June 4, 1998 SECY-98-128

FOR: The Commissioners

FROM: L. Joseph Callan /s/
Executive Director for Operations

SUBJECT: PROPOSED RULE: REVISION OF 10 CFR PART 35, MEDICAL USE OF BYPRODUCT MATERIAL

PURPOSE:

To request Commission approval to publish in the Federal Register a proposed rule to amend 10 CFR Part 35, “Medical Use of Byproduct Material.”

SUMMARY:

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

CONTACT: Catherine Haney, NMSS/IMNS
(301) 415-6825

Diane S. Flack, NMSS/IMNS
(301) 415-5681

BACKGROUND:

In its SRM dated June 30, 1997, "SECY-97-115, Program for Revision of 10 CFR Part 35, 'Medical Uses of Byproduct Material' and Associated Federal Register Notice" (Attachment 2), the Commission approved the staff's proposed plan for the revision of Part 35 and the Commission's 1979 Medical Use Policy Statement (MPS). The staff implemented that plan by establishing a Working Group and Steering Group that included headquarters and regional licensing and inspection staff and representatives of the Organization of Agreement States and the Conference of Radiation Control Program Directors.

The program for revising Part 35 and the associated guidance document has provided more opportunity for input from potentially affected parties (the medical community and the public) than is provided by the typical notice and comment rulemaking process. Early public input was solicited by requesting input through Federal Register notices; holding public meetings of the Working and Steering Groups; meeting with medical professional societies and boards; putting background documents, rulemaking alternatives, and a "strawman" draft proposed rule on the Internet and in the NRC's Public Document Room; and convening two facilitated public
workshops. Significant regulatory issues were discussed at the Part 35 Workshop that was held in conjunction with the All Agreement States Meeting in October 1997, the Advisory Committee on the Medical Uses of Isotopes (ACMUI) meetings in September 1997 and March 1998, and the ACMUI subcommittee meetings in February 1998. These interactions, and the comments received, are summarized in the proposed Federal Register notice (Attachment 3).

DISCUSSION:

In response to the SRM discussed above, staff has developed a draft proposed revision of Part 35, draft associated guidance, and a proposed revision of the MPS. The staff's proposed revision of the MPS has been transmitted separately for Commission approval for publication in the Federal Register. The draft proposed rule is consistent with the proposed revised MPS and is generally consistent with the current MPS (see Attachment 3, Section VII of the Supplementary Information).

Approach. The staff developed the proposed revision of Part 35 based upon the Commission's directions in the SRMs of March 20, 1997**,** and June 30, 1997. In addition, the staff moved to eliminate requirements from the draft proposed rule that were contained elsewhere in the Commission's regulations. Part 35 licensees will continue to be required to comply with these requirements, such as ALARA in Part 20, but the staff believes that there is no need to duplicate requirements, unless more specific requirements are needed for medical licensees, such as the frequency of area surveys.

The draft proposed rule provides for an overall change in regulatory philosophy. Consistent with a risk-informed, performance-based approach to medical use licensing, the amount of information needed from an applicant to possess and use byproduct material would be reduced. An applicant for an NRC medical use license would have to develop, maintain, and implement procedures, but would no longer be required to submit these procedures as part of the license

application. Furthermore, licensees would be provided maximum flexibility in developing their procedures because most of the requirements are stated in terms of the objectives to be achieved.

The staff has ensured, to the extent possible, that the regulations include all of the requirements for medical licensees. This responds to numerous comments that performance-based rules result in placement of requirements in guidance documents and license conditions. As a result, some prescriptive sections appear in the draft proposed rule where the requirements are necessary for safe operations. This approach was also taken with the development of the associated guidance document for medical use licensees. The draft guidance document provides model procedures to assist the applicant in developing various procedures required by the regulations, but it does not contain additional requirements. Licensees may choose to follow the specific models provided in the guidance document or develop alternatives to achieve the objectives (Attachment 4). Although the staff is providing this draft guidance for reference, it is not specifically seeking approval from the Commission on this draft guidance at this time.

The revised Part 35 includes several structural changes. The draft proposed rule has a modality-based structure; the current Teletherapy Subpart has been expanded to codify the requirements for remote afterloaders and gamma stereotactic radiosurgery devices, which are currently regulated through license conditions; a new subpart is proposed to allow for easier licensing of new medical procedures that use byproduct material or radiation from byproduct material for uses that are not specifically addressed in the current Part 35; and all of the requirements for records and reports have been moved to separate subparts.

In addition, the staff reviewed the applicable industry guidance and standards to determine if the needed standards are available; and, if they are available, to determine if they are consistent with NRC's regulatory needs and, if so, whether they should be incorporated or referenced in Part 35. The draft proposed rule takes into account industry standards, where appropriate. However, the staff has opted to codify the objectives to be accomplished, rather than referencing industry standards in the regulation, so that licensees would have increased flexibility in demonstrating compliance.

Specific Issues: Early in the rulemaking process, the staff identified five significant rulemaking issues, developed alternatives for them, and specifically sought public input on them. Two of the issues, patient notification and precursor events, were forwarded in SECY-98-054, "Commission Resolution of Significant Issues Associated with the Revision of 10 CFR Part 35, "Medical Uses of Byproduct Material" (March 22, 1998), for Commission direction (Attachment 5). Pending receipt of direction, the draft proposed rule includes the current requirements for patient notification and a requirement for capturing precursor events. (Attachment 6 contains the NRC Medical Visiting Fellow's view on patient notification following a medical event.) Revised requirements have been included in the proposed rulemaking for the other three issues: Radiation Safety Committee (RSC), Quality Management Program (QMP), and Training and Experience (T&E).

The requirement for a medical institution licensee to have an RSC has been deleted in the draft proposed rule. This change places the responsibility for the radiation safety program on the licensee management, but provides flexibility in using either an RSC, or other existing

management committees and structures.

The requirements for a medical licensee to establish and maintain a written QMP, to annually review the QMP, and to submit the QMP for NRC review have been deleted. The draft proposed rule requires licensees to have written directives for high-risk procedures, and to develop, maintain, and implement procedures to provide high confidence that each administration is in accordance with the written directive. This approach is consistent with Commission direction to re-evaluate and revise the QMP provisions to focus on those requirements that are essential for patient safety.

T&E requirements in the draft proposed rule have been revised to focus on radiation safety. The didactic and practical training requirements are focused upon radiation safety and the safe handling of radioactive material, and have been scaled based upon the risk posed by the diagnostic or therapy modality. The T&E requirements were extensively discussed with medical societies and boards, and were the primary issue in public comments received on the rulemaking. Approximately 90 percent of these comments were from radiation oncologists who feel very strongly that the current requirements for authorized users of brachytherapy and therapeutic medical devices should be retained because of the high risk associated with use of these modalities and because radiation safety training and clinical competence are intertwined for uses of these devices. As the rulemaking progressed, comments were also received expressing a viewpoint that T&E should not be reduced for diagnostic uses.

The draft proposed rule also addresses other ongoing medical issues, including a petition for rulemaking filed by the University of Cincinnati requesting a 500 mrem dose limit for visitation of individuals confined in accordance with § 35.75 (PRM-20-24); evaluation of the responsibilities of the authorized user and radiation safety officer, as a result of the Indiana, Pennsylvania brachytherapy incident; and the recommendations from internal staff audits. Revised requirements have also been developed in response to other ongoing rulemakings to address various technical and administrative issues identified in the Medical Management Plan, to revise brachytherapy procedures, and to eliminate or decrease the number of exemptions from the requirements for the medical uses of radiation by mobile services. In addition, a requirement for reporting unintended radiation exposure to an embryo, fetus, or nursing child has been proposed to respond to an ongoing rulemaking and to satisfy the NRC's requirement to report Abnormal Occurrences to Congress (Attachment 7, SRM-SECY-92-171, "Administration of Byproduct Material or Radiation from Byproduct Material to Patients Who May Be Pregnant or Nursing," June 25, 1992).

The schedule approved by the Commission in SRM-SECY-97-115 provides for the rulemaking to be completed by June 1999. Therefore, three facilitated public meetings are planned for August and September 1998 to discuss the proposed rule, as approved by the Commission for publication in the Federal Register, during the 75-day public comment period, projected to be from July 1 to mid-September 1998.

RESOURCES:

The resource levels expended on the proposed rulemaking have been somewhat greater than the resource levels identified in the FY 1998 and FY 1999 budget submissions. Resources have been reprogrammed from lower priority activities within NMSS. If the provisions in the proposed rule are approved in the final rule, increased resources to review and approve testing organizations and specialty boards will be required. The staff expects to refine the resource estimates based upon interactions with the public and professional societies during the public comment period, and to incorporate those resources within future program and

budget reviews.

COORDINATION:

The Office of the General Counsel has no legal objection to this proposed rulemaking. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections. The Office of the Chief Information Officer has reviewed the proposed rule for information technology and information management implications and concurs in it.

RECOMMENDATION:

That the Commission:

1. Approve the notice of proposed rulemaking for publication in the Federal Register.

2. Note:

   a. The rulemaking will be published in the Federal Register for a 75-day public comment period;

   b. A Draft Regulatory Analysis has been prepared for this rulemaking (Attachment 8);

   c. A Draft Environmental Assessment has been prepared for this rulemaking (Attachment 9);

   d. The appropriate Congressional committees will be informed (Attachment 10);

   e. The Office of Public Affairs has determined that a press release should be issued for this proposed rulemaking (Attachment 11);

   f. A draft Office of Management and Budget (OMB) Clearance package is attached (Attachment 12);

   g. Copies of the Federal Register notice of proposed rulemaking will be distributed to all affected Commission licensees, Agreement States, and potential Agreement States. The notice will be sent to other interested parties upon request;

h. The Enforcement Policy and inspection procedures will be reviewed and revised, if necessary, prior to publication of the final rule.

L. Joseph Callan
Executive Director
for Operations

Attachments:
1. SRM-COMSECY-96-057, dtd 3/20/97
2. SRM-SECY-97-115, dtd 6/30/97
3. Proposed Federal Register Notice
4. Draft NUREG 1556, Vol. 9
5. SECY- 98-054, dtd 3/22/98
6. Memorandum dtd 5/27/98, M. Pollycove to H. Thompson
7. SRM-SECY-92-171, dtd 6/25/92
8. Draft Regulatory Analysis
9. Draft Environmental Assessment
10. Congressional Letters
11. Press Release
12. OMB Clearance Package

Attachments provided to Commission offices, OGC, SECY and NMSS only. Copies of enclosures are available on request from Cathy Haney at (301) 415-6825.

h. The Enforcement Policy and inspection procedures will be reviewed and revised, if necessary, prior to publication of the final rule; and

L. Joseph Callan
Executive Director
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a:\35prcom2.wpd EDO 9700065/NMSS 9700139 File in PDR: ____Yes ____No

*SEE PREVIOUS CONCURRENCE **CP/PROOFED/MAY 20, 1998**

OFFICE	RGB:IMNS	RGB:IMNS	D:IMNS:NMSS	TECH ED	OGC
NAME:	DFlack	CHaney	DCool	EKraus*	STreby
DATE:	5 /20 /98	5 /20 /98	5/20 /98	04 / 29 /98	5/7/98 NLO

OFFICE:	AEOD	ADM	OE	OSP	CFO
NAME:	TMartin-FCongel for	EHalman	JLieberman	RBangart	SShortt for JFunches
DATE:	4 / 27/98	4 /29 /98	5 / 6 /98	5/8/98	4/20/98

OFFICE:	CIO	D:NMSS	DEDR	EDO
NAME:	BShelton for AGalante	CPaperiello	HThompson	LJCallan
DATE:	4 / 29 /98	5/21/98	/ /98	/ /98

OFFICIAL RECORD COPY

March 20, 1997

MEMORANDUM TO: L. Joseph Callan
Executive Director for Operations

FROM: John C. Hoyle, Secretary /s/

SUBJECT: STAFF REQUIREMENTS - COMSECY-96-057 MATERIALS/MEDICAL OVERSIGHT (DSI 7)

With respect to the overall materials program, the Commission continues to support its preliminary views on this issue which were a combination of two options -- Continue the Ongoing Program with Improvements (Option 2) and Decrease Oversight of Low-Risk Activities with Continued Emphasis in High-Risk Activities (Option 3). For the longer term, the Commission also believes that consideration should be given to broadening NRC's regulatory oversight to include one or more of the higher-risk activities identified in Option 1.

With respect to the medical program, the Commission was not persuaded by the National Academy of Sciences, Institute of Medicine (IOM) report that recommends that NRC should not be the Federal agency involved in the regulation of ionizing radiation in medicine. The Commission continues to believe that the conclusions in the report were not substantiated and that the recommendations should not be pursued.

The Commission continues to support the use of ACMUI and professional medical organizations and societies in developing regulatory guides and standards as was proposed in the Commission's preliminary views. In the longer term, the Commission would be willing to consider taking on broader regulatory responsibilities for higher risk activities involving other sources of ionizing radiation but such efforts should not divert resources from the 10 CFR Part 35 rulemaking discussed below.

In lieu of a rulemaking plan in the context of Management Directive 6.3 the staff should submit a program for Commission approval for revising 10 CFR Part 35, and associated guidance documents, and the Commission's 1979 Medical Policy Statement, if necessary. The program should describe how 10 CFR Part 35 can be restructured into a risk-informed, more performance-based regulation by a suspense date of 6/30/99. In developing the program the staff should consider the following:

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

(2) For diagnostic procedures, staff should consider regulatory oversight alternatives consistent with the lower overall risk of these procedures.

(3) The staff should address how best to capture not only relevant safety-significant events, but also precursor events.

(4) Changing the nomenclature from "misadministration" to "medical event" or comparable terminology.

(5) Part 35 should be redesigned so that it can incorporate necessary regulatory requirements for new treatment modalities in a timely manner.

(6) The Quality Management Program provisions (10 CFR Part 35.32) should be re-evaluated and revised to focus on those requirements that are essential for patient safety, e.g., confirming patient identity, requiring written prescriptions and verifying dose. To the maximum extent possible, the requirements should be revised to be risk-informed. Given this objective, a mixed approach of performance-based rules and otherwise prescriptive regulations should be pursued.

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

(8) The staff should consider a rulemaking process that provides more opportunity for input from potentially affected parties than is provided by the normal notice and comment rulemaking process but would be less consumptive of resources and time than the process recently used in the development of NRC's rule on radiological criteria for license termination.

The staff's program to implement the above should be submitted to the Commission for its consideration no later than June 6, 1997. The program should target June 30, 1999 as the date for completing the rulemaking process. This rulemaking and associated guidance development is a very high priority for the Commission. The Commission is prepared to provide additional resources to the extent necessary to complete the rulemaking process on this schedule.

(EDO - Program)	(SECY Suspense:	6/6/97)
(EDO - Complete Rulemaking)	(SECY Suspense:	6/30/99)

cc: Chairman Jackson
Commissioner Rogers
Commissioner Dicus
Commissioner McGaffigan
Commissioner Diaz
K. Cyr
D. Rathbun
H. Bell
A. Galante
R. Scroggins
W. Beecher

June 30, 1997

MEMORANDUM TO: L. Joseph Callan
Executive Director for Operations

FROM: John C. Hoyle, Secretary /s/

SUBJECT: STAFF REQUIREMENTS - SECY-97-115 - PROGRAM FOR REVISION OF 10 CFR PART 35, "MEDICAL USES OF BYPRODUCT MATERIAL" AND ASSOCIATED FEDERAL REGISTER NOTICE

The Commission has approved the staff proposal to revise 10 CFR Part 35 consistent with the alternative program proposed in
SECY-97-131 and subject to the following comments.

1. The staff should not only consider what regulations will be affected by the change to Part 35, but should also take a close look at existing guidance and draft guidance to determine what changes would be needed. To ensure that all regulatory rulemaking and guidance development potentially affecting medical uses will be consistent with the Commission's direction in DSI 7, the staff should identify in the public meetings and Federal Register notices all regulatory actions and proposed actions relating to or affecting Part 35 licensed activities. When appropriate, public comment should be invited.

2. The staff should continue to solicit input from members of the public to ensure, to the degree possible, that all interests are represented. The staff should include groups representing radiopharmacists and medical technologists, and other experts, as appropriate.

3. The staff should prepare alternatives with specific rule text to help focus the discussion during the first-round of facilitated meetings and assist the staff in developing draft rule language for publication and comment.

4. The staff should look for potential resource savings (FTE, consultants, and funds) that can be achieved through use of the internet, teleconferencing, etc. In making documents available over the internet, some caution should be exercised to ensure that the number of and versions

of available documents for comment are not so large and varied that they will overwhelm commenters and lead to confusion on the part of the staff and management responsible for the rulemaking.

A Federal Register notice and press release should be issued reflecting the approach outlined in SECY-97-131, attachments 1 and 2, and published in time to support the facilitated public meetings.
(EDO) (SECY Suspense: 9/5/97)

cc: Chairman Jackson
Commissioner Rogers
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
OGC
CIO
CFO
OCA
OIG
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)
PDR
DCS

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 20, 32 and 35

RIN 3150-AF97

Medical Use of Byproduct Material; Proposed Revision

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing a revision of its regulations governing the medical use of byproduct material. The proposed rule is one component of the Commission's overall program for revising its regulatory framework for medical use. The overall goals of this program are to focus NRC's regulations on those medical procedures that pose the highest risk and to structure its regulations to be risk-informed and performance-based, consistent with the NRC's "Strategic Plan for Fiscal Year 1997- Fiscal Year 2002." A separate notice in the Federal Register announced the Commission's proposed revision of its 1979 "Medical Use Policy Statement."

DATES: The comment period expires [insert date 75 days after publication]. Comments received after this date will be considered if it is practical to do so, but the Commission is only able to ensure consideration of comments received on or before this date.

ADDRESSES: Comments may be sent to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemakings and Adjudications Staff.

Deliver comments to: One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 am and 4:15 pm on Federal workdays.

Copies of comments received may be examined at: NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC.

You may also provide comments via the NRC's interactive rulemaking web site through the NRC home page (http://www.nrc.gov). From the home page, select "Rulemaking" from the tool bar. The interactive rulemaking website can then be accessed by selecting "New Rulemaking Website." This site provides the ability to upload comments as files (any format), if your web browser supports that function. For information about the interactive rulemaking web site, contact Ms. Carol Gallagher, (301) 415-5905; e-mail CAG@nrc.gov.

FOR FURTHER INFORMATION CONTACT: Catherine Haney, Office of Nuclear Material Safety and Safeguards, Nuclear Regulatory Commission, Washington, DC 20555-0001, (301) 415-6825, e-mail CXH@nrc.gov or Diane Flack, Office of Nuclear Material Safety and Safeguards, Nuclear Regulatory Commission, Washington, DC 02555-0001, (301) 415-5681, e-mail DSFI@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Use of Byproduct Material in Medicine

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. Diagnostic nuclear medicine in most cases 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.

State and Federal Regulations

Byproduct material or radiation from byproduct material is regulated by either State or Federal Laws. The NRC regulates the administration of byproduct material or radiation from byproduct material in 20 States, the District of Columbia, the Commonwealth of Puerto Rico, and various territories of the United States. There are approximately 1900 NRC licenses authorizing the medical use of byproduct material under 10 CFR Part 35, "Medical Uses of Byproduct Material." Thirty States, known as Agreement States, have entered into an agreement with the NRC to regulate the use of byproduct material (as authorized by section 274 of the Atomic Energy Act). These States issue licenses and currently regulate about 5000 institutions, e.g., hospitals, clinics, or physicians in private practice.

Revision of NRC's Regulatory Program

NRC's medical use program includes use of byproduct material in medical diagnosis, therapy, and research. NRC's requirements for medical licensees are in 10 CFR Part 35. Eleven million patients annually undergo medical procedures involving byproduct materials.

The Commission examined the issues surrounding its medical use program in detail during a 1993 internal senior management review, a 1996 independent external review by the National Academy of Sciences, Institute of Medicine, and the Commission's Strategic Assessment and Rebaselining Project (SA). In particular, medical oversight was addressed in the SA Direction-Setting Issue Paper Number 7 (DSI 7) (released September 16,1996). In September 1997, the Commission issued its "Strategic Plan" (NUREG-1614, Vol. 1) which stated that its goal in regulating nuclear materials safety is to "prevent radiation-related deaths or illnesses due to civilian use of source, byproduct, and special nuclear materials."

In its Staff Requirements Memorandum (SRM) - COMSECY-96-057, "Materials/Medical Oversight (DSI 7)," dated March 20,1997, the Commission stated that it supported continuation

of the ongoing medical use regulatory program with improvements, decreased oversight of low-risk activities, and continued emphasis on high-risk activities. This SRM also directed the NRC staff to revise Part 35, associated guidance documents, and, if necessary, the Commission's 1979 Medical Use Policy Statement (44 FR 8242; February 9, 1979). The Commission's SRM specifically directed the restructuring of Part 35 into a risk-informed, more performance-based regulation. In addition, the Commission expressed its support for the use of the Advisory Committee on the Medical Use of Isotopes (ACMUI) and professional medical organizations and societies in the revision of Part 35 and the medical policy statement. The Commission specifically directed the NRC staff to "consider a rulemaking process that provides more opportunity for input from potentially affected parties than is provided by the normal notice and comment rulemaking process but would be less consumptive of resources and time than the process recently used in the development of NRC's rule on radiological criteria for license termination."

During development of the rule and associated guidance, as well as during the review of the Medical Use Policy Statement, the Commission considered the following issues:

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

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

(3) The best way to capture not only relevant safety-significant events, but also precursor events;

(4) Changing the nomenclature from "misadministration" to "medical event" or comparable terminology;

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

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

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

The proposed rule that would revise Part 35 has been developed in response to these issues and concerns.

The Commission, in its SRM of June 30, 1997, "SECY-97-115 - "Program for Revision of 10 CFR Part 35, `Medical Uses of Byproduct Material` and Associated Federal Register notice," approved the NRC staff's proposed plan for the revision of Part 35. The Federal Register notice, "Medical Use of Byproduct Material: Issues and Request for Public Input" (62 FR 42219-42220; August 6,1997), solicited early public input on the proposed rulemaking.

The NRC staff implemented the approved plan using an approach involving public Working and Steering Group meetings, with significant opportunities for input from the public, potentially affected parties, the ACMUI, and professional medical organizations. Publicly noticed Working and Steering Group meetings were held in August, September, and December 1997, and in January, February, March, and April 1998. During the Working and Steering Group meetings, the groups identified significant crosscutting issues associated with the rulemaking. These issues included patient notification, precursor events, Radiation Safety Committee, quality management program, and training and experience for authorized users. Rulemaking alternatives were developed for these crosscutting issues and were made available on the Internet and in the NRC's Public Document Room for comment. These alternatives were discussed with (1) the ACMUI at its September 1997 meeting, (2) the public at facilitated public workshops held in Philadelphia, PA, in October and in Chicago, IL, in November 1997 (discussed below), (3) State regulators at a publicly noticed workshop that was conducted during the 1997 All Agreement States Meeting, and (4) meetings of medical professional societies.

In addition to the proposed revision of Part 35, the Commission is publishing for public comment, in a separate Federal Register notice, a proposed revision of its 1979 policy statement on the Medical Use of Byproduct Material (44 FR 8242; February 9,1979). The proposed revision of the medical policy

statement is another component of the Commission's overall program for revising its regulatory framework for medical use, including its regulations in Part 35. The proposed revision of Part 35 is consistent with the proposed revision of the Medical Use Policy Statement (MPS) and is generally consistent with the current MPS (see Section VII of the Supplementary Information section of this document).

Workshops

The Commission believes that it is important for interests affected by the medical use rulemaking to not only have an early opportunity to comment on the rulemaking issues, but also to have an opportunity to discuss the rulemaking with one another and the agency. Accordingly, the Commission convened two public workshops in which the interests that maybe affected by the rulemaking had the opportunity to discuss the rulemaking issues. Although the workshops were intended to foster a clearer understanding of the positions and concerns of the affected interests, as well as to identify areas of agreement or disagreement, it was not the intent of the workshop process to develop a consensus agreement of the participants on rulemaking issues.

In order to have a manageable discussion, the number of invited participants in the roundtable discussions at each workshop was limited. The Commission, through a facilitator for each workshop, attempted to insure participation by a broad spectrum of interests that may be affected by the rulemaking. These interests included nuclear medicine physicians, physician specialists such as 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 experts on risk analysis. Other members of the public were invited to attend and had the opportunity to comment on the rulemaking issues and the workshop discussions at periodic intervals during the workshops.

The workshops had a common, predefined agenda focused primarily on alternatives for major ("crosscutting") issues, some with draft regulatory text. The workshop format was sufficiently flexible to allow for the introduction of additional related issues that participants wanted to raise. The workshop commentary was transcribed and summarized in “Summary of Discussion: Facilitated Public Workshop on Revisions to 10 CFR Part 35 Held in Philadelphia, Pennsylvania, on October 28-30, 1997” (date of document to be inserted) and

“Summary of Discussion: Facilitated Public Workshop on Revisions to 10 CFR Part 35 Held in Chicago, Illinois, on November 12-14, 1997” (date of document to be inserted). The summary documents are available for inspection at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the summary documents are available as indicated in the For Further Information Contact section of this document. A brief summary of the participant's positions on the major crosscutting issues associated with this rulemaking is provided in Section III of the Supplementary Information section of this document.

The Commission plans to hold three public workshops during the formal comment period to facilitate public comments on the proposed rulemaking. Notices for these workshops will be published in the Federal Register.

II. Petition for Rulemaking

The Commission has incorporated into this rulemaking resolution of a Petition for Rulemaking (PRM) filed by the University of Cincinnati dated April 7,1996 (PRM 20-24), because of its pertinence to Part 35. On June 21, 1996 (61 FR 31874), the NRC published a notice of receipt and a request for comment on this petition for rulemaking.

The petitioner requested that the NRC amend 10 CFR 20.1301, "Dose limits for individual members of the public” to:

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

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

(3) Document compliance by issuing radiation dose monitoring devices (i.e., pocket dosimeter, film badge, TLD, or electronic dosimeter) to each specified visitor.

In response to the request for public comments, the Commission received comments from four members of the general public. All commenters agreed with the petition. One of the commenters suggested that the previous 5 mSv (0.5 rem) dose limit for the general public be reinstated for a "specific" public and, under unusual circumstances, also permit the authorized user to authorize even higher exposure provided the latter does not "receive more radiation than a radiation worker." Another commenter suggested permitting the authorized user to authorize even higher exposure provided it did not exceed the occupational dose limit of 50 mSv (5 rem).

Although a 50 mSv (5 rem) dose limit for adult visitors exposed to radionuclide therapy patients is consistent with the recommendations of the National Council on Radiation Protection and Measurements (NCRP Commentary No. 11, Dose Limits for Individuals Who Receive Exposure From Radionuclide Therapy Patients, February 28, 1995), this suggestion is not consistent with release of patients in accordance with § 35.75, or with the approach to protection of the public in 10 CFR Part 20. For this reason, the NRC decided not to adopt the suggested 50 mSv (5 rem) dose limit.

The NRC reviewed the petitioner's request and comments received on the petition and believes there is merit in granting the petition in part as discussed in detail later. This proposed rule responds to the petition by amending 10 CFR Part 20 to allow the licensee the discretion to permit visitors to receive up to 5 mSv (0.5 rem) in a year from exposure to hospitalized radiation patients.

III. Discussion and Input to Proposed Rule.

The program for revising Part 35 and the associated guidance documents has provided more opportunity for input from potentially affected parties (the medical community and the public) than is provided by the typical notice and comment rulemaking process. Early public input was solicited through several different mechanisms: requesting public input through Federal Register notices; holding open meetings of the government groups developing the revised rule language; meeting with medical professional societies and boards; putting background documents, options for the more significant regulatory issues associated with the rulemaking, and alternatives for revising the 1979 Medical Use Policy Statement on the Internet; and convening public workshops. The input received from the public during the development of the proposed rulemaking is categorized and summarized below, according to the significant regulatory issues that were identified very early in the rulemaking process.

A. Training and Experience.

1. Facilitated Workshops.

The issue of training and experience for authorized users generated the most discussion among workshop participants. Discussion of this topic was organized into segments that addressed "key current problems or advantages identified by participants"; certain "crosscutting" training and experience issues (including such questions as the role a professional degree, medical specialty certification, or testing should play in qualifying an authorized user); and various specific alternatives (developed by the Part 35 Working Group) for training and experience necessary to qualify a physician as an authorized user.

Based on specific questions posed to participants, certain issues emerged as important in determining the necessary training and experience for qualifying as an authorized user. For instance, some participants believed that the current requirements are unrealistically stringent. Other participants maintained that training and experience can be varied, based upon the degree of risk posed by a specific modality. (However, participants did not necessarily agree on how to rank various modalities based on risk.) One question raised was whether the training and experience requirements should be different for physicians already in practice, than for those physicians who are just starting out. Certain participants viewed Commission specification of clinical training and experience requirements as a serious intrusion into the practice of medicine, and, therefore, suggested that the term "clinical training and experience" should be replaced with the term "practical training and experience." The latter would cover safe handling of radioactive materials (i.e., such topics as: safe delivery of radionuclides to patients; time, distance, and shielding; use of a dose calibrator; assessing contamination; decontaminating areas; half-lives of radionuclides; and consequences of contamination). However, some therapy practitioners supported the requirement for clinical experience as part of training and experience. Another suggested approach to establishing training and experience requirements would be to have different requirements for physicians who use radionuclides for very limited purposes (i.e., cardiology and endocrinology), as opposed to physicians engaged in the general medical use of byproduct material.

The range of options for a physician to become an authorized user that was discussed at the workshops included --

(1) Status quo (i.e., a physician who is certified in any one of a number of medical specialities, or has had a set number of hours of classroom and laboratory training and supervised clinical experience, or has completed an approved training program that included classroom and laboratory training, work experience, and supervised clinical experience);

(2) Medical speciality certification, plus a specified number of hours of training and experience;

(3) Medical specialty certification plus a specified number of hours of training and passing an examination;

(4) Possessing an M.D. degree;

(5) Passing an examination focused on radiation safety; and

(6) Passing an examination focused on radiation safety and having specified clinical experience.

The options were primarily analyzed in terms of therapeutic versus diagnostic uses of byproduct material. Many participants involved in therapeutic medical uses supported the status quo requirements for such uses (generally requiring either medical speciality board certification or a specified number of hours of classroom and laboratory training) because such requirements have served patients and the public well. They maintained that board certification ensures the appropriate level of training and experience and were cautious about any change that could diminish assurance of competency. However, some proponents of the status quo would accept the use of medical specialty boards other than those currently listed in Part 35. Some participants also felt that clinical experience in handling radionuclides and patient cases, especially across a broad range of developing therapy, is crucial. Representatives of diagnostic uses of byproduct materials asserted that the status quo effectively prohibits some medical practitioners from using byproduct materials which they could safely use if the training requirements were decreased. They believe that an examination component of the training and experience requirements is extremely important in setting a standard for authorized users. Some diagnostic users recommended that about 150 hours of didactic training and associated clinical experience would be sufficient.

The discussion of training and experience requirements addressed the viewpoint that all professionals involved in handling radionuclides, including medical physicists, authorized nuclear pharmacists, nurses, technologists, dosimetrists, and physician's assistants, should be subject to the training and experience requirements. Some participants supported degree requirements, such as a master's degree in health physics.

Opposition to such a requirement was based on the concept that performance criteria, rather than a degree, should be the basis for determining competence for certain positions, such as the Radiation Safety Officer or nuclear technologist. Another viewpoint expressed was that the nuclear medicine technologist, rather than the authorized user physician, should be the focus of training and experience requirements, because the technologist actually handles the radioactive material.

Participants believed that training and experience requirements are essential for ensuring the competency of a Radiation Safety Officer. They generally expressed support for the status quo for training and experience requirements for the Radiation Safety Officer, but questioned whether an authorized user should automatically qualify as a Radiation Safety Officer. Specifically, some participants believed that an authorized user should not also be the Radiation Safety Officer because of "potential conflicts of interest" (i.e., the Radiation Safety Officer should not be influenced by the "administration" of a facility). Other participants noted that an authorized user physician might be a specialist whose practice includes a limited application of the medical use of byproduct material, and who does not have sufficient training in radiation safety to address problems that might occur. Certain participants believed that it may be appropriate for an authorized user to be a Radiation Safety Officer at a small hospital, even if that authorized user did not have the breadth of training to be a Radiation Safety Officer at a large hospital. A concern of some participants is that there may not be anyone other than the authorized user to assume the responsibility as a Radiation Safety Officer at small community hospitals. In those cases, an authorized user, who is also the Radiation Safety Officer, was seen to be preferable to not having a Radiation Safety Officer.

Workshop participants generally did not question the current training and experience requirements for the Radiation Safety Officer. Some suggested changes for the Radiation Safety Officer's training and experience were discussed, such as varying the training and experience to correspond to the type of license or duties performed by an individual Radiation Safety Officer; to have a "core competency" set of requirements (which

could be supplemented with additional requirements for modalities posing greater risks); or to substitute a Masters of Science degree for the 200-hour training requirement.

Certain participants involved in "low-dose" medical uses were unanimous in concluding that Part 35 include training and experience for medical physicists. They noted that training and experience requirements should correspond to the duties and responsibilities of the physicist for different modalities (i.e., instrumentation for nuclear medicine, radiation treatment planning, or administration of doses for radiation therapy).

Comments by participants on this issue were favorable regarding training and experience for the authorized nuclear pharmacists. Some participants specifically stated that, based on risk, radiopharmacy training and experience should be handled similarly to other diagnostic modalities.

Training and experience requirements for ancillary personnel, such as technologists, were briefly discussed. Some participants supported training and experience requirements for technologists because the technologists, rather than the physicians, handle the radioactive materials. One participant, a nuclear medicine technologist, indicated that there are already organizations that have established voluntary training and experience requirements for technologist certification. The individual did not believe that these organizations would endorse other exams. The individual also indicated that, if proposed, training for technologists should be risk-based.

2. Agreement State Workshop.

Discussions at the Agreement State Workshop focused on whether NRC's training and experience requirements should focus exclusively on the radiation safety aspects of an authorized user's training, leaving issues such as patient selection and reading scans to be part of the "practice of medicine." Workshop

participants were divided on this issue. Those answering this question affirmatively believed that NRC should focus on assuring that physicians are capable of safely handling and using byproduct material. One participant indicated that the level of education to demonstrate competence should be uniform regardless of the hazard posed by the material. Other participants believed that, from the patient's perspective, the physician's role goes beyond safety and into areas such as patient selection and scan interpretation.

One member of the public argued that NRC and Agreement States should require physicians to master quantitative radiation protection science before permitting them to become authorized users. The individual also believed that NRC and the Agreement States should rely solely on physician practice privilege committees, State Boards of Medicine, and the Joint Commission on the Accreditation of Health Care Organizations to determine the qualifications of physicians to practice nuclear medicine.

The Agreement States were concerned about the resources needed to develop and validate examinations. One participant stated that creating and validating a new exam would be costly in comparison to seeking out existing exams that were validated and acceptable to the NRC.

Training and experience requirements for ancillary personnel, such as technologists, were discussed. A representative of the nuclear medicine technologist profession stated that the role of the technologist entailed more than the safe handling of radioactive materials. The role of the technologist was to provide the physician with the information needed to treat the patient. The individual went on to indicate that the success of the entire diagnostic process correlated with the education and training of the technologist and physician. The individual indicated that groups currently certifying technologists support certification for technologists and State legislation mandating that technologists be licensed. The individual also indicated that these certifying groups did not favor NRC setting standards for training and experience for technologists because the NRC does not have the experience necessary to determine what the training requirements for technologists should be.

One workshop member confirmed that a number of States require that technologists be certified. The participant noted that the Conference of Radiation Control Program Directors (CRCPD) was planning on discussing minimum training and experience qualification criteria for technologists. These requirements would be added to the Suggested State Regulations.

3. Advisory Committee on Medical Uses of Isotopes (ACMUI).

Training and experience requirements have been discussed on numerous occasions with the ACMUI. The ACMUI most recently discussed training and experience for authorized users, authorized medical physicists, authorized nuclear pharmacists, and Radiation Safety Officers at its March 1-2,1998, meeting. The ACMUI agreed with the Commission's proposed general approach to training and experience, i.e., delete reference in the rule to the speciality boards names, require preceptor forms, and require that competency be demonstrated by successful completion of an examination. Members debated whether it is possible or prudent, with respect to authorized user physician training, to separate the hours required for radiation safety training from the entire clinical training period.

The ACMUI unanimously recommended that the current training requirements for authorized users of sealed sources and devices for therapeutic applications (proposed §§ 35.400 and 35.600) be maintained. Specifically, they recommended retaining the 3-year clinical training in an accredited program as an alternative to medical speciality board certification. The ACMUI agreed with the views expressed by members of the radiation oncology professional societies who made formal presentations at the March 1998, meeting. Specifically, they agreed that the current requirements for authorized users of brachytherapy and therapeutic medical devices should be retained because of the risk associated with use of these modalities and because radiation safety training and clinical competence are intertwined for uses of these devices.

The ACMUI unanimously recommended that the training requirements for authorized users of unsealed byproduct material for diagnostic uses (proposed §§ 35.100 and 35.200) be reduced to the levels proposed by the NRC staff (120 hours in a structured educational program). The ACMUI did not reach a consensus on the training requirements for authorized users of unsealed byproduct material for therapeutic uses. The NRC staff recommended reducing the training requirements to a 120-hour structured educational program and limited casework. Some members of the ACMUI were concerned that training for these uses should be addressed in a manner similar to that used for the therapeutic uses of sealed sources. Finally, they unanimously agreed with NRC staff's recommendation for training requirements for authorized nuclear pharmacists (700 hours in a structured educational program) and medical physicists (Masters of Science degree and 2 years).

4. Written Comments.

Authorized Users Training and Experience Requirements for Unsealed Byproduct Material

The Commission received numerous comments from professional societies and individual physicians on the training and experience requirements for use of unsealed byproduct material.

Many professional societies, as well as individual physicians, were concerned that a reduction in training hours, as proposed in a January 20, 1998, “strawman” version of the proposed rule, would not provide adequate training and might result in approval of poorly trained practitioners. They believe that it is impossible to distinguish between safety and competence. They indicated that the current requirement for 500 hours of clinical experience is an important “patient safety regulation.” Some professional organizations recommended that the Commission maintain the current training requirements in this area for authorized users, but also recommended that the training be provided only in programs accredited or approved by the American Council on Graduate

Medical Education. Others believed that training and experience should be developed, administered, and monitored by medical speciality organizations with experience in clinical radiation-related technologies.

One professional society supported the reduction in training hours. This organization recommended that physicians, who are not certified by an NRC-approved medical speciality board, be required to pass an examination and to obtain a written certification from a preceptor that indicates that the individual is able to function independently on all aspects of radiation safety.

Another society suggested that competence in radiation safety be demonstrated in a performance-based manner, e.g., NRC would not specify a specific number of hours, but would assess competency through a comprehensive examination.

One society urged the Commission to maintain the current training and experience requirements for use of byproduct material to treat hyperthyroidism or thyroid carcinoma. This organization opposed the proposal in the "strawman" proposed rule to increase the number of training hours needed to use material to treat hyperthyroidism or thyroid carcinoma and opposed the requirement for an examination. This organization believed that the proposed increase in training and experience requirements would have a detrimental effect for patient care, such as referral of patients to other specialists using less desirable alternative treatments.

One commenter indicated that a minimum of 120 hours of classroom and laboratory training and 240 hours supervised practical experience, or a 3-month training program in nuclear medicine, was appropriate for diagnostic nuclear medicine.

Training and Experience for Use of Sealed Sources in Therapy

The NRC received approximately 330 letters providing input to the rulemaking process. Approximately 90 percent of these comments were from radiation oncologists who feel very strongly that the current training and experience requirements for authorized users of brachytherapy and therapeutic medical devices should be retained because of the high risk associated with use of these modalities and because radiation safety training and clinical competence are intertwined for uses of these devices.

Commenters believed that training and experience requirements should be consistent with that required for certification by the American Board of Radiology (i.e., 3 years of therapeutic radiology and at least 6000 hours of direct clinical experience). If the Commission were to consider other medical speciality boards for certification of physicians seeking approval as authorized users to perform brachytherapy and teletherapy, the training required by those boards should be the same as that required by the American Board of Radiology for certification in therapeutic radiology. Certain comments specifically objected to either an NRC-developed or NRC-approved examination, because that would mean that the standards of the American Board of Medical Specialities and its twenty-four member boards are “too high.”

Most commenters believed that thorough training in radiation oncology should be required for all physicians seeking to perform applications of ionizing radiation to treat disease. According to certain comments, therapeutic treatments of the heart and brain are high-risk procedures and “relaxing” these requirements would not be in the best interest of patients or the medical profession at large. They maintained that training requirements for coronary artery brachytherapy and gamma stereotactic radiosurgery should be the same as those for other brachytherapy and teletherapy modes of treatment, respectively, and not broken into “tiny site-specific” modalities with different training requirements.

Other commenters noted that radiation oncologists should be involved, as part of a team with cardiologists and neurosurgeons, in brachytherapy treatment of the heart and use of gamma stereotactic radiosurgery of the brain. Other comments described the “full complement” of training for these medical uses as covering radiation biology, radiation physics, and radiation safety.

A professional organization offered criteria for training and credentialling of cardiologists performing brachytherapy involving coronary and vascular interventions. This organization believes that cardiologists should perform intravascular brachytherapy in collaboration with medical physicists, Radiation Safety Officers, and medical dosimetrists.

5. Resolution.

The Commission considered all of the input on training and experience that was provided during the development of this rulemaking. On the basis of the public input, the Commission is proposing the following training and experience criteria for authorized users, authorized medical physicists, authorized nuclear pharmacists, and Radiation Safety Officers:

(1) The requirements for training and experience should be risk-based and focused on radiation safety;

(2) Individuals should complete a structured educational program that consists of didactic training and practical experience;

(3) Specific reference to speciality boards, by name, should be deleted;

(4) Speciality boards will be approved by the Commission or an Agreement State if the board certification process includes all the training and experience requirements associated with the equivalent training pathway;

(5) Preceptors, when required, should certify that individuals have achieved a level of competency sufficient to function independently as an authorized user for the requested use, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer; and

(6) Individuals should demonstrate sufficient knowledge in radiation safety by passing an examination given by an organization or entity approved by the Commission or an Agreement State.

The Commission believes that training and experience criteria should be risk-based and focused on radiation safety. In addition, the Commission believes that, by requiring a combination of a structured education program, preceptorship, and examination focused on radiation safety, individuals will be able to safely handle byproduct material. It is important to note, however, that an individual's status as an authorized user, authorized medical physicist, authorized nuclear pharmacist, or Radiation Safety Officer means that an individual is qualified to handle byproduct material safety and is not an assessment of the individual's clinical or professional competency.

The Commission believes that individuals should complete a structured educational program that consists of didactic training and practical experience. The number of hours and type of training were extensively discussed with the medical societies and speciality boards and have been the primary issue in the public input received on the rulemaking. However, the Commission recognizes that radiation safety training and clinical competency may be intertwined, especially for uses of therapeutic medical devices. Because of the high risk associated with use of sealed sources in therapeutic medical devices, the Commission has not proposed significant changes in the current training requirements for authorized users in this area, with the exception of the training required for the use of strontium-90 eye applicators. Under the proposed rule, authorized users of strontium-90 eye applicators will need to meet the training requirements for authorized users of therapeutic medical devices. The Commission believes this change is warranted in light of the similarity between the use of strontium-90 eye applicators and the use of sealed byproduct material in medical devices and the recent

misadministrations involving strontium-90 eye applicators. It is important that the didactic training include courses in radiation physics, dosimetry, and radiation biology so that the authorized users have a clear understanding of what a dose means in terms of radiation damage to the exposed tissue.

The Commission has focused the training requirements for use of unsealed material for diagnostic administrations when a written directive is not required on radiation safety because of the low risk posed by the radionuclides. In doing so, the didactic and practical requirements for authorized users of unsealed byproduct material for diagnostic procedures were significantly reduced.

The didactic and practical requirements for use of unsealed byproduct material when a written directive is required were also reduced because of similarities between the use of unsealed material in a diagnostic setting and use in a therapeutic setting. However, the Commission recognized that the use of both therapeutic unsealed sources and sealed sources involve higher risks and, therefore, retained the requirement for clinical experience. The proposed rule would delete the specific training and experience sections that pertained to treatment of hyperthyroidism and thyroid carcinoma. Under the proposed revision of Part 35, individuals wishing to become authorized users of byproduct material for these medical uses would be required to meet the training requirements that apply to the use of unsealed material for therapeutic uses. The Commission believes that this change will not significantly affect authorized users in this area.

The Commission believes that any reference, by name, to specialty boards should be deleted from the regulation for two reasons. First, under the current Part 35, in which speciality boards are listed by name, a rulemaking is needed to add new boards or to delete existing boards. This has been a problem with the current Part 35 because on several occasions individuals requesting authorized user or medical physicist status have been certified by a speciality board that is not listed in the regulations. In these cases, NRC has had to evaluate the training of individuals, with the help of the ACMUI, on a case-by-case basis. Secondly, the current rule does

not provide for periodic review of certifying boards to determine if any changes have been made in their certifying programs.

The proposed rule would require that specialty boards be approved by the NRC or an Agreement State. A specialty board will be approved by NRC if the certification process includes all of the requirements listed in the equivalent training pathway, i.e., completion of a structured educational program of specific duration that covers specific topics; obtaining a signed preceptor certification; completion of patient casework, if required; and successful completion of an examination on radiation safety. The Commission plans to discuss proposed board approvals with the ACMUI prior to approving the boards. The NRC staff also plans to conduct periodic reviews of approved speciality boards to assure that they continue to meet commitments to NRC. If a board does not meet its previous training and experience commitments, it will be removed from NRC's list of approved boards. A list of approved boards will be maintained on the NRC external website. In addition, the Commission is contemplating noticing the approval of a speciality board in the Federal Register.

The Commission is proposing that preceptors, when required, should certify that individuals have achieved a level of competency sufficient to independently function as an authorized user for the use that they are requesting: a medical physicist, an authorized nuclear pharmacist; or a Radiation Safety Officer. In the current Part 35, a preceptorship is only required for authorized nuclear pharmacists. The current preceptors for authorized nuclear pharmacists are only required to attest to the fact that the individual has performed a specified number of cases/treatments. Preceptor forms will be revised to add a warning that 18 U.S.C. Section 1001 Act of June 25, 1948, 62 Stat. 749, makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

The Commission believes that individuals should demonstrate sufficient knowledge in radiation safety commensurate with the use requested by passing an examination given by an organization or entity approved by

the Commission or an Agreement State. Appendix A of the proposed rule provides the requirements for an examining organization or entity, examination programs, and written examinations. Of particular note is the requirement that procedures be established to ensure that examinations are not given to individuals who have also been instructed by the examining organization in the same subject area. This proposed requirement is consistent with current practices of medical specialty boards and was suggested for inclusion by ACMUI members. The Commission is soliciting specific public comment on whether this proposed requirement is too prescriptive in light of current industry practice.

It is expected that examinations will be specific to the risk associated with the medical use of the byproduct material. For example, it is reasonable to expect that one exam could be used to address an authorized user's competency for the medical use of material pursuant to §§ 35.100, 35.200, and 35.300, and that another examination would be needed to assess competency for use pursuant to §§ 35.400 and 35.600. The Commission plans to discuss the examination process with stakeholders at the facilitated public meetings scheduled to be held during the comment period of this rulemaking. In addition, the Commission solicits written comment on issues associated with the examination process.

NRC expects that it will take approximately 2 years for the industry to submit required information, to NRC or an Agreement State, for approval of specialty boards or organizations providing the exam and for NRC to approve the boards or examining organizations. This expectation is based on written and verbal support, received from professional organizations, for training and experience requirements that would require written examinations to assess competency and, on statements made by members of specialty boards indicating that only minor changes would need to be made to their current certification process to address the changes proposed by the Commission. The Commission anticipates that specialty boards and examining organizations will be prepared to submit requests for approval immediately following publication of the final rule. Nevertheless, the Commission is soliciting specific public comment on the amount of time that specialty boards and examining

organizations will need to prepare and submit an application for approval of the Commission or an Agreement State.

Since NRC expects that it will take approximately 2 years to complete approval of most specialty boards and examining organizations, NRC has maintained the current training requirements in subpart J of the proposed rule. As discussed under the Supplementary Information section of this document, for a 2-year period after publication of the final rule, licensees will have the option of meeting either the requirements in subpart J or the requirements in subparts B and D-H. After the 2-year period, the requirements in subpart J will be deleted, and the licensee will need to comply with the requirements in subparts B and D-H.

B. Quality Management Program.

I. Facilitated Workshops.

Workshop participants expressed both support for the quality management program and opposition to it. Those who support it described several benefits of the program, including the requirement for licensees to have a quality management program and related requirements for "recordable events" and written directives. Opponents of the quality management program rule described it as overly prescriptive, burdensome on licensees, and ineffective in reducing the number of misadministrations. According to certain participants, the current quality management program rule interferes with quality medical care. Many believed that the current quality management rule did little to reduce the number of misadministrations.

Some participants who did not support the quality management program expressed support for a performance-based rule that would not require licensees to submit the quality management program for regulatory approval. In their opinion, a performance-based rule would also provide a licensee with the flexibility to

custom-tailor a quality management program to meet that facility's quality management needs, including patient verification, ensuring that physician's directions are written, and verifying doses to patients. Some participants proposed that NRC work with other organizations or agencies to ensure quality assurance through other mechanisms in place. Another recommendation was that the proper way to reduce misadministrations is through better training and ensuring, during the licensing process, that personnel are qualified.

2. Agreement States Workshop.

Some Agreement States and members of the public agreed that the current quality management rule has not addressed the problem of misadministrations. In addition, they do not believe that the quality management rule goes beyond what would typically be considered "quality management." They believe that modifying the quality management program will not solve that problem.

Agreement States supported an option that would state the objectives of a quality management program (without being prescriptive), but would not require a written quality management program. Other States believed that the responsibility for quality management should lie exclusively with the medical facility, not with a regulatory agency.

A member of the public advocated, in lieu of a quality management program, a training requirement for technicians and a requirement that a physician be present whenever a therapeutic dose is administered. The individual stated that the latter requirement has significantly reduced the number of misadministrations in her State. Another member of the public suggested that a proposed rulemaking by the Health Care Financing Administration (HCFA) was expected to define three levels of supervision for imaging modalities. He explained that physicians would be required to be in the facility, if not in the room, when a dose was being administered in diagnostic nuclear medicine.

3. ACMUI.

Requirements for a quality management program have been discussed on numerous occasions with the ACMUI. At the September 1997 meeting, the Committee recommended that the Commission pursue development of a rule that would state only the objectives for a quality management program. At the March 1998 meeting, the ACMUI discussed the NRC staff's proposed revisions to the quality management program. The ACMUI agreed with the NRC staff's proposal to delete the requirements for a quality management program. Although the ACMUI would have preferred deletion of the requirement for written directives and the reference to assuring high confidence that the patient's or human research subject's identity is verified and that each administration is in accordance with the written directive, it recognized that the Commission finds these objectives to be fundamental.

4. Written Comments.

Approximately 10 written comments were submitted to the Commission on the quality management program. The majority of the comments favored deletion of any requirements in this area. Most believed that there were industry standards in place that adequately addressed administration of byproduct material; the rule intruded into medical practice; and regulation in this area was onerous. One professional society recommended that the title be changed to "Quality Assurance and Patient Safety Regulations" and believed that the regulations should be limited to requiring written prescriptions for therapy; requiring licensees to develop quality assurance programs for treatment planning and delivery devices; and requiring that independent checks be made against the written prescription before completion of a treatment. A limited number of commenters believed that the current requirements should be maintained because the quality management program provides a mechanism for reporting events and because licensees have already developed quality management plans that meet the intent of the rule.

5. Resolution.

The Commission has deleted the requirement for a quality management program. However, the Commission believes there are three elements of the current quality management program that should be addressed in the proposed rule: confirming patient identity, requiring written directives, and verifying dose. The Commission believes that some elements of the current quality management program requirements will continue to be implemented as part of the “standard of care” in medicine. In this regard, the Commission acknowledges that other factors, such as accreditation, have resulted in medical institutions adopting programs similar to those previously specified in the rule.

C. Reportable Events.

1. Facilitated Workshops.

The participants generally agreed that current threshold levels for reporting are too low and supported raising threshold levels. However, some participants supported the option of maintaining the current thresholds, arguing that they were familiar with the levels and reports and records of misadministrations are necessary. Participants agreed that threshold levels for recording and reporting events should be based on risk. Several participants argued that threshold levels for reportable events and Abnormal Occurrences should be the same. The NRC was commended for suggesting that the term "misadministration" be replaced with the term "reportable event."

2. Agreement State Workshop.

Discussion focused on the topic of precursor events, rather than on the threshold for reportable events. There was, however, a very brief discussion on reporting of misadministrations. Various statements made during the discussion included: regulatory agencies did not need to be informed of misadministrations, unless an event exceeded certain levels or occurred more than once; licensee management, rather than a regulatory agency, should be informed of misadministrations; and regulatory agencies should confirm, during periodic inspections, that licensee management is informed in cases of misadministrations, and that proper corrective actions are taken.

3. ACMUI.

The ACMUI discussed the threshold for reportable events at the September 1997 and March 1998 meeting. At the September 1997 meeting, the Committee reached a consensus, recommending that the current criteria for radiopharmaceutical misadministrations be reduced from three categories to two. The two categories would be "radiopharmaceuticals not requiring a written directive" and "radiopharmaceuticals requiring a written directive." The Committee pointed out that there is a major deficiency in the current misadministration definition, i.e., there is no threshold dose for wrong treatment site. They also stated that the reporting mechanism should be decoupled from patient notification. Finally, they agreed that an underdosage, if corrected in a clinically timely manner, should not have to be reported.

At the March 1998 ACMUI meeting, the NRC staff presented a proposed revision of the current reporting criteria. The proposed reporting requirement contained a dose threshold and modality-based criteria. The ACMUI discussed the proposed criteria and offered suggestions for minor technical corrections, but did not make a formal recommendation in this area. The Committee recognized that the NRC staff was still making changes in the proposed text to address the wrong treatment site and patient intervention.

4. Written Comments.

Sixteen comments were received in this area. Two of the commenters recommended raising the reporting threshold to the NRC's Abnormal Occurrence criteria for misadministrations. Several commenters provided general comments on the reporting criteria, including a name change from “misadministration" to "medical event." The remainder of the commenters provided specific recommendations for changes to the current reporting criteria, including recommendations for addressing patient intervention and wrong treatment site.

5. Resolution.

The Commission has a statutory responsibility to keep Congress and the public informed of incidents or events which the Commission considers significant from the standpoint of public health and safety. These criteria are specified in NRC's Abnormal Occurrence Policy Statement, dated April 17,1997 (62 FR 18820). Licensees must provide NRC with information on events meeting these criteria, in order for NRC to make needed reports to Congress.

The term "misadministration" has been deleted. The proposed rule would require licensees to report “medical events.” The criteria for a medical event is based on the current requirements in § 35.33, Notifications, reports, and records of misadministrations. Minor changes were made to make the reporting threshold dose-based, where possible, and to address two areas that have caused problems in implementing the current requirements in
§ 35.33, Patient intervention and wrong treatment site.

D. Precursor Events.

1. Facilitated Workshops.

Participants in the facilitated public workshops, as well as members of the public, believe that:

(1) There are already adequate mechanisms in place for identifying precursor events;

(2) Additional requirements for notifying NRC about precursor events could result in a significant financial burden for both NRC and licensees without an associated incremental increase in safety;

(3) Because of the nature of precursor events, it will be hard to precisely define a precursor event in rule language; and

(4) Inclusion of a requirement for reporting precursor events could lead to an additional basis for enforcement action.

2. Agreement State Workshop.

The discussion on this subject focused on how to identify "precursor events." Many of the participants opposed adding additional requirements for reporting precursor events. According to some Agreement States, mechanisms are already in place to provide information to licensees about incidents which may be “precursors” to reportable events. Most States were in favor of identifying precursors, but believe notification should be limited to facility management (especially the radiation safety organization). Some participants noted that reporting those events to a regulatory agency could actually inhibit their identification. They did, however, support internal programs for identifying precursor events. Finally, they stated that reporting to NRC or to the Agreement States would not be helpful unless a mechanism existed to share the information with the industry.

A member of the public noted that there are numerous event reporting requirements under which medical institutions document problem areas and conduct audits of potential problem areas. The individual encouraged NRC to avoid duplicating already existing programs.

3. ACMUI.

The ACMUI discussed the best way to capture precursor events at its September 1997 and March 1998 meetings. At the September 1997 meeting, most Committee members supported voluntary reporting of precursor events, provided there would be no punitive action taken by NRC against a licensee as a result of a report. One member recommended against reporting of precursors, whether mandatory or not, if it was going to have significant resource implications for NRC or the licensee.

At the March 1998 meeting, the ACMUI considered three alternatives proposed by NRC staff:

(1) Require reporting of conditions or incidents related to the use of radionuclides in medicine that caused or could cause serious injury to a patient, human research subject, worker, or the public;

(2) Require reporting deficiencies in equipment or procedures supplied by a manufacturer or vendor that, in the opinion of the Radiation Safety Officer, could lead to a medical event at that facility or could have detrimental health and safety implications beyond the licensee's facility; and

(3) Rely on current NRC reporting requirements in 10 CFR parts 20, 21, and 30 and the Memorandum of Understanding with the U.S. Food and Drug Administration and monitor/establish a system with U.S. Pharmacopeia to review its database on event reports.

The ACMUI acknowledged that the Commission wanted to capture precursor events. The ACMUI believed that it was appropriate to clearly define and limit the type of events that would be required to be reported in order to minimize the resource burden on licensees and the NRC. The ACMUI recommended that the NRC staff pursue the second alternative, with minor adjustments.

4. Written Comments.

Approximately five written comments were received on capturing precursor events. One commenter indicated that NRC should develop a nonpunitive method of capturing information while minimizing the burden on licensees, citing the FDA device malfunction reporting system as a model. Three other commenters felt that precursor events were not specifically enough defined (in an earlier draft of the proposed rule) and recommended that they not be included in the proposed rule. Of the remaining two commenters, one commenter did not support reporting precursor events under any condition, while the other supported voluntary reporting.

5. Resolution.

The Commission believes that identification and reporting of precursor events at some level is warranted. The Commission's objectives in capturing precursor events are to identify and analyze incidents that could lead to medical events, significant errors, or systematic problems that could have health and safety implications at the licensee's facility or at similar facilities.

The proposed rule contains a requirement for licensees to report, no later than the next calendar day, after identifying any defects, exclusive of ordinary equipment failures, in equipment (hardware and/or software), byproduct material, or procedures supplied by a manufacturer or vendor that, in the opinion of the Radiation Safety Officer or authorized user, could lead to a medical event.

E. Radiation Safety Committee.

1. Facilitated Workshops.

Workshop participants expressed different opinions about the benefits of radiation safety committees. Some participants stated that although radiation safety committees may be beneficial, the time and resources that must be devoted to managing the committees are excessive and the specific requirements in the regulation are overly prescriptive and not risk-based. Many participants believed that licensees should be given more flexibility in how they administer radiation safety programs. Some participants also expressed concern that the radiation safety committee may not be necessary for effective radiation safety management at small medical institutions.

Some participants believed that a single committee, focused on radiation safety, was an important element of a radiation safety program and, therefore, recommended that the requirement for a committee be maintained. They believed that the committee enhanced communication between disciplines and departments. They were concerned that, without a requirement for a radiation safety committee, administrative support for the committee would decline and there would be decreased management involvement in the radiation safety program.

2. Agreement States.

Discussions at the workshop centered around two issues:

(1) Whether the radiation safety committee plays a valuable role in all medical institutions, regardless of size and use of byproduct material; and

(2) Whether the current radiation safety committee requirements in Part 35 are too prescriptive and should be relaxed.

The majority of the participants in the workshop argued that the radiation safety committee requirements should recognize the differences between large and small institutions and between low- and high-risk procedures. Participants asserted that a radiation safety committee is unnecessary at smaller, diagnostic facilities. They generally supported the lessening of prescriptive requirements for smaller, diagnostic facilities. They argued that regulations place an unnecessary burden on facilities that conduct few procedures per year but still are required to conduct quarterly meetings. Another participant opposed a prescriptive rule, but acknowledged that it would be simpler to enforce than a performance-based rule.

3. ACMUI.

Requirements for a radiation safety committee were discussed with the ACMUI at its September 1997 and March 1998 meetings. At the September 1997 meeting, the ACMUI recommended that the NRC staff pursue developing a requirement for radiation safety committees at institutions that perform high-risk procedures. Facilities that use diagnostic, low-dose, sealed and unsealed byproduct material would not be required to have a radiation safety committee.

At the March 1998 meeting, the ACMUI agreed with the Commission's proposed deletion of the requirement for a radiation safety committee. ACMUI supported the addition of requirements for licensee management to approve licensing actions and minor revisions to the radiation safety program; and for a licensee to implement procedures for interdepartmental/ interdisciplinary coordination of the licensee's radiation protection program. They believed that the proposed language would not prohibit a large organization from utilizing a radiation safety committee, but would, at the same time, reduce regulatory burden on small rural hospitals which have small staffs and where a committee may not be needed to manage the radiation protection program.

4. Written Comments.

Approximately 10 written comments were submitted regarding the requirement for a radiation safety committee. The majority of the comments favored retention of the requirement for a radiation safety committee at larger facilities. These commenters believed that a committee was an effective way to ensure that management is involved in the operation of the radiation safety program. They recommended that a "graded" approach could be used in determining if a committee was needed, e.g., small facilities or facilities with limited use of material would not be required to have a committee. However, two commenters believed that the requirement for a radiation safety committee should be deleted in its entirety. Two others believed that the requirements should not be revised.

The Commission recognizes that medical facilities normally have a number of committees examining various areas, including safety issues, in response to accreditation requirements, etc. Specification of the objectives to be met by the radiation protection program (in the proposed § 35.24), rather than the particular mechanism to be used in meeting those objectives, is an effort to provide licensees flexibility in carrying out the responsibilities for radiation safety.

5. Resolution.

The Commission is proposing deletion of the requirement for a radiation safety committee. The Commission believes that key functions of the radiation safety committee could be transferred to licensee management and that the prescriptive requirements in the current rule should be deleted. The Commission believes that many institutions will continue to use a radiation safety committee to oversee use of radioactive material. However, it recognizes that radiation protection program oversight may be accomplished by other means. In particular, the Commission recognizes that medical facilities normally have a number of committees

examining various areas such as environmental safety. These committees are typically formed in response to hospital accreditation requirements.

In an effort to afford licensees flexibility in achieving the objectives of radiation safety, the proposed rule specifies objectives that must be achieved rather than specifying the mechanism to meet the objective. The proposed rule would require that the licensee approve licensing actions; individuals prior to allowing them to work as a Radiation Safety Officer, authorized user, authorized nuclear pharmacist, or authorized medical physicist; and radiation protection program changes that do not require a license amendment. The proposed rule also contains a requirement for the licensee to develop, implement, and maintain administrative procedures for interdepartmental/interdisciplinary coordination of the licensee's radiation protection program.

F. Notification Following a Misadministration or Medical Event.

I. Facilitated Workshops.

Many participants believed that the current requirements for licensees to notify the NRC, the referring physician, and the patient of a misadministration is an intrusion into both the practice of medicine and the confidential patient-physician relationship. They stated that the decision whether to notify the patient should be left solely to the physician. Those participants asserted that medical "standards of practice," "risk management" practices of medical institutions, and tort law are the mechanisms that should address notification of patients.

Therefore, according to these participants, Federal or State legal requirements for such notifications are unnecessary and inappropriate. Some participants believed that an authorized user would never withhold information from a referring physician because to do so would destroy the relationship between the authorized user and the referring physician.

Workshop participants did not believe that the requirement for a licensee to provide a written report to the individual was appropriate. They believed that a report that was submitted to NRC may greatly magnify, in the patient's mind, the significance of the event, when in fact, a medical event could be of minimal safety significance. However, other participants stated that without the NRC requirement for patient and referring physician notification, the physician's ethical obligation to make these notifications must be strong. Some commenters believed that the exchange of information between physicians should extend to patients as well. The participants espousing this viewpoint believe that such requirements may be necessary to protect patients and their right to know of misadministrations.

2. Agreement State Workshop.

Some participants noted that legal requirements for protecting the privacy of patients vary from State to State and may differ from Federal requirements. Other participants stated that medical standards of practice, tort law, and medical institution risk management are mechanisms to address fundamental patient notification and, therefore, State or Federal requirements for such notification are unnecessary.

3. ACMUI.

Notification requirements have been discussed on numerous occasions with the ACMUI. The ACMUI most recently discussed the requirements in this area at its March 1998 meeting. The ACMUI continues to affirm its position that it does not support any Federal regulation requiring notification of physicians and patients. The committee strongly believes that patient notification of medical events should occur as part of the patient-physician "fiduciary" relationship, in which the "standard of care" for a physician is to provide the patient with complete and accurate information.

4. Written Comments.

Three written comments directly addressed notification following a medical event. Two professional organizations recommended that the requirement be deleted. One State recommended that the requirement be maintained.

5. Resolution.

The Commission believes that the current requirements for notifying individuals following a misadministration should remain unchanged with the exception of substituting the term “medical event” for “misadministration.” Changing terminology in this way responds to objections that the term “misadministration” has possible connotations of carelessness and harm, which is not always the case. Furthermore, the term “medical event” used in the proposed rule is consistent with the terms used to characterize events in other activities regulated by the NRC. The proposed rule requires that the licensee notify the NRC, referring physician, and the individual who are the subject of a medical event, unless the referring physician personally informs the licensee that he will inform the individual or that, based on medical judgment, telling the individual would be harmful. In the latter case, or if for example, the patient is a minor, or is unconscious and incapable of comprehending the information. it is expected that the licensee would report to the patient’s responsible relative or guardian rather than to the patient. This position reaffirms statements made by the Commission, at the time the misadministration rule was proposed and/or promulgated (and later modified), that patient notification “. . . recognizes the right of individuals to know information about themselves which is contained in records both inside and outside the Federal sector.” “Human Uses of Byproduct Material, Misadministration Reporting Requirements,” 43 FR 2927; May 7, 1978; “Misadministration Reporting Requirements,” 45 FR 31701-31702; May 16, 1980; and “Basic Quality Assurance Program, Records, and Reports of Misadministrations or Events Relating to the Medical Use of Byproduct Material,” 55 FR 1439-1444; January 16, 1990. The Commission also

believes that patient notification enables patients, in consultation with their personal physicians to make timely decisions regarding any remedial and prospective medical care. This approach would also codify existing industry standards [American Medical Association Principles of Medical Ethics] obligating physicians to provide complete and accurate information to their patients.

This approach is consistent with the U.S. Food and Drug Administration (FDA) regulation and with how Congress is addressing similar issues in the mammography area. In October 1992, Congress passed the "The Mammography Quality Standards Act" (Public Law 102-539) to establish national quality standards for mammography. In December 1993, the FDA promulgated interim regulations setting forth quality standards for mammography facilities. In October 1997, the FDA issued a final rule that becomes effective in April 1999. The final rule requires that, in cases where "FDA determines that the mammography program at a facility may present a serious risk to human health, a facility must notify the patients or their designees, their physicians or the public of action that may be taken to minimize the effects of the risk." Currently, the Senate has passed and the House is considering bills (S. 537 and H.R. 1289) to amend the Mammography Quality Standards Act to, inter alia, add a new section to the Act on patient notification. The bills will provide FDA with the authority to require a facility to notify patients (and their referring physicians) of, among other things, the potential harm resulting from mammograms that may have been of poor quality because of deficiencies in the mammography program at that facility.

G. General Comments.

In addition to the comments on the crosscutting issues discussed above, NRC received comments on specific sections of the rule and on several general topical areas. These comments are available for review in the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC. Comments on specific

sections of the rule were taken into consideration in preparing the proposed rule. General comments are summarized below.

1. Process for Developing the Risk-Informed, Performance-based Rule.

a. Comments.

Workshop participants and written commenters discussed development of a risk-informed, performance-based rule. Some commenters recommended that NRC not proceed with any revision of Part 35 until it had performed an adequate and comprehensive evaluation of the risks associated with medical use. They recommended that the assessment should be performed by an "independent scientific organization" and completed in advance of any rulemaking. The risk analysis should follow the guidelines outlined by the Presidential Commission on Risk Assessment and Risk Management.

Some commenters did not believe that the current regulatory system makes optimal use of either NRC or licensee resources. They believed that NRC regulations and their associated paperwork burden inevitably contribute to the cost of providing clinically necessary procedures and may compromise the availability of the benefits of medical use of byproduct material. They recommended that NRC be guided by the following basic principles: rules should emphasize training and credentialling of professional staff deemed essential to safe operations, quality assurance and technical regulations should be based on available practice standards, and regulations should not be promulgated in the absence of a demonstrated risk to the public or patients.

Some commenters believe that Part 35 is duplicative of the Food and Drug Administration (FDA) statutes and implementing regulations and does not provide any added overall benefits to the regulatory framework. They believed that the FDA regulatory scheme is comprehensive, requiring documentation of adverse effects relating

to the use of all drug products, including radionuclides; regulations under 10 CFR Part 20 are adequate to protect health and safety; high-risk medical use can be regulated on a case-by-case basis through licensing conditions; and some prescriptive license conditions can be offset by performance-based flexibility, which is preferable to prescriptive regulations of medical users.

Finally, some commenters questioned the schedule for completion of the rulemaking. They believe that sufficient time must be provided to undertake a thorough effort to change the rule and for public comment on draft documents, including regulatory guides. They also believe that reorganization of Part 35 based on "similar subject areas" is appropriate, but the rule should include references to requirements in Part 20.

b. Resolution.

The Commission did not perform a formal risk assessment as part of this rulemaking effort. The Commission considered input from a 1993 internal senior management review report; external review report by the National Academy of Sciences, Institute of Medicine; and information presented in the Strategic Assessment Direction-Setting Issue Paper Number 7 (DSI-7) prior to determining the role of NRC regulation in the medical use area. On the basis of these reviews, the Commission believes that Part 35 should be restructured into a risk-informed, more performance-based regulation. In developing the regulation, the Commission considered information on risk provided by members of the public and professional societies, professional medical standards of practice, and event databases maintained by NRC.

2. Agreement State Compatibility.

a. Comments.

Commenters recommended that NRC follow its Strategic Plan to work with Agreement States to assure protection of the public health and safety nationwide, especially where constraints due to inconsistent regulation result in barriers to accessibility of medical use involving radionuclides. One commenter suggested that Agreement States should not be required to adopt any of the revised rule or accompanying guidance documents.

b. Resolution.

The Working Group and Steering Group established to revise Part 35 are comprised of NRC staff, as well as representatives of two Agreement States and a non-Agreement State. One of the Agreement State representatives on the Working Group is also a member of the Conference of Radiation Control Directors' Suggested State Regulation Committee on Medical Regulation, which is working toward parallel development of suggested state medical use regulations. The Working and Steering Groups received input from the Agreement States at several times during the rulemaking process. NRC representatives met with representatives of the Agreement States during the October 1997 All Agreement States Meeting. Agreement State representatives were invited participants at the facilitated public meetings. One Agreement State representative provided written comment during the early input stages of the proposed rule development.

The Commission has reviewed the proposed rule for issues of compatibility for Agreement States. Specific designations for the proposed rule are discussed under Section IX of the Supplementary Information section of this document.

3. Licensing and Enforcement Actions.

a. Comments.

Some commenters believed that NRC must change to a performance-based compliance system in order to have a significant impact on the entire medical use program. They believed that no change would occur if the NRC deleted regulatory requirements but had license reviewers demand that licensees make equivalent commitments in license applications or add equivalent conditions to the license. Some commenters stated that licensees should be allowed to operate their radiation safety programs without "procedure-by-procedure" approval by NRC and that regulations should cover all necessary requirements. Commenters recommended that NRC abandon an adversarial enforcement strategy based on punishment for infractions.

Commenters also believed that no change would occur if inspectors continued to apply regulatory and license requirements without regard to fault, and if inspectors continue the practice of issuing citations for minor regulatory requirements which can be attributed to normal human error and which have no safety significance. They stated that NRC must develop an enforcement system that allows for exercising clinical judgment, evaluating quality assurance policy deviations in terms of safety rather than legal significance, and accepting voluntary practice standards and measures of practice quality as the regulatory endpoints.

b. Resolution.

The proposed rule provides for an overall change in regulatory philosophy. Consistent with a risk-informed, performance-based approach to medical use licensing, the amount of information needed from an applicant to possess and use byproduct material would be reduced. An applicant for an NRC medical use license would have to submit a signed application, documentation of the training and experience of the individuals named on the license, and the facility diagram and list of instrumentation. While licensees would be required to develop, implement, and maintain procedures required by the regulations, they would no longer be required to submit these procedures as part of the license application. Furthermore, licensees will be provided maximum flexibility in

developing their procedures because most of the requirements for procedures provide performance-based objectives to be achieved, rather than a list of prescriptive details that need to be addressed in the procedures.

The NRC plans to review the enforcement policy as part of its overall revision of Part 35. This review will take into account written comments as well as those comments received during the facilitated public meetings that are scheduled to occur during the formal comment period.

IV. Discussion of Text of Proposed Rule

10 CFR PART 20--STANDARDS FOR PROTECTION AGAINST RADIATION

Section 20.1301, Dose limits for individual members of the public, would be revised. The proposed rule responds to the petition from the University of Cincinnati by amending § 20.1301 to allow a licensee the discretion to permit visitors to receive up to 5 mSv (0.5 rem) in a year from exposure to individuals who are not releasable pursuant to § 35.75. Currently, visitors are limited to 1 mSv (0.1 rem).

The Commission has used 5 mSv (0.5 rem) as a threshold for action in multiple locations in Parts 20 and 35. This threshold is used as both a dose limit and a reporting level. For example, § 35.75 uses the 5 mSv (0.5 rem) as a dose limit. The proposed change to § 20.1301 would also use 5 mSv (0.5 rem) as a dose limit. In contrast, however, the proposed changes to § 35.3047, Report of a dose to an embryo/fetus or a nursing child, would establish a 5 mSv (0.5 rem) reporting threshold (reference § 35.3047 for a more detailed discussion of the proposed change).

In accordance with § 35.75, patients containing radioactive material can be released from licensee control if the total dose to other individuals from exposure to the released patient is not likely to exceed 5 mSv (0.5 rem). The Commission recognizes that the provisions of § 35.75 and the proposed revision to § 20.1301(a) could result in rare instances in which certain individuals could receive a 10 mSv (1.0 rem) dose. For example, an individual could receive a 5 mSv (0.5 rem) dose while visiting a patient who can not be released pursuant to § 35.75, and then later receive a 5 mSv (0.5 rem) because of exposure from the released patient. The Commission believes that the authorized user is the appropriate individual to evaluate, on a case-by-case basis, the merits of allowing a visitor to potentially receive this additional dose and would do so only when it is warranted by the situation.

A potential consequence of this rulemaking is that pregnant visitors would not be excluded automatically from visiting individuals who could not be released pursuant to § 35.75. The pregnant visitor is subject to the same exposure limits that are applied to any other adult member of the public. The reasons for not excluding pregnant visitors under this rulemaking are two-fold. First, as noted in NCRP Commentary No. 11, members of a radionuclide therapy patient's family are likely to perceive that visitors will benefit from providing emotional and physical support to the patient during their treatment, and these visitors are likely to be willing to bear greater risk in order to achieve that benefit. Second, declaration of pregnancy by a prospective visitor is strictly voluntary. If a prospective visitor does not voluntarily declare her pregnant status, the authorized user is not expected to demand confirmation of the visitor's nonpregnant status.

As stated earlier, the proposed revision to § 20.1301 differs from the proposed revision to § 35.3047. The revision to § 20.1301 would revise the dose limit for a small population of individuals, namely visitors to individuals who can not be released pursuant to § 35.75. In contrast, the proposed revision to § 35.3047 would establish a reporting threshold for doses to an embryo/fetus or nursing child. For example, under the proposed § 20.1301, a pregnant visitor could receive 5 mSv (0.5 rem) as a result of a visit to a patient who has not been released.

Under the proposed revision to § 35.3047, if the dose to an embryo/fetus exceeds 5 mSv (0.5 rem), as a result of an unintended administration, a report must be submitted to NRC.

Finally, in the course of diagnosis and treatment, an authorized user may approve, in advance, an administration of byproduct material to a pregnant woman that may result in an absorbed dose to an embryo/fetus that exceeds 5 mSv (0.5 rem).

The Commission does not intend to require monitoring and recording of individual doses. The NRC evaluated the costs associated with monitoring individuals versus the benefits derived and determined that, at these low doses, monitoring is not justified. However, this does not preclude the licensee from monitoring and recording individual doses.

10 CFR PART 32--SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

Section 32.72, Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35, would be revised as a result of the proposed revision of Part 35. Paragraph (b)(1) would be revised to reference the proposed § 35.27 rather than the current § 35.25 which would be deleted. This change was necessitated because of the proposed renumbering of some Part 35 sections. Paragraph (b)(2)(ii) would be revised to include both the proposed and current training and experience requirements for authorized nuclear pharmacists and to reference the proposed § 35.59 rather than the current § 35.972 which would be deleted. As discussed in subpart J, the current training and experience requirements would be deleted 2 years after the effective date of the final rule.

Section 32.74, Manufacture and distribution of sources or devices containing byproduct material for medical use, would be revised as a result of the proposed revision of Part 35. Paragraphs (a) and (a)(3) would

be revised to add a reference to the proposed § 35.600. The current section does not include a reference to medical use of sealed sources in therapeutic devices. This oversight would be corrected by the proposed rule.

10 CFR PART 35--MEDICAL USE OF BYPRODUCT MATERIAL

Subpart A, General Information, contains general information regarding medical use of byproduct material.

Section 35.1, Purpose and scope, would be revised to specify that the requirements and provisions in Part 35 provide for the radiation safety of workers, the general public, patients, and human research subjects. Inclusion of the phrase “patients, and human research subjects" makes it clear that the provisions of this rule would apply to the radiation safety of those individuals. This addition is consistent with the proposed revision of the Medical Use Policy Statement that will be published separately in the Federal Register. The section would also be revised to add a reference to Part 171, “Annual Fees for Reactor Operating Licenses, and Fuel Cycle Licenses and Materials Licensed, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed By NRC.” This revision would make it clear that the provisions in Part 171 apply to medical licensees.

Section 35.2, Definitions, would be amended by deleting the definitions of “ALARA,” “dental use,” “ministerial change,” “misadministration,” “podiatric use,” and “recordable event” because they do not appear in the proposed rule.

The definitions for authorized nuclear pharmacist and authorized user would be revised to eliminate the specific board certifications by name and to refer to the specific section containing the requirements that the

individual must meet to be considered an authorized nuclear pharmacist or an authorized user. Reference to the specific board certifications would be deleted because the proposed rule contains provisions for NRC to approve boards. The definition of "authorized nuclear pharmacist" was also revised to recognize nuclear pharmacists that have been approved by a nuclear pharmacy that has been authorized by the Commission to approve authorized nuclear pharmacists.

The definition of "Radiation Safety Officer" would be revised to include a reference to the specific requirements that an individual must meet in order to be authorized as a Radiation Safety Officer. This change was done to make the definition of Radiation Safety Officer consistent with the definitions of authorized nuclear pharmacist, authorized user, and authorized medical physicist.

The definition of "written directive" would be revised to delete the provision for the date the directive was signed, and the signature of the authorized user before administration of any byproduct material or radiation from byproduct material to a specific patient or human research subject. These specific requirements have been moved to § 35.40.

The definition of "teletherapy physicist" would be deleted and replaced with a definition for "authorized medical physicist" because it is a broader term that includes physicists that work with all types of therapeutic units.

The definition of "mobile nuclear medicine" would be deleted and replaced with a definition for "mobile service" because it is a broader term that would encompass all modalities that could be performed by a mobile service. A new definition would be added for "temporary jobsite." This is needed since it is used in defining "mobile service." The definition of "temporary jobsite" is based, in part, on the definition of "temporary jobsite" as

used in 10 CFR Part 34, “Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations.”

Definitions would be added for “high dose-rate remote afterloader,” “low dose-rate remote afterloader,” “pulsed dose-rate remote afterloader,” and “stereotactic radiosurgery” because use of these units would be addressed in Part 35. The definitions of “high dose-rate remote afterloader” and “low dose-rate remote afterloader” contain dose rates specific to each type of afterloader. The Commission is not proposing to define the term “medium dose-rate remote afterloader” since it is not used in the proposed rule. The Commission noted that there was very little difference between the regulatory requirements for a medium dose-rate remote afterloader and high dose-rate remote afterloader and, therefore, has chosen to group the units. The Commission is soliciting public comment on whether the rule should specifically reference medium dose-rate remote afterloaders.

A definition for “medical event” would be added and refers to the criteria listed in § 35.3045(a), Reports of medical events. A new definition, “precursor event,” would be added and refers to the criteria listed in § 35.3046(a). (Reference Section III, C, of the Supplemental Information section of this document for more detailed discussion.)

A new definition, “treatment site,” would be added because it is used in § 35.2045 of the proposed rule. A new definition, “unit dosage,” was added because it is used in §§ 35.60 and 35.63 of the proposed rule.

Section 35.5, Maintenance of records, would be revised to insert “and” in the current phrase “drawings and specifications.”

Section 35.6, Provisions for research involving human subjects, would be unchanged.

Section 35.7, FDA, other Federal, and State requirements, would be unchanged.

Section 35.8, Information collection requirements; OMB approval, would be revised to reflect the renumbering of some sections within the rule and the additional recordkeeping and reporting sections in the proposed rule.

Section 35.10, Implementation, would be a new section that discusses the proposed provisions for implementing the final rule. A detailed discussion of the implementation provisions can be found in Section VIII of the Supplementary Information section of this document. This section would replace the current § 35.999, Resolution of conflicting requirements during transition period.

Section 35.11, License required, would be revised to reflect that the requirements for supervision in the current § 35.25 would be replaced by the proposed requirements in § 35.27.

Section 35.12, Application of license, amendment, or renewal, would be revised.

Paragraph (a) would be revised to state that any application for a license, amendment, or renewal must be signed by the management of the facility. The current rule indicates that any person may apply if the application is for medical use not sited in a medical institution and that only management may apply for a license if the application is for use in a medical institution. The Commission believes it is important that facility management apply for a license, regardless of where the material is used, because NRC holds the licensee responsible for any actions of its employees. Paragraphs (b) and (c) would be revised to more clearly state that separate applications must be submitted for medical uses listed in § 35.600, other than remote afterloaders. Paragraphs (b) and (c) would also be revised to delete the reference to the Regulatory Guides. Guidance for completing an application may be found in draft NUREG-1556, Vol. 9, “Consolidated Guidance About Materials Licenses,

Program-Specific Guidance about Medical Use Licenses." Draft NUREG-1556, Vol 9, is available for inspection at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the draft NUREG are available as indicated in the For Further Information Contact section of this document.

Paragraph (d) would be added to address applications for medical use of byproduct material that are not specifically included in subparts D through H of the proposed rule, henceforth referred to as "emerging technologies" (e.g., intravascular brachytherapy). The current rule does not provide for efficient licensing of emerging technologies. Paragraph (d) would provide a list of the information needed by NRC to approve a use that is not specifically addressed in subparts D through H of the proposed rule.

Section 35.13, License amendments, would be revised to reflect the new numbering as a result of the overall revision of Part 35. Paragraph (b) would be revised to indicate that a licensee does not need to amend its license before allowing anyone to work as an authorized medical physicist if that individual meets the training and experience requirements in § 35.51 or § 35.961, and the requirements were met within the 7 years preceding the date of the application. Paragraph (c) would be revised to delete the requirement for licensees to amend a license if the teletherapy physicist changes provided the individual meets the requirements in §§ 35.51(a) and 35.59 or §§ 35.961 and 35.59. This change is consistent with licensing requirements for authorized users and authorized nuclear pharmacists.

The Commission recognizes that unusual conditions may arise when the Radiation Safety Officer leaves a facility with little to no advance warning. In this event, the licensee may want to consider using an authorized user to fill the position, pending appointment of a new Radiation Safety Officer. Under these conditions, the licensee must move expeditiously to permanently fill the position of Radiation Safety Officer. In these situations, the licensee should contact the appropriate NRC regional office and explain the situation.

In order to reduce regulatory burden, paragraph (e) would be revised to delete the requirement for a licensee to apply for a license amendment if there is a change in the areas where byproduct material is used pursuant to §§ 35.100 and 35.200. However, this provision does not apply to storage or waste areas because of the potential for large quantities of materials to accumulate in these areas and the possibility of commingling of radioactive material that is used pursuant to other sections of the rule.

Section 35.14, Notifications, would be revised. Paragraph (a) would be revised to include a requirement for the licensee to notify NRC no later than 30 days after the date the licensee permits an individual to work as an authorized medical physicist pursuant to § 35.13(b). Paragraph (b) would be revised to require that the licensee notify NRC when an authorized medical physicist permanently discontinues performance of duties under the license. Paragraph (b) would also be revised to require that a licensee notify NRC when the licensee changes its name. This provision applies only if there is no change in ownership, as described in § 30.34 of this chapter. Otherwise, the licensee must take appropriate action to have its license amended. A licensee must also notify NRC of any changes in areas where materials are used pursuant to §§ 35.100 and 35.200. These revisions were warranted because of requirements in the proposed § 35.13.

Section 35.15, Exemptions regarding Type A specific licenses of broad scope, would be revised to add the term “authorized medical physicist” to paragraph (d). This revision is needed because of the requirements in the proposed § 35.13. Under this proposed section, broad scope licensees would have authority to appoint authorized users, authorized nuclear pharmacists, or authorized medical physicists without notifying NRC, provided the individuals meet approved criteria in subparts B, D-H, and J.

A new paragraph (e) would be added to also exempt these licensees from § 35.49(a). This change would codify in the regulations an exemption that is currently provided to these licensees through a standard condition. NRC’s medical use licensees with a Type A specific license of broad scope currently receive a standard license

condition that exempts the licensee from receiving sealed sources or devices manufactured only from licensees with medical distribution licenses issued pursuant to § 32.74. This change would replace the license condition.

Section 35.18, License issuance, would be revised. Requirements for a mobile service license would be added as paragraph (b). The NRC will issue a license for mobile service if the applicant meets the requirements specified in paragraph (a) of the section and if the individual or human research subject to whom the applicant administers byproduct material, or radiation from byproduct material, may be released following treatment in accordance with § 35.75. The later condition is necessary because mobile service licensees will not have the capability of controlling individuals that cannot be released pursuant to § 35.75.

Section 35.19, Specific exemptions, would be revised to delete the statement that the Commission will review requests for exemptions from training and experience requirements with the assistance of its Advisory Committee on the Medical Uses of Isotopes. This statement is a matter of Commission policy rather than a regulatory requirement.

Subpart B, General Administrative Requirements, contains general administrative requirements regarding medical use of byproduct material.

Section 35.20, ALARA program, would be deleted in its entirety from Part 35. ALARA is discussed in 10 CFR 20.1101, "Radiation protection programs," and medical licensees must comply with the requirements of that section. That section requires, in part, that a licensee develop, document, and implement a radiation protection program and use, to the extent practicable, procedures and engineering controls to achieve occupational doses and doses to members of the public ALARA. The Commission does not believe that § 35.20 is needed in light of the requirements in § 20.1101. A medical use licensee should have flexibility in developing and implementing a radiation protection program that meets the requirements of Part 20.

Section 35.21, Radiation Safety Officer, would be deleted in its entirety from Part 35. The requirements of paragraph (a) would be moved to the proposed § 35.24. Paragraph (b) would be deleted because it is overly prescriptive and in some cases overlaps with the requirements in § 20.1101. The Commission believes that the licensee should have the flexibility in developing, maintaining, and implementing its radiation protection program, including establishing the Radiation Safety Officer's duties.

Section 35.22, Radiation safety committee, would be deleted in its entirety. The issue of whether NRC should require a Radiation Safety Committee was identified as a cross-cutting issue and, therefore, was discussed at the public meetings and workshops held in Fall 1997. Comments received on this topic are discussed in Section III of the Supplementary Information section of this document. Based on the comments received prior to March 1, 1998, the Commission believes that key functions of the Radiation Safety Committee could be transferred to licensee management (reference proposed § 35.24) and that the prescriptive requirements in the current § 35.22 should be deleted. The Commission believes that many institutions will continue to use a Radiation Safety Committee to oversee use of radioactive material. However, it recognizes that radiation program oversight may be accomplished by other means. In particular, medical facilities normally have a number of committees examining various areas, such as environmental safety. These committees are typically formed in response to hospital accreditation requirements. Specifying responsibilities and functions to be accomplished, rather than the particular mechanism to be used, is an effort to afford licensees flexibility in achieving the objective of radiation safety (reference § 35.24).

Section 35.23, Statements of authority and responsibilities, would be deleted in its entirety and the requirements of this section, with minor modifications, would be moved to the proposed § 35.24.

Section 35.24, Authority and responsibilities for the radiation protection program, would appear as a new section. This requirement specifies objectives that must be achieved, rather than specifying how the objective is to be met, in an effort to afford licensees flexibility in achieving the objective of radiation safety.

Paragraphs (a) and (b) would replace the current requirements for the Radiation Safety Committee. The licensee is responsible for approving licensing actions; individuals before allowing them to work as a Radiation Safety Officer, authorized user, authorized nuclear pharmacist, or authorized medical physicist; and radiation protection program changes that do not require a license amendment.

The licensee must develop, implement, and maintain administrative procedures for interdepartmental/interdisciplinary coordination of the licensee's radiation protection program. Interdepartmental/interdisciplinary coordination is believed to be a major component of an effective radiation protection program. The Commission recognizes that there are many ways to meet this objective and believes that the licensee should have flexibility in identifying and implementing the most appropriate modes of coordination at its facility. Identified alternatives include, but are not limited to, meetings, electronic transfer of information, or verbal communication. This requirement applies to all medical use licensees and it is expected that the extent of the coordination will be dependent on the complexity of the licensee's program.

The requirement in paragraph (c) to appoint a Radiation Safety Officer is currently required by § 35.21. The proposed paragraph would require that the Radiation Safety Officer agree, in writing, to be responsible for implementing the radiation protection program. The requirements in paragraphs (d) and (e) are similar to the requirements in the current § 35.23. A record of management's approval of actions in paragraph (a); written acceptance of Radiation Safety Officer duties as specified in paragraph (c); and the duties, responsibilities, and authority of the Radiation Safety Officer specified in paragraph (d) would have to be maintained in accordance with § 35.2024, Records of authority and responsibility for radiation protection programs.

Section 35.25, Supervision, would be deleted in its entirety and the requirements of this section, with minor modifications, would be moved to the proposed § 35.27.

Section 35.26, Radiation protection program changes, would appear as a new section. The requirements in this section are similar to the requirements in the current § 35.31, which would be deleted. The proposed section states that a licensee may revise its radiation protection program without Commission approval if the revision does not require an amendment in accordance with § 35.13; the change will not reduce radiation protection; the change has been reviewed and approved in writing by the Radiation Safety Officer and licensee management; and the affected individuals have been instructed on the revised program before the changes are implemented. This requirement provides the licensees with flexibility to manage their radiation protection programs and clearly defines the situations that will not require an amendment. The Commission believes that many licensees were reluctant to make changes to their current program because the term “ministerial changes,” as defined in the current § 35.2 and as used in the current § 35.31, was not clearly understood. This change is intended to provide clear guidance to a licensee on when it can revise its radiation protection program without Commission approval.

The Commission believes that it is important to instruct individuals in program changes, including those permitted under § 35.26, before they are implemented. This instruction could be provided in writing or orally and may be conducted on an informal or formal basis. It is not necessary to document that this training has been provided to affected parties, because these changes should not reduce radiation safety. At the time of inspection, NRC inspectors may question whether this training was provided.

Section 35.27, Supervision, would appear as a new section. The requirements in this section are similar to the requirements in the current § 35.25, which would be deleted. Paragraph (a)(1) and (b)(1) would be revised to delete the requirement to instruct individuals in the principles of radiation safety. This type of instruction is

adequately addressed by § 19.12, Instructions to workers, of this chapter. Paragraph (a)(1) would also be revised to require that the licensee instruct supervised individuals in the written radiation protection procedures, written directives procedures, regulations of this chapter, and license conditions. Paragraph (a)(2) would require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures, regulations, and license conditions with respect to the medical use of byproduct material. Paragraphs (a)(3) and (b)(3) of the current § 35.25 would be deleted because the licensee should have flexibility in evaluating employee performance. Paragraph (b)(2) would be revised to require supervised individuals 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, and the regulations of this chapter and license conditions. Paragraph (c) would require that the licensee develop, implement, and maintain a policy for supervised individuals to request clarification, as needed, from the authorized user about instructions and requirements in a written directive prior to administering the byproduct material, or radiation from the byproduct material, and from the authorized user or authorized nuclear pharmacist about instructions and requirements provided in accordance with paragraphs (a) and (b) of the section. This change would be added so that a licensee's work environment would encourage supervised individuals to ask questions if they do not understand the instructions or requirements provided to them by an authorized nuclear pharmacist or an authorized user, especially when they have questions regarding administrations of byproduct material to patients or human research subjects. In the past, failure by licensee staff to ask questions has been identified as one of the key contributors to misadministrations.

Section 35.29, Administrative requirements that apply to the provision of mobile service, would be deleted. The conditions for the Commission to issue a mobile service license would be moved to § 35.18. The requirements in paragraphs (b) and (d) would be moved to the proposed § 35.80. Paragraph (c) would be deleted because this requirement was viewed as overly prescriptive. Individuals are required to comply with all provisions of the license that authorizes use, possession and transfer of material.

Section 35.31, Radiation safety program changes, would be deleted. The requirements, with minor changes, would be moved to § 35.26. This change is proposed so that all requirements that pertain to the management of the licensee's program appear in one area.

Section 35.32, Quality management program, would be deleted. The issue of whether the Commission should continue to require that a licensee develop, implement, and maintain a quality management program was identified as a cross-cutting issue and was discussed at the public meetings and workshops held in Fall 1997. Comments received on this topic are discussed in Section III of the Supplementary Information section of this document. Based on these comments, the Commission has deleted the requirements for a quality management program. However, the Commission believes there are three elements of the current quality management program that should be addressed in the proposed rule: confirming patient identity, requiring written directives, and verifying dose. Requirements for these three elements are found in proposed §§ 35.40 and 35.41. However, the Commission believes that some elements of the current quality management program requirements will continue to be implemented as a part of the "standard of care" in medicine. In this regard, the Commission acknowledges that other factors, such as accreditation, have resulted in medical institutions to adopting programs similar to those previously specified in the rule.

Section 35.33, Notifications, reports, and records of misadministrations, would be deleted. In this proposed revision, recordkeeping and reporting requirements contained in Part 35 would be moved to subparts L and M, respectively.

Section 35.40, Written directives, would appear as a new section. This section contains requirements for preparation of written directives. These requirements are similar to the requirements in the current §§ 35.2 and 35.32. Minor changes would be made in the information that must be placed in a written directive for gamma

stereotactic radiosurgery, remote afterloaders, and brachytherapy. These changes were based on comments received during public meetings of the Part 35 Working Group.

Section 35.41, Procedures for administrations requiring a written directive, would appear as a new section. It would require the licensee to develop, implement, and maintain written procedures to assure that, before each administration, the patient's or human research subject's identity is verified and that each administration is in accordance with the written directive, including verification of dose. It would also specify the objectives that should be addressed in the procedures. The specific details to be included in the written directives are in § 35.40. The topics identified in § 35.41 are viewed by the Commission as key elements of a program that will provide high confidence that byproduct material will be administered as directed by the authorized user. However, the regulations are not prescriptive as to how these objectives are met, allowing licensees the flexibility to develop procedures to meet their needs. There is no requirement for submittal or approval of the procedures as was previously required by the quality management rule.

Section 35.49, Suppliers for sealed sources or devices for medical use, would be unchanged.

Section 35.50, Training for Radiation Safety Officer, would appear as a new section that would revise the current requirements of § 35.900, Radiation Safety Officer. Section III of the Supplementary Information of this document contains a detailed discussion of the Commission's proposed changes to the training and experience requirements in Part 35. Note, 2 years after the final rule is published in the Federal Register, this section would replace the current requirements in § 35.900, Radiation Safety Officer.

Requirements in the current § 35.50, with minor modifications, would be moved to the proposed § 35.60.

Section 35.51, Training for an authorized medical physicist, would appear as a new section that would revise the training and experience requirements found in § 35.961, Training for an authorized medical physicist. Section III of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed changes to the training and experience requirements in Part 35. Note, 2 years after the final rule is published in the Federal Register, this section would replace the requirements in § 35.961, Training for authorized medical physicist.

Requirements in the current § 35.51, with minor modifications, would be moved to the proposed § 35.61.

Section 35.52, Possession, use, calibration, and check of instruments to measure dosages of alpha- or beta-emitting radionuclides, would be deleted in its entirely and the requirements of this section, with minor modifications, would be moved to the proposed § 35.63.

Section 35.53, Measurements of dosages of unsealed byproduct material for medical use, would be deleted in its entirety and the requirements of this section, with minor modifications, would be moved to the proposed § 35.63.

Section 35.55, Training for an authorized nuclear pharmacist, would appear as a new section that would revise the training and experience requirements found in § 35.980, Training for an authorized nuclear pharmacist. Section III of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed changes to the training and experience requirements in Part 35. Note, 2 years after publication in the Federal Register, this section would replace the current requirements in § 35.980, Training for an authorized nuclear pharmacist.

Section 35.57, Training for an experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist, would appear as a new section that would replace the current

requirements in §§ 35.901, 35.970, and 35.981, which would be deleted. Changes would be made in the regulatory text of this section to reflect the effective date of the rule.

Requirements in the current § 35.57, with minor modifications, would be moved to the proposed § 35.65.

Section 35.59, Recentness of training, would appear as a new section that would replace the current requirements in § 35.972. Although this is not a new requirement, questions have recently been raised regarding whether all elements of the requirements must have been obtained in the last 7 years. It is expected that either the individual has been board certified or has completed the training specified in the alternative pathway within the 7 years preceding the date of the application or must have had related continuing education and experience since completing the required training and experience requirements. Continuing education is reviewed on a case-by-case basis. The text has been revised to reference subparts B, D, E, F, G, H and J since training and experience requirements appear in multiple subparts.

Requirements in the current § 35.59, with minor modifications, would be moved to the proposed § 35.67.

Subpart C, General Technical Requirements, contains general technical requirements regarding medical use of byproduct material.

Section 35.60, Possession, use, calibration, and check of instruments to measure activity of photon-emitting radionuclides, would appear as a new section that would replace the current § 35.50. This section addresses calibration of all instruments used to measure the activity of photon-emitting radionuclides, rather than only dose calibrators. The change recognizes that there are various types of instruments that can be used to measure the activity of photon-emitting radionuclides.

The proposed rule would require that licensees develop, implement, and maintain procedures for use of the instrumentation. Licensees would be required to calibrate all instruments used to measure the activity of photon-emitting radionuclides.

Licensees would be required by § 35.63 to determine the activity of each dosage before medical use. If a licensee uses only unit dosages of radiopharmaceuticals, § 35.63 would allow the licensee to determine the dosage by a decay correction based on the measurement by a manufacturer or preparer licensed pursuant to § 32.72 or equivalent Agreement State. If a licensee chooses to determine the dosage using this method, it would not be necessary for the licensee to possess instrumentation to measure the activity of the photon-emitter. In this case, the licensee would not be required to comply with this section. If, however, a licensee chooses to re-assay a unit dosage to either confirm the activity or for the purpose of adjusting the dosage, the licensee must comply with this section. This requirement is appropriate because confirmation of a dosage, or adjustment of dosages, must be made based on properly-calibrated equipment.

Many of the prescriptive requirements for calibration would be deleted from the current requirements in § 35.50. The requirements that would remain are viewed by the Commission as essential elements of a calibration program and are generally consistent with the recommendations of ANSI N42.13-1986 (R 1993), "Calibration and Usage of Dose Calibrator Ionization Chambers for the Assay of Radionuclides." Licensees would be required to perform accuracy, linearity, and geometry dependence tests before initial use and following repair; perform accuracy tests annually; perform linearity tests annually over the range of medical use; and check constancy and proper operation at the beginning of each day of use. Note, it would not be necessary to test for linearity for all activities that might be measured, e.g., the first elution from a fresh generator or a multidose vial, because this would subject the worker to an unnecessary radiation dose. Paragraph (c) would require that accuracy tests be performed using a source with a principle photon energy of between 100 and 500 keV whose activity is traceable to the National Institutes of Standards and Technology (NIST). The allowance for a licensee

to mathematically correct dosage has been revised to raise the level for correction to 30 μCi to make the level consistent with § 35.63. The allowance for a licensee to mathematically correct dosage readings remains, but has been re-numbered § 35.60(d). The recordkeeping requirements for this section would appear in § 35.2060, Records of instrument calibrations.

Requirements in the current § 35.60, with minor modifications, would be moved to the proposed § 35.69.

Section 35.61, Calibration and check of survey instruments, would appear as a new section that would replace the current § 35.51. The requirement in the current § 35.51(a)(3) to note the apparent exposure rate from a dedicated check source, as determined at the time of calibration, and the daily check source requirement in paragraph (c) would be deleted. These changes would give the licensee greater flexibility in instrument calibrations. Paragraph (b) would require that the licensee attach a correction chart or graph to the instrument if the indicated exposure rate differs from the calculated exposure rate by more than 10 percent. Paragraph (c) would require that survey instruments be removed from use if the indicated exposure rate differs from the calculated exposure rate by more than 20 percent. Previously, there was no threshold for attaching a correction chart or for removing instruments from use. The requirements in this section are generally consistent with ANSI N323-1978 (R 1993), “Radiation Protection Instrumentation Test and Calibration.” The recordkeeping requirements for this section would appear in § 35.2061, Records of radiation survey instrument calibrations.

Requirements in the current § 35.61, with minor modifications, would be moved to the proposed § 35.69.

Section 35.62, Possession, use, calibration, and check of instruments to measure dosages of alpha- or beta-emitting radionuclides, would appear as a new section that would replace the current § 35.52. This section addresses calibration of all instruments used to measure the activity of alpha- or beta-emitting radionuclides. Paragraph (a) from the current § 35.52 would be deleted. This text is no longer needed since the term "unit

dosage" has been defined in § 35.2. The new paragraph (b) would require that a licensee develop, implement, and maintain written procedures for use of the instrumentation. The Commission recognizes that it may not be possible to test linearity and geometry dependency on all instrumentation. However, the Commission believes that all instruments used to measure alpha- or beta-emitting radionuclides can be tested for accuracy or constancy. The new paragraph (c) would require that accuracy tests be performed using sources whose activity is traceable to NIST. The recordkeeping requirements for this section would appear in § 35.2060, Records of instrument calibrations.

Section 35.63, Determination of dosages of unsealed byproduct material for medical use, would appear as a new section that would replace the current § 35.53. This section would require licensees to determine and record the activity of each dosage before medical use. For unit dosages of an alpha-, beta-, or photon-emitting radionuclides, this determination must be made either by direct measurement or by a decay correction, based on the measurement made by a manufacturer or preparer licensed pursuant to § 32.72 or equivalent Agreement State requirements. For other than unit doses, a licensee may determine the dosage by direct measurement or by combination of measurements and calculations. Previously, photon measurements could only be made by direct measurement. This action allows licensees flexibility in determining dosages and does not distinguish between the type of the radiation (e.g., alpha, beta, or photon) and the way the determination is made. Paragraph (d) would not permit a licensee to use a dosage if it differed from the prescribed dosage by more than 20 percent. This change would codify requirements that are currently imposed on licensees by license conditions. This does not prevent an authorized user from revising the prescribed dosage at any time prior to the administration. The recordkeeping requirements for this section would appear in § 35.2063, Records of dosage measurements.

Section 35.65, Authorization for calibration and reference sources, would appear as a new section that would replace the current § 35.57. The references in the current § 35.57, to §§ 35.100 and 35.200, would be

deleted because specific radionuclides were not listed in these sections. Paragraph (b) in the current § 35.57 would be revised to extend the half-life from 100 days to 120 days to be consistent with the financial assurance regulations in 10 CFR Part 30. The limit of 10^{-3} would be added to the regulation to allow receipt, possession, and use of radionuclides in quantities that do not exceed the limits requiring financial assurance. The possession limit for Tc-99m would be deleted. The Commission believes that it is not necessary to limit the possession of Tc-99m for calibration and reference sources because there are no possession limits for Tc-99m associated with use of Tc-99m pursuant to §§ 35.100 or 35.200.

Section 35.67, Requirements for possession of sealed sources and brachytherapy sources, would appear as a new section that would replace the current § 35.59. Paragraph (b) would require that a source be tested for leakage before its first use, unless the licensee has a certificate from the supplier indicating that the source was tested within 6 months, and the source is tested for leakage at intervals not to exceed 6 months or at other intervals approved in the Sealed Source and Device Registry (SSDR).[1] The SSDR certificates, in most cases, will include a requirement for leak-testing. Approved intervals for testing are based on information regarding source design construction that is provided by the manufacturer.

Prescriptive requirements in the current § 35.59(c) would be deleted to reflect the risk-informed, performance-based nature of this proposed rule. Paragraph (d) would require that leak test records be maintained in accordance with § 35.2067, Records of possession of sealed sources and brachytherapy sources. Paragraph (e) would be revised to give the licensee two additional alternatives for action after a leaking source has been identified. The proposed rule would allow the licensee the added flexibility of repairing or disposing of

[1] A national registry that contains all the registration certificates generated by both NRC and the Agreement States. Registration certificates summarize the radiation safety information submitted by the applicant, and describe the licensing and use conditions approved for the product.

the source, in accordance with 10 CFR parts 20 and 30, if the leakage test reveals the presence of 185 Becquerels(Bq) (0.005 microcuries) or more of removable contamination. The current rule only allows the licensee to withdraw the sealed source from use and store it in accordance with the requirements in 10 CFR parts 20 and 30. The licensee would still be required to report to NRC if a leakage test reveals the presence of 0.005 microcuries or more of removable contamination. Reporting requirements for this section would appear in § 35.3059, Reports of leaking sources.

Paragraph (g) of the current rule would be revised to change the frequency for source inventories from quarterly to semi-annually, to reduce the regulatory burden on licensees. It does not, however, preclude the licensee from conducting an inventory on a more frequent basis. Paragraph (h) of the current rule would be deleted because radiation surveys are addressed under 10 CFR Part 20. The recordkeeping requirements for this section would appear in § 35.2067, Records of possession of sealed sources and brachytherapy sources.

Section 35.69, Labeling and shielding of vials and syringes, would appear as a new section that would replace the current §§ 35.60 and 35.61. It would require licensees to develop, implement, and maintain procedures for labeling and shielding radiopharmaceuticals and instruct individuals in those procedures. Procedures must ensure that a syringe, syringe shield, or vial shield is conspicuously labeled as containing radioactive material and is labeled with the radiopharmaceutical name. These requirements were needed because the Commission does not believe that the labeling and shielding requirements in Part 20 are sufficient to ensure that syringes, syringe shields, or vial shields are properly labeled to identify radioactive contents. In addition, the Commission believes that labeling helps to reduce administration errors. The proposed rule would require that licensees instruct individuals, commensurate with that individual’s assigned duties, on the labeling and shielding procedures. It is expected that technologists preparing radiopharmaceuticals and nuclear pharmacists will be given instruction in the licensee's procedures. Records of instructions would not be required to be maintained.

Section 35.70, Surveys for ambient radiation exposure rate, would be revised and retitled. The proposed rule would require that licensees survey, at the end of each day of use, all areas where radiopharmaceuticals requiring a written directive were prepared for use or administered with an appropriate radiation detection survey instrument unless the material was prepared for use or administered in an area where patients or human research subjects could not be released pursuant to § 35.75. All other requirements in this section would be deleted. Licensees are required to show compliance with the public and occupational dose limits specified in Part 20 of this chapter and specifically to develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities (10 CFR 20.1101). In situations where radioactive material was used at levels that would not have required a survey pursuant to this section, the licensee should be aware that a survey may be required by § 20.1501, General. Maintaining the requirement for surveys in areas where radiopharmaceuticals requiring a written directive are used is consistent with the Commission direction for a risk-informed rule. The Commission believes that licensees will continue to perform radiation surveys as dictated by “good health physics” practices. Recordkeeping requirements for this section would appear in § 35.2070, Records of surveys for ambient radiation exposure rate.

Section 35.75, Release of individuals containing radiopharmaceuticals or implants, would be retitled and revised. The title of the section and paragraph (a) would be revised to delete the term "permanent." This was done to clarify that this section applies to all individuals released from licensee control. Paragraph (b) would be revised to specify that licensees may provide instructions to either the released individual or to the individual's parent or guardian and to replace the term "dose" with the term "total effective dose equivalent." The first change acknowledges that, in some cases, it is not appropriate to provide the individual being released with instructions (e.g., the individual is a minor or incapable of understanding the instructions). The later term was changed to clarify what was intended by "dose."

Paragraph (b)(2) would be modified to state “potential consequences, if any," of failure to follow the guidance. The Commission recognizes that, at low doses, there may be no consequences to continued breast-feeding. A patient may be unnecessarily alarmed if he/she is provided with information on consequences. Therefore, if consequences are not anticipated, the licensee would not be required to provide information to the individual. The Commission has recently received comments from the public on the provisions in § 35.75 at the public workshops and in writing. Professional societies and representatives of the Agreement States have expressed concerns about the release criteria in § 35.75. It is believed that the new criteria permit the release of patients with a body burden of as much as several hundred millicuries of I-131. Commenters believed that the released individual is a “leaking-source” that creates a contamination and exposure problem that extends beyond the control of the licensee. There is concern that pressure from those paying for such medical procedures will undermine the Radiation Safety Officer’s ability to protect the public health and safety and to control contamination within the medical facility. In addition, there is concern about the recent increase of radiation alarms going off at landfills caused by household trash from a released patient. As a result of these concerns, the Commission is specifically soliciting public comment on whether any changes need to be made to the release criteria in this rule. The recordkeeping requirements for this section would appear in § 35.3075, Records of the release of individuals containing radiopharmaceuticals or implants.

Section 35.80, Provision of mobile service, would be retitled and revised. The title would be changed to make it clear that the provisions in this part apply to all mobile services and not just to mobile nuclear medicine services. Current paragraphs (a), (b), and (c) would be deleted because radiopharmaceutical usage is limited by the requirements in §§ 35.100 and 35.200, and control and security of material are addressed in 10 CFR Part 20.

Proposed paragraph (a) would require the mobile service provider to obtain a letter from its client, which permits the use of byproduct material at the client's address of use and that clearly delineates the authority and responsibility of each entity. Paragraph (c) would require that the mobile service provider check instruments for

proper function, as described in §§ 35.60 and 35.62, before use at each address of use or on each day of use, whichever is more frequent. For example, if a mobile service licensee provides service to more than one client in a day, the instruments would need to be checked at each client's address of use. The Commission recognizes that the standard of practice is to check other types of equipment, such as gamma cameras, for proper operation at each place of use. Therefore, the Commission has not included any requirements to check this type of equipment in the proposed rule. Currently, mobile nuclear medicine services may be required by license conditions to check gamma camera operation.

Based on discussions with the States, this section is designated as a Category D item of compatibility since there is no potential for medical use of byproduct material in other regulatory jurisdictions under reciprocity. NRC specifically requests comment on this issue relative to whether mobile medical licensees operate under reciprocity in other regulatory jurisdictions.

Paragraph (d) would require that the licensee check survey instruments for proper operation with a dedicated check source, before use, at each address of use. The NRC staff believes this is appropriate, because extensive movement in a transport vehicle may cause the instruments to become damaged or uncalibrated. Paragraph (e) would be revised to require a licensee to survey all areas of use to comply with the dose limits in 10 CFR Part 20 before leaving each client's address of use. This is necessary to assure that all radioactive material is removed from a client's facility. Recordkeeping requirements for this section would appear in § 35.2080, Records of administration and technical requirements that apply to the provision of mobile services.

Section 35.90, Storage of volatiles and gases, would be deleted in its entirety. Licensees are required to comply with the public and occupational public dose limits in 10 CFR Part 20 and to maintain exposures ALARA. The Commission believes that licensees should have flexibility in complying with 10 CFR Part 20, and, therefore, a prescriptive requirement in Part 35 is not needed.

Section 35.92, Decay-in-storage, would be revised to allow decay in storage for byproduct material with a physical half-life of less than 120 days. If a licensee would like to decay material with a physical half life greater than 120 days, it would have to apply for and receive an amendment that would permit the decay-in-storage.

The current Part 35 only permits decay-in-storage for materials with a half-life of less than 65 days. This change provides licensees with greater flexibility in handling radioactive waste. NRC has received multiple requests to amend licenses to allow for decay-in-storage for materials greater than 65 days, and NRC has amended licenses to allow for decay-in-storage for materials with half-lives up to 120 days. This revision to § 35.92 would codify current licensing practice.

The requirement in the current paragraph (a)(1) to hold byproduct material for 10 half-lives would be deleted. This requirement is not needed in light of the requirement in paragraph (a) that precludes disposal of radioactive material as ordinary trash until radiation levels adjacent to the material do not exceed background levels. The Commission is soliciting specific public comment on whether this provision should be deleted. Concerns have been raised regarding licensees' ability to detect low levels of some beta-emitters such as sulfur-35. In this case, the requirement to hold material for 10 half-lives provides added assurance that material has decayed to background levels prior to release.

The requirement in paragraph (a)(4) to separate and monitor each generator column would be deleted. This level of prescriptiveness is not warranted in light of the requirements in paragraph (a)(1). The recordkeeping requirements for this section would appear in § 35.2092, Records of waste disposal.

Subpart D would be retitled Unsealed Byproduct Material - Low Dose. This subpart would combine the requirements in the current subpart D, Uptake, dilution, and excretion and subpart E, Imaging and localization. This change is consistent with the Commission's intent to make Part 35 modality specific where appropriate.

Section 35.100, Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required, would be retitled and revised. The title would be changed to clearly state that the provisions in this subpart do not apply to the medical use of byproduct material that would require a written directive. Changes would be made to paragraph (b) to reflect the renumbering of sections in the proposed rule.

Section 35.120, Possession of survey instruments, would be deleted because these specific requirements are not needed in Part 35. Section 20.1501 of this chapter requires that the licensee make, or cause to be made, surveys to demonstrate compliance with
10 CFR Part 20, and requires the licensee to ensure that instruments and equipment used to show compliance with Part 20 are periodically calibrated. In addition, § 30.33(a)(2) of this chapter requires licensee to have adequate instrumentation. Information on the types of instruments recommended for medical licensees is available in draft NUREG-1556, Vol. 9.

Section 35.200, Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required, would be retitled and revised. The title would be changed to clearly state that the provisions in this part do not apply to the medical use of byproduct material that would require a written directive. Changes would be made to paragraph (b) to reflect the renumbering of sections in the proposed rule.

Section 35.204, Permissible molybdenum-99 concentration, would be revised. Paragraph (b) would be revised to require that a licensee measure the molybdenum-99 concentration of the first eluate from a generator. The Commission recognizes that the industry standard for molybdenum breakthrough is specified in the United States Pharmacopia (USP) 23 U.S. Pharmacopial Convention, Inc., 1994, page 486-487. The Commission believes that the licensee should measure the molybdenum-99 concentration in the first elution of a generator after the generator is received at the licensee's facility. Although the frequency of molybdenum breakthrough is exceedingly rare, an initial check may detect generators that have been damaged in transport. The term "extract"

was deleted because the term is no longer needed. NRC is not aware of any licensees that prepare technetium-99m by the solvent extraction method. The recordkeeping requirements for this section would appear in § 35.2204, Records of molybdenum-99 concentration.

Section 35.205, Control of aerosols and gases, would be deleted in its entirety. Part 35 licensees must comply with the occupational and public dose limits of 10 CFR Part 20. Additional prescriptive requirements for limiting airborne concentrations of radioactive material are not warranted in Part 35.

Section 35.220, Possession of survey instruments, would be deleted in its entirety because specific requirements are not needed in Part 35. Section 20.1501 of this chapter requires that the licensee make, or cause to be made, surveys to demonstrate compliance with 10 CFR Part 20, and requires the licensee to ensure that instruments and equipment used to show compliance with 10 CFR Part 20 are periodically calibrated. In addition, § 30.33(a)(2) of this chapter requires licensees to have adequate instrumentation. Information on the types of instruments recommended for medical licensees is available in draft NUREG-1556, Vol. 9.

Section 35.290, Training for uptake, dilution, and excretion studies, would appear as a new section that would revise the training and experience requirements found in § 35.910, Training for uptake, dilution, and excretion studies. Section III of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed changes to the training and experience requirements in Part 35. Note, 2 years after publication of the final rule, this section would replace the current requirements in § 35.920, Training for uptake, dilution, and excretion studies.

Section 35.292, Training for imaging and localization studies, would appear as a new section that would revise the training and experience requirements found in § 35.920, Training for imaging and localization studies. Section III of the Supplementary Information section of this document contains a detailed discussion of the

Commission's proposed changes to the training and experience requirements in Part 35. Note, 2 years after publication of the final rule, this section would replace the current requirements in § 35.920, Training for imaging and localization studies.

Subpart E would be retitled, Unsealed byproduct material - high dose. The subpart contains the requirements for any medical use of unsealed byproduct material for which a written directive is required. This subpart would replace the requirements in the current subpart F, Radiopharmaceuticals for therapy.

Section 35.300, Use of unsealed byproduct material for which a written directive is required, would be retitled and revised. The title would be changed to clearly state that the provisions in this subpart apply to the medical use of unsealed byproduct material that would require a written directive. Changes would be made to paragraph (b) to reflect the renumbering of sections in the proposed rule.

Section 35.310, Safety instruction, would be revised to explicitly state that the instruction requirements of this section are in addition to, and not in lieu of, the training requirements in 10 CFR 19.12. The Commission believes that it is important that personnel caring for patients or human research subjects that have received radiopharmaceutical therapy (and cannot be released in accordance with § 35.75) receive instruction in limiting radiation exposure to the public or occupational workers and the actions to be taken in the case of a death or medical emergency. The proposed rule would require that safety instruction be provided initially and at least annually. Instruction topics are specific to medical use of unsealed radiopharmaceuticals. It is not expected that the same level of training be provided to all individuals caring for the patient. The level of training should be commensurate with the type of care that the personnel may render to the patient or human research subject. For example, the instruction provided to the registered nurse will not necessarily be the same as the instruction provided to a nursing assistant.

Paragraph (a) would be revised to require that instruction on visitor control include instruction on routine visitation authorized under the provisions in § 20.1301(a)(1), as well as visitation that is authorized under the proposed provisions of § 20.1301(a)(3). Paragraph (a) would also be revised to state that personnel should notify the authorized user and Radiation Safety Officer, or his/her designee, if the patient or human research subject dies or has a medical emergency. The recordkeeping requirements for this section would appear in § 35.2310, Records of instruction and training.

Section 35.315, Safety precautions, would be revised. Paragraph (a) would be revised to clarify that the requirements in this section only apply if a patient has been confined pursuant to § 35.75. Paragraph (a)(2) would be revised to require that the patient's room, rather than the door, be visibly posted to give the licensee some flexibility in determining where to place the posting. These requirements are in addition to the posting requirements in 10 CFR Part 20. The Commission believes that posting requirements in 10 CFR Part 20 are not adequate to ensure that individuals entering the room would be aware of the presence of radioactive materials in the room. The current requirements in paragraphs (a)(3), (4), (6), (7), and (8) would be deleted because they are radiation protection requirements that are covered under 10 CFR Part 20. Paragraph (b) would be revised to state that personnel should notify the authorized user and the Radiation Safety Officer, or his/her designee, as soon as possible, if the patient or human research subject dies or has a medical emergency. This change was made to recognize that the licensee's primary responsibility is the care of the patient and to provide the Radiation Safety Officer flexibility in designating who should be notified to address radiation protection issues.

The Commission is soliciting specific comments on whether the requirement for a private room with a private sanitary facility in paragraph (a)(1) should be maintained in the final rule.

Section 35.320, Possession of survey instruments, would be deleted in its entirety because these specific requirements are not needed in Part 35. Section 20.1501 of this chapter requires that the licensee make or

cause to be made surveys to demonstrate compliance with 10 CFR Part 20 and requires the licensee to ensure that instruments and equipment used to show compliance with Part 20 are periodically calibrated. In addition, 10 CFR 30.33(a)(2) requires a licensee to have adequate instrumentation. Information on the types of instruments recommended for medical licensees is available in draft NUREG-1556, Vol. 9.

Section 35.390, Training for therapeutic use of unsealed byproduct material, would appear as a new section that would revise the training and experience requirements found in § 35.930, Training for therapeutic use of unsealed byproduct material, and subsumes the training requirements for treatment of hyperthyroidism and treatment of thyroid carcinoma. Section III of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed changes to the training and experience requirements in Part 35. Note, 2 years after publication of the final rule, this section would replace the current requirements in § 35.930, Training for therapeutic use of unsealed byproduct material, § 35.932, Training for treatment of hyperthyroidism, and § 35.934, Training for treatment of thyroid carcinoma.

Subpart F would be retitled Manual brachytherapy. This subpart contains the requirements for medical use of sealed sources for manual brachytherapy and replaces the requirements in the current subpart G, Sources for brachytherapy.

Section 35.400, Use of sources for manual brachytherapy, would be retitled and revised to delete the specific sources and uses listed in the current paragraphs (a) through (g). This conforms with the risk-informed, performance-based nature of this proposed rule. The licensee would have the flexibility to use sealed sources for therapeutic medical uses as approved in the Sealed Source and Device Registry.

Section 35.404, Radiation surveys of patients or human research subjects treated with implants, would be retitled and revised. Paragraph (a) would be revised to delete the requirement that a licensee may not release a

patient or a human research subject treated by temporary implant until all sources have been removed and would be retitled paragraph (b). Release of patients or human research subjects is addressed in § 35.75. The proposed paragraph (a) contains requirements that were previously required by § 35.406(c) with one modification. Licensees would be required to survey adjacent areas of use. This change was done to group radiation survey requirements. The recordkeeping requirements for this section would appear in § 35.2404, Records of radiation surveys of patients and human research subjects.

Section 35.406, Brachytherapy sources inventory, would be revised. Paragraph (a) requires that the licensee maintain accountability for all brachytherapy sources in storage or use. The majority of the prescriptive requirements and associated recordkeeping requirements in the current section have been deleted to give the licensee flexibility in program management. The requirements in paragraph (c) would be moved to the proposed § 35.404. The Commission believes that the requirements that were maintained are essential to the radiation safety program. The recordkeeping requirements for this section would appear in § 35.2406, Records of brachytherapy source inventory.

Section 35.410, Safety instruction, would be revised to explicitly state that the instruction requirements in this section are in addition to, and not in lieu of, the training requirements of 10 CFR 19.12. The Commission believes that it is important that personnel caring for patients or human research subjects, that have received implant therapy and cannot be released in accordance with § 35.75, receive instruction in limiting radiation exposure to the public and workers and the actions to be taken in the case of a death or medical emergency. The proposed rule would require that safety instruction be provided initially and at least annually. Instruction topics are specific to medical use of manual brachytherapy sources. It is not expected that the same level of training be provided to all individuals caring for the patient. The level of training should be commensurate with the type of care that the personnel may render to the patient or human research subject. Paragraph (a) would be revised to require that instruction on visitor control include instruction on routine

visitation authorized under the provisions in the current § 20.1301(a)(1), as well as visitation that is authorized under the provisions of revised § 20.1301(a)(3). Paragraph (a) would also be revised to state that personnel should notify the authorized user and Radiation Safety Officer, or designee, if the patient or human research subject dies or has a medical emergency. The recordkeeping requirements for this section would appear in § 35.2310, Records of instruction and training.

Section 35.415, Safety precautions, would be revised. Paragraph (a) would be revised to clarify that the requirements in this section apply only if a patient or human research subject cannot be released pursuant to § 35.75. The current requirements in paragraphs (a)(3) and (4) would be deleted because they are radiation protection requirements that are covered under 10 CFR Part 20. A new requirement would be added (paragraph b) to require the licensee to have equipment such as shields and remote handling tools available near each treatment room. This change codifies requirements that are currently imposed on licensees by license conditions. Current paragraph (b) would be relettered as paragraph (c) and would be revised to state that personnel should notify the authorized user and the Radiation Safety Officer, or his/her designee, as soon as possible if the patient or human research subject dies or has a medical emergency. This change was made to recognize that the licensee's primary responsibility is the care of the patient and to provide the Radiation Safety Officer flexibility in who should be notified to address radiation protection issues. The Commission is soliciting public comment on whether the requirement for a licensee to not quarter a patient in the same room as an individual who is not receiving radiation therapy be maintained in the final rule.

Section 35.420, Possession of survey instruments, would be deleted in its entirety because these specific requirements are not needed in Part 35. Section 20.1501 of this chapter requires that the licensee make, or cause to be made, surveys to demonstrate compliance with 10 CFR Part 20, and requires the licensee to ensure that instruments and equipment used to show compliance with Part 20 are periodically calibrated. In addition,

10 CFR 30.33(a)(2) requires licensees to have adequate equipment. Information on the types of instruments recommended for medical licensees is available in draft NUREG-1556, Vol. 9.

Section 35.432, Full calibration measurements of brachytherapy sources, would appear as a new section that would require a licensee authorized to use brachytherapy sources for medical use to perform full calibration measurements on brachytherapy sources before the first medical use. The requirements in this section are based on recommendations found in American Association of Physicists in Medicine (AAPM) Task Group 40 - Comprehensive QA for Radiation Oncology (1994) and 56 - Code of Practice for Brachytherapy Physics (1997), and are consistent with the calibration requirements for sealed sources and devices for therapy. The proposed rule would not allow the licensee to rely on the output measurement provided by the manufacturer or distributor. The Commission is soliciting specific comment on whether the final rule should allow licensees to rely on the output measurements provided by the manufacturer or distributor provided the dosimetry equipment used by the manufacturer or distributor met the calibration requirements in § 35.630. In addition, the Commission is soliciting specific public comment on calibration for sources where there is no standard traceable to the National Institute of Standards and Technology (e.g. palladium-103).

The Regulatory Analysis for this section of the rule assumes that the majority of licensees using long-lived radionuclides will need to calibrate the sources to show compliance with this section. It is estimated that licensees will spend approximately $1000 to calibrate these sources resulting in a $8M burden on NRC and Agreement State licensees. The Commission has not calculated the impact of determining the output of short-lived sealed therapy sources (e.g. iodine-125, iridium-192) because of the limited information available on the number of sources and variability in the type of dosimeter equipment available at a licensee's facility to perform the calibration. The Commission is soliciting specific public input on the number of short and long-lived sources that will need to be calibrated on an annual basis; whether licensees will need to procure additional equipment to perform the calibrations; and the time needed to calibrate the sources.

Recordkeeping requirements for this section would appear in § 35.2432, Records of full calibrations on brachytherapy sources.

Section 35.490, Training for use of manual brachytherapy sources, would appear as a new section that would revise the training and experience requirements found in § 35.940, Training for use of brachytherapy sources, and subsumes the requirements for training for ophthalmic use of strontium-90. Section III of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed changes to the training and experience requirements in Part 35. Note, 2 years after publication of the final rule, this section will replace the current requirements in § 35.940, Training for use of brachytherapy and in § 35.941, Training for ophthalmic use of strontium-90.

Subpart G would be retitled Sealed sources for diagnosis. This subpart would contain the requirements for diagnostic medical use of sealed sources and replace the requirements in the current subpart H, Sealed Sources for Diagnosis.

Section 35.500, Use of sealed sources for diagnosis, would be revised to delete the specific sources and uses listed in paragraphs (a) and (b). This conforms with the risk-informed, performance-based nature of this proposed rule. The licensee would have flexibility to use sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.

Section 35.520, Availability of survey instruments, would be deleted in its entirety because these specific requirements are not needed in Part 35. Section 20.1501 of this chapter requires that the licensee make or cause to be made surveys to demonstrate compliance with 10 CFR Part 20 and requires the licensee to ensure that instruments and equipment used to show compliance with 10 CFR Part 20 are periodically calibrated. In

addition, § 30.33(a)(2) of this chapter requires the licensee to have adequate instrumentation. Information on the types of instruments recommended for medical licensees is available in draft NUREG-1556, Vol. 9.

Section 35.590, Training for use of sealed sources for diagnosis, would appear as a new section. This section is a revision of the training and experience requirements found in § 35.950, Training for use of sealed sources for diagnosis. Section III of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed changes to the training and experience requirements in Part 35. Note, 2 years after publication of the final rule, this section would replace the current requirements in § 35.920, Training for use of sealed sources for diagnosis.

Subpart H, Therapeutic medical devices, would be retitled and revised to address all medical uses of sealed sources and devices for therapy. Devices such as teletherapy, remote afterloaders, and gamma radiosurgery units are addressed in this subpart. This section does not contain requirements for manual brachytherapy, which are in subpart F. This subpart would replace the requirements in the current subpart I, Teletherapy.

Section 35.600, Use of a sealed source in a device for therapeutic medical uses, would be retitled and revised to delete any references to specific radionuclides and devices. The licensee would have the flexibility to use sealed sources and devices for therapeutic medical uses as approved in the Sealed Source and Device Registry.

Section 35.604, Radiation surveys of patients and human research subjects treated with remote afterloaders, would appear as a new section. This section would require that a licensee make a radiation survey of a patient or human research subject to confirm that the sources have been removed from the individual and returned to a shielded position before releasing the individual from licensee control. For fractionated treatments

where the patient is not releasable pursuant to § 35.75, surveys need only be performed after the last time the source is returned to the shielded position. For example, a survey of the patient is not required every time that the source is retracted into the shielded safe when nursing personnel enter the patient treatment room to provide care to patients undergoing fractionated treatments using a low- or pulsed-dose rate remote afterloader. This new requirement was previously imposed on remote afterloader licensees by license condition. Recordkeeping requirements for this section would appear in § 35.2404, Records of radiation surveys of patients and human research subjects.

Section 35.605, Installation, maintenance and repair, would be retitled and revised to clarify that only a person specifically licensed by the Commission or an Agreement State can install, maintain, adjust, or repair a device that involves work on the source shielding, source driving unit, or other electronic or mechanical mechanism that could expose the source, reduce the shielding around the source, or compromise the radiation safety of the device or the sources. It would also be revised to include additional types of devices, rather than just teletherapy units. The Commission is soliciting specific comment on whether the restrictions in paragraph (a) should apply to low dose-rate remote afterloaders.

Paragraph (b) would also specify that, except for low dose-rate remote afterloaders, 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 a device. For a low dose-rate remote afterloader, installation, replacement, relocation, or removal of a sealed source must be done by a person specifically licensed by the Commission or an Agreement State or by an authorized medical physicist. The exception to allow an authorized medical physicist to perform these activities for low-dose rate remote afterloaders was included in the proposed rule because the Commission believes that the radiation hazards associated with installation, replacement, relocation, or removal of a sealed source in these devices are similar to that of manipulation of manual brachytherapy

sources. The recordkeeping requirements for this section would appear in § 35.2605, Records of installation, maintenance, and repair.

Section 35.606, License amendments, would be deleted in its entirety. The requirements in the current paragraphs (a), (b), and (d) would be addressed in the proposed revision to § 35.13(e). Paragraph (c) would be deleted because the licensees must comply with the dose limit requirements in 10 CFR Part 20 and no further limitations are warranted. The requirement in paragraph (e) to file an amendment before allowing an individual to perform the duties of the authorized medical physicist is addressed in the proposed § 35.13(b). Paragraph (e) would be deleted because the proposed requirements in subpart H would require that the authorized medical physicist perform specific duties. Any deviations from these requirements would necessitate an exemption from Part 35.

Section 35.610, Safety procedures and instructions for remote afterloaders, teletherapy units, and gamma stereotactic radiosurgery units, would be retitled and revised to include remote afterloaders and gamma stereotactic radiosurgery units.

Paragraph (a) would require that a licensee develop, implement, and maintain safety procedures; locate safety procedures at the unit console; post safety instructions at the device console; and train operators.

Paragraphs (a) (1) and (a)(3) would codify requirements that are currently imposed on licensees by license conditions related to use of remote afterloaders. Because of the applicability of the requirements to all therapy device uses, they were added to the rule with the intent of having the requirements apply to all such device uses. Paragraph (a)(2) would be expanded to apply to all types of therapy devices. However, the Commission recognizes that there are certain design conditions that will necessitate an individual, other than the patient, being in the treatment room during the treatment. An example of this condition is use of a low energy

beta or gamma source in a therapeutic medical device where the authorized user may need to be in the room with the patient. This exception does not relieve the licensees from complying with the dose limits for occupationally-exposed individuals or the general public in 10 CFR Part 20.

Paragraph (b) would be revised to require that a copy of the licensee's procedures be located at the unit console, and paragraph (c) would be revised to require that the location of the procedures and emergency response telephone numbers be posted. Previously, all of the above procedures were required to be posted. This was impractical with the addition of remote afterloaders because error conditions and responses are often several pages in length.

Paragraph (d) would be revised to require that, in addition to the initial instruction required in § 35.610, the licensee must provide initial instruction, annual training, and annual practice drills, in specifically identified procedures to all individuals who operate the device. The level of instruction should be commensurate with the individual's assigned duties. For example, an individual need not be instructed in equipment inspection, unless it is expected that during the normal course of the day, the individual will be required to inspect the unit. The Commission believes that due to the complexity of therapeutic treatment devices, refresher training and practice drills on emergency response are warranted. The recordkeeping requirements for this section would appear in § 35.2310, Records of instruction and training.

Section 35.615, Safety precautions for remote afterloaders, teletherapy units, and gamma stereotactic radiosurgery units, would be retitled and revised to include remote afterloaders and gamma stereotactic radiosurgery units. Many of the prescriptive requirements (e.g., beam condition indicator light and radiation monitor) were deleted from this section because they are currently addressed in 10 CFR Part 20.

The requirement in paragraph (d) for intercom systems, and the requirements in paragraphs (e), (f) and (g) would be added to codify requirements that are currently imposed on licensees by license conditions. Current license conditions were modified when they were incorporated into the proposed rule. For example, the presence of an authorized user and medical physicist during patient treatments was clarified for each type of use. As used in this provision, physically present means to be within ear shot of normal voice. Immediately available means that the individual is available on an on-call basis to respond to an emergency. At a minimum, this person must be available by telephone.

The Commission believes that the inherent risk of these procedures justifies the prescriptiveness of this regulation and believes that it is important that a properly trained physician be available at all times to respond to an emergency requiring source removal.

New sources, using pure beta emitters, are being considered for use in low and high dose-rate remote afterloading brachytherapy units. Because these beta sources present lower radiation risks to medical personnel and the public, the requirements for some of the safety precautions in this section may not be appropriate. The Commission is soliciting specific public comment on whether the requirements in this section should be waved for licensees that are using remote afterloaders with beta-emitting sources.

Section 35.620, Possession of survey instruments, would be deleted in its entirety because these specific requirements are not needed in Part 35. Section 20.1501 of this chapter requires that the licensee make, or cause to be made, surveys to demonstrate compliance with 10 CFR Part 20, and requires the licensee to ensure that instruments and equipment used to show compliance with 10 CFR Part 20 are periodically calibrated. In addition, § 30.33(a)(2) of this chapter requires licensees to have adequate equipment. Information on the types of instruments recommended for medical licensees is available in draft NUREG-1556, Vol. 9.

Section 35.630, Dosimetry equipment, would be revised to provide calibration requirements for instruments used in this subpart and subpart F. Paragraph (a)(1) would require that dosimetry systems be calibrated using a source whose activity is traceable to NIST and in accordance with published protocols approved by a nationally recognized body or by a calibration laboratory approved by AAPM. This change would give licensees two alternatives for direct traceability of dosimetry equipment calibration; i.e., either a source or the measurement instrument (e.g., well chamber) can be calibrated against a national standard. The Commission acknowledges that the industry standards for instrument calibration provide adequate assurance that equipment is properly calibrated. Paragraph (a)(2) would be revised to delete the reference to intercomparison meetings sanctioned by a calibration laboratory or radiologic physics centers accredited by the AAPM. This provision is no longer necessary because the AAPM does not sanction intercomparison meetings. References to cobalt-60 and cesium-137 contained within teletherapy units were deleted from the rule text to make the section applicable to dosimetry equipment for all radionuclides and therapy units. The recordkeeping requirements for this section would appear in § 35.2630, Records of dosimetry equipment.

Section 35.632, Full calibration measurements on teletherapy units, would be revised and retitled to clarify that the requirements in this section apply to teletherapy units. Paragraph (d) would be revised to delete the reference to the AAPM Task Group Reports and replace it with a requirement that full calibration measurements be done in accordance with published protocols approved by nationally recognized bodies. This allows the licensee more flexibility in choosing appropriate protocols. The Commission acknowledges that the industry standards for teletherapy unit calibration provide adequate assurance that equipment is properly calibrated. Paragraph (f) would be revised to replace the term "teletherapy physicist" with the term "authorized medical physicist." The recordkeeping requirements for this section would appear in § 35.2632, Records of teletherapy full calibration.

Section 35.633, Full calibration measurements on remote afterloaders, would appear as a new section that would contain the requirements for the calibration of remote afterloaders. This section is similar in content to § 35.632. Requirements in this section would be based on recommendations found in AAPM Task Group Report No. 56. Recordkeeping requirements for this section would appear in § 35.2633, Records of remote afterloader full calibrations.

Section 35.634, Periodic spot-checks, would be deleted in its entirety and the requirements of this section, with minor modifications, would be moved to § 35.643.

Section 35.635, Full calibration measurements for gamma stereotactic radiosurgery units, would appear as a new section. This section would contain the requirements for the calibration of gamma stereotactic radiosurgery units and is similar in content to § 35.632. Requirements in this section are based on recommendations found in AAPM Report No. 54 - Stereotactic Radiosurgery (Task Group 42, 1995). Recordkeeping requirements for this section would appear in § 35.2635, Records of gamma stereotactic radiosurgery unit full calibrations.

The current § 35.636, Safety checks for teletherapy facilities, would be deleted in its entirety and the requirements in this section would be incorporated into proposed §§ 35.642, 35.643, 35.644, and 35.645.

The current § 35.641, Radiation surveys for teletherapy facilities, would be deleted in its entirety. Radiation surveys at the surface of the main source safe would be addressed under proposed § 35.652. The remaining requirements in the current § 35.641 would be deleted to allow the licensee more flexibility in managing its radiation protection program.

Section 35.642, Periodic spot-checks for teletherapy units, would be retitled and revised. The phrase "teletherapy physicist" would be replaced with the term "authorized medical physicist" throughout the section. The requirement in paragraph (c) to maintain a copy of the physicist's notification of the results of spot-checks to the licensee would be deleted to reduce the recordkeeping requirements for licensees. Paragraph (d) would be modified to require that the safety spot-checks be performed monthly and after each source installation. This revision would replace the safety check requirements after each source replacement in the current § 35.634, which would be deleted in the proposed rule. Paragraph (d)(3) would be modified to replace the term "beam condition indicator" with "source exposure indicator" to clarify that indicators were needed to note whether the source was exposed and note to what degree the source was exposed. Paragraph (d)(4) would be revised to include a requirement for an intercom system that was previously imposed on licensees by license condition. An intercom is needed to assure that the licensee's staff and the patients have the ability to communicate verbally, in addition to the ability to communicate visually. Paragraph (e) would be revised to require that the licensee 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, in case of any malfunction identified during a safety spot-check. This revision is intended to make § 35.642 consistent with the requirement in the current § 35.650 regarding immediate actions to be taken when a malfunctioning system is identified. Recordkeeping requirements for this section would appear in § 35.2642, Records of periodic spot-checks for teletherapy units.

Section 35.643, Periodic spot-checks for high and pulsed dose-rate remote afterloaders, would appear as a new section that would replace the current requirements in § 35.643. The requirements in the current § 35.643 would be deleted because they were considered to be overly prescriptive. A licensee should have flexibility in designing a radiation protection program that is specific to its facility and which assures that the dose limits in 10 CFR Part 20 are not exceeded.

The revised section contains the requirements for periodic spot-checks of high and pulsed dose-rate remote afterloaders, and is similar in content to § 35.642. Requirements in this section are based on recommendations in AAPM Task Group Report No. 56. Recordkeeping requirements for this section would appear in § 35.2643, Records of periodic spot-checks for remote afterloaders.

Section 35.644, Periodic spot-checks for low-dose rate remote afterloaders, would appear as a new section. This revised section would contain the requirements for periodic spot-checks of low dose-rate remote afterloaders and would be similar in content to § 35.642. These proposed requirements are based on recommendations found in the AAPM Task Group Report No. 56. Some requirements were added to make the safety checks, and associated corrective actions, consistent with the requirements in § 35.642. The Commission is soliciting comment on whether the requirements for electrical interlocks and audiovisual systems should apply to low-dose rate remote afterloaders. Recordkeeping requirements for this section would appear in § 35.2643, Records of periodic spot-checks for remote afterloaders.

Section 35.645, Periodic spot-checks for gamma stereotactic radiosurgery units, would be retitled and revised to address gamma stereotactic radiosurgery units. This section would replace the current requirements in § 35.645, which were deleted to reduce the reporting burden on medical use licensees. The Commission believes that there is no need to submit survey results to the appropriate Regional Office because the survey results are maintained by a licensee to show compliance with 10 CFR Part 20 and, therefore, are available for review.

The revised section would contain requirements for periodic spot-checks of gamma stereotactic radiosurgery units, and is similar in content to § 35.642. Requirements in this section are based on recommendations found in AAPM Report No. 54. Some requirements were added to make the safety checks, and associated corrective actions, consistent with the requirements in § 35.642. Recordkeeping requirements for

this section would appear in § 35.2645, Records of periodic spot-checks for gamma stereotactic radiosurgery units.

Section 35.647, Additional technical requirements for mobile remote afterloaders, would replace the current § 35.647. Requirements in the current § 35.647 were moved to the proposed § 35.655. The new section would contain the requirements for mobile remote afterloaders which were previously listed in an internal NRC document entitled, "Supplement 1 to Policy and Guidance Directive FC 86-4; Revision 1, Mobile Remote Afterloading Brachytherapy Licensing Module." Recordkeeping requirements for this section would appear in § 35.2647, Records of additional technical requirements for mobile remote afterloaders.

Based on discussions with the States, this section is designated as a Category D item of compatibility since there is no potential for medical use of byproduct material in other regulatory jurisdictions under reciprocity. NRC specifically requests comment on this issue relative to whether mobile medical licensees operate under reciprocity in other regulatory jurisdictions.

Section 35.652, Radiation surveys, would appear as a new section. This section would replace the current § 35.641. This section would require that, in addition to the surveys required by 10 CFR 20.1501, the licensee make surveys to assure that the maximum radiation levels and average radiation levels from the surface of the main source safe do not exceed the levels stated in the Sealed Source and Device Registry. These surveys provide added assurance that a device has been manufactured and that source(s) have been installed properly. Recordkeeping requirements for this section would appear in § 35.2652, Records of surveys of therapeutic treatment units.

Section 35.655, Five-year inspection for teletherapy and gamma stereotactic radiosurgery units, would appear as a new section and would contain the requirements for inspections which are in the current § 35.647.

Proposed § 35.655 would require that teletherapy units and gamma stereotactic radiosurgery units be inspected and serviced during source replacement, or at intervals not to exceed 5 years, to assure proper functioning of the source exposure mechanism. Most gamma stereotactic radiosurgery licensees are required, by license condition, to inspect the units every 7 years; however, professionals in the medical community have indicated that the units are inspected on a more frequent bases. The Commission believes that the risk associated with using gamma stereotactic radiosurgery units justifies a change in the inspection frequency. Recordkeeping requirements for this section would appear in § 35.2655, Records of 5-year inspection for teletherapy and gamma stereotactic radiosurgery units.

Section 35.657, Therapy-related computer systems, would appear as a new section that would require licensees to verify that the computerized operating system and treatment planning system associated with a therapy device are operating appropriately and to perform acceptance testing on the treatment planning systems in accordance with published protocols approved by nationally recognized bodies. These changes are consistent with recommendations found in AAPM Task Group Report No. 40 - Comprehensive QA for Radiation Oncology (1994).

This proposed requirement is especially important in light of recent information on the inability of computers to correctly recognize dates beyond December 31, 1999. Therapy-related computer systems may misread the year 2000 and cause the systems to fail, generate faulty data, or act in an incorrect manner. In particular, computer software used to calculate dose or to account for radioactive decay may not recognize the turn of the century, which could lead to incorrectly calculated doses or exposure times for treatment planning. The potential for system failures, such as this, would be identified when determining compliance with this proposed section.

Section 35.690, Training for use of therapeutic medical devices, would appear as a new section. This section would revise the training and experience requirements found in § 35.960, Training for teletherapy, and would be expanded to include training for authorized uses of teletherapy, remote afterloaders, and gamma stereotactic radiosurgery units. Section III of the Supplementary Information section of this document contains a detailed discussion of training and experience. Note, 2 years after publication of the final rule, this section would replace the current requirements in § 35.960, Training for teletherapy.

Subpart J, Training and Experience Requirements, is in the current Part 35. Licensees would have the option to comply with the training and experience requirements in this subpart or in subparts B, and D-H until 2 years after the final rule is published in the Federal Register. At that time this subpart will be deleted. A more detailed discussion of the Commission's proposed changes to the training and experience requirements is in Section III of the Supplementary Information section of this document. The proposed schedule for implementation of the training and experience requirements is in Section VIII of the Supplementary Information section of this document.

Section 35.900, Radiation Safety Officer, is in the current Part 35. Two changes would be made in this section to correspond to the revised numbering system: § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist; and § 35.24, Authority and responsibilities for the radiation protection program. This section would be deleted 2 years after the final rule is published in the Federal Register at which time licensees would be required to comply with the training and experience requirements in the new § 35.50, Training for Radiation Safety Officer. Section VIII of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed implementation of the training and experience requirements.

Section 35.901, Training for experienced Radiation Safety Officer, would be deleted in its entirety and the requirements of this section would be moved to the proposed § 35.57.

Section 35.910, Training for uptake, dilution, and excretion studies, is in the current Part 35. One change would be made in this section to correspond to the revised numbering system: § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist. This section would be deleted 2 years after the final rule is published in the Federal Register, at which time licensees would be required to comply with the training and experience requirements in the new § 35.290, Training for uptake, dilution, and excretion studies. Section VIII of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed implementation of the training and experience requirements.

Section 35.920, Training for imaging and localization studies, is in the current Part 35. One change would be made in this section to correspond to the revised numbering system:
§ 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist. This section would be deleted 2 years after the final rule is published in the Federal Register, at which time licensees would be required to comply with the training and experience requirements in the new § 35.292, Training for imaging and localization studies. Section VIII of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed implementation of the training and experience requirements.

Section 35.930, Training for therapeutic use of unsealed byproduct material, is in the current Part 35. One change would be made in this section to correspond to the revised numbering system: § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist. This section would be deleted 2 years after the final rule is published in the Federal Register, at which time licensees would be required to comply with the training and experience requirements in the new § 35.390,

Training for use of unsealed byproduct material for therapy or for use of unsealed byproduct material that requires a written directive. Section VIII of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed implementation of the training and experience requirements.

Section 35.932, Training for treatment of hyperthyroidism, is in the current Part 35. One change would be made in this section to correspond to the revised numbering system: § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist. This section would be deleted 2 years after the final rule is published in the Federal Register, at which time licensees would be required to comply with the training and experience requirements in the new § 35.390, Training for use of unsealed byproduct material for therapy or for use of unsealed byproduct material that requires a written directive. Section VIII of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed implementation of the training and experience requirements.

Section 35.934, Training for treatment of thyroid carcinoma, is in the current Part 35. One change would be made in this section to correspond to the revised numbering system:
§ 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist. This section would be deleted 2 years after the final rule is published in the Federal Register, at which time licensees would be required to comply with the training and experience requirements in the new § 35.390, Training for use of unsealed byproduct material for therapy or for use of unsealed byproduct material that requires a written directive. Section VIII of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed implementation of the training and experience requirements.

Section 35.940, Training for use of brachytherapy sources, is in the current Part 35. One change would be made in this section to correspond to the revised numbering system:

§ 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist. This section would be deleted 2 years after the final rule is published in the Federal Register, at which time licensees would be required to comply with the training and experience requirements in the new § 35.490, Training for use of manual brachytherapy sources. Section VIII of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed implementation of the training and experience requirements.

Section 35.941, Training for ophthalmic use of strontium-90, is in the current Part 35. One change would be made in this section to correspond to the revised numbering system:
§ 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist. This section would be deleted 2 years after the final rule is published in the Federal Register, at which time licensees would be required to comply with the training and experience requirements in the new § 35.490, Training for use of manual brachytherapy sources. Section VIII of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed implementation of the training and experience requirements.

Section 35.950, Training for use of sealed sources for diagnosis, is in the current Part 35. One change would be made in this section to correspond to the revised numbering system: § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist. This section would be deleted 2 years after the final rule is published in the Federal Register, at which time licensees would be required to comply with the training and experience requirements in the new § 35.590, Training for use of sealed sources for diagnosis. Section VIII of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed implementation of the training and experience requirements.

Section 35.960, Training for use of therapeutic medical devices, is in the current Part 35. One change would be made in this section to correspond to the revised numbering system: § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist. This section would be deleted 2 years after the final rule is published in the Federal Register, at which time licensees would be required to comply with the training and experience requirements in the new § 35.690, Training for use of therapeutic medical devices. Section VIII of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed implementation of the training and experience requirements.

Section 35.961, Training for an authorized medical physicist, is in the current Part 35. The title of this section would be revised to reflect that the training and experience requirements in this section apply to authorized medical physicists rather than just teletherapy physicists. In addition, the list of tasks in paragraph (c) has been changed to reflect the new numbering system. This section would be deleted 2 years after the final rule is published in the Federal Register, at which time licensees would be required to comply with the training and experience requirements in the new § 35.51, Training for an authorized medical physicist. Section VIII of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed implementation of the training and experience requirements.

Section 35.971, Physicians training in a three month program, would be deleted in its entirety. Three month nuclear medicine programs are no longer available. Criteria for authorized users are now specified in other areas of the rule.

Section 35.970, Training for an authorized nuclear pharmacist, would be deleted in its entirely and the requirements would be moved to the proposed § 35.57.

Section 35.980, Training for an authorized nuclear pharmacist, would not be changed. This section would be deleted 2 years after the final rule is published in the Federal Register, at which time licensees would be required to comply with the training and experience requirements in the new § 35.55, Training for an authorized nuclear pharmacist. Section VIII of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed implementation of the training and experience requirements.

Section 35.981, Training for experienced nuclear pharmacists, has not been changed. This section would be deleted 2 years after the publication of the final rule in the Federal Register, at which time licensees would be required to comply with the training and experience requirements in the new § 35.55, Training for an authorized nuclear pharmacist. The Commission solicits specific comment on the impact of deleting this section. Section VIII of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed implementation of the training and experience requirements.

Section 35.990, Violations, would be deleted in its entirety, and the requirements of this section, with minor modifications, would be moved to the proposed § 35.4001

Section 35.991, Criminal penalties, would be deleted in its entirety, and the requirements of this section, with minor modifications, would be moved to the proposed § 35.4002.

Section 35.999, Resolution of conflicting requirements during transition period, would be deleted in its entirety, and the requirements of this section, with modifications, would be moved to the proposed § 35.10.

Subpart K, Other Medical Uses of Byproduct Material or Radiation from Byproduct Material, would be a new subpart. This subpart was developed to accommodate use of radioactive material in an emerging technology.

Section 35.1000, Other medical uses of byproduct material or radiation from byproduct material, is new. It would be added to accommodate emerging technologies. Specific information that must be provided to the Commission in support of an application for use under § 35.1000 is provided in § 35.12(d).

Subpart L, Records, is a new subpart. This subpart would contain all the specific recordkeeping requirements necessary to implement the proposed requirements in Part 35. General requirements for record maintenance, such as electronic storage, are provided in
§ 35.5. Grouping of records into one subpart was done to facilitate use by the licensees. A licensee may reference this section when determining whether something must be recorded, rather than having to review the entire regulation to find out if there is a particular recordkeeping requirement. Many of the recordkeeping requirements remain unchanged. However, some new sections have been added as a result of new requirements, especially in subpart H. The Commission is soliciting public comment on whether all recordkeeping requirements should be grouped into one subpart or whether all recordkeeping requirements should be included in the section requiring the record.

Section 35.2024, Records of authority and responsibility for radiation protection programs, would require the licensee to retain a record of actions taken by the licensee's management in accordance with § 35.24(a) for 5 years. The 5-year retention period is a reduction from current requirements to maintain records of the approval of licensing actions, individuals, and radiation protection program changes. Currently, similar records are required to be maintained for the duration of the license (reference current § 35.22 and § 35.31). This period would allow sufficient time for NRC to review records of licensee actions.

It would also require the licensee to retain the copy of the authorities, duties, and responsibilities of the Radiation Safety Officer for the duration of the license. In many cases, these records would take the place of the Radiation Safety Committee meeting minutes. The Commission believes that it is important to document

licensees' management review and approval of licensing actions, changes to the radiation protection program, and the authorities, duties, and responsibilities of the Radiation Safety Officer. The record of licensing actions and radiation protection program changes must include a summary of actions and a signature of licensee management.

In addition, this section would require the licensee to retain a copy of the authorities, duties and responsibilities of the Radiation Safety Officer that includes the signatures of the radiation safety officer and licensee management for the duration of the license. This extended period is warranted in light of the importance of the functions performed by the Radiation Safety Officer.

Section 35.2026, Records of radiation protection program safety changes, would require the licensee to retain a record of each radiation protection program change, as required by § 35.26 for 5 years. The record must include a copy of the old and new procedure, the effective date of the change, and the signature of the Radiation Safety Officer and licensee management that reviewed and approved the change. The Commission recognizes that this requirement for management's signature is redundant to the requirement in § 35.2024; however, it believes this approach is warranted in light of the importance of these actions and the intent to keep requirements that are closely related in one subject area. Currently, licensees must retain a record of each "radiation safety program" change until the license has been renewed or terminated; therefore, this proposed change represents a reduction in burden. This record is needed to document what radiation changes were made in the program. This record facilitates the Commission's evaluation of minor radiation safety program changes and provides licensees with a record of the changes.

Section 35.2040, Records of written directives, would require the licensee to retain a copy of written directives required by § 35.40 for 3 years. These records will help to ensure that administrations were in accordance with the written directives. The 3-year recordkeeping retention period corresponds with the current

retention period for written directives. Only minor changes were made to the specific items that must currently be recorded in the written directive. These changes were discussed under § 35.40.

Section 35.2045, Records of medical events and precursor events, would require that the licensee maintain a record of medical events and precursor events reported pursuant to §§ 35.3045 and 35.3046 for 3 years. This section, in part, is intended to replace the current recordkeeping requirements in § 35.33 and to establish recordkeeping requirements for precursor events. The records made pursuant to §§ 35.3045 and 35.3046 must contain the licensee's name; the name of the prescribing physician; the affected or potentially affected individual's social security number or other identification number if one has been assigned; a brief description of the medical event or precursor event; why it occurred; the effect on the individual; and the actions taken to prevent recurrence. This record is needed to document medical events and precursor events for licensee and Commission review. The requirement to maintain records of medical events is similar to the current requirement for maintaining records of misadministrations. This proposed requirement would provide for a reduction in licensee burden since medical events records would be required to be maintained for 3 years rather than 5 years.

Section 35.2060, Records of instrument calibrations, would require the licensee to maintain a record of dose calibrator calibrations performed in accordance with §§ 35.60 and 35.62 for 3 years. These records are required to document that the instruments are functioning correctly. The name, rather than the signature, of the individual who performed the calibration would be required so that licensees would have the flexibility of using paper records or computer-generated records. This requirement does not prohibit licensees from continuing to have the individual who performed the calibration sign the record. The 3-year recordkeeping retention period is consistent with the current retention period for instrument calibrations.

Section 35.2061, Records of radiation survey instrument calibrations, would require the licensee to maintain a record of radiation survey instrument calibrations required by § 35.61 for 3 years. No changes have been made from the current recordkeeping requirements for radiation survey instrument calibrations. These records are required to document that the instruments are functioning correctly. The 3-year recordkeeping retention period is consistent with the current retention period for instrument calibrations.

Section 35.2063, Records of dosage of unsealed byproduct material for medical use, would require the licensee to maintain a record of dosage determinations required by § 35.63 for 3 years. Minor changes have been made from the current recordkeeping requirements for dosage measurement to delete the requirement to record the expiration date of the radiopharmaceutical. This was done because the expiration date is primarily related to drug stability and sterility. The term “dosage measurement” has been replaced by the term “dosage determination” to be consistent with the change proposed in § 35.63. Finally, a change would be made to require that the name of the individual who determined the dosage be documented. The licensee will be required to record dosages administered to patients or human research subjects. This record is required for licensees to show that they are maintaining control of radioactive material. The 3-year recordkeeping retention period corresponds with the current retention period for dosage records.

Section 35.2067, Records of possession of sealed sources and brachytherapy sources, would require the licensee to retain records of the leak tests and inventory required by § 35.67 (b) and (g) for 3 years. The record retention period was reduced from 5 years to 3 years to reduce regulatory burden. The Commission does not believe the extra period is warranted. One change has been made from the current recordkeeping requirements for leak tests and inventories. The name of the individual performing the leak test and inventory would be recorded rather than the signature of the Radiation Safety Officer. Leak test records are required to show that the leak test was done at the appropriate time interval and that sealed sources are not leaking. Inventory records

are necessary to show that the possession of sealed sources did not exceed the amount authorized by the license.

Section 35.2070, Records of surveys for ambient radiation exposure rate, would require the licensee to maintain records of radiation surveys for 3 years. One change has been made from the current recordkeeping requirements for radiation surveys. The name of the individual performing the survey rather than the initials of the individual would be required to be recorded. These records are needed to document that surveys were performed. The 3-year recordkeeping retention period is consistent with the current retention period for radiation surveys.

Section 35.2075, Records of the release of individuals containing radiopharmaceuticals or implants, would require the licensee to maintain records of patient release required by § 35.75 for 3 years. No changes have been made from the current recordkeeping requirements in § 35.75. This record is needed to show compliance with the requirements in § 35.75.

Section 35.2080, Records of administrative and technical requirements that apply to the provision of mobile services, would require the licensees to maintain a copy of the letter that permits the use of byproduct material at a client's address of use for 3 years after the last provision of service; and to retain the records of the surveys for 3 years. One change has been made in these records that are required by § 35.80. The name of the individual performing the survey rather than the initials of the individuals would be required to be recorded. The records are needed to show compliance with the requirements in § 35.80.

Section 35.2092, Records of waste disposal, would require the licensee to maintain records of the disposal of licensed materials made in accordance with § 35.92 for 3 years. Minor changes have been made in the recordkeeping requirements in the current Part 35. The licensee would no longer be required to record the

date that the material was placed in storage because the requirement to store material for 10 half-lives would be deleted in the proposed rule. The record must include the date of the disposal, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal. This record is needed to document that radioactive material is not disposed of as ordinary waste. The 3-year recordkeeping retention period is consistent with the current retention period for waste disposal records.

Section 35.2204, Records of molybdenum-99 concentration, would require the licensee to maintain a record of the molybdenum-99 concentration tests required by § 35.204(b) for 3 years. Minor changes have been made in the recordkeeping requirements from the current rule. The licensee would no longer be required to record the measured activity of the technetium expressed in millicuries, and the measured activity of the molybdenum expressed in microcuries. The record must include, for each measured elution of technetium-99m, the ratio for the measures expressed as microcuries of molybdenum per millicurie of technetium, the time and date of the measure, and the name of the individual who performed the disposal. This record is needed to document that the concentration measurement was made and that the maximum molybdenum-99 concentration level was not exceeded. The 3-year recordkeeping retention period is consistent with the current retention period for records of molybdenum-99 concentration.

Section 35.2310, Records of instruction and training, would require the licensee to maintain a record of radiation safety instructions required by §§ 35.310, 35.410, and 35.610 for 3 years. The record must include a list of the topics covered, the date of the instruction or training, the name(s) of the attendee(s) and the name of the individual who gave the instruction. This record is needed to document that the instruction and training was given. The 3-year recordkeeping retention period is consistent with the current retention period for training records.

Section 35.2404, Records of radiation surveys of patients and human research subjects, would require the licensee to maintain a record of the radiation surveys required by § 35.404 for 3 years. The licensee would no longer be required to record the dose rate from the patient or the human research subject expressed as millirem per hour and measured at 1 meter from the patient or human research subject. Each record must include the date, location, results of the survey, an identification of the patient or the human research subject, survey instrument used, and the name of the individual who made the survey. These records are used to show that sources have not been misplaced and that all sources have been removed from the patient. The 3-year recordkeeping retention period is consistent with the current retention period for surveys.

Section 35.2406, Records of brachytherapy source inventory, would require the licensee to maintain a record of brachytherapy source accountability required by § 35.406 for 3 years. Changes have been made in the recordkeeping requirements that are in the current rule. The licensee would no longer be required to record the following items since they would be deleted from discussion in § 35.406: the names of the individuals permitted to handle the sources; name and room number of the patient or the human research subject receiving the implant; number and activity of the sources in storage after the removal; and the number and activity of sources in storage after the return.

The proposed rule would require that, for temporary implants, the record must include the number and activity of sources removed from and returned to storage; the time and date they were removed from and returned to storage; the location of use; and the name of the individual who removed and returned the sources to storage. For permanent implants, the record must include the number and activity of sources removed from and returned to storage; the date they were removed from and returned to storage; the number and activity of sources removed from and returned to storage; the number and activity of sources permanently implanted in the patient or human research subject; and the name of the individual who removed and returned the sources to storage. This record is required so that, if a brachytherapy source is misplaced or missing, the licensee is immediately

alerted and can take appropriate action. The 3-year recordkeeping retention period is consistent with the current retention period for inventory records.

Section 35.2432, Records of full calibrations on brachytherapy sources, would require the licensee to retain a record of the results of brachytherapy source calibrations for 3 years after the last use of the source. This is a new recordkeeping section. The record must contain the date of the calibration; the manufacturer's name, model number, and serial number for the source and instruments used to calibrate the source; the source output; source positioning accuracy within applicators; and the signature of the authorized medical physicist. These records are needed to document that the brachytherapy sources have been calibrated.

Section 35.2605, Records of installation, maintenance, and repair, would require the licensee to retain a record of the installation, maintenance, and repair of therapeutic medical devices, as required by § 35.605, for 3 years. This is a new recordkeeping section. Previously, licensees were not required to keep records of installation, maintenance, and repair. For each installation, maintenance, and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work. This record is necessary to document that the devices are properly installed, maintained, and repaired; to establish trends in device performance; and to establish a service history that may be used in evaluation of generic equipment problems.

Section 35.2630, Records of dosimetry equipment, would require the licensee to retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with § 35.630 for the duration of the license. No changes have been made in the recordkeeping requirements from the current rule. These records are needed to show that calibrations of medical devices were made with properly calibrated instruments.

Section 35.2632, Records of teletherapy full calibrations, would requires the licensee to maintain a record of the teletherapy full calibrations required by § 35.632 for 3 years. The record retention period was decreased from the duration of the use of the teletherapy unit source to 3 years to reduce regulatory burden. The term "teletherapy physicist" was replaced with the term "authorized medical physicist." No other changes were made to the current recordkeeping requirements for this section. These records are needed to document that calibrations were performed in accordance with § 35.632.

Section 35.2633, Records of remote afterloader full calibrations, would require the licensee to maintain a record of the remote afterloader full calibrations required by § 35.633 for 3 years. This is a new recordkeeping section. The recordkeeping requirements in this section are similar to the recordkeeping requirements for teletherapy units in § 35.2632. The record must include the date of the calibration; the manufacturer's name, model number, and serial number for the remote afterloader, source, and instruments used to calibrate the unit; the source output; an assessment of timer accuracy and linearity, source positioning accuracy, source guide tube and connector lengths, source retraction functionality; and the signature of the authorized medical physicist who performed the full calibration. These records are needed to document that calibrations were performed in accordance with § 35.633.

Section 35.2635, Records of gamma stereotactic radiosurgery unit full calibrations, would require the licensee to maintain a record of the calibrations required by § 35.635 for 3 years. This is a new recordkeeping section. The recordkeeping requirements in this section are similar to the recordkeeping requirements for teletherapy units in § 35.2632. The record must include the date of the calibration; the manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit, source, and instruments used to calibrate the unit; the unit output; an assessment of the relative helmet factors, isocenter coincidence, timer accuracy and linearity, on-off error, and trunnion centricity; and the signature of the authorized medical physicist

who performed the full calibration. These records are needed to document that calibrations were performed in accordance with § 35.635. This change reflects corresponding changes made in § 35.642.

Section 35.2642, Records of periodic spot-checks for teletherapy units, would require the licensee to retain a record of each periodic spot-check for teletherapy units required by § 35.642 for 3 years. Minor changes have been made in the recordkeeping requirements from the current rule. The licensee would no longer be required to record the operability of the beam condition indicator light, but would be required to record the operability of the source exposure indicator light. This change reflects corresponding changes made in § 35.642. The record must include the date of the spot-check; the manufacturer's name, model number, and serial number for the teletherapy unit source, and instrument used to measure the output of the teletherapy unit; an assessment of timer linearity and constancy; the calculated on-off error, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device; the determined accuracy of each distance measuring and localization device; the difference between the anticipated output and the measured output; notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; name of the individual who performed the test and the signature of the authorized medical physicist who reviewed the periodic spot-check. These records are needed to document that spot-checks were performed in accordance with § 35.642. The 3-year recordkeeping retention period is consistent with the current retention period for periodic spot-checks.

Section 35.2643, Records of periodic spot-checks for remote afterloaders, would require the licensee to retain a record of each spot-check for remote afterloaders required by §§ 35.643 and 35.644 for 3 years. This is a new recordkeeping section. The record must include the date of the spot-check; the manufacturer's name, model number, and serial number for both the remote afterloader, source, and instrument used to measure the output of the remote afterloader; the difference between the anticipated output and the measured output; notations indicating the operability of each entrance door electrical interlock, source retraction mechanism,

radiation monitors, source exposure indicator lights, viewing and intercom, applicators and connectors, and source positioning accuracy; the name of the individual who performed the periodic spot-check; and signature of the authorized medical physicist who reviewed the periodic spot-check. These records are needed to document that spot-checks were performed in accordance with §§ 35.643 and 35.644.

Section 35.2645, Records of periodic spot-checks for gamma stereotactic radiosurgery units, would require the licensee to retain a record of each spot-check for gamma stereotactic radiosurgery units required by § 35.645 for 3 years. This is a new recordkeeping section. The record must include the date of the spot-check; the manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit, and the instrument used to measure the output of the unit; the measured source output and source output against computer calculations; notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination systems, hydraulic cutoff mechanism, and stereotactic frames and localizing devices (trunnions); and the name of the individual who performed the periodic spot-check; and the signature of the authorized medical physicist who reviewed the periodic spot-check. This record is needed to show that spot-checks were performed in accordance with § 35.645.

Section 35.2647, Records of additional technical requirements for mobile remote afterloaders, would require the licensee to retain a record of each check for mobile remote afterloaders required by § 35.647 for 3 years. The record must include the date of the check; the manufacturer's name, model number, and serial number for the remote afterloader; notations accounting for all sources before departing from a client’s facility; notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators and connectors, and source positioning accuracy; and the signature of the individual who performed the check. This record is needed to show that required spot-checks

were performed in accordance with § 35.647 and that the unit is operable. The 3-year recordkeeping retention period is consistent with the current retention period for checks on mobile remote afterloaders.

Section 35.2652, Records of surveys of therapeutic treatment units, would require the licensee to maintain a record of radiation surveys made in accordance with § 35.652 for the duration of use of the unit. This recordkeeping section has been changed to require that the records of radiation surveys of the treatment unit must be maintained for the duration of use of the unit, rather than for the duration of the license, to reduce regulatory burden. In addition, the licensee is no longer required by this section to maintain a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in millirem per hour, and the calculated maximum quantity of radiation over a period of 1 week for each restricted and unrestricted area. This change reflects corresponding changes made in § 35.652. The record must include the date of the measurements; the manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels; and each dose rate measured around the source while the unit is in the off position and the average of all measurements and the signature of the individual who performed the surveys. This record is needed to document radiation levels in areas surrounding therapeutic devices.

Section 35.2655, Records of 5-year inspection for teletherapy and gamma stereotactic surgery units, would require the licensee to maintain a record of the 5-year inspection for teletherapy and gamma stereotactic radiosurgery units required by § 35.655 for the duration of the unit. This recordkeeping section has been changed to require that the records of inspections of the treatment units must be maintained for the duration of use of the unit, rather than for the duration of the license, to reduce regulatory burden. A minor change was made to delete the requirement to maintain a record of the components replaced to also reduce regulatory burden. The record must contain the inspector's name; the inspector's radioactive materials license number; the date of inspection; the manufacturer's name and model number and serial number for both the treatment unit and

source; a list of components inspected and serviced; the type of service; and the signature of the inspector. This record is needed to document the type of service that was performed.

Subpart M, Reports, is a new subpart in Part 35. This subpart would contain all the reporting requirements necessary to implement the proposed requirements in Part 35. Grouping of reporting requirements into one subpart was done to facilitate use by the licensee. A licensee may reference this section when determining whether something must be reported, rather than having to review the entire regulation to find out if there is a particular reporting requirement. Many of the reporting requirements remain unchanged. The Commission is soliciting public comments on whether the reporting requirements should be included in the section requiring the report.

Section 35.3045, Reports of medical events, would provide criteria for reporting medical events. The criteria are based on the current requirements in § 35.33. Changes would be made to make the reporting threshold dose-based where possible to add a dose threshold of 0.5 Sv (50 rem) shallow dose equivalent to the skin; and to address two areas that have caused problems in implementing the current requirements in § 35.33 -- patient intervention and wrong treatment site. With respect to patient intervention, the licensee is expected to act reasonably, in accordance with prevailing standards of care, to prevent a medical event. Generally speaking, patient intervention involves actions by the patient such as dislodging or removing treatment devices or prematurely terminating treatment. In cases where patient intervention is probable, the licensee should take reasonable actions (e.g., extra sutures, taping, or more frequent checks by the nursing staff) to avoid a medical event. Factors which may be considered in determining whether a licensee's actions are reasonable include whether the licensee monitors the patient routinely and whether the licensee responds properly once it becomes aware of the disruption of treatment. The Commission is soliciting input from the public on whether the proposed changes adequately address patient intervention and wrong treatment site.

The proposed rule would require that licensees notify, by telephone, the NRC Operations Center no later than the next calendar day after discovery of the medical event. The licensee would be required to submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6 within 15 days after discovery of the medical event. In addition, the licensee would be required to notify the referring physician and the individual affected by the medical event, or the responsible relative or guardian, no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the individual or that, based on medical judgment, telling the individual would be harmful. This reporting requirement is needed to ensure that NRC is aware of medical events. Section III of the Supplementary Information of this document contains a detailed discussion of the Commission's views on the notification requirements.

Section 35.3046, Reports of precursor events, would require that the licensee notify NRC of precursor events. The section would require the licensee to report, no later than the next calendar day after identifying any defects, exclusive of ordinary equipment failures, in equipment (hardware and/or software), byproduct material, or procedures supplied by a manufacturer or vendor that, in the opinion of the Radiation Safety Officer or authorized user, could lead to a medical event. The licensee would be required to submit a written report to the appropriate NRC Regional Office listed in § 30.6 within 15 days after discovery of the event. The written report must include the licensee's name; a brief description of the event; why the event occurred; what improvements are needed to prevent recurrence; and actions taken to prevent recurrence.

This requirement was added to the rule in response to Commission direction to staff to determine the best way to "capture precursor events." Issues associated with capturing precursor events and associated public comment are presented in Section III of the Supplementary Information section of this document. The Commission has attempted to estimate the burden on licensees associated with this requirement. The Regulatory Analysis for this rule contains a detailed discussion of this issue. The Commission estimates that approximately 50 reports would be received from NRC and Agreement State licensees on an annual basis and

that it will take approximately 5 hours of licensee effort to prepare the report required by this section. This results in an annual burden on NRC and Agreement State licensees of approximately $14,000. The Commission is soliciting input from the public on whether the estimated number of reports and number of hours to prepare the written report is reasonable in light of current practice.

Section 35.3047, Report of a dose to an embryo/fetus or a nursing child, is a new section. Paragraph (a) would require that a licensee report to NRC any administration of byproduct material, or radiation from byproduct material, to a pregnant woman that results in a dose to an embryo/fetus that is greater than 5 mSv (500 mrem) absorbed dose unless specifically approved, in advance, by the authorized user. It should be emphasized that only unintended exposures would be reported to NRC. This report does not include exposure of individuals in excess of the public dose limits in Part 20. Paragraph (b) would require a licensee to report to NRC any administration of byproduct material to a breast feeding woman that results in a dose to the nursing child that is greater than 5 mSv (500 mrem) total effective dose equivalent unless the administration was specifically approved, in advance, by the authorized user. Oral reports must be made to the NRC Operations Center within 5 days of discovery and followed with a written report no later than 30 days.

Information required by this section is needed so that NRC can comply with Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438), as amended, to annually submit to Congress a report of unscheduled incidents or events which the Commission considers significant from the standpoint of public health and safety, e.g., abnormal occurrences.

NRC identifies an abnormal occurrence using the revised abnormal occurrence criteria that was published in the Federal Register on April 17, 1997 (62 FR 18820). Section II of the policy statement defines unintended radiation exposure as “any occupational exposure, exposure to the general public or exposure as a result of a medical misadministration (as defined in § 35.2) involving the wrong individual that exceeds the

reporting values established in the regulations." This section also states that "All other reported medical misadministrations will be considered for reporting as an Abnormal Occurrence under the criteria for medical licensees. In addition, unintended radiation exposures include any exposure to a nursing child, fetus, or embryo as a result of an exposure (other than an occupational exposure to an undeclared pregnant woman) to a nursing mother or pregnant woman above specified values." Appendix A, Section I. A, of the policy statement, states that NRC will provide information on "any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual total effective dose equivalent of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more."

At the present time, NRC has no regulatory requirements that would require reporting of those types of events. The Commission considered two alternatives that could be pursued: revise the current Abnormal Occurrence Criteria to delete the requirement to inform Congress of this type of event; or develop a reporting requirement that would provide information needed by the Commission to comply with Section 208. The Commission did not pursue the first option because the Abnormal Occurrence reporting criteria were recently revised.

Only two comments were received on the proposed criteria in this area. One commenter believed that the threshold for reporting a dose to any minor or embryo/fetus should be reduced to less than 0.350 rem instead of the proposed 5 rem. The second commenter recommended that the criteria related to a nursing infant, fetus or embryo as a result of an exposure to a nursing mother or a pregnant woman should be deleted from the criteria until the issue can be resolved through consultation with the ACMUI and a separate public comment period on that issue.

The Commission is not inclined to revise the criteria without public comments indicating that it is not appropriate for NRC to report this type of event to Congress and that the proposed reporting requirement in §

35.3047 is overly burdensome or unwarranted. As a result, the Commission has decided to pursue the second alternative. However, the Commission does solicit specific comments in this area regarding whether modification of the Abnormal Occurrence Policy Statement criteria is needed.

The proposed rule would require that licensees report to NRC any unintended exposures to an embryo/fetus or nursing child that exceeds the dose threshold, as specified in the proposed § 35.3047. The Commission recognizes that the proposed reporting threshold is less than the Abnormal Occurrence reporting level. This was done to make the Part 35 reporting threshold consistent with the reporting thresholds in 10 CFR Part 20. The time period for reporting is similar for the reporting requirements in 10 CFR parts 20 and 35. The period for initial notification to NRC is longer than the period for reporting medical events. The Commission believes it appropriate to provide for a longer reporting period because the threshold for reporting and the risk associated with this threshold are lower than those for a medical event.

The Commission recognizes that the standard of practice for authorized users is to assess the pregnancy or nursing status of their patients (reference American College of Radiology “Standard for the Performance of Therapy with Unsealed Radio nuclide Sources,” 1996, and “Society of Nuclear Medicine General Procedure Guidelines for Imaging with Radionuclides,” 1997). As a result, NRC does not believe that it is appropriate to propose a rule that would require a licensee to assess the pregnancy or nursing status of patients. It does, however, believe that it is appropriate to propose a rule that would require the licensee to inform NRC when it learns of an unintended dose to an embryo/fetus or a nursing child that exceeds the thresholds discussed above. Reporting under § 35.3047 would not necessarily be subject to enforcement action if the licensee had complied with § 35.75. Although the regulation requires that the licensee provide information on the cause of the incident and corrective actions to prevent recurrence, NRC acknowledges that in many, and if not all, incidents, the licensee might not have been able to prevent the incident because the individual may have opted not to disclose

her pregnancy or nursing status. NRC is soliciting specific public comment on the impacts of this reporting requirement on licensee procedures, activities, or medical practices.

Section 35.3067, Reports of leaking sources, would require the licensee to file a report with the appropriate NRC Office listed in § 30.6 of this chapter, with a copy to Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, within 5 days if a leakage test required by § 35.67 reveals the presence of 185 Bq (0.005 microcurie) or more of removable contamination. This reporting requirement is similar to the current requirements for leaking sources. The report must contain the model number and serial number if assigned, of the leaking source; Radio nuclide and its estimated activity; the measured activity of each test sample expressed in microcuries; a description of the method used to measure each test sample; the date of the test; and the action taken.

Subpart N, Enforcement, contains statements regarding enforcement. This subpart would replace the statements in the current Subpart K, Enforcement.

Section 35.4001, Violations, would appear as a new section and replace the current § 35.990 which would be deleted in the proposed rule. This section reflects the new numbering system for the revised Part 35.

Section 35.4002, Criminal penalties, would appear as a new section and replace the current § 35.991 which would be deleted in the proposed rule. This section reflects the new numbering system for the revised Part 35.

Appendix A to Part 35, Examining Organization or Entity, would appear as a new appendix. This appendix would provide the requirements for an examining organization or entity; examination programs; and written examinations. This appendix is needed because of the proposed revision to the training and experience criteria

for an authorized user, medical physicist, authorized nuclear pharmacist, and radiation safety officer that would require an individual to pass an examination given by an organization or entity approved by NRC or an Agreement State. All criteria in Appendix A are considered by the Commission as necessary to assure that an individual's competency is adequately assessed.

NRC is proposing that an independent examining organization be an organization that would make its examination process available to the general public nationwide and not restrict access because of race, color, religion, sex, age, national origin or disability. The independent examining organization or entity would need to:

(1) Have adequate staff;

(2) Have a viable system of financing its operations;

(3) Have a policy and decision making review board;

(4) Be governed by written organizational by-laws and policies;

(5) Provide NRC or an Agreement State with a description of its procedures for choosing examination sites and for providing an appropriate examination environment;

(6) Submit its request for approval to the Director, Office of Nuclear Materials Safety and Safeguards.

An independent examining organization or entity would also need to have:

(1) A committee to review and approve the examination guidelines and procedures, and to advise the organization's staff in implementing the examination program;

(2) A committee to review complaints from examined individuals;

(3) Written procedures describing all aspects of its examination program;

(4) An agreement to exchange information about examined individuals with the Commission and the Agreement States;

(5) Procedures to ensure that examinations are not given to individuals who have also been instructed by the examining organization in the same subject area;

(6) Procedures to ensure that examined individuals are provided due process with respect to the administration of its examination program;

(7) Procedures for proctoring examinations; and

(8) Procedures to ensure that all examination questions are protected from disclosure.

NRC is proposing in Section II of Appendix A that all examination programs must (1) require applicants for examination to receive training in the topics set forth in §§ 35.50(b)(1), 35.51(b)(1), 35.55(b)(3), 35.290(b)(1), 35.292(b)(1), 35.390(b)(1), 35.490(b)(1) or 35.690(b)(1) and satisfactorily complete a written examination covering these topics. NRC is proposing in Section III that:

(1) The written examination must be designed to test an individual's knowledge and understanding of the topics listed in the above sections;

(2) The written examination must have test items drawn from a question bank containing psychometrically valid questions based on the material in the above listed questions; and

(3) A sample examination must be submitted to the Commission for review initially and every 5 years.

A 5-year review cycle is consistent with the review of residency programs by the Accreditation Council for Graduate Medical Education.

Summary of Specific Issues Identified for Public Comment

The Commission is soliciting specific public comment on various issues associated with this rulemaking action. These issues are discussed in detail in the noted sections.

1. Training and Experience -- Is the proposed requirement for examining organizations to ensure that examinations are not given to individuals who have also been instructed by the examining organization in the

same subject area too prescriptive in light of current industry practice? What is the projected amount of time needed for specialty boards and examining organizations to prepare and submit an application to NRC or Agreement States.

2. Section 35.2 -- Should the term “medium dose-rate remote afterloader” be defined since it not used in the rule? (Requirements for medium dose-rate remote afterloaders have been grouped with high dose-rate remote afterloaders in this rulemaking.)

3. Section 35.75 -- Should any changes be made to the release criteria specified in this section?

4. Section 35.92 -- Is it appropriate to delete the requirement to hold byproduct material for a minimum of ten half-lives?

5. Section 35.315 -- Should the requirement for a private room with a private sanitary facility be maintained in the final rule?

6. Section 35.415 -- Should the requirement for a licensee to not quarter a patient in the same room as an individual who is not receiving radiation therapy be maintained in the final rule?

7. Section 35.432 -- Should the final rule allow licensees to rely on the brachytherapy source output provided by the manufacturer or distributor if the dosimetry equipment used by the manufacturer or distributor met the calibration requirements in § 35.630? How should sources be calibrated if there is no standard traceable to the National Institute of Standards and Technology? What is the estimated number of short- and long-lived brachytherapy sources that will need to be calibrated on an annual basis and how long will it take to perform the calibration? Will licensees need to procure additional equipment to perform the calibrations?

8. Section 35.605 -- Should the restrictions in paragraph (a) of the proposed rule apply to low dose-rate remote afterloaders?

9. Section 35.615 -- Should the requirements in this section be waived for licensees that are using remote afterloaders with beta-emitting sources?

10. Section 35.644 -- Should the restrictions for electrical interlocks and audiovisual systems apply to low dose-rate remote afterloaders?

11. Section 35.981 -- What is the impact of deleting this section?

12. Subpart L -- Should all recordkeeping requirements be grouped into one subpart or should they be incorporated into the section requiring the record?

13. Subpart M -- Should all reporting requirements be grouped into one subpart or should they be incorporated into the section requiring the report?

14. Section 35.3045 -- Do the proposed rule changes adequately address patient intervention and wrong treatment site?

15. Section 35.3046 -- Are the estimated number of reports that would be submitted to NRC and the number of hours needed to prepare the written report reasonable in light of current practice?

16. Section 35.3047 -- Should the Abnormal Occurrence Policy Statement criteria for reporting of exposures to an embryo/fetus or nursing child be modified? What is the impact of the proposed reporting requirement on licensee procedures, activities, or medical practices?

V. Coordination With The Advisory Committee on the Medical Uses of Isotopes

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) is an advisory body established to advise the NRC staff on matters that involve the administration of radioactive material and radiation from radioactive material. At the public ACMUI meetings on September 25-26, 1997, and March 1-2, 1998, held in Rockville, MD., the NRC staff presented alternatives for major cross-cutting issues related to revising Part 35, recommendations for revising the NRC's Medical Use Policy Statement, and draft proposed rule text.

These meetings were transcribed. The ACMUI's comments at the September 1997 meeting are summarized in "Summary of Discussion: Meeting of the Advisory Committee on the Medical Uses of Isotopes

(ACMUI) Held in Rockville, Maryland on September 25-26, 1997" (date of document to be inserted). The summary document is available for inspection at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the summary document are available as indicated in the For Further Information Contact section of this document. A brief summary of the ACMUI positions on the major crosscutting issues associated with this rulemaking is provided in Section III of the Supplementary Information section of this document.

Working group members also met with separate ACMUI subcommittees for diagnostic and therapeutic medical uses on February 9-10, 1998 (Rockville, MD.) and February 12-13, 1998 (Freeport, IL.), respectively. The subcommittee meetings provided the Working Group with an opportunity to discuss in depth the specific provisions of the draft proposed rule with ACMUI members.

VI. Coordination With NRC Agreement States

NRC staff discussed the proposed revision of Part 35 with representatives of the Agreement States at a workshop on October 18, 1997. The workshop commentary was transcribed, and the participant's comments are summarized in "Summary of Discussion: Facilitated Public Workshop on NRC's Medical Rulemaking Initiative Held at All Agreement States Meeting, Los Angeles, California, October 18, 1997" (date of document to be inserted). The summary document is available for inspection at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the summary document are available as indicated in the For Further Information Contact section of this document. A brief summary of the workshop participants' positions on the major cross-cutting issues associated with this rulemaking is provided in Section III of the Supplementary Information section of this document.

Both the Working Group and Steering Group that developed the draft proposed rule included representatives of Agreement States. The Agreement State representative on the Working Group is also a member of the Conference of Radiation Control Directors' Suggested State Regulation Committee on Medical Regulation, which is working toward parallel development of suggested state medical regulations. State participation in the process has provided an early opportunity for State input and should enhance development of corresponding rules in State regulations. In addition, it will allow the State staff to assess the potential impacts of NRC draft language on the regulation of non-Atomic Energy Act materials used in medical diagnosis, treatment, or research in the States.

VII. Consistency with Medical Policy Statement

The Commission is proposing a revision to its General Policy on the Regulation of the Medical Uses of Radioisotopes that was issued on February 9, 1979 (44 FR 8424), as part of the efforts undertaken to revise 10 CFR Part 35. The proposed revision and detailed discussion on the need for the revision is being published for comment in the Federal Register concurrently with the proposed revision to Part 35. Because of the nature of the proposed revision to the policy, consistency with each policy will be discussed separately.

Consistency with the proposed revision to the Medical Use Policy Statement

The proposed revision to Part 35 is consistent with the Commission's proposed revision to the Medical Use Policy Statement.

The first statement of the proposed policy reads "NRC will continue to regulate the uses of radionuclides in medicine as necessary to provide for the radiation safety of workers and the general public." The proposed

rule is consistent with the statement because one of its purposes is to provide for the radiation safety of workers and individual members of the public, which is central to fulfillment of the Commission's statutory mandate to "protect health and minimize danger to life."

The second statement of the proposed policy reads "NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public." The proposed rule would also be consistent with this statement because its focus is on protecting the public and workers from patients who have been administered byproduct material or radiation from byproduct material for medical use.

The third statement of the proposed policy reads "NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides is in accordance with the physician's directions." The proposed rule is consistent with this statement because it includes provisions, where warranted by the risk, to provide high confidence that the authorized user's directions for the administration of byproduct material are followed.

The fourth statement of the proposed policy reads "NRC, in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches of achieving radiation safety." The proposed rule is consistent with this statement because the rulemaking process included examining relevant industry and professional standards to determine if specific areas of concern were included in the standards, or whether regulatory requirements needed to be included in Part 35.

Consistency with the 1979 Medical Use Policy Statement

The proposed revision to Part 35 is generally consistent with the Commission's General Policy on the Regulation of the Medical Uses of Radioisotopes issued on February 9, 1979 (44 FR 8242).

The first statement of the policy reads "The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public." The proposed rule is consistent with this statement because its purpose is to provide for the radiation safety of workers and individual members of the public, which is central to fulfillment of the Commission's statutory mandate to "protect health and minimize danger to life."

The second statement of the policy is "The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate." The proposed rule is generally consistent with this statement. The proposed rule includes requirements to ensure the radiation safety of patients in areas where justified by the risk to patients. The rulemaking process included examining relevant industry and professional standards to determine if specific areas of concern were included in the standards, or whether additional regulatory requirements needed to be developed for inclusion in Part 35. The process did not include an assessment of licensee compliance with these standards. Where appropriate, the proposed revision includes references to published protocols approved by nationally recognized bodies. Where warranted by risk, key elements of the standards were included as performance objectives. Prescriptive compliance requirements for these performance objectives were not included in the rule because it is expected that licensees will use voluntary standards to achieve the objective. This approach is consistent with a performance-based, risk-informed rule.

The third statement of the policy reads, "The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine." The proposed rule is consistent with this statement because it includes no requirements associated with the diagnosis and treatment of patients.

VIII. Implementation

The Commission intends to have different implementation dates for particular requirements of this proposed rule. With one exception (discussed below), the proposed requirements would be effective 6 months after publication of the final rule in the Federal Register. Because the consolidated guidance document for medical use licensees is being developed in parallel with the revised regulatory requirements in Part 35, the Commission believes that a longer implementation period will not be necessary. The 6-month implementation period would allow the NRC time to train licensing and inspecting staff so that the revised Part 35 will be uniformly implemented; and provide licensees the time to understand the specific features of the revised Part 35, and to develop and implement any changes in their radiation safety programs or procedures that are required to comply with the revised requirements. NRC workshops might be offered for the benefit of licensees, Regional Offices, States, and others who are affected by the revision.

The Commission proposes that licensees would have up to 2 years after the effective date of the final rule to comply with the proposed training requirements for authorized users, authorized medical physicists, authorized nuclear pharmacists, and Radiation Safety Officers. During this 2-year period, licensees will have the option of complying with either the existing training requirements, which will be retained in subpart J, or the training requirements in subparts B and D-H of the proposed rule.

The 2-year implementation period will allow time for potential examining organizations and entities to prepare an application in accordance with Appendix A of the proposed rule; and for NRC to review and approve the applications submitted in accordance with Appendix A, and to review and approve certification of the specialty boards in §§ 35.50(a), 35.51(a), 35.55(a), 35.290(a), 35.292(a), 35.390(a), 35.490(a), 35.590(a), and 35.690(a). The 2-year time period will also allow individuals from Agreement States time to satisfy the proposed training

requirements in order to work in NRC jurisdiction. After the 2-year implementation period, the requirements in subpart J will be deleted.

Section 35.10 of the proposed rule addresses how a licensee can determine if it must comply with the requirements of its license conditions or the requirements of the revised Part 35, when it becomes effective.

The Commission invites comments and suggestions on the effective date of implementation, including specific information on time and economic considerations, and on additional guidance or documents that would be needed or useful in implementing the proposed revision.

IX. Issues of Compatibility for Agreement States

10 CFR PART 35--MEDICAL USE OF BYPRODUCT MATERIAL

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997 (62 FR 46517), specific requirements within this rule should be adopted by Agreement States for purposes of compatibility or because of their health and safety significance. Implementing procedures for the Policy Statement establish specific categories which have been applied to categorize the requirements in Part 35. A Category "A" designation means the requirement is a basic radiation protection standard or deals with related definitions, signs, labels or terms necessary for a common understanding of radiation protection principles. Category "A" designated Agreement State requirements should be essentially identical to those of the NRC. A Category "B" designation means the requirement has significant direct transboundary implications. Category "B" designated Agreement State requirements should be essentially identical to those of the NRC. A Category "C" designation means the essential objectives of the requirement

should be adopted by the State to avoid conflicts, duplications or gaps. The manner in which the essential objectives are addressed in the Agreement State requirement need not be the same as NRC provided the essential objectives are met. A Category "D" designation means the requirement does not need to be adopted by an Agreement State for purposes of compatibility. The Health and Safety (H&S) Category identifies requirements which are not required for compatibility, but which have particular health and safety significance. Agreement States should adopt the essential objectives of such requirements in order to maintain an adequate program.

The following discussion identifies the compatibility designations for each section:

Subpart A, "General Information," § 35.2, "Definitions," is assigned to Compatibility Category "D," with the exception of the terms "Agreement State", "authorized user," "medical event," "medical use," "precursor event," "prescribed dosage," "prescribed dose," "sealed source," "treatment site" and "written directive." The terms "Agreement State" and "sealed source" are assigned to Compatibility Category "B" because they have significant direct transboundary implications. The terms "authorized user," "medical event," "medical use," "precursor event," "prescribed dosage," "prescribed dose," "treatment site" and "written directive" have been assigned to Compatibility Category "C." Section 35.11, "License required," is assigned to Compatibility Category "C."

Subpart B, "General Administrative Requirements," is assigned to Compatibility Category "D," with the exception of four sections. Section 35.24, "Authority and responsibilities for the radiation protection program"; § 35.27, "Supervision"; § 35.40, "Written directives"; and § 35.41(a), "Procedures for administrations requiring a written directive" are all assigned to the Health and Safety Category. Section 35.50, "Training for radiation safety officer"; § 35.51, "Training for authorized medical physicist"; § 35.55 "Training for an authorized nuclear pharmacist"; and § 35.57, "Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist" are assigned to Compatibility Category "C."

Subpart C, “General Technical Requirements,” is assigned to Compatibility Category “D,” with the exception of four sections. Section 35.61, “Calibration and check of survey instruments”; § 35.63(a), “Determination of dosages of unsealed byproduct material for medical use”; § 35.67, “Requirements for possession of sealed sources and brachytherapy sources”; and § 35.70, “Surveys of ambient radiation exposure rate” are assigned to the Health and Safety Category. Section 35.75, “Release of individuals containing radiopharmaceuticals or implants,” paragraph (a), is assigned to Compatibility Category “C.”

Subpart D, “Unsealed Byproduct Material - Low Dose”; and Subpart E, “Unsealed Byproduct Material - High Dose” are assigned to Compatibility Category “D,” except for § 35.100, “Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required”; § 35.200, “Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required”; § 35.204, “Permissible molybdenum-99 concentration”; and § 35.300, “Use of unsealed byproduct material for which a written directive is required,” which are assigned to the Health and Safety Category. Section 35.290, “Training for uptake, dilution, and excretion studies”; and § 35.292, “Training for imaging and localization studies”; and § 35.390, “Training for use of unsealed byproduct material for therapy or for use of unsealed byproduct material that requires a written directive,” are assigned to Compatibility Category “C.”

Subpart F, “Manual Brachytherapy” is assigned to Compatibility Category “D,” with the exception of five sections. Section 35.400, “Use of sources for manual brachytherapy”; § 35.404(a) and (b), “Radiation surveys of patients or human research subjects treated with implants”; § 35.406(a) and (b), “Brachytherapy sources inventory”; and § 35.432(a-e), “Full calibration measurements of brachytherapy sources” are assigned to the Health and Safety Category. Section 35.490, “Training for use of manual brachytherapy sources,” is assigned to Compatibility Category “C.”

Subpart G, “Sealed Sources for Diagnosis,” is assigned to Compatibility Category “D,” with the exception of Section 35.590, “Training for use of sealed sources for diagnosis” which is assigned to Compatibility Category “C.”

Subpart H, “Therapeutic Medical Devices,” is assigned to Compatibility Category “D,” with the exception of 16 sections. The following sections are assigned to the Health and Safety Category: §§ 35.600; 35.604(a); 35.605; 35.610(a)(1), (a)(2), and (a)(4); 35.615(a), (b)(1), (b)(2), (d), and (e); 35.630; 35.632; 35.633; 35.635; 35.642; 35.643; 35.644; 35.645; 35.655; and 35.657. Section 35.690, “Training for use of therapeutic medical devices” is assigned to Compatibility Category “C.”

Subpart K, “Other Medical Uses of Byproduct Material or Radiation from Byproduct Material,” and Subpart L, “Records,” are assigned to Compatibility Category “D.”

Subpart M, “Reports,” is assigned to Compatibility Category “C.” Section 35.3045, “Reports of medical events”; § 35.3046, “Reports of precursor events”; § 35.3047, “Reports of a dose to an embryo/fetus or a nursing child,” and § 35.3069, “Reports of leaking sources” are assigned to Compatibility Category “C.”

Subpart N, “Enforcement,” is assigned to Compatibility Category “D.”

Appendix A, “Examining Organization or Entity,” is assigned to Compatibility Category “B.”

PART 20--STANDARDS FOR PROTECTION AGAINST RADIATION

Section 20.1301(a)(3) is assigned to Compatibility Category “A.”

PART 32--SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

Section 32.72 (b)(1) and (b)(2)(ii) and § 32.74 (a) and (a)(3) are assigned to Compatibility Category “B.”

As discussed under Section VIII of this document, the Commission proposes that licensees would have up to 2 years after the effective date of the final rule to comply with the proposed training requirements for authorized users, authorized medical physicists, authorized nuclear pharmacists, and Radiation Safety Officers. During this 2-year period, licensees would have the option of complying with either the existing training requirements in subpart J, or the proposed training requirements in subparts B and D through H. At the end of the 2 years, subpart J would be deleted and licensees would have to comply with the proposed training and experience criteria. The training and experience requirements in the proposed subpart J are assigned to Compatibility Category “D,” as they are in the current rule. Subparts B and D through H of the proposed rule have been assigned to Compatibility Category “C” for Agreement States. Under the “Policy Statement on Adequacy and Compatibility of Agreement State Programs,” approved by the Commission on June 30, 1997, the Agreement States are required to adopt NRC program elements (or promulgate regulations) required for compatibility within 3 years of the effective date of the NRC rulemaking. Therefore, the Commission recognizes that if an Agreement State does not revise its regulations until 2 years after the effective date of the NRC rule, it may choose not to include subpart J training and experience requirements in the newly promulgated rules, since the subpart J requirements are assigned to Compatibility Category “D” (not required for compatibility). In this case, the Agreement States would only be expected to adopt the proposed training and experience requirements in subparts B and D through H.

X. Finding of No Significant Environmental Impact: Availability

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in subpart A of 10 CFR Part 51, that the proposed amendments, if adopted, would be a major Federal action but would not significantly affect the quality of the human environment, and therefore an environmental impact statement is not required. The proposed amendments would relax certain requirements and eliminate other procedural restrictions associated with the medical use of byproduct material. The Commission believes these proposed amendments would provide greater flexibility in the medical use of byproduct material while continuing to adequately protect public health and safety. The proposed amendments to Part 35, if adopted, would not cause any significant increase in radiation exposure to the public or radiation release to the environment beyond the exposures or releases currently resulting from the medical use of byproduct material. The proposed amendment to 10 CFR 20.1301 is expected to result in an increase in radiation exposure to the public. However, this alternative is consistent with generally accepted radiation protection principles, such as those expressed by the International Commission on Radiation Protection (ICRP), the National Council on Radiation Protection and Measurements (NCRP), and the International Atomic Energy Agency (IAEA).

The draft environmental assessment on which this determination is based is available for inspection at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the environmental assessment are available as indicated in the For Further Information Contact section of this document.

XI. Paperwork Reduction Act Statement

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). This rule has been submitted to the Office of Management and Budget for review and approval of the paperwork requirements.

Because the rule will reduce existing information collection requirements, the public burden for this information collection is expected to be decreased by [hours to be inserted when OMB package is completed] hours per licensee. This reduction includes the time required for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. The U.S. Nuclear Regulatory Commission is seeking public comment on the potential impact of the information collection in the proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?

2. Is the estimate of burden accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques?

Send comments on any aspect of this proposed information collection, including suggestions for further reducing the burden, to the Information and Records Management Branch (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail at BJS1@nrc.gov; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0010 and 3150-0120), Office of Management and Budget, Washington, DC, 20503.

Comments to OMB on the information collections or on the above issues should be submitted by (insert date 30 days after publication in the Federal Register). Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date.

Public Protection Notification

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

XII. Regulatory Analysis

The Commission has prepared a draft regulatory analysis for the proposed rule. The analysis examines the costs and benefits of the alternatives considered by the Commission. The draft analysis is available for inspection at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the regulatory analysis are available as indicated in the For Further Information Contact section of this document.

The Commission requests public comment on the draft regulatory analysis. Comments on the draft regulatory analysis may be submitted to the NRC as indicated under the Addresses section of this document.

XIII. Regulatory Flexibility Analysis

The NRC has prepared an initial regulatory flexibility analysis of the impact of this proposed rule on small entities. The preliminary regulatory flexibility analysis indicates that the proposed rule will have an economic

impact of approximately $8,000 annually on medical licensees, of which 36 percent are small entities. However, the NRC notes that this would be a substantial reduction in the cost to the average licensee under the current regulations. The NRC estimates that the proposed requirements would reduce the annual cost to an average medical licensee by approximately $ 900. The NRC believes that the proposed alternative is the least costly alternative that provides adequate protection from radiation exposure for patients and workers. The regulatory flexibility analysis appears as Appendix A to this document.

Because of the widely differing conditions under which small medical licensees operate, the NRC is seeking comments on the impact of the rule and any suggested modifications that may affect its economic impact. Any small medical licensee that would be subject to this regulation that determines, because of its size, that it is likely to bear a disproportionate adverse economic impact, should notify the Commission of this in a comment that indicates-

(a) The licensee's size and how this proposed regulation would result in a significant economic burden upon the licensee as compared to the economic burden on a larger licensee;

(b) How the proposed regulations could be modified to take into account the licensee's differing needs or capabilities;

(c) The benefits that would accrue, or the detriments that would be avoided, if the proposed regulations were modified as suggested under paragraph (b) above;

(d) How the proposed regulation, as modified, would more closely equalize its impact as opposed to providing special advantages to any individual licensee or groups of licenses; and

(e) How the proposed regulations, as modified, would still adequately protect the public health and safety.

The comments should be sent to the NRC as indicated under the Addresses section of this document.

XIV. Backfit Analysis

The NRC has determined that the backfit rule does not apply to this proposed rule and, therefore, that a backfit analysis is not required for this proposed rule because these amendments would not involve any provision that would impose backfits as defined in 10 CFR Chapter I.

List of Subjects

10 CFR Part 20

Byproduct material, Criminal penalties, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Special nuclear material, Source material, Waste treatment and disposal.

10 CFR Part 32

Byproduct material, Criminal penalties, Labeling, Nuclear materials, Radiation Protection, Reporting and recordkeeping requirements.

10 CFR Part 35

Byproduct material, Criminal penalties, Drugs, Health facilities, Health professions, Medical devices, Nuclear materials, Occupational safety and health, Radiation protection, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is proposed to adopt the following amendments to 10 CFR parts 20, 32 and 35.

PART 20--STANDARDS FOR PROTECTION AGAINST RADIATION

1. The authority citation for Part 20 continues to read as follows:

AUTHORITY: Secs. 53, 63, 65, 81, 103, 104, 161, 182, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 953, 955, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2232, 2236, 2297f), secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

2. In § 20.1301, paragraph (a)(3) is added to read as follows:

§ 20.1301 Dose limits for individual members of the public.

(a) * * *

(3) Notwithstanding paragraph (a)(1) of this section, a licensee may permit visitors to individuals who are not released in accordance with § 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.

* * * * *

PART 32--SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

3. The authority citation for Part 32 continues to read as follows:

AUTHORITY: Secs. 81, 82, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

§ 32.72 [Amended]

4. In § 32.72, in paragraph (b)(1), the reference to “10 CFR 35.25" is revised to read “10 CFR 35.27" and in paragraph (b)(2)(ii), the reference to “10 CFR 35.980(b) and 35.972" is revised to read “10 CFR 35.55(b) and 35.59 or 10 CFR 35.980(b) and 35.972."

§ 32.74 [Amended]

5. In § 32.74, in paragraph (a), the reference to ”§§ 35.400 and 35.500" is revised to read “§§ 35.400, 35.500, and 35.600" and in paragraph (a)(3), the reference to “§§ 35.58, 35.400, or 35.500" is revised to read “§§ 35.400, 35.500, and 35.600."

6. 10 CFR Part 35 is revised to read as follows:

PART 35--MEDICAL USE OF BYPRODUCT MATERIAL

Subpart A--General Information

Sec.

35.11 License required.

35.12 Application for license, amendment, or renewal.

35.13 License amendments.

35.14 Notifications.

35.15 Exemptions regarding Type A specific licenses of broad scope.

35.18 License issuance.

35.19 Specific exemptions.

Subpart B--General Administrative Requirements

35.24 Authority and responsibilities for the radiation protection program.

35.26 Radiation protection program changes.

35.27 Supervision.

35.40 Written directives.

35.41 Procedures for administrations requiring a written directive.

35.49 Suppliers for sealed sources or devices for medical use.

35.50 Training for Radiation Safety Officer.

35.51 Training for an authorized medical physicist.

35.55 Training for an authorized nuclear pharmacist.

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

35.59 Recentness of training.

Subpart C--General Technical Requirements

35.60 Possession, use, calibration, and check of instruments to measure the activity of photon-emitting radionuclides.

35.61 Calibration and check of survey instruments.

35.62 Possession, use, calibration, and check of instruments to measure dosages of alpha- or beta-emitting radionuclides.

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

35.65 Authorization for calibration and reference sources.

35.67 Requirements for possession of sealed sources and brachytherapy sources.

35.69 Labeling and shielding of vials and syringes.

35.70 Surveys for ambient radiation exposure rate.

35.75 Release of individuals containing radiopharmaceuticals or implants.

35.80 Provision of mobile service.

35.92 Decay-in-storage.

Subpart D--Unsealed Byproduct Material - Low Dose

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

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

35.204 Permissible molybdenum-99 concentration.

35.290 Training for uptake, dilution, and excretion studies.

35.292 Training for imaging and localization studies.

Subpart E -- Unsealed Byproduct Material - High Dose

35.300 Use of unsealed byproduct material for which a written directive is required.

35.310 Safety instruction.

35.315 Safety precautions.

35.390 Training for use of unsealed byproduct material for therapy or for use of unsealed byproduct material that requires a written directive.

Subpart F-Manual Brachytherapy

35.400 Use of sources for manual brachytherapy.

35.404 Radiation surveys of patients or human research subjects treated with implants.

35.406 Brachytherapy sources inventory.

35.410 Safety instruction.

35.415 Safety precautions.

35.432 Full calibration measurements of brachytherapy sources.

35.490 Training for use of manual brachytherapy sources.

Subpart G --Sealed Sources for Diagnosis

35.500 Use of sealed sources for diagnosis.

35.590 Training for use of sealed sources for diagnosis.

Subpart H--Therapeutic Medical Devices

35.600 Use of a sealed source in a device for therapeutic medical uses.

35.604 Radiation surveys of patients and human research subjects treated with remote afterloaders.

35.605 Installation, maintenance, and repair .

35.610 Safety procedures and instructions for remote afterloaders, teletherapy units, and gamma stereotactic radiosurgery units.

35.615 Safety precautions for remote afterloaders, teletherapy units, and gamma stereotactic radiosurgery units.

35.630 Dosimetry equipment.

35.632 Full calibration measurements on teletherapy units.

35.633 Full calibration measurements on remote afterloaders.

35.635 Full calibration measurements on gamma stereotactic radiosurgery units.

35.642 Periodic spot-checks for teletherapy units.

35.643 Periodic spot-checks for high dose-rate and pulsed dose-rate remote afterloaders.

35.644 Periodic spot-checks for low dose-rate remote afterloaders.

35.645 Periodic spot-checks for gamma stereotactic radiosurgery units.

35.647 Additional technical requirements for mobile remote afterloaders.

35.652 Radiation surveys.

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

35.657 Therapy-related computer systems.

35.690 Training for use of therapeutic medical devices .

Subpart I -- Reserved

Subpart J--Training and Experience Requirements

35.900 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.

Subpart K--Other Medical Uses of Byproduct Material or Radiation from Byproduct Material

Subpart L -- Records

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

35.2092 Records of waste disposal.

35.2204 Records of molybdenum-99 concentration.

35.2310 Records of instruction and training.

35.2404 Records of radiation surveys of patients and human research subjects.

35.2406 Records of brachytherapy source inventory.

35.2432 Records of full calibrations on brachytherapy sources.

35.2605 Records of installation, maintenance, and repair.

35.2630 Records of dosimetry equipment.

35.2632 Records of teletherapy full calibrations.

35.2633 Records of remote afterloader full calibrations.

35.2635 Records of gamma stereotactic radiosurgery unit full calibrations.

35.2642 Records of periodic spot-checks for teletherapy units.

35.2643 Records of periodic spot-checks for remote afterloaders.

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

35.2647 Records of additional technical requirements for mobile remote afterloaders.

35.2652 Records of surveys of therapeutic treatment units.

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

AUTHORITY: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

Subpart A--General Information

§ 35.1 Purpose and scope.

This part prescribes requirements and provisions 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 radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of this part are in addition to, and not in substitution for, others in this chapter. The requirements and provisions of parts 19, 20, 21, 30, 71, 170, and 171 of this chapter apply to applicants and licensees subject to this part unless specifically exempted.

§ 35.2 Definitions.

Address of use means the building or buildings that are identified on the license and where byproduct material may be received, used, or stored.

Agreement State means any State with which the Commission or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended.

Area of use means a portion of an address of use that has been set aside for the purpose of receiving, using, or storing byproduct material.

Authorized medical physicist means a physicist who --

(1) Meets the requirements in §§ 35.51(a) and 35.59 or §§ 35.961 and 35.59; or

(2) Is identified as a medical physicist on a Commission or Agreement State license; or

(3) Is identified as a medical physicist on a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the use of byproduct material.

Authorized nuclear pharmacist means a pharmacist who --

(1) Meets the requirements in §§ 35.55(a) and 35.59 or §§ 35.980(a) and 35.59; or

(2) Is identified as an authorized nuclear pharmacist on a Commission or Agreement State license that authorizes the use of byproduct material in the practice of nuclear pharmacy; or

(3) Is identified as an authorized nuclear pharmacist on a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the use of byproduct material in the practice of nuclear pharmacy; or

(4) Is approved as an authorized nuclear pharmacist by a nuclear pharmacy authorized by the Commission to approve authorized nuclear pharmacists.

Authorized user means a physician, dentist, or podiatrist who --

(1) Meets the requirements in §§ 35.290(a), 35.292(a), 35.390(a), 35.490(a), 35.590(a), or 35.690(a) and § 35.59, or §§ 35.910, 35.920, 35.930, 35.932, 35.934, 35.940, 35.941, 35.950, 35.960 and § 35.59; or

(2) Is identified as an authorized user on a Commission or Agreement State license that authorizes the medical use of byproduct material; or

(3) Is identified as an authorized user on a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of byproduct material.

Brachytherapy source means a radioactive sealed source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

Dedicated check source means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years.

Dentist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry.

Diagnostic clinical procedures manual means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.

High dose-rate remote afterloader, as used in this part, means a device that remotely delivers a dose rate in excess of 2 gray (200 rads) per hour at the point or surface where the dose is prescribed.

Low dose-rate remote afterloader as used in this part, means a device that remotely delivers a dose rate of less than 2 gray (200 rads) per hour at the point or surface where the dose is prescribed.

Management means the chief executive officer or that person's delegate or delegates.

Medical event means an event that meets the criteria in § 35.3045(a).

Medical institution means an organization in which several medical disciplines are practiced.

Medical use means the intentional internal or external administration of byproduct material or the radiation from byproduct material to patients or human research subjects under the supervision of an authorized user.

Mobile service means the transportation and medical use of byproduct material by the same licensee at temporary jobsites.

Output means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

Pharmacist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

Physician means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

Podiatrist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.

Prescribed dosage means the quantity of radiopharmaceutical activity as documented --

(1) In a written directive; or

(2) Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.

Prescribed dose means --

(1) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(2) For teletherapy, the total dose and dose per fraction as documented in the written directive;

(3) For brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

(4) For remote afterloaders, the total dose as documented in the written directive.

Precursor event means an event that meets the criteria in § 35.3046(a).

Pulsed dose-rate remote afterloader means a special type of remote afterloading device that uses a single source capable of delivering dose rates in the “high dose rate” range, but is used to simulate the radiobiology of a low dose rate treatment by inserting the source for a given fraction of each hour.

Radiation Safety Officer means the individual identified as the Radiation Safety Officer on a Commission license who --

(1) Meets the requirements in §§ 35.50 and 35.59 or §§ 35.900 and 35.59; or

(2) Is identified as a Radiation Safety Officer on a Commission or Agreement State license.

Sealed source means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.

Sealed Source and Device Registry means the national registry that contains all the registration certificates, generated by both NRC and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

Stereotactic radiosurgery means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a dose to a tissue volume.

Structured educational program means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

Temporary jobsite means a location where mobile services are conducted other than those location(s) of use authorized on the license.

Treatment site means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

Unit dosage means a dosage intended for medical use in a single patient or human research subject that has been obtained from a manufacturer or preparer licensed pursuant to
§ 32.72 of this chapter or equivalent Agreement State requirements.

Written directive means an authorized user's written order for the administration of byproduct material or radiation from byproduct material to a specific patient or human research subject, as specified in § 35.40.

§ 35.5 Maintenance of records.

Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

§ 35.6 Provisions for research involving human subjects.

A licensee may conduct research involving human subjects using byproduct material provided that the research is conducted, funded, supported, or regulated by another Federal Agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its NRC license before conducting such research. Both types of licensees shall, at a minimum, obtain informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects.

§ 35.7 FDA, other Federal, and State requirements.

Nothing in this part relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs or devices.

§ 35.8 Information collection requirements: OMB approval.

(a) The Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements in this part under control number 3150-0010.

(b) The approved information collection requirements contained in this part appear in §§ 35.6, 35.12, 35.13, 35.14, 35.19, 35.24, 35.26, 35.27, 35.40, 35.41, 35.50, 35.51, 35.55, 35.57, 35.60, 35.61, 35.62, 35.63, 35.67, 35.69, 35.70, 35.75, 35.80, 35.92, 35.204, 35.290, 35.292, 35.310, 35.315, 35.390, 35.404, 35.406, 35.410, 35.415, 35.432, 35.490, 35.590, 35.604, 35.605, 35.610, 35.630, 35.632, 35.633, 35.635, 35.642, 35.643, 35.644, 35.645, 35.647, 35.652, 35.655, 35.690, 35.900, 35.910, 35.920, 35.930, 35.940, 35.950, 35.960, 35.961, 35.980, 35.2024, 35.2026, 35.2040, 35.2045, 35.2060, 35.2061, 35.2063, 35.2067, 35.2070, 35.2075, 35.2080, 35.2092, 35.2204, 35.2310, 35.2404, 35.2406, 35.2432, 35.2605, 35.2630, 35.2632, 35.2633, 35.2635, 35.2642, 35.2643, 35.2645, 35.2647, 35.2652, 35.2655, 35.3045, 35.3046, 35.3047, 35,3067, and Appendix A.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved as follows:

(1) In § 35.12, NRC Form 313, including NRC Forms 313A, and 313B which licensees may use to provide supplemental information, is approved under control number 3150-0120.

(2) [Reserved]

§ 35.10 Implementation.

(a) A licensee shall implement the provisions in this part on or before [insert date 6 months from publication of the Final Rule], with the exception of the requirements listed in paragraph (b) of this section.

(b) A licensee shall implement the training requirements in §§ 35.50(a), 35.51(a), 35.55(a), 35.290(a), 35.292(a), 35.390(a), 35.490(a), 35.590(a), and 35.690(a) on or before [insert date-- 2 years from publication of the Final Rule].

(c) Prior to [insert date-- 2 years from publication of the Final Rule], a licensee shall satisfy the training requirements of this part for a Radiation Safety Officer, an authorized medical physicist, an authorized nuclear pharmacist, or an authorized user by complying with either:

(1) The appropriate training requirements in subpart J; or

(2) The appropriate training requirements in subpart B or subparts D-H.

(d) If the requirements of this part are more restrictive than the existing license condition, the licensee shall comply with this part unless exempted by paragraph (f) of this section.

(e) Any existing license condition that is more restrictive than a requirement in this part remains in effect until there is a license amendment or license renewal.

(f) If a license condition exempted a licensee from a provision of Part 35 on [insert date--6 months from publication of the Final Rule], it will continue to exempt a licensee from the corresponding provision in this part.

(g) If a license condition cites provisions in Part 35 that will be deleted on [insert date-- 6 months from publication of the Final Rule], then the license condition remains in effect until there is a license amendment or license renewal that modifies or removes this condition.

§ 35.11 License required.

(a) 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 paragraph (b) or (c) of this section.

(b) An individual may receive, possess, use, or transfer 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.

(c) An individual may prepare 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.

§ 35.12 Application for license, amendment, or renewal.

(a) An application must be signed by the management of the facility.

(b) An application for a license for medical use of byproduct material as described in §§ 35.100, 35.200, 35.300, 35.400, and 35.500, and for medical use of remote afterloaders in § 35.600, must be made by filing an original and one copy of NRC Form 313, "Application for Material License." A request for a license amendment or renewal may be submitted as an original and one copy in letter format.

(c) Except for medical use of remote afterloaders, a separate license application must be filed for each medical use of byproduct material as described in § 35.600 of this part by filing an original and one copy of NRC Form 313. A request for a license amendment or renewal may be submitted as an original and one copy in letter format.

(d) An application for a license for medical use of byproduct material as described in § 35.1000 of this part must be made by filing an original and one copy of NRC Form 313.

(1) In addition to the information required in NRC Form 313, the application must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in Subparts A through C of this part, as well as any specific information necessary for --

(i) Radiation safety precautions and instructions;

(ii) Training and experience of proposed users;

(iii) Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

(iv) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

(2) The applicant or licensee shall also provide any other information requested by the Commission in its review of the application.

(e) An applicant that satisfies the requirements specified in § 33.13 may apply for a Type A specific license of broad scope.

§ 35.13 License amendments.

A licensee shall apply for and must receive a license amendment --

(a) Before it receives or uses byproduct material for a clinical procedure that is permitted under this part, but that is not authorized on the licensee's current license issued pursuant to this part;

(b) Before it permits anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license, except an individual who is --

(1) An authorized user who meets the requirements §§ 35.290(a), 35.292(a), 35.390(a), 35.490(a), 35.590(a), or 35.690(a) and § 35.59, or §§ 35.910, 35.920, 35.930, 35.932, 35.934, 35.940, 35.941, 35.950, 35.960 and § 35.59;

(2) An authorized nuclear pharmacist who meets the requirements in § 35.55(a) and § 35.59; or §§ 35.980 and 35.59;

(3) An authorized medical physicist who meets the requirements in § 35.51(a) and § 35.59; or §§ 35.961 and 35.59;

(4) Identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist on a Commission or Agreement State license that authorizes the use of byproduct material in medical use or in the practice of nuclear pharmacy, respectively; or

(5) Identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist on a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy, respectively.

(c) Before it changes Radiation Safety Officers;

(d) Before it orders byproduct material in excess of the amount, or radionuclide or form that is different than the radionuclide or form authorized on the license;

(e) Before it adds to or changes the areas identified in the application or on the license, except for areas where byproduct material is used in accordance with §§ 35.100 and 35.200; and

(f) Before it changes the address or addresses of use identified in the application or on the license.

§ 35.14 Notifications.

(a) A licensee shall provide to the Commission a copy of the board certification, the Commission or Agreement State license, or the permit issued by a licensee of broad scope for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, an authorized medical physicist, pursuant to § 35.13 (b)(1) through (b)(5).

(b) A licensee shall notify the Commission by letter no later than 30 days after:

(1) An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;

(2) The licensee's mailing address changes;

(3) The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in § 30.34(b) of this chapter; or

(4) The licensee has added to or changed the areas where byproduct material is used in accordance with §§ 35.100 and 35.200.

(c) The licensee shall mail the documents required in this section to the appropriate address identified in § 30.6 of this chapter.

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

A licensee possessing a Type A specific license of broad scope for medical use is exempt from --

(a) The provisions of § 35.13(b);

(b) The provisions of § 35.13(e) regarding additions to or changes in the areas of use only at the addresses specified in the license;

(c) The provisions of § 35.14(a);

(d) The provisions of § 35.14(b)(1) for an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist; and

(e) The provisions of § 35.49(a).

§ 35.18 License issuance.

(a) The Commission shall issue a license for the medical use of byproduct material if --

(1) The applicant has filed Form NRC-313 "Application for Materials License" in accordance with the instructions in § 35.12;

(2) The applicant has paid any applicable fee as provided in Part 170 of this chapter;

(3) The Commission finds the applicant equipped and committed to observe the safety standards established by the Commission in this Chapter for the protection of the public health and safety; and

(4) The applicant meets the requirements of Part 30 of this chapter.

(b) The Commission shall issue a license for mobile services if the applicant:

(1) Meets the requirements in paragraph (a) of this section; and

(2) Assures that individuals or human research subjects to whom radiopharmaceuticals or radiation from implants will be administered may be released following treatment in accordance with § 35.75.

§ 35.19 Specific exemptions.

The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

Subpart B--General Administrative Requirements

§ 35.24 Authority and responsibilities for the radiation protection program.

(a) In addition to the radiation protection program requirements of § 20.1101 of this chapter, a licensee's management must approve in writing --

(1) Requests for license application, renewal, or amendments before submittal to the Commission;

(2) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, authorized medical physicist; and

(3) Radiation protection program changes that do not require a license amendment and are permitted under § 35.26;

(b) A licensee with multiple modalities or multiple users shall also develop, implement, and maintain written administrative procedures for interdepartmental/interdisciplinary coordination of the licensee's radiation protection program.

(c) A licensee's management shall appoint a Radiation Safety Officer, who agrees in writing to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements in the daily operation of the licensee's radiation protection program

(d) A licensee shall establish in writing the authority, duties, and responsibilities of the Radiation Safety Officer.

(e) A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to --

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide corrective actions;

(3) Stop unsafe operations; and,

(4) Verify implementation of corrective actions.

(f) A licensee shall retain a record of actions taken pursuant to paragraphs (a), (c), and (d) of this section in accordance with § 35.2024.

§ 35.26 Radiation protection program changes.

(a) A licensee may revise its radiation protection program without Commission approval if --

(1) The revisions do not require an amendment under § 35.13;

(2) The revisions do not reduce radiation safety;

(3) The revisions have been reviewed and approved by the Radiation Safety Officer and licensee management; and

(4) The affected individuals are instructed on the revised program before the changes are implemented.

(b) A licensee shall retain a record of each change in accordance with § 35.2026.

§ 35.27 Supervision.

(a) 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) of this part shall --

(1) 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

(2) Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures established by the licensee, regulations of this chapter; and license conditions with respect to the medical use of byproduct material.

(b) 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(c), shall --

(1) Instruct the supervised individual in the preparation of byproduct material for medical use, as appropriate to that individual's use of byproduct material; and

(2) 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.

(c) A licensee shall establish, implement, and maintain a policy for all supervised individuals to request clarification, as needed, from --

(I) The authorized user, before initiating or continuing any procedure that requires a written directive, if the supervised individual has any question about what should be done or how it should be done; and

(ii) The authorized user or authorized nuclear pharmacist about the instructions and requirements provided to the supervised individual in accordance with paragraphs (a) and (b) of this section.

(d) A licensee that permits supervised activities under paragraph (a) and (b) of this section is responsible for the acts and omissions of the supervised individual.

§ 35.40 Written directives.

(a) A written directive must be prepared, dated, and signed by an authorized user prior to administration of I-131 sodium iodide greater than 1.11 Megabequerels (MBq) (30 microcuries (μCi)), any therapeutic dosage of a radiopharmaceutical, or any therapeutic dose of radiation from byproduct material.[2]

(b) The written directive must contain the patient or human research subject's name and the following:

(1) For any administration of quantities greater than 1.11 MBq (30 μCi) of sodium iodide I-131: the dosage;

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[2] If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in writing in the patient's record and a written directive is prepared within 48 hours of the oral directive.

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 will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose.

(2) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-131: the radiopharmaceutical, dosage, and route of administration;

(3) For gamma stereotactic radiosurgery: target coordinates (including gamma angle), collimator size, plug pattern, total dose for the treatment, and the total treatment volume;

(4) For teletherapy: the total dose, dose per fraction, number of fractions, treatment site, and overall treatment period;

(5) For remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or

(6) For all other brachytherapy:

(I) Prior to implantation: treatment site, the radionuclide, number of sources and source strengths or dose; and

(ii) After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

(c) The licensee shall retain the written directive in accordance with § 35.2040.

§ 35.41 Procedures for administrations requiring a written directive.

(a) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

(1) The patient's or human research subject's identity is verified before each administration; and

(2) Each administration is in accordance with the written directive.

(b) The procedures required by paragraph (a) of this section must, at a minimum, address --

(1) Verifying the identity of the patient or human research subject;

(2) Verifying that the specific details of the administration are in accordance with the written directive and treatment plan;

(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 devices authorized by § 35.600.

§ 35.49 Suppliers for sealed sources or devices for medical use.

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 of this chapter 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.

§ 35.50 Training for Radiation Safety Officer

Except as provided in § 35.57, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer (RSO) as provided in § 35.24 to be an individual who --

(a) Is certified by a speciality board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been approved by the Commission or;

(b)(1) Has completed a structured educational program consisting of both:

(I) 200 hours of didactic training in the following areas--

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Radiation biology; and

(E) Radiation dosimetry; and

(ii) One year of full-time radiation safety experience under the supervision of the individual identified as the RSO on a Commission or Agreement State license that authorizes similar type(s) of use(s) of byproduct material involving the following;

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of dose calibrators, survey meters, and instruments used to measure radionuclides;

(C) Securing and controlling byproduct material;

(D) Using administrative controls to avoid mistakes in the administration of byproduct material;

(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(F) Disposing of byproduct material; and

(2) Has obtained written certification, signed by a preceptor RSO, that the requirements in paragraph (b)(1) of this section have been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently function as an RSO for medical uses of byproduct material; and

(3) Following completion of the requirements in paragraph (b) of this section, has demonstrated sufficient knowledge in radiation safety commensurate with the use requested by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A of this part; or

(c) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has RSO responsibilities.

§ 35.51 Training for authorized medical physicist.

The licensee shall require the authorized medical physicist to be an individual who --

(a) Is certified by a speciality board whose certification process includes all of the training and experience requirements in paragraph (b) of this section and whose certification has been approved by the Commission; or

(b)(1) Holds a master's or doctor's degree in physics, biophysics, radiological physics, medical physics, or health physics, or an equivalent training program approved by the NRC, and has completed one year of full-time training in therapeutic radiological physics and an additional year of full-time practical experience under the supervision of a medical physicist at a medical institution that includes the tasks listed in §§ 35.67, 35.632, 35.633, 35.634, 35.635, 35.642, 35.643, 35.644, 35.645 and 35.652 of this part; and

(2) Has obtained written certification, signed by a preceptor authorized medical physicist, that the requirements in paragraph (b)(1) in this section have been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently function as an authorized medical physicist; and,

(3) Following completion of the requirements in paragraph (b)(1) of this section, has demonstrated sufficient knowledge in radiation safety commensurate with the use requested by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A of this part.

§ 35.55 Training for an authorized nuclear pharmacist.

The licensee shall require the authorized nuclear pharmacist to be a pharmacist who --

(a) Is certified as a nuclear pharmacist by a speciality board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been approved by the Commission, or

(b)(1) Has completed 700 hours in a structured educational program consisting of both:

(I) Didactic training in the following areas --

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Supervised practical experience in a nuclear pharmacy involving --

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(C) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(D) Using administrative controls to avoid medical events in the administration of byproduct material; and

(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(2) Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the requirements in paragraph (b)(1) have been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy; and

(3) Following completion of the requirements in paragraph (b)(1) of this section, has demonstrated sufficient knowledge in radiation safety commensurate with the use requested by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A of this part.

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

(a) An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, or a nuclear pharmacist on a Commission or Agreement State license before [insert date--6 months from publication of the Final Rule] need not comply with the training requirements of §§ 35.50 and 35.51, respectively.

(b) Physicians, dentists, or podiatrists identified as authorized users for the medical, dental, or podiatric use of byproduct material on a Commission or Agreement State license issued before [insert date--6 months from publication of the Final Rule] who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of Subparts C-H.

§ 35.59 Recentness of training.

The training and experience specified in subparts B, D, E, F, G, H, and J must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

Subpart C--General Technical Requirements

§ 35.60 Possession, use, calibration, and check of instruments to measure the activity of photon-emitting radionuclides.

(a) For other than unit dosages, a licensee shall possess and use instrumentation to measure the activity of photon-emitting radionuclides prior to administration to each patient or human research subject.

(b) If a licensee uses instrumentation to measure the activity of dosages of photon-emitting radionuclides, including unit dosages, it shall develop, implement, and maintain written procedures for proper operation of the instrumentation. At a minimum, a licensee shall --

(1) Perform tests, before initial use and following repair, on each instrument for accuracy, linearity, and geometry dependence;

(2) Perform an accuracy test annually;

(3) Perform a linearity test annually over the range of medical use; and

(4) Check each instrument for constancy and proper operation at the beginning of each day of use.

(c) Accuracy tests must be performed with source(s) with a principal photon energy of between 100 and 500 keV whose activity is traceable to the National Institute of Standards and Technology (NIST) or by a supplier who has compared the source to a source that was calibrated by NIST.

(d) A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 1.11 MBq (30 μCi) and shall repair or replace the instrumentation if the accuracy or constancy error exceeds 10 percent.

(e) A licensee shall retain a record of each check and test required by this section in accordance with § 35.2060.

§ 35.61 Calibration and check of survey instruments.

(a) A licensee shall calibrate the survey instruments used to show compliance with this part and 10 CFR Part 20 before first use, annually, and following repair. A licensee shall --

(1) Calibrate all scales with readings up to 10 mSv (1000 mrem) per hour with a radiation source;

(2) Calibrate two separated readings on each scale that will be used to show compliance with this part; and

(3) Conspicuously note on the instrument the date of calibration.

(b) A licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent, and conspicuously attach a correction chart or graph to the instrument if the indicated exposure rate differs from the calculated exposure rate by more than 10 percent.

(c) Survey instruments must be removed from use if the indicated exposure rate differs from the calculated exposure rate by more than 20 percent.

(d) A licensee shall retain a record of each survey instrument calibration in accordance with § 35.2061.

§ 35.62 Possession, use, calibration, and check of instruments to measure dosages of alpha- or beta-emitting radionuclides.

(a) For other than unit dosages, a licensee shall possess and use instrumentation to measure the radioactivity of alpha- or beta-emitting radionuclides. A licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha- or beta-emitting radionuclides prior to administration to each patient or human research subject.

(b) A licensee shall develop, implement, and maintain written procedures for use of the instrumentation. At a minimum, a licensee shall --

(1) Perform tests before initial use, and following repair, on each instrument for accuracy, linearity, and geometry dependence, unless it is not appropriate for the use of the instrument; and make adjustments when necessary;

(2) Perform accuracy annually;

(3) Perform linearity tests annually over the range of medical use; and

(4) Check each instrument for constancy and proper operation at the beginning of each day of use.

(c) Accuracy tests must be performed with source(s) that are traceable to NIST or by a supplier who has compared the source to a source that was calibrated by NIST.

(d) A licensee shall retain a record of each check and test required by this section in accordance with § 35.2060.

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

(a) A licensee shall determine and record the activity of each dosage prior to medical use.

(b) For a unit dosage of an alpha-, beta-, or photon-emitting radionuclide, this determination must be made either by direct measurement or by a decay correction, based on the measurement made by a manufacturer or preparer licensed pursuant to § 32.72 of this chapter or equivalent Agreement State requirements.

(c) For a dosage of a alpha-, beta-, or photon-emitting radionuclide prepared by the licensee, this determination must be made by direct measurement or by combination of measurements and calculations.

(d) A licensee shall not use a dosage if the dosage differs from the prescribed dosage by more than 20 percent.

(e) A licensee shall retain a record of the dosage determination required by this section in accordance with § 35.2063.

§ 35.65 Authorization for calibration and reference sources.

Any person authorized by § 35.11 for medical use of byproduct material may receive, possess, and use the following byproduct material for check, calibration, and reference use:

(a) Sealed sources manufactured and distributed by a person licensed pursuant to § 32.74 of this chapter or equivalent Agreement State regulations and that do not exceed 1.11 kBq (30 mCi) each;

(b) Any byproduct material with a half-life not longer than 120 days in individual amounts not to exceed 0.555 MBq (15 mCi);

(c) Any byproduct material with a half-life longer than 120 days in individual amounts not to exceed 7.4 MBq (200 μCi) each and not to exceed 1000 times the quantities in Appendix B of Part 30 whichever is more limiting; and

(d) Technetium-99m in amounts as needed.

§ 35.67 Requirements for possession of sealed sources and brachytherapy sources.

(a) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer, and shall maintain the instructions for the duration of source use in a legible form convenient to users.

(b) A licensee in possession of a sealed source shall --

(1) Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within 6 months before transfer to the licensee; and

(2) Test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the Commission or an Agreement State in the Sealed Source and Device Registry.

(c) To satisfy the leak test requirements of this section, the licensee shall measure the sample so that the leakage test can detect the presence of 185 Bq (0.005 μCi) of radioactive material on the sample.

(d) A licensee shall retain leakage test records in accordance with § 35.2067.

(e) If the leakage test reveals the presence of 185 Bq (0.005 μCi) or more of removable contamination, the licensee shall --

(1) Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements in parts 20 and 30 of this chapter; and

(2) File a report within 5 days of the leakage test in accordance with § 35.3067.

(f) A licensee need not perform a leakage test on the following sources:

(1) Sources containing only byproduct material with a half-life of less than 30 days;

(2) Sources containing only byproduct material as a gas;

(3) Sources containing 3.7 MBq (100 μCi) or less of beta or gamma-emitting material or 0.37 MBq (10 μCi) or less of alpha-emitting material;

(4) Sources stored for less than a 10-year period and not being used. The licensee shall, however, test each such source for leakage before any use or transfer unless it has been leakage-tested within 6 months before the date of use or transfer; and

(5) Seeds of iridium-192 encased in nylon ribbon.

(g) A licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources in its possession. The licensee shall retain each inventory record in accordance with § 35.2067.

§ 35.69 Labeling and shielding of vials and syringes.

(a) A licensee shall develop, implement, and maintain written procedures for --

(1) Labeling each syringe, syringe shield, or vial shield that contains a radiopharmaceutical to identify the radiopharmaceutical name, or its abbreviation, and to ensure that the contents are conspicuously identified as containing radioactive material; and

(2) Shielding vials and syringes containing radiopharmaceuticals.

(b) A licensee shall instruct individuals, commensurate with the individual's assigned duties, in the procedures required by paragraph (a) of this section.

§ 35.70 Surveys for ambient radiation exposure rate.

(a) Except as provided in paragraph (b) of this section, a licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals requiring a written directive were prepared for use or administered.

(b) A licensee does not need to perform the surveys required by paragraph (a) of this section in an area(s) where patients or human research subjects can not be released pursuant to § 35.75.

(c) A licensee shall retain a record of each survey in accordance with § 35.2070.

§ 35.75 Release of individuals containing radiopharmaceuticals or implants.

(a) A licensee may authorize the release from its control of any individual who has been administered radiopharmaceuticals or 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 5 mSv (0.5 rem).[3]

(b) A licensee shall provide the released individual, or the individual's parent or guardian, 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 1 mSv (0.1 rem). If the total effective dose equivalent to a breast-feeding infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions shall also include --

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

(2) Information on the potential consequences, if any, of failure to follow the guidance.

(c) A licensee shall maintain a record of the basis for authorizing the release of an individual, in accordance with § 35.2075(a).

(d) The licensee shall maintain a record of instructions provided to breast-feeding women in accordance with § 35.2075(c).

§ 35.80 Provision of mobile service.

(a) A licensee providing mobile service shall --

(1) Obtain a letter signed by the management of each client for which services are rendered that permits the use of byproduct material at the client's address of use and clearly delineates the authority and responsibility of each entity;

(2) Check instruments as described in §§ 35.60 and 35.62 for proper function before medical use at each address of use or on each day of use, whichever is more frequent;

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[3] Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 0.5 rem (5 mSv).

(3) Check survey instruments for proper operation with a dedicated check source before use at each address of use;

(4) Before leaving a client's address of use, survey all areas of use to ensure compliance with the requirements in Part 20 of this chapter; and

(b) A mobile nuclear medicine service may not have 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. Radioactive material delivered to the client's address of use must be received and handled in conformance with the client's license.

(c) Retain the letter required in paragraph (a)(1) and the record of each survey required in paragraph (a)(4) of this section in accordance with § 35.2080.

§ 35.92 Decay-in-storage.

(a) A licensee may hold byproduct material with a physical half-life of less than 120 days for decay-in-storage before disposal in ordinary trash if it --

(1) Monitors byproduct material at the surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and

(2) Removes or obliterates all radiation labels;

(b) A licensee shall retain a record of each disposal permitted under paragraph (a) of this section in accordance with § 35.2092.

Subpart D--Unsealed Byproduct Material - Low Dose

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

A licensee may use for uptake, dilution, or excretion studies any unsealed byproduct material, except in quantities that require a written directive pursuant to § 35.40, prepared for medical use that is either --

(a) Obtained from a manufacturer or preparer licensed pursuant to § 32.72 of this chapter or equivalent Agreement State requirements; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in § 35.292, or an individual under the supervision of either as specified in § 35.27.

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

A licensee may use for imaging and localization studies any unsealed byproduct material, except in quantities that require a written directive pursuant to § 35.40, prepared for medical use that is either --

(a) Obtained from a manufacturer or preparer licensed pursuant to § 32.72 of this chapter or equivalent Agreement State requirements; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in § 35.292, or an individual under the supervision of either as specified in § 35.27.

§ 35.204 Permissible molybdenum-99 concentration.

(a) A licensee may not administer to humans a radiopharmaceutical containing more than 5.55 kBq (0.15 µCi) of molybdenum-99 per millicurie of technetium-99m.

(b) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration of the first eluate after receipt of a generator to demonstrate compliance with paragraph (a) of this section.

(c) A licensee that must measure molybdenum concentration shall retain a record of each measurement in accordance with § 35.2204.

§ 35.290 Training for uptake, dilution, and excretion studies.

Except as provided in §§ 35.57, the licensee shall require the authorized user of a radiopharmaceutical for the uses listed in § 35.100 to be a physician who --

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been approved by the Commission or --

(b)(1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of diagnostic radiopharmaceuticals, consisting of both --

(I) 40 hours of didactic training in the following areas --

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) 20 hours of supervised practical experience under the supervision of an authorized user involving --

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(F) Administering dosages to patients or human research subjects; and

(2) Has obtained written certification, signed by a preceptor authorized user, that the requirements in paragraph (b)(1) of this section have been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently function as an authorized user of a diagnostic radiopharmaceutical for the uses listed in § 35.100; and

(3) Following completion of the requirements in paragraph (b)(1) of this section, has demonstrated sufficient knowledge in radiation safety commensurate with the use requested by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A of this part.

§ 35.292 Training for imaging and localization studies.

Except as provided in §§ 35.57, the licensee shall require the authorized user of diagnostic radiopharmaceuticals and generators for the uses listed in § 35.200 to be a physician who --

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been approved by the Commission; or

(b)(1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of diagnostic radiopharmaceuticals and generators, consisting of both --

(I) 80 hours of didactic training in the following areas --

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) 40 hours of supervised practical experience under the supervision of an authorized user involving --

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures;

(F) Eluting technetium-99m from generator systems, measuring and testing the eluate for molybdenum-99, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and

(G) Administering dosages to patients or human research subjects; and

(2) Has obtained written certification, signed by a preceptor authorized user, that the requirements in paragraph (b)(1) of this section have been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently function as an authorized user of diagnostic radiopharmaceuticals and generators for the uses listed in § 35.200; and

(3) Following completion of the requirements in paragraph (b)(1) of this section, has demonstrated sufficient knowledge in radiation safety commensurate with the use requested by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A of this part.

Subpart E--Unsealed Byproduct Material - High Dose

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

A licensee may use any unsealed byproduct material prepared for medical use and for which a written directive is required that is either --

(a) Obtained from a manufacturer or preparer licensed pursuant to § 32.72 of this chapter or equivalent Agreement State requirements; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in § 35.292, or an individual under the supervision of either as specified in § 35.27.

§ 35.310 Safety instruction.

In addition to the requirements of § 19.12 of this chapter,

(a) A licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that have received radiopharmaceutical therapy and can not be released in accordance with § 35.75. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include --

(1) Patient or human research subject control;

(2) Visitor control, including --

(I) Routine visitation to hospitalized individuals in accordance with § 20.1301(a)(1); and

(ii) Visitation authorized in accordance with § 20.1301(a)(3);

(3) Contamination control;

(4) Waste control; and

(5) Notification of the authorized user and the Radiation Safety Officer, or his designee, if the patient or the human research subject dies or has a medical emergency.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with § 35.2310.

§ 35.315 Safety precautions.

(a) For each patient or human research subject that cannot be released in accordance with § 35.75, a licensee shall --

(1) Provide a private room with a private sanitary facility;

(2) Visibly post the patient's or the human research subject's room with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room; and

(3) Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle such material and items as radioactive waste.

(b) A licensee 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 and, immediately, if the patient dies.

§ 35.390 Training for use of unsealed byproduct material for therapy or for use of unsealed byproduct material that requires a written directive.

Except as provided in § 35.57, the licensee shall require the authorized user of a radiopharmaceutical for the uses listed in § 35.300 to be a physician who --

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been approved by the Commission; or

(b)(1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of unsealed byproduct material consisting of both --

(I) 80 hours of didactic training in the following areas --

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity; and

(D) Radiation biology; and

(ii) 40 hours of supervised practical experience under the supervision of an authorized user at a medical institution involving --

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Calibrating dose calibrators, as appropriate, and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(2) Has had experience, obtained under the direct supervision of an authorized user, involving at least five cases for each procedure with radiation safety hazards similar to that use for which the individual is requesting authorized user status;

(3) Has obtained written certification, signed by a preceptor authorized user, that the requirements in paragraphs (b)(1) and (2) of this section have been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently function as an authorized user of unsealed byproduct material for the uses listed in § 35.300; and

(4) Following completion of the requirements in paragraph (b)(1) and (2) of this section, has demonstrated sufficient knowledge in radiation safety commensurate with the use requested by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A of this part.

Subpart F-- Manual Brachytherapy

§ 35.400 Use of sources for manual brachytherapy.

A licensee shall use only brachytherapy sources for therapeutic medical uses as approved in the Sealed Source and Device Registry.

§ 35.404 Radiation surveys of patients or human research subjects treated with implants.

(a) Immediately after implanting sources in a patient or a human research subject, the licensee shall make a radiation survey of the patient or the human research subject and the adjacent area of use to confirm that no sources have been misplaced.

(b) 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.

(c) A licensee shall retain a record of patient or human research subject surveys in accordance with § 35.2404.

§ 35.406 Brachytherapy sources inventory.

(a) A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.

(b) Promptly after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

(c) A licensee shall maintain a record of the brachytherapy source accountability in accordance with § 35.2406.

§ 35.410 Safety instruction.

In addition to the requirements of § 19.12 of this chapter,

(a) The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that are undergoing implant therapy and cannot be released in accordance with § 35.75. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include the --

(1) Size and appearance of the brachytherapy sources;

(2) Safe handling and shielding instructions;

(3) Patient or human research subject control;

(4) Visitor control, including both:

(I) Routine visitation of hospitalized individuals in accordance with § 20.1301(a)(1); and

(ii) Visitation authorized in accordance with § 20.1301(a)(3); and

(5) Notification of the authorized user and Radiation Safety Officer, or his or her designee, if the patient or the human research subject dies or has a medical emergency.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with § 35.2310.

§ 35.415 Safety precautions.

(a) For each patient or human research subject receiving brachytherapy and confined pursuant to § 35.75 of this part, a licensee shall --

(1) Not quarter the patient or the human research subject in the same room as an individual who is not receiving radiation therapy; and

(2) Visibly post the patient's or human research subject's room with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.

(b) A licensee shall have available, near each treatment room, emergency response equipment. The emergency response equipment must include, as applicable --

(1) A device to assist in placing the source(s) in the shielded position;

(2) A shielded source/applicator storage container;

(3) Remote handling tools; and

(4) Supplies necessary to surgically remove applicators or sources from a patient or human research subject treated internally with sealed sources.

(c) A licensee shall notify the authorized user and the Radiation Safety Officer, or his designee, as soon as possible, if the patient or human research subject has a medical emergency and, immediately, if the patient dies.

§ 35.432 Full calibration measurements of brachytherapy sources.

(a) A licensee authorized to use brachytherapy sources for medical use shall perform full calibration measurements on brachytherapy sources before the first medical use of the source or source/applicator configuration.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of --

(1) The output or activity within +/- 5 percent; and

(2) Source positioning accuracy within applicators.

(c) A licensee shall use the dosimetry system described in § 35.630(a) to measure the output or activity of the brachytherapy source.

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs or activities determined in paragraph (b) of this section for physical decay at intervals consistent with 1 percent physical decay.

(f) A licensee shall retain a record of each calibration in accordance with § 35.2432.

§ 35.490 Training for use of manual brachytherapy sources.

Except as provided in § 35.57, the licensee shall require the authorized user of a manual brachytherapy source for the uses listed in § 35.400 to be a physician who --

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been approved by the Commission; or

(b)(1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources consisting of both --

(I) 200 hours of didactic training in the following areas;

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity; and

(D) Radiation biology;

(ii) 500 hours of supervised practical experience, under the supervision of an authorized user at a medical institution, involving --

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Checking survey meters for proper operation;

(C) Preparing, implanting, and removing sealed sources;

(D) Maintaining running inventories of material on hand;

(E) Using administrative controls to prevent a medical event involving the use of byproduct material;

(F) Using emergency procedures to control byproduct material; and

(2) Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association or equivalent program approved by the NRC, and an additional two years of clinical experience under the supervision of an authorized user; and

(3) Has obtained written certification, signed by a preceptor authorized user, that the requirements in paragraphs (b)(1) and (2) of this section have been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently function as an authorized user of manual brachytherapy sources for the uses listed in § 35.400; and,

(4) Following completion of the requirements in paragraph (b)(1) and (2) of this section, has demonstrated sufficient knowledge in radiation safety commensurate with the use requested by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A of this part.

Subpart G--Sealed Sources for Diagnosis

§ 35.500 Use of sealed sources for diagnosis.

A licensee shall use only sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.

§ 35.590 Training for use of sealed sources for diagnosis.

Except as provided in § 35.57, the licensee shall require the authorized user of a diagnostic sealed source for the use in a device listed in § 35.500 to be a physician, dentist, or podiatrist who --

(a) Is certified by a speciality board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been approved by the Commission; or

(b) Has had 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device that includes --

(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.

Subpart H--Therapeutic Medical Devices

§ 35.600 Use of a sealed source in a device for therapeutic medical uses.

A licensee shall use sealed sources and devices for therapy as approved in the Sealed Source and Device Registry for medical use.

§ 35.604 Radiation surveys of patients and human research subjects treated with remote afterloaders.

(a) Before releasing a patient or a human research subject from licensee control, a licensee shall make a survey of the patient or the human research subject and the afterloader device 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.

(b) A licensee shall retain a record of patient or human research subject surveys in accordance with § 35.2404.

§ 35.605 Installation, maintenance, and repair.

(a) Only a person specifically licensed by the Commission or an Agreement State shall install, maintain, adjust, or repair a device that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the device or the source(s).

(b) Except for low dose-rate remote afterloader devices, 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 a device,

(c) For a low dose-rate remote afterloader device, only a person specifically licensed by the Commission or an Agreement State or an authorized medical physicist shall perform the functions listed in paragraph (b) of this section.

(d) A licensee shall retain a record of the installation, maintenance, and repair done on therapeutic medical devices in accordance with § 35.2605.

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

(a) A licensee shall develop, implement, and maintain written procedures for --

(1) Securing the device, the console, the console keys, and the treatment room when not in use or unattended;

(2) Except for low dose-rate remote afterloaders, ensuring that only the patient or the human research subject is in the treatment room before initiating treatment with the source(s), unless contraindicated, or after a door interlock interruption;

(3) Preventing dual operation of more than one radiation producing device in a treatment room if applicable; and

(4) 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. This procedure must include --

(I) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

(ii) Process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

(iii) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the device or console operates abnormally.

(b) A copy of the procedures required by § 35.610(a) must be physically located at the unit console.

(c) A licensee shall post instructions at the device console to inform the operator of --

(1) The location of the procedures required by § 35.610(a); and

(2) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the device or console unit or console operates abnormally.

(d) A licensee shall provide instruction and practice drills, initially and at least annually, in the procedures identified in paragraph (a) of this section and the operating procedures to all individuals who operate the device, as appropriate to the individual's assigned duties. A licensee shall ensure that operators receive refresher training in the operation of the unit and that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures.

(e) A licensee shall retain a record of individuals receiving instruction required by paragraph (b) of this section, in accordance with § 35.2310.

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

(a) A licensee shall control access to the treatment room by a door at each entrance.

(b) A licensee shall equip each entrance to the treatment room with an electrical interlock system that will --

(1) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

(2) Cause the sources to be shielded immediately when an entrance door is opened; and

(3) Prevent the primary beam of radiation from being turned on following an interlock interruption until all treatment room entrance doors are closed and the beam on-off control is reset at the console.

(c) A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

(d) Except for low-dose remote afterloaders, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

(e) 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.

(f) In addition to the requirements specified in paragraphs (a) through (e) of this section, a licensee shall --

(1) For low dose-rate remote afterloader devices, require --

(I) An authorized user or an authorized medical physicist to be physically present during the initiation of all patient treatments involving the device; and

(ii) An authorized medical physicist and an authorized user or a physician, who has been designated by the authorized user and who is a radiation oncology physician trained in emergency response for the device, to be immediately available during continuation of all patient treatments involving the device.

(2) For high dose-rate remote afterloader devices, require --

(I) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the device; and

(ii) An authorized medical physicist and an authorized user or a physician, who has been designated by the authorized user and who is a radiation oncology physician that has been trained in emergency response for the device, to be physically present during continuation of all patient treatments involving the device.

(3) For pulsed dose-rate remote afterloader devices, require --

(I) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the device; and

(ii) An authorized medical physicist and an authorized user or a physician, who has been designated by the authorized user and who is a radiation oncology physician that has been trained in emergency response for the device, to be immediately available during continuation of all patient treatments involving the device.

(4) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

(g) The licensee shall have available, near each treatment room, emergency response equipment. The emergency response equipment must include, as applicable --

(1) A device to assist in placing the source(s) in the shielded position;

(2) A shielded source/applicator storage container;

(3) Remote handling tools; and

(4) Supplies necessary to surgically remove applicators or sources from a patient or human research subject treated internally with sealed sources**.**

§ 35.630 Dosimetry equipment.

(a) A licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met.

(1) The system must have been calibrated using a source traceable to the National Institute of Standards and Technology and published protocols approved by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous 2 years and after any servicing that may have affected system calibration; or

(2) The system must have been calibrated within the previous 4 years; 18 to 30 months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by the National Institute of Standards and Technology or by a calibration laboratory accredited by the AAPM. The results of the intercomparison must have indicated that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic devices, the licensee shall use a comparable device with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

(b) The licensee shall have available for use a dosimetry system for spot-check measurements. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with paragraph (a) of this section. 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 requirement in paragraph (a) of this section.

(c) The licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with § 35.2630.

§ 35.632 Full calibration measurements on teletherapy units.

(a) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit --

(1) Before the first medical use of the unit; and

(2) Before medical use under the following conditions:

(I) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) Following replacement of the source or following reinstallation of the teletherapy unit in a new location;

(iii) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding 1 year.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of --

(1) The output within +/-3 percent for the range of field sizes and for the distance or range of distances used for medical use;

(2) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(3) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(4) Timer constancy and linearity over the range of use;

(5) On-off error; and

(6) The accuracy of all distance measuring and localization devices in medical use.

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

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols approved by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section for physical decay for intervals not exceeding 1 month for cobalt-60, 6 months for cesium-137, or at intervals consistent with 1 percent decay for all other nuclides.

(f) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (e) of this section must be performed by the authorized medical physicist.

(g) A licensee shall retain a record of each calibration in accordance with § 35.2632.

§ 35.633 Full calibration measurements on remote afterloaders.

(a) A licensee authorized to use a remote afterloader for medical use shall perform full calibration measurements on each unit --

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions:

(I) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

(iii) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding 120 days for high dose-rate and pulsed dose-rate remote afterloaders; and

(4) At intervals not exceeding 1 year for low dose-rate remote afterloaders.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of:

(1) The output within +/- 5 percent;

(2) Source positioning accuracy to within +/- 1 millimeter;

(3) Source retraction with backup battery upon power failure; and

(4) The operability of the electrically assisted treatment room doors with the high-dose rate remote afterloader unit electrical power turned off.

(c) In addition to the requirements for full calibrations for all remote afterloaders in paragraph (b) of this section, a licensee shall:

(1) For high dose-rate and pulsed dose-rate remote afterloaders, calibrate --

(I) At intervals not exceeding one quarter:

(A) The source guide tubes;

(B) Timer accuracy and linearity over the typical range of use; and

(C) Length of the connectors; and

(ii) Annually, the function of the source tube guides and connectors.

(2) For low dose-rate remote afterloaders, perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement and a spot check of the absolute timer accuracy at intervals not exceeding one quarter.

(d) A licensee shall use the dosimetry system described in § 35.630(a) to measure the output.

(e) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols approved by nationally recognized bodies.

(f) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section for physical decay at intervals consistent with 1 percent physical decay.

(g) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (f) of this section must be performed by the authorized medical physicist.

(h) A licensee shall retain a record of each calibration in accordance with § 35.2633.

§ 35.635 Full calibration measurements on gamma stereotactic radiosurgery units.

(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit --

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions --

(I) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

(iii) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

(3) At intervals not exceeding 1 year.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of --

(1) The output within +/-3 percent;

(2) Relative helmet factors;

(3) Isocenter coincidence;

(4) Timer accuracy and linearity over the range of use;

(5) On-off error; and

(6) Trunnion centricity.

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

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols approved by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

(f) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (e) of this section must be performed by the authorized medical physicist.

(g) A licensee shall retain a record of each calibration in accordance with § 35.2635.

§ 35.642 Periodic spot-checks for teletherapy units.

(a) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination
of --

(1) Timer constancy, and timer linearity over the range of use;

(2) On-off error;

(3) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(4) The accuracy of all distance measuring and localization devices used for medical use;

(5) The output for one typical set of operating conditions measured with the dosimetry system described in § 35.630(b) and

(6) The difference between the measurement made in paragraph (b)(5) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

(b) A licensee shall perform measurements required by paragraph (a) of this section in accordance with procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(c) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall promptly notify the licensee in writing of the results of each spot-check.

(d) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of --

(1) Electrical interlocks at each teletherapy room entrance;

(2) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);

(3) Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

(4) Viewing and intercom systems;

(5) Treatment room doors from inside and outside the treatment room; and

(6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(e) If the results of the checks required in paragraph (d) of this section 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.

(f) A licensee shall retain a record of each spot-check required by paragraphs (a) and (d), in accordance with § 35.2642

§ 35.643 Periodic spot-checks for high dose-rate and pulsed dose-rate remote afterloaders.

(a) A licensee authorized to use high dose-rate or pulsed dose-rate remote afterloaders for medical use shall perform spot-checks on each unit:

(1) At the beginning of each week of use;

(2) At the beginning of each day of use; and.

(3) After each source installation.

(b) The licensee shall have the authorized medical physicist:

(1) Establish written procedures for performing the spot-checks required in paragraph (a) of this section; and

(2) Review the results of each spot-check required by paragraph (a)(1) of this section within 15 days of the check. The authorized medical physicist need not actually perform the spot-check measurements.

(c) To satisfy the requirements of paragraphs (a)(1) of this section, spot-checks must, at a minimum --

(1) Verify source positioning accuracy;

(2) Determine output with the dosimetry system described in § 35.630(b); and

(3) Calculate the difference between the measurement made in paragraph (c)(2) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration mathematically corrected for physical decay).

(d) To satisfy the requirements of paragraphs (a)(2) and (a)(3) of this section, spot-checks must, at a minimum, assure proper operation of --

(1) Electrical interlocks at each remote afterloader room entrance;

(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(3) Viewing and intercom systems;

(4) Emergency response equipment;

(5) Radiation monitors used to indicate the source position;

(6) Timer constancy; and

(7) Clock (date and time) in the unit's computer.

(e) In addition to the requirements for spot checks in paragraph (d), a licensee shall ensure overall proper operation of the unit by conducting a simulated cycle of treatment as part of the spot-checks.

(f) A licensee shall arrange for prompt repair of any system identified in paragraph (c) of this section that is not operating.

(g) If the results of the checks required in paragraph (d) of this section 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.

(h) A licensee shall retain a record of each check required by paragraphs (c) and (d) of this section in accordance with § 35.2643.

§ 35.644 Periodic spot-checks for low dose-rate remote afterloaders.

(a) A licensee authorized to use low dose-rate remote afterloaders for medical use shall perform spot-checks on each unit prior to each patient treatment and after each source installation that include proper operation of --

(1) Electrical interlocks at each remote afterloader room entrance;

(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(3) Viewing and intercom systems;

(4) Emergency response equipment;

(5) Radiation monitors used to indicate the source position;

(6) Timer constancy; and

(7) Clock (date and time) in the unit's computer.

(b) In addition to the requirements for spot checks in paragraph (a), a licensee shall ensure overall proper operation of the unit by conducting a simulated cycle of treatment as part of the spot-checks.

(c) The licensee shall have the authorized medical physicist --

(1) Establish written procedures for performing the spot-checks required in paragraph (a) of this section; and

(2) Review the results of each spot-check required by paragraph (a) of this section within 15 days of the check. The authorized medical physicist need not actually perform the spot-check measurements.

(d) If the results of the checks required in paragraph (a) of this section 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.

(e) A licensee shall retain a record of each check required by paragraph (a) of this section in accordance with § 35.2643.

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

(a) A licensee authorized to use gamma stereotactic radiosurgery units for medical use shall perform spot-checks on each unit --

(1) Monthly,

(2) At the beginning of each day of use, and

(3) After each source installation.

(b) The licensee shall have the authorized medical physicist --

(1) Establish written procedures for performing the spot-checks required in paragraph (a) of this section; and

(2) Review the results of each spot-check required by paragraph (a)(1) of this section within 15 days of the check. The authorized medical physicist need not actually perform the spot-check measurements.

(c) To satisfy the requirements of paragraph (a)(1) of this section, spot-checks must, at a minimum --

(1) Assure proper operation of --

(I) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(ii) Helmet microswitchs;

(iii) Emergency timing circuits;

(iv) Emergency off buttons; and

(v) Stereotactic frames and localizing devices (trunnions).

(2) Determine --

(I) The output for one typical set of operating conditions measured with the dosimetry system described in § 35.630(b);

(ii) The difference between the measurement made in paragraph (c)(2)(I) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);

(iii) Source output against computer calculation;

(iv) Timer accuracy and linearity over the range of use;

(v) On-off error; and

(vi) Trunnion centricity.

(d) To satisfy the requirements of paragraphs (a)(2) and (a)(3) of this section, spot-checks must assure proper operation of --

(1) Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

(2) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

(3) Viewing and intercom systems;

(4) Timer termination;

(5) Radiation monitors used to indicate room exposures; and

(6) Hydraulic cutoff mechanism (if applicable).

(e) A licensee shall arrange for prompt repair of any system identified in paragraph (c) of this section that is not operating properly.

(f) If the results of the checks required in paragraph (d) of this section 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.

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

§ 35.647 Additional technical requirements for mobile remote afterloaders.

(a) A licensee providing mobile remote afterloader service shall --

(1) Check survey instruments before medical use at each address of use or on each day of use, which ever is more frequent; and

(2) Account for all sources before departure from a client's address of use.

(b) In addition to the periodic spot-checks required by § 35.643, a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader before each address of use. At a minimum, checks must be made to verify the operation of --

(1) Electrical interlocks on treatment area access points;

(2) Source exposure indicator lights on the remote afterloader, on the control console, and in the facility;

(3) Viewing and intercom systems;

(4) Applicators and connectors;

(5) Radiation monitors used to indicate room exposures;

(6) Source positioning (accuracy); and

(7) Radiation monitors used to indicate whether the source has returned to a safe shielded position.

(c) In addition to the requirements for checks in paragraph (b), a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

(d) A licensee shall arrange for prompt repair of any system identified in paragraph (b) of this section that is not operating properly.

(e) A licensee shall retain a record of each check required by paragraph (b) of this section in accordance with § 35.2647.

§ 35.652 Radiation surveys.

(a) In addition to the survey requirement in § 20.1501 of this chapter, a licensee shall make such surveys as defined in the Sealed Source and Device Registry to assure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position does not exceed the levels stated in the Registry.

(b) The licensee shall make the survey required by paragraph (a) of this section at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the device or the source(s).

(c) A licensee shall retain a record of the radiation surveys required by paragraph (a) of this section in accordance with § 35.2652.

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

(a) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(b) This inspection and servicing may only be performed by persons specifically licensed to do so by the Commission or an Agreement State.

(c) A licensee shall keep a record of the inspection and servicing in accordance with § 35.2655.

§ 35.657 Therapy-related computer systems.

The licensee shall:

(a) Verify that the computerized operating system and treatment planning system associated with the therapy device are operating appropriately; and

(b) Perform acceptance testing on the treatment planning system in accordance with published protocols approved by nationally recognized bodies.

§ 35.690 Training for use of therapeutic medical devices.

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 --

(a) Is certified by a specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been approved by the Commission; or;

(b)(1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical device consisting of both --

(I) 200 hours of didactic training in the following areas --

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity; and

(D) Radiation biology; and

(ii) 500 hours of supervised practical experience, under the supervision of an authorized user at a medical institution, involving --

(A) Review of the full calibration measurements and periodic spot checks;

(B) Preparing treatment plans and calculating treatment doses and times;

(C) Using administrative controls to prevent a medical event involving the use of byproduct material;

(D) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical device or console;

(E) Checking and using survey meters; and

(F) Selecting the proper dose and how it is to be administered; and

(2) Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association or equivalent program approved by the NRC and an additional two years of clinical experience under the supervision of an authorized user; and

(3) Has obtained written certification, signed by a preceptor authorized user, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently function as an authorized user of the therapeutic medical device for which the individual is requesting authorized user status; and

(4) Following completion of the requirements in paragraph (b)(1) and (2) of this section, has demonstrated sufficient knowledge in radiation safety commensurate with the use requested by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A of this part.

Subpart I- -Reserved

Subpart J--Training and Experience Requirements

§ 35.900 Radiation Safety Officer.

Except as provided in § 35.57, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in § 35.24 to be an individual who --

(a) Is certified by the --

(1) American Board of Health Physics in Comprehensive Health Physics;

(2) American Board of Radiology;

(3) American Board of Nuclear Medicine;

(4) American Board of Science in Nuclear Medicine;

(5) Board of Pharmaceutical Specialties in Nuclear Pharmacy;

(6) American Board of Medical Physics in radiation oncology physics;

(7) Royal College of Physicians and Surgeons of Canada in nuclear medicine;

(8) American Osteopathic Board of Radiology; or

(9) American Osteopathic Board of Nuclear Medicine; or

(b) Has had classroom and laboratory training and experience as follows --

(1) 200 hours of classroom and laboratory training that includes --

(I) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Radiation biology; and

(v) Radiopharmaceutical chemistry; and

(2) One year of full time experience as a radiation safety technologist at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on a Commission or Agreement State license that authorizes the medical use of byproduct material; or

(c) Be an authorized user identified on the licensee's license.

§ 35.910 Training for uptake, dilution, and excretion studies.

Except as provided in § 35.57, the licensee shall require the authorized user of a radiopharmaceutical in § 35.100(a) to be a physician who --

(a) Is certified in --

(1) Nuclear medicine by the American Board of Nuclear Medicine;

(2) Diagnostic radiology by the American Board of Radiology;

(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;

(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(5) American Osteopathic Board of Nuclear Medicine in nuclear medicine; or

(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, and supervised clinical experience as follows --

(1) 40 hours of classroom and laboratory training that includes --

(I) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Radiation biology; and

(v) Radiopharmaceutical chemistry; and

(2) 20 hours of supervised clinical experience under the supervision of an authorized user and that includes --

(I) Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

(ii) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

(iii) Administering dosages to patients or human research subjects and using syringe radiation shields;

(iv) Collaborating with the authorized user in the interpretation of radioisotope test results; and

(v) Patient or human research subject follow up; or

(c) Has successfully completed a 6-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section.

§ 35.920 Training for imaging and localization studies.

Except as provided in § 35.57, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit in § 35.200(a) to be a physician who --

(a) Is certified in --

(1) Nuclear medicine by the American Board of Nuclear Medicine;

(2) Diagnostic radiology by the American Board of Radiology;

(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;

(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(5) American Osteopathic Board of Nuclear Medicine in nuclear medicine; or

(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, supervised work experience, and supervised clinical experience as follows --

(1) 200 hours of classroom and laboratory training that includes --

(I) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Radiopharmaceutical chemistry; and

(v) Radiation biology; and

(2) 500 hours of supervised work experience under the supervision of an authorized user that includes --

(I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;

(iii) Calculating and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent the medical event of byproduct material;

(v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(vi) Eluting technetium-99m from generator systems, measuring and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and

(3) 500 hours of supervised clinical experience under the supervision of an authorized user that includes --

(I) Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

(ii) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

(iii) Administering dosages to patients or human research subjects and using syringe radiation shields;

(iv) Collaborating with the authorized user in the interpretation of radioisotope test results; and

(v) Patient or human research subject follow up; or

(c) Has successfully completed a 6-month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section.

§ 35.930 Training for therapeutic use of unsealed byproduct material.

Except as provided in § 35.57, the licensee shall require the authorized user of radiopharmaceuticals in § 35.300 to be a physician who --

(a) Is certified by --

(1) The American Board of Nuclear Medicine;

(2) The American Board of Radiology in radiology, therapeutic radiology, or radiation oncology;

(3) The Royal College of Physicians and Surgeons of Canada in nuclear medicine; or

(4) The American Osteopathic Board of Radiology after 1984; or

(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of therapeutic radiopharmaceuticals, and supervised clinical experience as follows --

(1) 80 hours of classroom and laboratory training that includes --

(I) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology; and

(2) Supervised clinical experience under the supervision of an authorized user at a medical institution that includes --

(I) Use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals; and

(ii) Use of iodine-131 for treatment of thyroid carcinoma in 3 individuals.

§ 35.932 Training for treatment of hyperthyroidism.

Except as provided in § 35.57, 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 as follows --

(a) 80 hours of classroom and laboratory training that includes --

(1) Radiation physics and instrumentation;

(2) Radiation protection,

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology; and

(b) 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.

§ 35.934 Training for treatment of thyroid carcinoma.

Except as provided in § 35.57, 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 as follows --

(a) 80 hours of classroom and laboratory training that includes --

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology; and

(b) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for the treatment of thyroid carcinoma in 3 individuals.

§ 35.940 Training for use of brachytherapy sources.

Except as provided in § 35.57, the licensee shall require the authorized user of a brachytherapy source listed in § 35.400 for therapy to be a physician who --

(a) Is certified in --

(1) Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

(2) Radiation oncology by the American Osteopathic Board of Radiology;

(3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(b) Is in the active practice of therapeutic radiology, has had classroom and laboratory training in radioisotope handling techniques applicable to the therapeutic use of brachytherapy sources, supervised work experience, and supervised clinical experience as follows --

(1) 200 hours of classroom and laboratory training that includes --

(I) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology;

(2) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes --

(I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Checking survey meters for proper operation;

(iii) Preparing, implanting, and removing sealed sources;

(iv) Maintaining running inventories of material on hand;

(v) Using administrative controls to prevent a medical event involving byproduct material; and

(vi) Using emergency procedures to control byproduct material; and

(3) Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes --

(I) Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;

(ii) Selecting the proper brachytherapy sources and dose and method of administration;

(iii) Calculating the dose; and

(iv) Post-administration follow up and review of case histories in collaboration with the authorized user.

§ 35.941 Training for ophthalmic use of strontium-90.

Except as provided in § 35.57, the licensee shall require the authorized user of only strontium-90 for ophthalmic radiotherapy to be a physician who is in the active practice of therapeutic radiology or ophthalmology, and has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy as follows --

(a) 24 hours of classroom and laboratory training that includes --

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology;

(b) 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 --

(1) Examination of each individual to be treated;

(2) Calculation of the dose to be administered;

(3) Administration of the dose; and

(4) Follow up and review of each individual's case history.

§ 35.950 Training for use of sealed sources for diagnosis.

Except as provided in § 35.57, the licensee shall require the authorized user of a sealed source in a device listed in § 35.500 to be a physician, dentist, or podiatrist who --

(a) Is certified in --

(1) Radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

(2) Nuclear medicine by the American Board of Nuclear Medicine;

(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(b) Has had 8 hours of classroom and laboratory training in basic radioisotope handling techniques specifically applicable to the use of the device that includes --

(1) Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;

(2) Radiation biology;

(3) Radiation protection; and

(4) Training in the use of the device for the uses requested.

§ 35.960 Training for use of therapeutic medical devices.

Except as provided in § 35.57, the licensee shall require the authorized user of a sealed source listed in § 35.600 to be a physician who --

(a) Is certified in --

(1) Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

(2) Radiation oncology by the American Osteopathic Board of Radiology;

(3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(b) Is in the active practice of therapeutic radiology, and has had classroom and laboratory training in basic radioisotope techniques applicable to the use of a sealed source in a therapeutic medical device, supervised work experience, and supervised clinical experience as follows --

(1) 200 hours of classroom and laboratory training that includes --

(I) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology;

(2) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes --

(I) Review of the full calibration measurements and periodic spot-checks;

(ii) Preparing treatment plans and calculating treatment times;

(iii) Using administrative controls to prevent medical events;

(iv) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical device or console; and

(v) Checking and using survey meters; and

(3) Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes --

(I) Examining individuals and reviewing their case histories to determine their suitability for teletherapy, remote afterloader, or gamma stereotactic radiosurgery treatment, and any limitations or contraindications;

(ii) Selecting the proper dose and how it is to be administered;

(iii) Calculating the doses and collaborating with the authorized user in the review of patients' or human research subjects' progress and consideration of the need to modify originally prescribed doses as warranted by patients' or human research subjects' reaction to radiation; and

(iv) Post-administration follow up and review of case histories.

§ 35.961 Training for authorized medical physicist.

The licensee shall require the authorized medical physicist to be an individual who --

(a) Is certified by the American Board of Radiology in --

(1) Therapeutic radiological physics;

(2) Roentgen ray and gamma ray physics;

(3) X-ray and radium physics; or

(4) Radiological physics; or

(b) Is certified by the American Board of Medical Physics in radiation oncology physics; or

(c) Holds a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and has completed 1 year of full time training in therapeutic radiological physics and an additional year of full time work experience under the supervision of a medical physicist at a medical institution that includes the tasks listed in §§ 35.67, 35.632, 35.633, 35.634, 35.635, 35.642, 35.643, 35.644, 35.645 and 35.652.

§ 35.980 Training for an authorized nuclear pharmacist.

The licensee shall require the authorized nuclear pharmacist to be a pharmacist who - -

(a) Has current board certification as a nuclear pharmacist by the Board of Pharmaceutical Specialties; or

(b)(1) Has completed 700 hours in a structured educational program consisting of both --

(I) Didactic training in the following areas:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Supervised experience in a nuclear pharmacy involving the following --

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(C) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(D) Using administrative controls to avoid mistakes in the administration of byproduct material;

(E) Using procedures to prevent or minimize contamination and using proper decontamination procedures; and

(2) Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

§ 35.981 Training for experienced nuclear pharmacists.

A licensee may apply for and must receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist. A pharmacist who has completed a structured educational program as specified in § 35.980(b)(1) before December 2, 1994, and who is working in a nuclear pharmacy would qualify as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with the requirements for a preceptor statement (§ 35.980(b)(2)) and recentness of training (§ 35.59) to qualify as an authorized nuclear pharmacist.

Subpart K--Other Medical Uses of Byproduct Material or Radiation from Byproduct Material

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

A licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of this part if --

(a) The applicant or licensee has submitted the information required by § 35.12(d); and

(b) The applicant or licensee has received written approval from the Commission in a license and uses the material in accordance with the regulations and specific conditions the Commission considers necessary for the medical use of the material.

Subpart L--Records

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

(a) A licensee shall retain a record of actions taken by the licensee's management in accordance with § 35.24(a) for 5 years. The record must include a summary of the actions taken and a signature of licensee management.

(b) The licensee shall retain a current copy of the authorities, duties and responsibilities of the radiation safety officer as required by § 35.24(d). The record must include the signature of the radiation safety officer and licensee management.

§ 35.2026 Records of radiation protection program safety changes.

A licensee shall retain a record of each radiation protection program change made in accordance with § 35.26(a) for 5 years. The record must include a copy of the old and new procedures; the effective date of the

change; and the signature of the radiation safety officer and the licensee management that reviewed and approved the change.

§ 35.2040 Records of written directives.

A licensee shall retain a copy of each written directive as required by § 35.40 for 3 years.

§ 35.2045 Records of medical events and precursor events.

A licensee shall retain a record of medical events and precursor events reported pursuant to §§ 35.3045 and 35.3046 for 3 years. The record must contain the licensee's name, names of all the individuals involved, the affected or potentially affected individual's social security number or other identification number if one has been assigned, a brief description of the medical event or precursor event, why it occurred, the effect on the individual, and the actions taken to prevent recurrence.

§ 35.2060 Records of instrument calibrations.

A licensee shall maintain a record of instrument calibrations required by §§ 35.60 and 35.62 for 3 years. The records must include --

(a) For constancy, the model and serial number of the instrument, the identity of the radionuclide contained in the check source, the date of the check, and the activity measured, and the name of the individual who performed the check;

(b) For accuracy, the model and serial number of the instrument, the model and serial number of each source used, the identity of the radionuclide contained in the source and its activity, the date of the test, and the results of the test, and the name of the individual who performed the test --

(c) For linearity, the model and serial number of the instrument, the calculated activities, the measured activities, and the date of the test, and the name of the individual who performed the test; and

(d) For geometric dependence, the model and serial number of the instrument, the configuration of the source measured, the activity measured for each volume measured, and the date of the test, and the name of the individual who performed the test.

§ 35.2061 Records of radiation survey instrument calibrations.

A licensee shall maintain a record of radiation survey instrument calibrations required by § 35.61 for 3 years. The record must include --

(a) A description of the calibration procedure; and

(b) The date of the calibration, a description of the source used and the certified exposure rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, and the name of the individual who performed the calibration.

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

(a) A licensee shall maintain a record of dosage determinations required by § 35.63 for 3 years.

(b) To satisfy this requirement, the record must contain the --

(1) Radionuclide, generic name, trade name, or abbreviation of the radiopharmaceutical, and its lot number;

(2) Patient's or human research subject's name, or identification number if one has been assigned;

(3) Prescribed dosage and activity of the dosage at the time of determination, or a notation that the total activity is less than 1.1 MBq (30 µCi);

(4) Date and time of the dosage determination; and

(5) Name of the individual who determined the dosage.

§ 35.2067 Records of possession of sealed sources and brachytherapy sources.

(a) A licensee shall retain records of leak tests required by § 35.67(b) for 3 years. The records must contain the model number, and serial number if one has been assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample, a description of the method used to measure each test sample, the date of the test, and the name of the individual who performed the test.

(b) A licensee shall retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by § 35.67(g) for 3 years. The inventory records must contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

§ 35.2070 Records of surveys for ambient radiation exposure rate.

A licensee shall retain a record of each survey required by § 35.70 for 3 years. The record must include the date of the survey, a plan of each area surveyed, the trigger level established for each area, the detected dose rate at several points in each area expressed in millirem per hour or the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters, the instrument used to make the survey or analyze the samples, and the name of the individual who performed the survey.

§ 35.2075 Records of the release of individuals containing radiopharmaceuticals or implants.

(a) A licensee shall retain records of the release of individuals containing pharmaceuticals or implants in accordance with § 35.75 for 3 years after the date of release.

(b) A licensee shall retain a record in accordance with § 35.2075(a) that describes the basis for authorizing the release of individuals 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 1 meter;

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

(4) Considering the shielding by tissue.

(c) A licensee shall retain a record that the instructions required by § 35.75(b) 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 5 mSv (0.5 rem).

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

(a) A licensee shall retain a copy of the letter(s) that permits the use of byproduct material at a client's address of use, in accordance with § 35.80(a)(1). This letter must clearly delineate the authority and responsibility of each entity and must be retained for 3 years after the last provision of service.

(b) A licensee shall retain the record of each survey required by § 35.80(a)(4) for 3 years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use expressed in millirem per hour, the instrument used to make the survey, and the name of the individual who performed the survey.

§ 35.2092 Records of waste disposal.

A licensee shall maintain records of the disposal of licensed materials made in accordance with § 35.92 for 3 years. The record must include the date of the disposal, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

§ 35.2204 Records of molybdenum-99 concentrations.

A licensee shall maintain a record of the molybdenum-99 concentration tests required by § 35.204(b) for 3 years. The record must include, for each measured elution of technetium-99m, the ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium, the time and date of the measurement, and the name of the individual who made the measurement.

§ 35.2310 Records of instruction and training.

A licensee shall maintain a record of instructions and training required by §§ 35.310, 35.410, and 35.610 for 3 years. The record must include a list of the topics covered, the date of the instruction or training, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

§ 35.2404 Records of radiation surveys of patients and human research subjects.

A licensee shall maintain a record of the radiation surveys of patients and human research subjects required by §§ 35.404 and 35.604 for 3 years. Each record must include the date, location, and results of the survey, an identifier for the patient or the human research subject, the survey instrument used, and the name of the individual who made the survey.

§ 35.2406 Records of brachytherapy source inventory.

(a) A licensee shall maintain a record of brachytherapy source accountability required by § 35.406 for 3 years.

(b) For temporary implants, the record must include --

(1) The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use; and

(2) The number and activity of sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them from storage.

(c) For permanent implants, the record must include --

(1) The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;

(2) The number and activity of sources returned to storage, the date they were returned to storage, and the name of the individual who returned them to storage; and

(3) The number and activity of sources permanently implanted in the patient or human research subject.

§ 35.2432 Records of full calibrations on brachytherapy sources.

A licensee shall maintain a record of the full calibrations on brachytherapy sources required by § 35.432 for 3 years after the last use of the source. The record must include the date of the calibration; the manufacturer's name, model number, and serial number for the source and instruments used to calibrate the source; the source output; source positioning accuracy within applicators; and the signature of the authorized medical physicist.

§ 35.2605 Records of installation, maintenance, and repair.

A licensee shall retain a record of the installation, maintenance, and repair of therapeutic medical devices as required by § 35.605 for 3 years. For each installation, maintenance, and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work.

§ 35.2630 Records of dosimetry equipment.

(a) A licensee shall 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. (b) For each calibration, intercomparison, or comparison, the record must include --

(1) The date;

(2) The model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by paragraphs (a) and (b) of § 35.630;

(3) The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

(4) The names of the individuals who performed the calibration, intercomparison, or comparison.

§ 35.2632 Records of teletherapy full calibrations.

(a) A licensee shall maintain a record of the teletherapy full calibrations required by § 35.632 for 3 years.

(b) The record must include --

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number for the teletherapy unit, source, and instruments used to calibrate the teletherapy unit;

(3) Tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy;

(4) A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

(5) An assessment of timer accuracy and linearity;

(6) The calculated on-off error;

(7) The estimated accuracy of each distance measuring and localization device; and

(8) The signature of the authorized medical physicist who performed the full calibration.

§ 35.2633 Records of remote afterloader full calibrations.

(a) A licensee shall maintain a record of the remote afterloader full calibrations required by § 35.633 for 3 years.

(b) The record must include--

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number for the remote afterloader, source, and instruments used to calibrate the unit; the source output;

(3) An assessment of timer accuracy and linearity, source positioning accuracy, source guide tube and connector lengths, and source retraction functionality; and

(4) The signature of the authorized medical physicist who performed the full calibration.

§ 35.2635 Records of gamma stereotactic radiosurgery unit full calibrations.

(a) A licensee shall maintain a record of the gamma stereotactic radiosurgery full calibrations required by § 35.635 for 3 years.

(b) The record must include --

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit, source, and instruments used to calibrate the unit;

(3) The unit output;

(4) An assessment of the relative helmet factors, isocenter coincidence, timer accuracy and linearity, on-off error, and trunnion centricity; and

(5) The signature of the authorized medical physicist who performed the full calibration..

§ 35.2642 Records of periodic spot-checks for teletherapy units.

(a) A licensee shall retain a record of each periodic spot-check for teletherapy units required by § 35.642 for 3 years.

(b) The record must include --

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number for the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;

(3) An assessment of timer linearity and constancy;

(4) The calculated on-off error;

(5) A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

(6) The determined accuracy of each distance measuring and localization device;

(7) The difference between the anticipated output and the measured output;

(8) Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and

(9) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

§ 35.2643 Records of periodic spot-checks for remote afterloaders.

(a) A licensee shall retain a record of each spot-check for remote afterloaders required by §§ 35.643 and 35.644 for 3 years.

(b) The record must include --

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number for the remote afterloader, source, and instrument used to measure the output of the remote afterloader;

(3) The difference between the anticipated output and the measured output;

(4) Notations indicating the operability of each entrance door electrical interlock, source retraction mechanism, radiation monitors, source exposure indicator lights, viewing and intercom, applicators and connectors, and source positioning accuracy; and

(5) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

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

(a) A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by § 35.645 for 3 years.

(b) The record must include --

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

(3) The measured source output and source output against computer calculations;

(4) Notations indicating the operability of radiation monitors, helmet microswitchs, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination systems, hydraulic cutoff switch and stereotactic frames and localizing devices (trunnions); and

(5) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

§ 35.2647 Records of additional technical requirements for mobile remote afterloaders.

(a) A licensee shall retain a record of each check for mobile remote afterloaders required by § 35.647 for 3 years.

(b) The record must include --

(1) The date of the check;

(2) The manufacturer's name, model number, and serial number of the remote afterloader;

(3) Notations accounting for all sources before the licensee departs from a facility;

(4) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators and connectors, and source positioning accuracy; and

(5) The signature of the individual who performed the check.

§ 35.2652 Records of surveys of therapeutic treatment units.

(a) A licensee shall maintain a record of radiation surveys of treatment units made in accordance with § 35.652 for the duration of use of the unit.

(b) The record must include --

(1) The date of the measurements;

(2) The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;

(3) Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

(4) The signature of the individual who performed the test.

§ 35.2655 Records of 5-year inspection for teletherapy and gamma stereotactic surgery units.

(a) A licensee shall maintain a record of the 5-year inspections for teletherapy and gamma stereotactic radiosurgery units required by § 35.655 for the duration of use of the unit.

(b) The record must contain --

(1) The inspector's radioactive materials license number;

(2) The date of inspection;

(3) The manufacturer's name and model number and serial number of both the treatment unit and source;

(4) A list of components inspected and serviced, and the type of service; and

(5) The signature of the inspector.

Subpart M--Reports

§ 35.3045 Reports of medical events.

(a) A licensee shall report any administration, except for administrations resulting from a direct intervention of a patient or human research subject that could not have been reasonably prevented by the licensee, that results in either --

(1) A dose that differs from the prescribed dose by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

(i) The total dose or dosage delivered differs from the prescribed dose or dosage by 20 percent or more; or

(ii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

(2) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following --

(I) An administration of a wrong pharmaceutical;

(ii) An administration of a radiopharmaceutical by the wrong route of administration; (iii) An administration of a dose or dosage to the wrong individual or human research subject;

(iv) An administration of a dose or dosage delivered by the wrong treatment mode; or (v) A leaking sealed source.

(3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 20 percent the dose expected from the administration defined in the written directive.

(b) The licensee shall notify by telephone the NRC Operations Center[4] no later than the next calendar day after discovery of the medical event .

(c) The licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter within 15 days after discovery of the medical event.

(1) The written report must include --

[4] The commercial telephone number of the NRC Operations Center is (301) 951-0550.

(I) The licensee's name;

(ii) The name of the prescribing physician;

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) The effect on the individual(s) who received the administration;

(vi) What improvements are needed to prevent recurrence;

(vii) Actions taken to prevent recurrence;

(viii) Whether the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not; and

(ix) If there was notification, what information was provided.

(2) The report may not contain the individual's name or any other information that could lead to identification of the individual.

(d) The licensee shall notify the referring physician and also notify the individual affected by the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgement, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this section, the notification of the individual receiving the medical event may be made instead to that individual’s responsible relative or guardian, when appropriate.

(e) If the individual was notified pursuant to paragraph (d) of this section, the licensee shall also furnish, within 15 days after discovery of the medical event, a written report to the individual by sending either --

(1) A copy of the report that was submitted to the NRC; or

(2) A brief description of both the event and the consequences as they may affect the individual, provided a statement is included that the report submitted to the NRC can be obtained from the licensee.

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

§ 35.3046 Reports of precursor events.

(a) A licensee shall notify by telephone the NRC Operations Center[5] no later than the next calendar day after identifying any defects, exclusive of ordinary equipment failures, in equipment (hardware and/or software), byproduct material, or procedures supplied by a manufacturer or vendor that, in the opinion of the radiation safety officer or authorized user, could lead to a medical event.

(b) The licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 within 15 days after discovery of the precursor event. The written report must include the licensee's name; a brief description of the event; why the event occurred; what improvements are needed to prevent recurrence; and actions taken to prevent recurrence.

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

(a) A licensee shall report any dose to an embryo/fetus that is greater than 5 mSv (500 mrem) absorbed dose that is a result of an administration of byproduct material or radiation from byproduct material to a pregnant woman unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

(b) A licensee shall report any dose to a nursing child that is greater than 5 mSv (500 mrem) total effective dose equivalent that is a result of an administration of byproduct material to a breast feeding woman.

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[5] The commercial telephone number of the NRC Operations Center is (301) 951-0550.

(c) A licensee shall notify by telephone the NRC Operations Center within 5 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in paragraphs (a) or (b) in this section.

(d) A licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 no later than 30 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in paragraphs (a) or (b) in this section.

(1) The written report must include --

(I) The licensee's name;

(ii) The name of the prescribing physician ;

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) The effect on the individual(s) who received the administration;

(vi) What improvements are needed to prevent recurrence; and

(vii) Actions taken to prevent recurrence.

(2) The report may not contain the individual's name or any other information that could lead to identification of the individual.

§ 35.3067 Reports of leaking sources.

A licensee shall file a report within 5 days if a leakage test required by § 35.67 reveals the presence of 185 Bq (0.005 µCi) or more of removable contamination. The report must be filed with the appropriate NRC Regional Office listed in § 30.6 of this chapter, with a copy to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The written report must include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the measured activity of each test sample expressed in microcuries; a description of the method used to measure each test sample; the date of the test; and the action taken.

Subpart N--Enforcement

§ 35.4001 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of--

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under Section 234 of the Atomic Energy Act:

(1) For violations of--

(I) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(I) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(I) of this section.

(2) For any violation for which a license may be revoked under Section 186 of the Atomic Energy Act of 1954, as amended.

§ 35.4002 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or

161o of the Act. For purposes of Section 223, all the regulations in 10 CFR Part 35 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in 10 CFR Part 35 that are not issued under subsections 161b, 161i, or 161o for the purposes of Section 223 are as follows: §§ 35.1, 35.2, 35.7, 35.8, 35.12, 35.15, 35.18, 35.19, 35.65, 35.100, 35.200, 35.300, 35.600, 35.4001, and 35.4002 .

Appendix A to 10 CFR Part 35--Examining Organization or Entity

I. Requirements for an examining organization or entity.

An independent organization or entity that submits an application for approval of the Commission to examine individuals pursuant to §§ 35.50(b)(3), 35.51(b)(3), 35.55(b)(3), 35.290(b)(3), 35.292(b)(3), 35.390(b)(4), 35.490(b)(4), or 35.690(b)(4) shall:

1. Make its examination process available to the general public nationwide and ensure that it is not restricted because of race, color, religion, sex, age, national origin, or disability;

2. Have an adequate staff, a viable system for financing its operations, and a policy-and decision-making review board;

3. Have a set of written organizational by-laws and policies that provide adequate assurance of lack of conflict of interest and a system for monitoring and enforcing those by-laws and policies;

4. Have a committee, whose members can carry out their responsibilities impartially, to review and approve the examination guidelines and procedures, and to advise the organization's staff in implementing the examination program;

5. Have a committee, whose members can carry out their responsibilities impartially, to review complaints by examined individuals;

6. Have written procedures describing all aspects of its examination program, maintain records of the current status of each individual's examination and the administration of its examination program;

7. Have procedures to ensure that examinations are not given to individuals who have also been instructed by the examining organization in the same subject area;

8. Have procedures to ensure that examined individuals are provided due process with respect to the administration of its examination program, including the process of being examined;

9. Have procedures for proctoring examinations, including qualifications for proctors.

10. Exchange information about examined individuals with the Commission and other independent examining organizations and/or Agreement States and allow periodic review of its examination program and related records;

11. Provide a description to the Commission of its procedures for choosing examination sites and for providing an appropriate examination environment; and

12. Submit its request to the Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

II. Requirements for Examination Programs.

All examination programs must --

1. Require applicants for examination to receive training in the topics set forth in §§ 35.50(b)(1), 35.51(b)(1), 35.55(b)(1), 35.290(b)(1), 35.292(b)(1), 35.390(b)(1), 35.490(b)(1) or 35.690(b)(1), or equivalent Agreement State regulations, and satisfactorily complete a written examination covering these topics; and

2. Include procedures to ensure that all examination questions are protected from improper disclosure.

III. Requirements for Written Examinations.

1. All examinations must be designed to test an individual's knowledge and understanding of the topics listed in §§ 35.50(b)(1), 35.51(b)(1), 35.55(b)(1), 35.290(b)(1), 35.292(b)(1), 35.390(b)(1), 35.490(b)(1) or 35.690(b)(1), or equivalent Agreement State regulations;

2. Test questions must be drawn from a question bank containing psychometrically valid questions based on the material in §§ 35.50(b)(1), 35.51(b)(1), 35.55(b)(1), 35.290(b)(1), 35.292(b)(1), 35.390(b)(1), 35.490(b)(1) or 35.690(b)(1), or equivalent Agreement State regulations; and

3. Sample examinations must be submitted to the Commission for review initially and every 5 years.

Dated at Rockville, Maryland, this ____ day of _____, 1998.

For the Nuclear Regulatory Commission.

_____
John C. Hoyle,
Secretary of the Commission.

APPENDIX A

Preliminary Regulatory Flexibility Analysis

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

An assessment of small entity impacts involves three major tasks: (1) defining “small entities” for the rule being analyzed, including “small businesses,” “small governments,” and “small organizations;” (2) determining what number constitutes a “substantial number” of these entities; and (3) determining if “significant impacts” will be incurred by licensees under the proposed rule.

1.1 Defining “Small Entities” Affected by the Rule

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

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

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

For purposes of this analysis, therefore, "small entity" refers to any specific licensee under 10 CFR Part 35 with annual gross receipts of $5 million or less.

The proposed rule would affect 1902 NRC licensees. These licenses are issued principally to medical institutions, with at least 1216 of the Part 35 licensees classified as medical institutions (codes 2110, 2120, and 2121 in NRC's licensee tracking system). Review of available data indicates that at most 8 of these medical institutions had operating revenues of less than $5 million in 1996.

First, all hospitals in States in which Part 35 licensees are regulated by NRC were screened for revenues, using data obtained from Profiles of U.S. Hospitals, 1996, HCIA Inc. HCIA collects, analyzes, and publishes data on hospitals, based on financial submissions to the Health Care Financing Administration (HCFA). Revenues were measured as operating revenue, which is the sum of net patient revenue and other operating revenue, such as revenue from sources such as cafeterias and parking facilities, but which does not include revenue from non-operating sources such as investment income or donations. Operating revenue therefore is a less inclusive measure of revenues than gross revenues. All hospitals identified as having operating revenues less than $5 million then were checked against the NRC License Tracking System to identify those medical institutions that both had revenues less than $5 million and were regulated by NRC under Part 35. Of the eight institutions that were identified as meeting both criteria, three had operating revenues above $4.4 million, and therefore may have gross revenues above $5 million. They have, however, been included in the group of institutions with less than $5 million in revenues for this analysis.

The balance of the licenses, approximately 686 licenses, are issued principally to physicians in private practice. Information on gross revenues for such physicians suggests that all may be "small entities."

First, data from the AMA's Socioeconomic Monitoring System, provided in Physician Marketplace Statistics 1996: Profiles for Detailed Specialties, Selected States and Practice Arrangements, Center for Health Policy Research, American Medical Association, were reviewed for physicians' revenues or income. Table 89 of that source, which reports "Total Practice Revenue per Self-Employed Nonfederal Physician (in thousands of

dollars), 1995" indicates that even at the 75th percentile no physician specialty, geographic area, or practice arrangement exceeded even $1 million in revenues. Similar data from the Physician Compensation and Production Survey: 1996 Report Based on 1995 Data, Medical Group Management Association, indicate that the median for "production," defined as gross charges, for all physicians was $422,937 in 1995 (p. 10). Although "production" generally is larger for specialists than all physicians, the difference is too small to place specialists above the $5 million criterion.

In total, therefore, an upper bound estimate of 36 percent of Part 35 licensees, or approximately 686 licensees, may be "small entities."

1.2 Determining What Number Constitutes a Substantial Number

This analysis applied a figure corresponding to 20 percent of small entities in determining whether a “substantial number” of small entities are likely to be impacted by the rule. Therefore, based on the analysis in section 1.1, the proposed rule would affect a substantial number of small entities.

1.3 Measuring "Significant Impacts"

To evaluate the impact that a small entity is expected to incur as a result of the rule, the analysis should calculate the entity’s ratio of annualized compliance costs as a percentage of gross receipts. Entities are classified as facing potentially “significant” impacts if this ratio exceeds one percent.

Determining annual compliance costs for the revisions to Part 35, however, is complicated by the fact that the proposed rule would comprehensively address a wide variety of uses of byproduct materials in medicine. The

entities likely to be most affected by the rule are broad scope medical institutions with a large number of different modalities and conducting a large number of medical procedures involving byproduct material or radiation from byproduct material. However, the preceding analysis indicated that such broad scope licensees are not small entities. The costs attributable to Part 35 compliance for such broad scope licensees will be substantially greater than the annual compliance costs likely to be incurred by those licensees most likely to be small entities (i.e., single private practice physicians performing diagnostic procedures).

The Part 35 rule addresses contingent actions as well as actions that must be carried out by all licensees. In particular, the lower risk posed by diagnostic procedures reduces the likelihood that private practice physicians performing diagnostic procedures will experience medical events or precursor events involving costs of reporting and follow up.

All licensees will incur annual compliance costs for general administrative and technical requirements established by Part 35, although the level of such compliance costs will vary significantly depending on certain contingencies and on the activities being performed by the licensee. Annual compliance costs for licensees are expected, in all cases, to involve compliance with requirements to establish and maintain a radiation protection program;
possess, use, calibrate, and check survey instruments, and satisfy the requirements pertinent to the modality or modalities used by the licensee.

NRC estimates that annual compliance costs for a licensee carrying out any level of activities under Part 35 will in all cases exceed 80 hours annually at $100 per hour, or $8,000. Assuming annual revenues of $244,000 for a single private practitioner subject to Part 35, as estimated in Socioeconomic Characteristics of Medical Practice, 1997, American Medical Association, Center for Health Policy Research, Table 43. "Mean Physician Net Income (in thousands of dollars) after Expenses before Taxes, 1995," for the net income for "all

physicians-rad," a very conservative surrogate for gross revenues, these annual compliance costs exceed both the one percent cutoff level and the three percent cutoff level under SBREFA for "significant impacts." Assuming an average "production" of $423,000, (Section 1.1 of this analysis), however, the 1 percent but not the 3 percent cutoff is exceeded. Therefore, the proposed rule appears to have significant impacts on a significant number of licensees.

NRC has taken a number of actions in this proposed rule to ensure that the proposed alternative is the least costly alternative that adequately protects workers and patients from radiation exposure. As the Regulatory Analysis prepared for the proposed rule demonstrates, the total annual cost to licensees of compliance with the proposed rule would be approximately $6 million less than the cost of compliance with the current rule (See XII. Regulatory Analysis of the Supplementary Information section of this document). This is equivalent to savings of approximately $900 per licensee. Although savings to small licensees can be expected to be proportionately less than savings to licensees with more extensive operations, smaller licensees also can be expected to incur smaller compliance costs.

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

Finally, the program for revising Part 35 and the associated guidance documents has involved more interactions and consultations with potentially affected parties (the medical community and the public, including representatives of small licensees) than is provided by the typical notice and comment rulemaking process. Early public input was solicited through several different mechanisms: requesting public input through Federal Register notices; holding open meetings of the government groups developing the revised rule language; meeting with medical professional societies and boards; putting background documents, options for the more significant regulatory issues associated with the rulemaking, and a "strawman" draft proposed rule on the Internet; and convening public workshops. Participants from the broad spectrum of interests that may be affected by the rulemaking were invited to attend the public workshops in Philadelphia, PA., and Chicago, IL., held in October and November 1997. The public was also welcome to attend these workshops, as well as the Part 35 Workshop that was held in conjunction with the All Agreement States Meeting in October 1997, and the NRC's Advisory Committee on the Medical Uses of Isotopes meetings in September 1997 and March 1998.

As indicated in the Regulatory Flexibility Analysis statement included in the proposed rule, the NRC requests comments from small medical licensees concerning the impacts of the proposed rule and any suggested modifications that may affect the economic impact of the proposed requirements.

March 20, 1998 SECY-98-054

FOR: The Commissioners

FROM: L. Joseph Callan /s/

Executive Director for Operations

SUBJECT: COMMISSION RESOLUTION OF SIGNIFICANT ISSUES ASSOCIATED WITH THE REVISION OF 10 CFR PART 35, "MEDICAL USES OF BYPRODUCT MATERIAL"

PURPOSE:

To obtain Commission direction on: (1) retaining the current requirement for medical use licensees to notify individuals and referring physicians of a medical event,[6] pursuant to 10 CFR 35.33(a)(3) and (a)(4); and (2) capturing precursor events.

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[6] The Part 35 Working Group has replaced the term "misadministration" with "medical event," based on SRM - COMSECY-96-057, "Materials/Medical Oversight (DSI-7)," March 20, 1997 (Attachment 1), in which the Commission said the staff should consider ". . . changing the nomenclature from 'misadministration' to 'medical event' or comparable terminology." However, in historical discussions, the term "misadministration" is still used.

CONTACTS: Catherine Haney, NMSS/IMNS
(301) 415-6825

Marjorie Rothschild, OGC
(301) 415-1633

CATEGORY:

This paper addresses significant rulemaking issues requiring Commission consideration and approval.

CONTACTS: Catherine Haney, NMSS/IMNS
(301) 415-6825

Marjorie Rothschild, OGC
(301) 415-1633

BACKGROUND:

The Commission, in its Staff Requirements Memorandum (SRM) of June 30, 1997, SECY-97-115, "Program for Revision of 10 CFR Part 35, 'Medical Uses of Byproduct Material' and Associated Federal Register Notice," approved the staff's proposed plan for the revision of 10 CFR Part 35 (Attachment 2). The staff implemented that plan by establishing a U.S. Nuclear Regulatory Commission Working Group and Steering Group, and by actively soliciting input from the public, the medical professional societies, States, and the Advisory Committee on the Medical Uses of Isotopes (ACMUI). The staff has benefitted from these interactions with the regulated community and the public and has received many useful comments.

The Working Group considered the input from the public and the medical community in developing the "strawman" revision of the Part 35 rule that was placed on the INTERNET and in the Public Document Room on January 30, 1998. That "strawman" revision included: (1) the current requirements for notifying NRC, referring physicians, and individuals of medical events, because of the controversy associated with individual (patient) notification; and (2) a proposed definition of a "significant precursor" (and related recordkeeping and reporting requirements).

DISCUSSION:

Notification Following a Medical Event

CONTACTS: Catherine Haney, NMSS/IMNS
(301) 415-6825

Marjorie Rothschild, OGC
(301) 415-1633

The current regulations in 10 CFR 35.33(a) and (b) require, in part, that NRC medical use licensees inform NRC, the referring physician, and the individual receiving the misadministration (medical event) within 24 hours of 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 would be harmful. Background information on 10 CFR 35.33(a) and (b) is presented in Attachment 3.

Staff is not requesting guidance on whether licensees should notify NRC of a medical event. Staff and licensees recognize that this notification is needed, at a minimum, for NRC to comply with Section 208 of the Energy Reorganization Act for reporting "Abnormal Occurrences" to Congress. However, because of medical community and public comments, staff has been evaluating whether the current regulations should be revised to require notification of NRC only, or of NRC and the referring physician.

The majority of the comments received on notification following a medical event (including those of two "patient rights advocates"[7]), indicated that there should not be an NRC requirement for patient and/or referring physician notification in the case of a medical event. Individuals who do not favor patient notification assert that there are no other areas of medicine in which there is a Federal requirement for patient notification and that an NRC requirement for patient notification is contrary to the 1979 Medical Policy Statement. According to some of the ACMUI members and the NRC medical consultant advising the Working Group, patient notification of medical events should occur as part of the patient-physician "fiduciary" relationship, in which it is the "standard of care" for a physician to

[7] However, a patient's right advocate at the ACMUI meeting on March 2, 1998, expressed concern about the risk to the patient, if the patient or referring physician is not notified.

provide the patient with complete and accurate information.[8] Members of the medical community have pointed out that they view the "fiduciary" relationship between the patient and physician as different from that between a licensee and an individual receiving a dose in excess of the 10 CFR Part 20 limits. In addition, some members of the medical community particularly object to the requirement, in 10 CFR 35.33(a)(I)-(ii), for licensees to provide the informed individual with a copy of the licensee's report to the Commission (or a similar report), believing that the report greatly magnifies the significance of the event when, in fact, a medical event could be of minimal safety significance.

Although patient (and referring physician) notification of medical mistakes or events is the "standard of care," that practice may not be uniformly followed. Based on recent articles in a professional medical journal and the national news media (Attachment 5), the issue of whether physicians should notify patients of medical "events" is the subject of considerable debate and is not at all well-settled. Thus, reliance on physicians to follow either the "standard of care" or the AMA ethical standards,[3] may result in patients not receiving information necessary for their medical care.

Those opposing and those favoring retention of the requirement to notify the individual, referring physician and NRC agree that the issue is not whether patients should be notified of medical events. Rather, the issue is whether, in light of existing medical ethical and practice standards obligating physicians to make such notifications, NRC should retain the provisions in Part 35 requiring licensees to do so.[9]

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[8] A patient's right to receive information from physicians is an element of the patient-physician relationship and is also part of "informed consent," based on American Medical Association (AMA) "Principles of Medical Ethics." (See Attachment 4).

[9] If there is such a requirement, the Working Group/Steering Group agree that the rule should retain the provision permitting the referring physician to inform the patient and for the licensee not to notify the patient, if, based on medical judgment, telling the patient would be harmful. 10 CFR 35.33(a)(3).

Staff has identified three possible alternatives for notification of NRC, referring physician, and individuals, in the case of a medical event. Attachment 6 provides a detailed discussion of these alternatives.

Alternative 1: Retain the current reporting requirements in Part 35, with minor changes intended to clarify the term “responsible relative.”

Alternative 2: Revise the current reporting requirement to require a licensee to inform NRC and the referring physician (but not the patient) of the medical event.

Alternative 3: Revise the current reporting requirement to require a licensee to inform only NRC of a medical event.

On March 2, 1998, the ACMUI voted 8-0, with one abstention, in favor of notifying only NRC (Alternative 3).

Precursor Events

The Commission, in COMSECY- 96-057, directed staff to determine the best way to capture precursor events. Staff’s objectives in capturing precursor events are to identify and analyze incidents that could lead to medical events, significant errors, or systematic problems that could have health and safety implications at the licensee’s facility or at similar facilities.

Alternative pathways for capturing precursor events were discussed with the ACMUI at the September and March semi-annual meetings, and with the public during two facilitated public workshops (October and November 1997). In September 1997, the ACMUI recommended that NRC make reporting of precursor

events voluntary. Participants in the facilitated public workshops, as well as members of the public, believe that: (1) there are already adequate mechanisms in place for identifying precursor events; (2) additional NRC requirements for notification of precursor events could result in a significant financial burden for both NRC and licensees, without an associated incremental increase in safety; (3) because of the nature of precursor events, it will be hard to precisely define a precursor event in rule language; and (4) inclusion of a requirement for reporting of precursor events could lead to an additional basis for enforcement action.

Staff believes that identification and reporting of precursor events at some level is warranted, given that a "significant precursor" may have future implications for that facility or for similar facilities (generic incidents), and thus such reporting could lead to improved radiation safety programs at licensed facilities. Therefore, staff identified three possible alternatives for capturing precursor events. Attachment 7 provides a detailed discussion of these alternatives.

Alternative 1: Revise Part 35 to require reporting of "significant precursors."

Alternative 2: Revise Part 35 to require reporting of deficiencies in equipment (hardware and/or software), byproduct material, or procedures supplied by a manufacturer or vendor that, in the opinion of the radiation safety officer, could lead to a medical event at that facility or could have detrimental health and safety implications beyond the licensee's facility.

Alternative 3: Rely on current NRC reporting requirements in 10 CFR Parts 20, 21, and 30, and the Memorandum of Understanding with the Food and Drug Administration and monitor/establish a system with U. S. Pharmacopeia to review its database.

On March 2, 1998, the ACMUI voted 8-0, with one abstention, in favor of Alternative 2.

RECOMMENDATIONS:

The staff is seeking Commission guidance on the preferred alternative for notification of individuals and referring physicians of a medical event. This guidance is necessary because of the sensitivity associated with medical event reporting, the differences of opinion that exist among the staff, patient right's advocates, and the regulated community, and the fact that this is a major policy issue.

Staff recommends that Alternative 2 be chosen as the preferred alternative for identification of precursor events because it: (1) clearly states the types of incidents and conditions that NRC needs to identify and analyze events and incidents that could lead to medical events, significant errors, or systematic problems that could have health and safety implications at the licensee's facility or at similar facilities; (2) requires licensees to submit reports of precursor events; and (3) should not significantly increase the regulatory burden on licensees and the NRC.

COORDINATION:

OGC reviewed this paper and has no legal objection. The Office of the Chief Information Officer has no objection to this paper. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections; resources to implement the rule will be considered in developing the FY 2000 budget.

L. Joseph Callan

Executive Director

for Operations

Attachments:

1. SRM-COMSECY-96-057, dtd 3/20/97
2. SRM-SECY-97-115, dtd 6/30/97
3. Background Info on 10 CFR 35.33(a) and (b)
4. AMA, "Code of Medical Ethics, Current Opinions with Annotations"
5. Journal and Media Articles
6. Notification Following a Medical Event
7. Precursor Events

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L. Joseph Callan

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5. Journal and Media Articles
6. Notification Following a Medical Event
7. Precursor Events

File in PDR: ____Yes ____No Pending SECY Review. *SEE PREVIOUS CONCURRENCE

CP/PROOFED/MARCH 10, 1998

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March 20, 1997

MEMORANDUM TO: L. Joseph Callan

Executive Director for Operations

FROM: John C. Hoyle, Secretary /s/

SUBJECT: STAFF REQUIREMENTS - COMSECY-96-057 MATERIALS/MEDICAL OVERSIGHT (DSI 7)

With respect to the overall materials program, the Commission continues to support its preliminary views on this issue which were a combination of two options -- Continue the Ongoing Program with Improvements (Option 2) and Decrease Oversight of Low-Risk Activities with Continued Emphasis in High-Risk Activities (Option 3). For the longer term, the Commission also believes that consideration should be given to broadening NRC's regulatory oversight to include one or more of the higher-risk activities identified in Option 1.

With respect to the medical program, the Commission was not persuaded by the National Academy of Sciences, Institute of Medicine (IOM) report that recommends that NRC should not be the Federal agency involved in the regulation of ionizing radiation in medicine. The Commission continues to believe that the conclusions in the report were not substantiated and that the recommendations should not be pursued.

The Commission continues to support the use of ACMUI and professional medical organizations and societies in developing regulatory guides and standards as was proposed in the Commission's preliminary views. In the longer term, the Commission would be willing to consider taking on broader regulatory responsibilities for higher risk activities involving other sources of ionizing radiation but such efforts should not divert resources from the 10 CFR Part 35 rulemaking discussed below.

In lieu of a rulemaking plan in the context of Management Directive 6.3 the staff should submit a program for Commission approval for revising 10 CFR Part 35, and associated guidance documents, and the Commission's 1979 Medical Policy Statement, if necessary. The program should describe how 10 CFR Part 35 can be restructured into a risk-informed, more performance-based regulation by a suspense date of 6/30/99. In developing the program the staff should consider the following:

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

(2) For diagnostic procedures, staff should consider regulatory oversight alternatives consistent with the lower overall risk of these procedures.

(3) The staff should address how best to capture not only relevant safety-significant events, but also precursor events.

(4) Changing the nomenclature from "misadministration" to "medical event" or comparable terminology.

(5) Part 35 should be redesigned so that it can incorporate necessary regulatory requirements for new treatment modalities in a timely manner.

(6) The Quality Management Program provisions (10 CFR Part 35.32) should be re-evaluated and revised to focus on those requirements that are essential for patient safety, e.g., confirming patient identity, requiring written prescriptions and verifying dose. To the maximum extent possible, the requirements should be revised to be risk-informed. Given this objective, a mixed approach of performance-based rules and otherwise prescriptive regulations should be pursued.

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

(8) The staff should consider a rulemaking process that provides more opportunity for input from potentially affected parties than is provided by the normal notice and comment rulemaking process but would be less consumptive of resources and time than the process recently used in the development of NRC's rule on radiological criteria for license termination.

The staff's program to implement the above should be submitted to the Commission for its consideration no later than June 6, 1997. The program should target June 30, 1999 as the date for completing the rulemaking process. This rulemaking and associated guidance development is a very high priority for the Commission. The Commission is prepared to provide additional resources to the extent necessary to complete the rulemaking process on this schedule.

(EDO - Program) (SECY Suspense: 6/6/97)

(EDO - Complete Rulemaking) (SECY Suspense: 6/30/99)

cc: Chairman Jackson

Commissioner Rogers

Commissioner Dicus

Commissioner McGaffigan

Commissioner Diaz

K. Cyr

D. Rathbun

H. Bell

A. Galante

R. Scroggins

W. Beecher

June 30, 1997

MEMORANDUM TO: L. Joseph Callan

Executive Director for Operations

FROM: John C. Hoyle, Secretary /s/

SUBJECT: STAFF REQUIREMENTS - SECY-97-115 - PROGRAM FOR REVISION OF 10 CFR PART 35, "MEDICAL USES OF BYPRODUCT MATERIAL" AND ASSOCIATED FEDERAL REGISTER NOTICE

The Commission has approved the staff proposal to revise 10 CFR Part 35 consistent with the alternative program proposed in SECY-97-131 and subject to the following comments.

1. The staff should not only consider what regulations will be affected by the change to Part 35, but should also take a close look at existing guidance and draft guidance to determine what changes would be needed. To ensure that all regulatory rulemaking and guidance development potentially affecting medical uses will be consistent with the Commission's direction in DSI 7, the staff should identify in the public meetings and Federal Register notices all regulatory actions and proposed actions relating to or affecting Part 35 licensed activities. When appropriate, public comment should be invited.

2. The staff should continue to solicit input from members of the public to ensure, to the degree possible, that all interests are represented. The staff should include groups representing radiopharmacists and medical technologists, and other experts, as appropriate.

3. The staff should prepare alternatives with specific rule text to help focus the discussion during the first-round of facilitated meetings and assist the staff in developing draft rule language for publication and comment.

4. The staff should look for potential resource savings (FTE, consultants, and funds) that can be achieved through use of the internet, teleconferencing, etc. In making documents available over the internet, some caution should be exercised to ensure that the number of and versions of available documents for comment are not so large and varied that they will overwhelm commenters and lead to confusion on the part of the staff and management responsible for the rulemaking.

A Federal Register notice and press release should be issued reflecting the approach outlined in SECY-97-131, attachments 1 and 2, and published in time to support the facilitated public meetings.

(EDO) (SECY Suspense: 9/5/97)

cc: Chairman Jackson
Commissioner Rogers
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
OGC
CIO
CFO
OCA
OIG
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)
PDR
DCS

BACKGROUND INFORMATION ON 10 CFR 35.33(a) and (b)

The provision for notifying patients or the patient's "responsible relative" of a misadministration has been a feature of the misadministration rule since it was first proposed in 1973. "Medical Uses of Radioisotopes (Byproduct Material)," 38 Fed. Reg. 6399, 6400 (March 9, 1973). That proposed rule would have required medical use licensees to report to a patient (or responsible relative) a misadministration that could cause ". . . a demonstrably adverse effect, unless in the physician's professional judgment, such notification would be contrary to the best interests of the patient or a surviving relative of the patient." 38 Fed. Reg. 6400, 6401. No explicit explanation was provided in the Statements of Consideration (SOC) of the purpose of such a requirement. However, the Commission's discussion of an exception in 10 CFR Part 20 for intentional exposure of patients to radiation for medical purposes and Part 20 requirements for reporting radiation exposures to other individuals,[10] implied as a goal, achieving consistency between reporting requirements in Parts 35 and 20.[11] Specifically, the Commission cited former 10 CFR 20.107 (1973), which provided that nothing in the regulations in Part 20 ". . . shall be interpreted as limiting the intentional exposure of patients to radiation for the purpose of medical diagnosis or therapy." Based on former 10 CFR 20.107, notifications had not been required ". . . of incidents involving the exposure of patients to radiation if the patient were receiving any intentional medical exposure." 38 Fed. Reg. 6399-6400. According to the Commission, since the incidents involving medical exposure that had been brought to its attention ". . . generally involved accidental or erroneous exposures of patients to radiation in amounts or forms other than intended, it does not seem appropriate to continue . . . not requiring reports of such misadministrations to patients." 38 Fed. Reg. 6400.

The Commission withdrew the 1973 proposed rule in 1978 (citing as a reason the passage of a five-year period) and proposed new misadministration record keeping and reporting requirements. It changed, without explanation, the threshold for reporting a diagnostic misadministration to NRC, to the patient's referring physician, and the patient's responsible relative. "Human Uses of Byproduct Material, Misadministration Reporting Requirements," 43 Fed. Reg. 29297 (May 7, 1978). The threshold of "a demonstrably adverse effect" became a "clinically detectable adverse effect." 43 Fed. Reg. at 29297-98. Noting that a purpose of the misadministration rule ". . . is to inform the patient or

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[10] 10 CFR 20.405(c) (1973) required that "Any exposure of an individual to radiation which is required to be reported to the Commission shall also be reported to the individual." This provision has been carried over in current 10 CFR 20.2205, "Reports to Individuals of exceeding dose limits," under which, when a licensee is required, pursuant to 10 CFR 20.2203, 2204, or 20.2206, to report the Commission any exposure of an identified occupationally exposed individual, or an identified member of the public, to radiation or radioactive material, the licensee shall also provide a copy of the report submitted to the Commission to the individual.

[11] 10 CFR 20.1002 states the scope of present Part 20 as not applying ". . . to doses due to background radiation, exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released in accordance with [10 CFR] § 35.75, or to exposure from voluntary participation in medical research programs."

a patient's responsible relative[12] so that corrective action can be taken," the Commission expressed ". . . concern about the possibility of undue intrusion into the patient-physician relationship." 43 Fed. Reg. 29297. Consequently, the Commission specifically sought comment about "those portions of the proposed amendments which deal with the manner in which referring physicians and their patients are informed of misadministrations." Id.

Ninety percent of the comments were opposed to the proposed rule, with most citing it as ". . . an unprecedented intrusion into medical practice." Misadministration Reporting Requirements," 45 Fed. Reg. 31701 (May 14, 1980). A majority of the commenters who opposed the rule were opposed to the requirement for reporting diagnostic misadministrations to patients. 45 Fed. Reg. at 31703. The Commission determined that the threshold of a "clinically detectable adverse effect" in the proposed rule for reporting a diagnostic misadministration was a "moving target" and ". . . not well understood in the medical community." 43 Fed. Reg. at 31703. Therefore, In the final rule, although the Commission required licensees to report to NRC all diagnostic and therapeutic misadministrations, it required that only therapy misadministrations be reported to the referring physician and the patient or a responsible relative.[13] Id.

Many of the objections to the patient notification provisions specifically addressed by the Commission (as described above) have been raised again over the years, and those objections, as well as the Commission's response, warrant discussion here. Although the Commission recognized, in promulgating the rule in 1980, that the misadministration reporting requirement may be unique to medical practice, ". . . it is necessary to protect patients." 45 Fed. Reg. at 31702. The Commission also recognized the rule's intrusion into the physician-patient relationship ". . . in the sense that the rule does affect, to a limited degree, the nature of the physician's obligation to his or her patient." Id. Noting that some physicians supported the rule, the Commission did not, however, believe that objections warranted abandoning the rule. Id.

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[12]The Commission explained that:

> [I]t is expected that the licensee would report to the patient's responsible relative rather than the patient when, for example, the referring physician tells the licensees that in his medical judgment informing the patient would be harmful to the patient; the patient is a minor; or the patient is unconscious and incapable of comprehending the information.

43 Fed. Reg. at 29297.

[13]The Commission also made two changes to the rule regarding patient notification of the patient or "responsible relative": First, it added a parenthetical "(or guardian)" to "responsible relative" to cover persons who do not have relatives. 45 Fed. Reg. at 31704. Secondly, as amended, the rule would permit referring physicians, if they wish, to inform the patient of the misadministration. Id.

As explained by the Commission:

> The "physician-patient" relationship is a concept that was developed to advance the needs of the patient. The relationship involves duties of reasonable care and skill, confidentiality, and good faith owed by the physician to the patient. Nothing in the rule would detract from these duties. Thus, in a strict sense, the rule would not interfere with the relationship.

Id.

As to the comment noting the lack of a similar requirement in aspects of radiation medicine not regulated by the Commission (e.g., x-rays, accelerator-produced isotopes), the Commission stated that it ". . . must operate under the assumption that Congress intended a disproportionate degree of Federal regulatory control be exercised over nuclear materials as opposed to . . . other sources of radiation." 45 Fed. Reg. at 31702. As the Commission pointed out, the U.S. Nuclear Regulatory Commission was not the only Federal agency with requirements or policies to which the medical community objected on the ground of unwarranted interference in the physician-patient relationship. Id. According to the Commission, the Food and Drug Administration (FDA) had recently rejected an objection on that basis to its request for assistance in developing a policy on labeling of prescription drugs to promote patient understanding of drugs prescribed for them. Id. The FDA determined that patients have a right to know about a drug's benefits, risks, and directions for use. Id.

Although the Commission acknowledged possible truth to the comment that the patient notification provisions would invite unwarranted malpractice suits and thereby boost medical costs, the Commission stated that ". . . there is nothing in the rule that would in any way modify the legal rules governing malpractice suits arising out of misadministrations." 45 Fed. Reg. at 31703. "The requirement . . . to report therapy misadministrations to patients or a responsible relative is important." 45 Fed. Reg. at 31702. "Patients have a right to know when they have been involved in a serious misadministration, unless this information would be harmful to them." Id. The Commission's response also cited ". . . parallel requirements for licensee reports to workers on occupational overexposures" and the trend at the time in Federal legislation recognizing the right of individuals to know information about themselves that is contained in the records of institutions both inside and outside of the Federal sector." Fed. Reg. at 31702-03.

In a major revision of 10 CFR Part 35 (effective in 1987), the Commission changed the misadministration rule to require a report to NRC and the referring physician for a misadministration resulting ". . . in a dose to a patient greater than the dose to a member of the public permitted under [former] 10 CFR § 20.105(a)." "Medical Use of Byproduct Material," 51 Fed. Reg. 36932, 36942 (October 16, 1986). The Commission responded to renewed objections to misadministration reporting by agreement with assertions that the misadministration rate for radiopharmaceuticals is much lower than that for other drugs, that there is no reporting

requirement for non-Atomic Energy Act radiopharmaceuticals and other drugs, and that the risk to patients, workers, and the public is small. 51 Fed. Reg. at 36942. Nevertheless, the Commission concluded that ". . . the fact that there are other greater potential hazards found in the medical arena does not relieve NRC of its responsibility to assure public health and safety as it may be affected by material under its jurisdiction." Id.

The Quality Management rulemaking retained provisions for patient notification of misadministrations, but added events of arguably lesser significance ("recordable events") for which reporting to NRC or others was not required. "Quality Management Program and Misadministrations," 56 Fed. Reg. 34104 (July 25, 1991). In proposing to retain the patient notification provisions, the Commission reaffirmed the two primary purposes of those provisions, discussed above: (1) to effectuate the rights of patients to know about misadministrations unless that information would be harmful to them, and (2) to achieve consistency with parallel requirements that NRC licensees report to an individual certain radiation exposure data pertaining to that individual. "Basic Quality Assurance Program, Records and Reports of Misadministrations or Events Relating to the Medical Use of Byproduct Material," 55 Fed. Reg. 1439, 1444 (January 16, 1990).

Most recently, as part of the "wrong patient" rulemaking,[14] the Commission amended the definition of "misadministration" in 10 CFR 35.2, and the reporting requirements in
10 CFR 35.33 to substitute the word "individual" for the phrase "patient or human research subject." 60 Fed. Reg. at 48624. (The latter term had been added in another rulemaking[15] to reflect inclusion of research subjects in the definition of "medical use" in 10 CFR 35.2). The Commission noted that if a misadministration occurs because the material was administered to the wrong individual, there may be no referring physician, in which case the licensee is relieved of complying with that portion of 10 CFR 35.33. Id. However, the licensee must comply with all other requirements in 10 CFR 35.33. Id.

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[14] "Medical Administration of Radiation and Radioactive Materials," 60 Fed. Reg. 48623, (September 20, 1995).

[15] "Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use," 59 Fed. Reg. 61767 at 61772, 61781, 61783, (December 2, 1994).

NOTIFICATION FOLLOWING A MEDICAL EVENT

The January 30, 1998, "strawman" version of the proposed revision of 10 CFR Part 35, which was put on the Internet for public comment, included the following draft rule text for reporting medical events:

(a) A licensee shall report any administration of byproduct material or radiation therefrom that:

(1) Results in a dose that is greater than 5 rem effective dose equivalent or 50 rem to an organ, and

(2) Represents either:

(I) A total dose or dosage that differs by at least 20 percent from that prescribed in a written directive;

(ii) A fractioned dose that differs by at least 30 percent from that prescribed in a written directive; or

(iii) A prescribed dose or dosage that is the wrong pharmaceutical; delivered to the wrong patient; delivered by the wrong route of administration; delivered to the wrong treatment site;

(iv) delivered by the wrong treatment mode; or from a leaking source(s); and

(3) Is not the direct result of patient intervention that could have been reasonably prevented by the licensee.

That version stated that the issue of whom should be notified following a medical event was still under discussion, and therefore, the current notification requirements were included. As noted in the Commission paper, staff has identified three possible alternatives for notification of the U.S. Nuclear Regulatory Commission, the referring physician, and individuals in the case of a medical event.

Alternative 1 Retain the current reporting requirements in 10 CFR Part 35 with minor changes intended to clarify the term “responsible relative.”

The requirement to inform individuals about a medical event is consistent with other NRC requirements (e.g., 10 CFR 19.13(d) and 20.2205) for licensees to provide reports to individuals receiving radiation exposure when licensees are required to report such exposure to NRC. As articulated by the Commission at the time the misadministration rule was promulgated (and later modified), patient notification “... recognizes the right of individuals to know information about themselves which is contained in records both inside and outside the Federal sector.” “Misadministration Reporting Requirements,” 45 Federal Register 31701, at 31702 (May 16, 1980) and “Basic Quality Assurance Program, Records, and Reports of Misadministrations or Events Relating to the Medical Use of Byproduct Material,” 55 Federal Register 1439, at 1444 (January 11, 1990). This alternative recognizes physician discretion to withhold information from the patient if, based on medical judgment, such information would be “harmful” to the patient. Patient notification also enables patients, in consultation with their personal physicians, to make timely decisions regarding their remedial and prospective medical care. “Quality Management Program and Misadministrations,” 56 Federal Register 34104, at 34117 (July 25, 1991). In addition, this alternative codifies existing industry standards [American Medical Association

(AMA) Principles of Medical Ethics] [16] obligating physicians to provide complete and accurate information to their patients.

As stated on numerous occasions, the medical community perceives the current requirements to be an unnecessary intrusion into the practice of medicine and asserts that this is the only area of medicine where there are Federal Government requirements for notifying individuals of medical errors.

If the Commission prefers this alternative, staff recommends that the current rule text be revised to clarify the provision for notifying the individual's "responsible relative," in lieu of the individual, in certain circumstances (e.g., the individual is a minor or unconscious) because that term is not defined legally, and therefore may be subject to different interpretations by the medical community.

The 1996 OMB submittal estimated that the regulatory burden: for NRC and Agreement State licensees to report misadministrations (medical events) to NRC or the appropriate Agreement State, the referring physician, and the individual is approximately $214,200/year (based on 105 misadministrations/year); and for NRC to respond to and follow-up on the events, and to review

[16] Although AMA discusses patients' rights to receive information from physicians as "Fundamental Elements of the Patient-Physician Relationship" and to effectuate "informed consent," AMA ethical standards for informing patients of physicians' mistakes reflect a threshold of "significant complications" to the patient that may have resulted from the physician's mistake or judgment. "AMA Council on Ethical and Judicial Affairs, Code of Medical Ethics," Current Opinions with Annotations at xxxix, 120, 125 (§8.12), 1996-1997.

the written reports is approximately $288,000/year. Staff does not anticipate any change in the regulatory burden for licensees and the NRC if this alternative is pursued.

ALTERNATIVE 2: Revise the current reporting requirement to require a licensee to inform only NRC and the referring physician (but not the patient) of the medical event.

This alternative would rely on the authorized user or referring physician's voluntary compliance with "ethical principles" and "standards of care" to present complete and accurate medical facts to patients. This approach, as compared with Alternative 1, could be viewed as intruding less into the practice of medicine. Staff believes that requiring licensees to inform the referring physician of the medical event would help to assure that individuals, in consultation with their personal physicians (referring physicians), will have the needed information to make timely decisions about their remedial and prospective medical care. Staff does recognize that in some cases there will be not be a referring physician and the responsibility to inform the individual will fall to the authorized user physician.

This alternative does not ensure that individuals will be informed of a medical event and, therefore, might not receive information, viewed necessary by NRC, to make informed medical care decisions. This alternative is not consistent with other NRC requirements, in 10 CFR Parts 19 and 20, regarding reporting radiation exposures to individuals when such reports are made to NRC. Also, if the referring physician does not follow the "ethical principles," this approach would not effectuate the specific Commission determination that individuals have a right to know when they have been involved in a misadministration. 45 Fed. Reg. at 31702.

Regulatory burden would be approximately the same as Alternative 1 if this alternative is pursued. Although the Federal government would no longer require licensees to provide information to individuals or responsible relatives, there would still be a requirement for licensees to report to NRC, notify the referring physician, and document the event.

ALTERNATIVE 3: Revise the current reporting requirement to require a licensee to inform only NRC of a medical event.

This alternative has many of the benefits previously discussed under Alternative 2: (1) it is consistent with NRC's policy of recognizing that physicians have the primary responsibility for the protection of patients and that they will act in the best interest of their patients, "Regulation of the Medical Uses of Radioisotopes; Statement of General Policy," 44 Fed. Reg. 8242, at 8244 (February 9, 1979); (2) it would not require that the referring physician be informed of a medical event; and (3) it reflects the viewpoint of the medical community members noted in the Commission paper under the general discussion of patient notification.

This alternative does not contain a Federal requirement that would ensure that patients are informed of a medical event; therefore, individuals may not have information necessary for making informed medical care decisions. In addition, individuals who are the subject of medical events would not be accorded the same protection as occupational workers and members of the public, in terms of the requirements to be informed of radiation exposures when licensees are required to report such exposures to NRC (see discussion following Alternative 1 above). Also, this alternative does not effectuate a specific Commission determination that patients have a right to know when they have been involved in a misadministration.

The regulatory burden on licensees would be decreased if this alternative is pursued. Licensees would no longer be required, by the Federal government, to provide information to individuals or responsible relatives and the referring physician. No change in burden on staff is anticipated.

PRECURSOR EVENTS

The staff has identified three possible alternatives for capturing precursor events.

Alternative 1: Revise 10 CFR Part 35 to require reporting of "significant precursors."

Part 35 would be revised to: (1) define "significant precursor" in 10 CFR 35.2; (2) require that licensees report "significant precursors" to the U.S. Nuclear Regulatory Commission; and (3) require that licensees keep records of significant precursors. In addition, the statements of consideration for the revised rule would contain examples of conditions and incidents that staff would consider to be "significant precursors" [e.g., failure of computer hardware or software, interlock systems, or source containment systems (afterloaders)]; malfunction of a treatment timer system; or mislabeling of a therapeutic radiopharmaceutical).

This alternative was included in the "strawman rule" that was made publicly available January 1998 and was based on the definitions used by the Food and Drug Administration (FDA) in the medical device reporting area. A significant precursor was defined as "a condition or incident, except for a medical event, related to the use of radionuclides in medicine that caused or could cause serious injury to a patient, human research subject, worker, or the public." Although "serious injury" was not defined in the January 1998 version, subsequent versions of the draft rule text have defined it to mean an injury or illness that: (1) is life-threatening; (2) results in permanent impairment of a body function or permanent damage to body structure; or (3) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

This alternative would capture a range of precursor events and, therefore, would fully meet the objective of the Staff Requirements Memorandum (SRM) COM-SECY-96-057, "Materials/Medical Oversight," March 20, 1997, to "capture" precursor events. However, if the intent of identifying precursor events is to improve licensees' radiation protection programs, then this alternative could potentially go beyond the intended objective (e.g., NRC would receive reports involving certain human errors that could not be applied to improvements in other licensees' programs). This alternative is risk-based, in that a reporting threshold is set, for significant precursors, that is similar to the FDA's threshold for medical device reporting.

It is anticipated that this alternative will increase the regulatory burden on licensees and NRC. However, staff did attempt to limit reporting of precursors to only those events that could have a significant impact on public health and safety, and, consequently limit the increase in regulatory burden. Licensees may need to revise operating procedures and would need to report and record "significant precursors." NRC resources would be needed to process, review, and investigate reported precursor events. (NOTE: If Alternative 1 is preferred, the estimated resources for this alternative will be addressed in the Regulatory Analysis.)

Alternative 2: Revise Part 35 to require reporting of deficiencies in equipment (hardware and/or software), byproduct material, or procedures supplied by a manufacturer or vendor that, in the opinion of the radiation safety officer (RSO), could lead to a medical event at that facility or could have detrimental health and safety implications beyond the licensee's facility.

Part 35 would be revised to require reporting of deficiencies in equipment (e.g., hardware and/or software failures), byproduct material (e.g., the wrong material in a container), or procedures supplied by a manufacturer or vendor (e.g., vendor-supplied operating procedures that could result in a source being exposed for a time period beyond that anticipated by the licensee) that, in the opinion of the licensee, could lead to a medical event at that facility or could have implications beyond the licensee's facility. Licensees would be required to keep records of incidents reported to NRC.

This alternative would limit the number of precursor events reported to NRC, but would still meet the objective of capturing precursor incidents or conditions that could improve licensees' radiation protection programs.

It is anticipated that this alternative will increase the regulatory burden on licensees and NRC. However, it is expected that the increase for licensees and NRC will be about the same as that associated with Alternative 1 because, although the types of reports to be submitted in Alternative 2 are more limiting, the threshold for reporting events is set lower than the level in Alternative 1, i.e., NRC would receive approximately the same number of reports under Alternatives 1 and 2. (NOTE: If Alternative 2 is preferred, the estimated resources for this alternative will be addressed in the Regulatory Analysis.)

Enforcement action under Alternative 2 would only occur if it is demonstrated that the RSO concluded that the requisite standard was met. Where individual licensee employees believed the standard was met, investigations might be needed to determine if the RSO had reached the same conclusion and did not report it. This would be similar to enforcement of 10 CFR 30.9(b).

Alternative 3 Rely on current NRC reporting requirements in 10 CFR Parts 20, 21, and 30, and the Memorandum of Understanding (MOU) with the FDA and monitor/establish system with U.S. Pharmacopeia (USP) to review its database.

This alternative relies on the existing regulatory framework in Parts 20, 21, and 30 and 21 CFR Part 803 to capture precursor events. Staff recognizes that all precursor events may not be captured under this alternative. This alternative captures: (1) precursors that would have significant implications for public health and safety or common defense and security, pursuant to 10 CFR 30.9; (2) events that prevent taking immediate protective actions necessary to avoid exceeding the regulatory limits because of exposures to radiation or radioactive materials, and certain other events involving licensed material pursuant to 10 CFR 30.50; (3) information provided to the FDA, which is currently available to NRC via the FDA/NRC MOU, pursuant to 21 CFR Part 803, “Medical Device Reporting”; and (4) reporting requirements pursuant to Parts 20 and 21. In addition, staff would recommend that NRC monitor, on an ongoing basis, information errors that are available via voluntary reporting systems, such as the voluntary Medication Errors Reporting Program at USP (see Enclosure for information on USP). Note, staff discussions with both USP and the medical community have noted that voluntary reporting systems do not capture all events.

There is no increased burden on licensees associated with this alternative. NRC medical use licensees are already required to report specified events to NRC and the FDA, and many of them already participate in the USP voluntary reporting system. It is not anticipated that this approach would result in an significant increase in expenditure of NRC resources. Some minor resources (less than 0.1 full time equivalent) would be required to monitor information provided

by USP. If this alternative is pursued, staff believes that an Information Notice should be issued describing the NRC position on capturing precursor events, using existing mechanisms.

Enclosure:

1. Information on USP and Its Initiatives and Programs

June 25, 1992

MEMORANDUM FOR: James M. Taylor
Executive Director for Operations

Barry A. Siegel, Chairman
Advisory Committee on the Medical Uses of Isotopes

FROM: Samuel J. Chilk, Secretary /s/

SUBJECT: SECY-92-171 - ADMINISTRATION OF BYPRODUCT MATERIAL OR RADIATION FROM BYPRODUCT MATERIAL TO PATIENTS WHO MAY BE PREGNANT OR NURSING

The Commission (with all Commissioners agreeing) has approved the development of a performance-based rule and a modified regulatory guide which addresses the administration of byproduct material or radiation from byproduct material to patients who may be pregnant or nursing.

(EDO) (SECY Suspense: 12/24/92)

In preparing the rulemaking package, the staff should consider the following:

1) the precautions which are already in use to guard against improper administration of nonradiological drugs, chemicals or other procedures to patients who are pregnant or nursing and the feasibility of simply mandating their use for radiological procedures,

2) the philosophies espoused by NCRP and ICRP for addressing the radiation safety concerns associated with administration of radiation or radioactive materials to patients who may be pregnant or nursing,

3) consistency with the information on radioactive drugs available from the U.S. Pharmacopeia for the health professional and for the patient,

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SECY NOTE: THIS SRM, SECY-92-171 (WITHOUT COPYRIGHTED MATERIAL CONTAINED IN ENCLOSURE 8), AND THE VOTE SHEETS OF THE CHAIRMAN, AND COMMISSIONERS ROGERS, CURTISS AND de PLANQUE WILL BE MADE PUBLICLY AVAILABLE 10 WORKING DAYS FROM THE DATE OF THIS SRM

4) consultation with Oak Ridge Associated Universities to establish an appropriate dose threshold for reporting unintended exposures to embryos, fetuses, and nursing infants from diagnostic administrations,

5) a second independent study to be done by a qualified, disinterested party to assist in preparing the regulatory analysis, and

6) developing a sound regulatory analysis that quantifies, to the extent available data permits, the risks and benifits, in order to have confidence that the solution being recommended is consistent with the problem being addressed.

The staff should continue to interact closely with the Advisory Committee on the Medical Uses of Isotopes (ACMUI) on the development of the proposed rule and regulatory guide.

The Commission (with all Commissioners agreeing) requests that the ACMUI formulate recommendations on how the ACMUI could develop and document its views for the staff and Commission on major policy issues and provide an estimate of the resources required to carry out the recommendations. The staff should advise the ACMUI to present its recommendations at the July 31, 1992 briefing.

(ACMUI) (SECY Suspense: 7/31/92)

cc: The Chairman
Commissioner Rogers
Commissioner Curtiss
Commissioner Remick
Commissioner de Planque
OGC
OCAA
OIG

The Honorable James M. Inhofe, Chairman
Subcommittee on Clean Air, Wetlands, Private
Property and Nuclear Safety
Committee on Environment and Public Works
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

Enclosed for the Subcommittee's information is a copy of a notice of a proposed rulemaking, to be published in the Federal Register for a 75-day public comment period (Enclosure 1) . A copy of the press release for the rulemaking is provided in Enclosure 2.

The U.S. Nuclear Regulatory Commission (NRC) is proposing to revise its regulations in 10 CFR Part 35, "Medical Uses of Byproduct Material," as part of an overall program to revise the Commission's regulatory framework for medical use. The goal of this proposed rulemaking is to restructure Part 35 into a risk-informed, more performance-based regulation that focuses the regulations on those medical procedures that pose the highest risk, from a radiation safety aspect, with a subsequent decrease in the oversight of low-risk activities. Another component of the program, revision of NRC's 1979 "Medical Use Policy Statement," is being separately published and transmitted to the Subcommittee.

The process used to revise Part 35 has provided more opportunity for input from potentially affected parties (the medical community and the public) than is provided by the typical notice and comment rulemaking process. Early public input was solicited through several different mechanisms: requesting public input through Federal Register notices; holding open meetings of the government groups developing the revised rule language; meeting with medical professional societies and boards; putting background documents, options for the more significant regulatory issues associated with the rulemaking, and an early "strawman" revision of the draft proposed rule on the Internet and in NRC's Public Document Room; and convening public workshops. The staff benefitted from these interactions and received many useful comments.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosures:
1. Federal Register Notice
2. Press Release

cc: Senator Bob Graham
The Honorable James M. Inhofe, Chairman

An identical letter was sent to

Subcommittee on Clean Air, Wetlands, Private Property and Nuclear Safety
Committee on Environment and Public Works
United States Senate
Washington, DC 20510

The Honorable Dan Schaefer

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Office of Congressional Affairs

Enclosures:
1. Federal Register Notice
2. Press Release

cc: Senator Bob Graham

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The Honorable Dan Schaefer, Chairman
Subcommittee on Energy and Power
Committee on Commerce
United States House of Representatives
Washington, DC 20515

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Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosures:
1. Federal Register Notice
2. Press Release

cc: Representative Ralph Hall

The Honorable Dan Schaefer, Chairman
Subcommittee on Energy and Power
Committee on Commerce
United States House of Representatives
Washington, DC 20515

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Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosures:
1. Federal Register Notice
2. Press Release

cc: Representative Ralph Hall
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Draft press release -- 5/20/98, 10:35 a.m.

NRC PROPOSES EXTENSIVE REVISIONS TO REGULATIONS ON MEDICAL USES OF RADIOACTIVE MATERIAL

The Nuclear Regulatory Commission is proposing extensive revisions to its regulations on medical uses of radioactive material. The revisions, designed to be risk-informed and performance-based, focus regulation on the medical procedures that pose the highest risk from a radiation safety aspect.

The NRC regulates the use of radioactive material in medical diagnosis and treatment, as well as research. The material is administered to about eleven million patients a year.

In developing the proposed changes to the regulations, the NRC provided extensive opportunities for public input. Publicly announced meetings and workshops were held last year and this year where rulemaking alternatives for significant "cross-cutting issues" were discussed. The alternatives for the cross-cutting issues were discussed with the NRC's Advisory Committee on the Medical Uses of Isotopes, as well as with state regulators, medical professional societies, and the public at meetings in Philadelphia and Chicago. In addition, the rulemaking alternatives and an early "strawman" version of the NRC staff's proposed revisions to the regulations were made available for comment on the Internet and in the NRC's Public Document Room in Washington, DC.

In general, the proposed changes to the regulations reflect an overall change in regulatory philosophy to make the regulations performance based and to delete some of the more detailed requirements. An applicant for an NRC medical-use license would have to develop and implement procedures, but would no longer be required to submit those procedures as part of the license application. Further, licensees would have maximum flexibility in developing their procedures, because most of the requirements in the proposed changes to the regulations are stated in terms of the objectives to be achieved, rather than stated with a list of prescriptive details.

The significant cross-cutting issues that were identified, and their resolutions in the proposed revisions to the regulations, are:

(1) Patient notification/reportable events -- The requirements in the current regulations for notifying individuals following a misadministration would remain unchanged, with the exception of substituting the term "medical event' for "misadministration." The term, defined in detail in the proposed revisions to the regulations, generally refers to the administration of radioactive materials or radiation in a manner that differs substantially from the physician's direction. Using "medical event" responds to objections that the term "misadministration" has possible connotations of carelessness and harm, which is not always the case. In addition, "medical event" is consistent with terms used to characterize events in non-medical activities regulated by the NRC. The proposed regulations would continue to require that, when a medical event occurs, licensees must notify the NRC, the referring physician and the affected patient -- unless the referring physician personally informs the licensee either that he will inform the individual or that, based on medical judgment, telling the individual would be harmful. If the patient is a minor, or is unconscious and incapable of comprehending the information, it is expected that the licensee would report to the patient's responsible relative or guardian rather than to the patient.

(2) Radiation safety committee -- The proposed revisions to the regulations delete the requirement for a medical institution licensee to have a radiation safety committee, with specified membership and duties, to oversee the use of radioactive material. The key functions of the committee would be transferred to licensee management. The proposed regulations specify the responsibilities for and functions to be accomplished by the radiation safety program, including some of the functions previously listed as those of the radiation safety committee.

(3) Quality management program -- Provisions in this area have been revised to focus more on patient safety. Detailed requirements for a medical licensee to have a quality management program have been deleted. Instead, the proposed revisions to the regulations require licensees to have written directives for procedures involving greater risk. Licensees would also have to develop, implement and maintain procedures to provide high confidence that the right patient receives the correct dose at the correct treatment site, consistent with the physician's written directive. This

proposed revision not only eliminates unnecessary details, but is more consistent with the recently proposed revision to the agency's NRC's medical policy statement, which states that "NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides in accordance with the physician's directions."

(4) Training and experience -- Requirements in both the current regulations and the proposed revisions differ for diagnostic versus therapeutic uses of nuclear material. The proposed regulations basically retain the current training requirements for therapeutic uses of sealed sources of radioactive material because of the high risk associated with the types of material in such uses. However, the proposed revisions would reduce some of the training requirements for diagnostic and therapeutic procedures using radioactive materials in unsealed form, because of the lower risk associated with these procedures. Training and experience were the primary concerns expressed by the public comments during development of the proposed changes to the regulations. Most of the commenters thought the current requirements should be retained. Under the proposed revisions, the current training requirements would stay in effect for two years to allow licensees time to implement the new requirements. During the intervening period, licensees would have the option of meeting either the current or the revised requirements.

(5) Precursor events -- The proposed revisions to the regulations require licensees to notify the NRC after identifying any defects, exclusive of ordinary equipment failures, in equipment (hardware and/or software), radioactive material, or procedures supplied by a manufacturer or vendor that, in the opinion of the radiation safety officer or an authorized user, could lead to a medical event.

The proposed changes to the regulations also address a petition for rulemaking filed by the University of Cincinnati. The petition requests a 500-millirem radiation dose limit for certain individuals visiting patients who are required to be confined to the hospital while receiving radiation treatment, where the visitors are determined by the physician to be necessary for the patient's emotional or physical support. The current limit of 100 millirems for visitors is the same as for members of the public under other circumstances. The proposed regulations would respond to this

petition by allowing licensees the discretion to permit visitors to receive up to 500 millirems in a year from exposure to hospitalized radiation patients.

In addition, the proposed changes add a requirement for reporting unintended radiation exposure of an embryo, fetus, or nursing child, and add specific requirements for medical uses of radiation by a licensee at temporary job sites and for specific technologies that are not currently addressed in the regulations. They also add a section to allow easier licensing of new medical procedures that use radioactive material or radiation.

Details of these and other aspects of the proposed changes to the regulations are contained in a Federal Register notice to be published shortly. Interested persons are invited to submit comments within 75 days of publication of the Federal Register notice to the Secretary, U.S. Nuclear Regulatory Commission, Attention: Rulemakings and Adjudications Staff.

The NRC plans to hold three public meetings in August and September to discuss the proposed revisions to the regulations. Details of time and place will be announced later.

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