
M	**35.3045**	0	0	0
	35.3047	6,000	0	6,000
	35.3067	0	0	0

Subpart	Section	Change in Licensee Costs (nominal $)	Change in NRC and Agreement States Costs (nominal $)	Total Change in Costs (nominal $)
N	**35.4001**	0	0	0
	35.4002	0	0	0
10 CFR 20.1301	**Alternative 3**	0	0	0
TOTAL COST SAVINGS		$8,687,000	$2,038,000	$10,725,000

6.2 Estimated Lifetime Costs of Rule

NRC estimates the revisions to 10 CFR Part 35 will result in total annual cost savings of $10,725,000. NRC notes, however, that these estimated cost savings will not necessarily result in lower charges to licensees.

Based on OMB guidance, lifetime costs are estimated using a seven percent discount rate, which approximates the marginal pre-tax real rate of return on an average investment in the private sector in recent years.

Using both a seven percent discount rate and a 20-year time-horizon (i.e., base year plus 20), NRC estimates the lifetime cost savings of 10 CFR Part 35 to be $124,346,000 in year 2000 dollars.

7. DECISION RATIONALE

7.1 Decision rationale for revisions to 10 CFR Part 35

1. Alternative 2 is less expensive than Alternative 1 (status quo).

7.2 Decision rationale for PRM-20-24

1. All of the alternatives are acceptable according to generally accepted radiation protection principles, such as those expressed by NRC, NCRP, IAEA and ICRP (see Section 4.3, Evaluation of the Alternatives with Respect to Accepted Radiation Protection Principles).

2. Alternative 1 (status quo) is the least expensive to the public compared to Alternative 2, but Alternative 1 also conveys the least physical and emotional benefit to the patient. If the qualitative benefits of increased visitor-patient access is overlooked, a benefit which has not been expressed in dollar terms, the additional cost of Alternative 2 relative to Alternative 1 is about $334,800 per year. The preponderance of this additional cost is associated with badging visitors and providing ALARA instruction.

3. Alternative 1 and Alternative 3 have essentially the same relative licensee costs. The major difference is the qualitative benefits that the patient and visitor receive under Alternative 3.

4. Alternative 3 relative to Alternative 2 also has a net cost differential of $251,050 per year, mostly due to less prescriptive nature of the alternative in that there is no requirement to provide dosimetry and basic radiation safety instruction for each visitor and there are reduced recordkeeping requirements. Also, both Alternative 2 and Alternative 3 bestow similar qualitative benefits to the patient and visitors because of the increased visitor access. Thus, Alternative 3 is more cost effective in comparison with Alternative 2.

8. IMPLEMENTATION

No impediments to implementation of any of the alternatives have been identified.

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