August 3, 1999 SECY-99-201

FOR: The Commissioners

FROM: William D. Travers /s/
Executive Director for Operations

SUBJECT: DRAFT FINAL RULE - 10 CFR PART 35, "MEDICAL USE OF BYPRODUCT MATERIAL"

PURPOSE:

This paper provides the Commission with: (1) draft final rule language for the revision of 10 CFR Part 35; (2) a summary of the public comments received on the proposed rule, the staff's draft responses to the comments, and resulting changes made in the proposed rule; and (3) a comparison of the requirements in the current Part 35, as codified in Title 10, and the draft final rule. The paper also requests Commission approval to complete the final Part 35 rulemaking package using the draft final rule language and to notify specialty boards that we will begin accepting requests for recognition of specialty boards before publication of the final rule.

SUMMARY:

In its Staff Requirements Memorandum (SRM) dated April 23, 1999 ("Staff Requirements: Briefing on Part 35 Rulemaking," Attachment 1) the Commission requested that staff provide it with a paper that includes a draft Federal Register notice, containing the draft final rule text and enough information to allow comparison of the changes from the current rule to the proposed rule and the current rule to the draft final rule. This paper provides the requested information and discusses three key issues for Commission consideration.

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BACKGROUND:

In its SRM-COMSECY-96-057, "Materials/Medical Oversight (DSI 7)," dated March 20, 1997 (Attachment 2), the Commission directed the revision and restructuring of Part 35 into a risk-informed, more performance-based regulation. During the rulemaking process, the staff forwarded several Commission Papers that either provided information on the major issues addressed during the rulemaking or requested direction on specific issues. A chronological list of these papers and associated SRMs is provided in Attachment 3. Any outstanding issues from the SRM are highlighted in Attachment 4.

Members of the public, stakeholders, Agreement States, non-Agreement States, and the Advisory Committee on the Medical Uses of Isotopes (ACMUI) were given the opportunity to provide input and to discuss the proposed requirements for medical use licensees on numerous occasions. Since August 1997, the staff has held seven facilitated public workshops with stakeholders, four of which were held during the public comment period on the proposed rule, and has made formal presentations at approximately 20 professional society meetings. We also discussed key rulemaking issues twice with the full ACMUI and 4 times with the ACMUI subcommittees. We held two workshops with the Agreement States. In addition, we have maintained a continuing dialogue with the professional societies on particular issues of interest to them [e.g., training and experience (T&E) requirements].

We worked closely with the Organization of Agreement States (OAS) and the Conference of Radiation Control Program Directors, Inc. (CRCPD) in preparing the proposed and draft final rule. Two individuals from the OAS and CRCPD participated as members of the Part 35 Working Group and a representative of the OAS participated as a member of the Steering Group. In addition, the Chair and a member of the Part 35 Working Group participated in meetings with the CRCPD SR-6 Committee, which is tasked with revising Part G, "Medical Uses of Radionuclides," of the "Suggested State Regulations". As a result of the interactions with the SR-6 Committee, we have identified four areas in which the Committee plans on recommending that the States adopt more restrictive rule language than that proposed in the draft final rule. These areas are identified in Attachment 5.

In preparing the draft final rule, we also carefully reviewed and considered approximately 225 written letters that were submitted during the public comment period. All written and oral comments on the rule were consolidated in a Lotus notes database that is available to the Commission for review. In addition, all comment letters, transcripts and written summaries of the public meetings, and the April 30, 1999, version of the draft final rule were placed on the NRC rulemaking website for review by stakeholders. All working group meetings were open to the public and stakeholder representatives frequently attended.

On March 25, 1999, representatives of the staff and the ACMUI briefed the Commission on the status of the rulemaking and on the staff's proposed resolution of comments on the major issues. Since the briefing, the staff has considered comments made by the Commission and

ACMUI (Attachment 6, ACMUI minutes), as well as comments from various stakeholders that were submitted after the March meeting, in further developing the draft final rule text and the responses to comments. As a result, we have revised our position on some of the issues that were presented at the March 25 briefing. Subsequent to the briefing, the Commission directed us, in an SRM dated April 23, 1999 ("Staff Requirements: Briefing on Part 35 Rulemaking," Attachment 1) to provide the Commission with a paper that provides a draft Federal Register notice to include the draft final rule text and enough information to allow comparison of the changes from the current rule to the proposed rule and from the current rule to the draft final rule.

DISCUSSION:

Attachment 7 is a draft Federal Register notice for your review. This document summarizes and responds to comments received on the proposed rule ("Supplementary Information Section III and IV"). This document also provides a narrative comparison between the current rule and the draft final rule text (Section V). Attachment 8 provides a comparison between the current, proposed, and draft final rule. Attachment 9 provides detailed information on the compatibility levels associated with the draft final rule.

A risk-informed approach was used in developing the draft final rule and in responding to comments. The staff used risk insights, together with other factors, to establish requirements that better focus licensee and regulatory attention on design and operational issues commensurate with their importance to health and safety. We considered all comments, provided by the stakeholders and the public, about general risk issues as well as comments about specific sections in the rule. We reviewed several extensive assessments, including the external review and report by the National Academy of Sciences-Institute of Medicine, a 1993 Nuclear Regulatory Commission (NRC) internal senior management review and report, and the Commission's Strategic Assessment and Rebaselining Project. We also reviewed events in the Nuclear Materials Event Database and technical issues previously addressed in technical assistance requests from the regions.

A risk-informed, performance-based approach was also used in revising the licensing requirements. The draft final rule significantly reduces the amount of information needed from an applicant or licensee to possess and use byproduct material for medical purposes. For example, most applicants will no longer be required to submit detailed procedures in support of their license applications or amendment requests. License or amendment applicants will only be required, if applicable, to submit procedures required by Subpart H, "Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units." This change will significantly reduce unnecessary regulatory burden on both diagnostic nuclear medicine licensees and NRC licensing staff. The Commission should note that we received numerous comments both in support of, and in opposition to, the proposed revision of NRC's licensing policy (see Attachment 7).

Although Attachment 7 provides proposed resolutions for all medical use issues associated with this rulemaking, there are several issues that we believe should be brought to the Commission's attention. These issues are discussed below.

1. Training and Experience

T&E was one of the most important issues addressed during the rulemaking because adequately trained personnel are key to the safe use of byproduct material in medicine. In addition, the majority of comments submitted on the rule were in this area. The summary of public comments and our proposed response to those comments, as well as a more detailed discussion of the two T&E issues identified below, are provided in Attachment 7, Section III.

There are two significant differences in the T&E requirements between the proposed rule and the draft final rule. First, we have deleted the proposed requirement for an examination to demonstrate that an individual has sufficient knowledge in radiation safety commensurate with the use requested. Second, we increased the requirements for individuals who want authorized user status for medical uses under 10 CFR 35.200, "Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required," and 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required." Both of these changes were made because of the comments received on the proposed rule.

The T&E requirements in the draft final rule also differ from the T&E requirements staff presented at the March 25, 1999, Commission briefing. At that time, the staff proposed specific hourly/yearly requirements for authorized users, authorized nuclear pharmacists, authorized medical physicists, and Radiation Safety Officers. We also proposed that the training be obtained in an NRC-approved program. Since the briefing, we added specific sections for use of strontium-90 for ophthalmic use and sodium iodide I-131 in quantities less than or equal to 1.22 Gigabecquerels (33 microcuries) and in quantities greater than 1.22 Gigabecquerels (33 microcuries). In addition, we are no longer recommending that NRC review and approve training programs. We believe that NRC review of training programs is not warranted because of comments received from the ACMUI during its March meeting and additional comments received from stakeholders after the Commission briefing. The draft final rule provides for NRC recognition of boards whose certification processes includes all of the requirements in a given section containing T&E requirements.

As a result of the changes noted above, we believe the T&E requirements in Subpart J of the proposed rule can be deleted. The T&E requirements in Subpart J were maintained in the proposed rule because alternative routes to the revised T&E criteria were needed until radiation safety examinations and specialty boards were approved by NRC. (More detailed information on deletion of Subpart J can be found in Attachment 7, Section III.) To ensure that the specialty boards have adequate time to request NRC recognition and for NRC to recognize the boards, we request Commission approval to begin the recognition process before the publication of the final rule. Attachment 10 is a sample letter that would be mailed to the specialty boards. This letter explains that the Commission will accept requests for recognition and identifies the information that must be provided to the Commission.

2. Notification Following a Medical Event (10 CFR 35.3045)

We received numerous comments supporting the deletion of the requirement for licensees to notify and provide a written report to the patient or responsible relative after a medical event. These comments are summarized in Attachment 7, Section III, 10 CFR 35.3045.

We have retained the current reporting requirements in the draft final rule, except for a modification to the patient notification requirement. However, as requested in the April 1999 SRM, we have evaluated the pros and cons of revising the Part 35 patient notification provisions to require: (1) verbal notification of the patient (or the individual's responsible relative or guardian) of the medical event, while retaining the current caveat that allows referring physicians to exercise discretion on notifying the patient; (2) written documentation of the medical event in the patient's file; and (3) a written certification by the referring physician to NRC stating that the patient was notified, unless discretion was exercised. The pros and cons of this approach and the requirements in the proposed rule are provided in Attachment 3. The Attachment also contains suggested rule text that could be used to implement the approach outlined in the SRM.

3. Reporting Threshold for Unintended Exposure to an Embryo, Fetus, and Nursing Child (10 CFR 35.3047)

The proposed rule contained a requirement for licensees to notify us of any unintended exposure to an embryo, fetus, or nursing child that exceeds 5 milliSievert (500 millirem). This requirement was included in the rule to satisfy one of the provisions, in the "Abnormal Occurrence Policy," that requires us to report to Congress any unintended radiation exposure, to any minor, 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 milliSievert (500 millirem) or more. [A more extensive discussion on the need for this rulemaking can be found in the Federal Register notice for the proposed rule (63 FR 43516)]. Note that the requirement is a reporting requirement, not a dose limit.

We received numerous comments from the stakeholders on this reporting requirement. Many commenters believe that this proposed requirement should not be in the final rule because it will interfere with the practice of medicine. However, they indicated that if the requirement were included in the final rule, the reporting level should be raised to 5 rem because: (1) a lower threshold would negatively affect the practice of medicine; and (2) no deterministic effects of radiation exposure are noted in the embryo, fetus and nursing child at 5 milliSievert (500 millirem). A summary of the public comments and our proposed resolution of those comments are provided in Attachment 7, Section III, 10 CFR 35.3047.

At the March 25, 1999, Commission briefing, the staff presented the Commission with two options for addressing this issue. Option 1 was to place the requirement in 10 CFR Part 20, "Standards for Protection Against Radiation." This was our preferred option because the requirement would apply to all uses of byproduct, source, and special nuclear material, rather than just medical users. Option 2 was to place the requirement in Part 35, but raise the reporting threshold to 50 milliSievert (5 rem). After further

review, now we believe it is more appropriate to go forward with Option 2, at this time, because the majority of incidents that would warrant reporting occur during medical use. Subsequently, we would evaluate whether rulemaking is needed to add a similar requirement in 10 CFR Part 20 or Parts 30, 40, and 70.

NOTE:

This paper does not contain an enforcement and inspection plan. Office of Nuclear Material Safety and Safeguards (NMSS) staff, in coordination with Office of Enforcement staff, will develop a plan and will provide it to the Commission when the final rulemaking is submitted for Commission approval.

RESOURCES:

The resources expended on this rulemaking have been somewhat greater than those identified in the fiscal years (FYs) 1998 and 1999 budgets. As a result, resources have been reprogrammed from lower-priority rulemaking activities within NMSS. Rulemaking activities will continue into FY 2000 to accommodate the revised rulemaking schedule. Staff estimates that an additional 3 full-time equivalents will be required in FY 2000 to complete the rulemaking, associated guidance, and related documents. These resources are included in the proposed FY 2000 budget.

RECOMMENDATIONS:

That the Commission

1. Inform the staff, within 2 business days from the date of the Commission Paper, if the paper should not be made available to the public;
2. Approve the staff's draft final rule language and draft responses to comments;
3. Direct staff to submit the revised Medical Policy Statement, if possible, and complete the final Part 35 rulemaking package to the Commission approximately 3 months from the date of the SRM for this paper;
4. Direct staff to prepare a rulemaking plan to revise Part 20 or Parts 30, 40, and 70 to require reporting of unintended exposures to an embryo, fetus, or nursing child;
5. Inform staff if a public briefing on the draft final rule is needed; and
6. Direct the staff to begin the process to recognize specialty boards.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection. The Office of the Chief Information Officer has information collection and information management technology implications and has no objections. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objection.

William D. Travers
Executive Director
for Operations

Attachments:
1. SRM on March 25, 1999, Briefing, dated April 23, 1999
2. SRM: COMSECY-96-057, dated March 20, 1997
3. “Chronological List of Part 35 Commission Papers and SRMs”
4. “Outstanding Issues from Previously Issued SRMs”
5. “CRCPD SR-6 Committee Concerns”
6. ACMUI Meeting Minutes, March 1999
7. Draft Federal Register Notice
8. Comparison - Current, Proposed, and Draft Rule
9. Detailed Information on Compatibility Designations
10. Sample Letter for Specialty Boards

ATTACHMENT 1

IN RESPONSE, PLEASE REFER TO M990325B

April 23, 1999

MEMORANDUM TO: William D. Travers
Executive Director for Operations

FROM: Annette Vietti-Cook, Secretary /s/

SUBJECT: STAFF REQUIREMENTS: BRIEFING ON PART 35 RULEMAKING, 1:30 P.M. THURSDAY, MARCH 25, 1999, COMMISSIONERS CONFERENCE ROOM, ONE WHITE FLINT NORTH, ROCKVILLE, MARYLAND (OPEN TO PUBLIC ATTENDANCE)

The Commission was briefed by the NRC staff and members of the Advisory Committee on Medical Uses of Isotopes on the status of proposed amendments to 10 CFR part 35, "Medical Use of Byproduct Material." The proposed rule, as contained in SECY-98-128 and modified by SRM S98-128, dated July 21, 1998, was issued for public comment from August 13, 1998 to November 12, 1998. SRM S98-263 extended the comment period 30 days.

At the meeting, there were no requirements identified for staff action. However, the Commission indicated that it would provide guidance on the schedule for the completion date of the revised final rule. This staff requirements memorandum (SRM) provides such guidance.

The staff should provide the Commission with a brief paper that provides a draft Federal Register notice (FRN) to include the draft final rule text and those portions of the statements of consideration (SOC) that discuss resolution of public comments and provide enough information to allow comparison of the changes from the current rule to the proposed rule and draft final rule. The staff should offer rule language options in either the draft FRN or as an attachment to the paper on any issues where the staff does not have a preferred approach.
(EDO) (Suspense Date: 07/23/99)

The Commission requests that in addition to the current patient notification language the staff consider and provide the pros and cons in the July paper of revising the Part 35 patient notification provisions to require: 1) verbal notification of the patient (or the individual's responsible relative or guardian) of the medical event while retaining the current caveat regarding referring physician discretion on patient notification; 2) written documentation of the medical event in the patient's file; and 3) a written certification by the referring physician to the NRC that the patient was notified, unless discretion was exercised, as part of the event report submitted to NRC.

The staff should plan to make the July paper publicly available two business days from the date of the paper unless directed otherwise by the Commission. The Commission may choose to conduct a public briefing on the draft final rule after receipt of the paper. An SRM would then be issued to require submittal of the complete final rulemaking package to the Commission approximately three months from the date of the SRM. The package should include the final FRN, the Office of Management and Budget package for clearance, related rule guidance and, if possible, the revised medical policy statement.

The staff is encouraged to keep the Commission informed on these important issues through informal briefings to the Commissioner Assistants previously designated for each office. Mr.

John Thoma is designated as the contact for Commissioner Merrifield.

cc: Chairman Jackson

Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
OGC
CIO
CFO
OIG
OCA
OPA
Office directors, regions, ACRS, ACNW, ASLBP (by E-Mail)
PDR
DCS

ATTACHMENT 2

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

ATTACHMENT 3

CHRONOLOGICAL LIST OF PART 35
COMMISSION PAPERS AND SRMS

April 23, 1999 Staff Requirements: Briefing on Part 35 Rulemaking, March 25, 1999

November 13, 1998 Staff Requirements: SECY-98-263- Proposed Rule: Revision of 10 CFR Part 35, Medical Use of Byproduct Material

November 9, 1998 SECY-98-263: Proposed Rule: Revision of 10 CFR Part 35, Medical Use of Byproduct Material

July 21, 1998 Staff Requirements: SECY-98-128- Proposed Rule: Revision of 10 CFR Part 35, Medical Use of Byproduct Material

July 9, 1998 Staff Requirements: SECY-98-127- Draft Proposed Policy Statement on the Medical Use of Byproduct Material

June 26, 1998 Memo from John C. Hoyle to L. Joseph Callan on SECY-98-054: Commission Resolution of Significant Issues Associated with the Revision of 10 CFR Part 35, Medical Uses of Byproduct Material

June 4, 1998 SECY-98-128: Proposed Rule: Revision of 10 CFR Part 35, Medical Use of Byproduct Material

June 4, 1998 SECY-98-127: Draft Proposed Policy Statement on the Medical Use of Byproduct Material

March 20, 1998 SECY-98-054: Commission Resolution of Significant Issues Associated with the Revision of 10 CFR Part 35, Medical Uses of Byproduct Material

June 30, 1997 Staff Requirements: SECY-97-115- Program for Revision of 10 CFR Part 35, Medical Uses of Byproduct Material and Associated Federal Register Notice

June 20, 1997 SECY-97-131: Supplemental Information on SECY-97-115, Program for Revision of 10 CFR Part 35, Medical Uses of Byproduct Material and Associated Federal Register Notice

June 5, 1997 SECY-97-115: Program for Revision of 10 CFR Part 35, Medical Uses of Byproduct Material and Associated Federal Register Notice

March 20, 1997 Staff Requirements: COMSECY-96-057- Materials/Medical Oversight (DSI 7)

ATTACHMENT 4

OUTSTANDING ISSUES FROM PREVIOUSLY ISSUED SRMS

The staff has received direction on the Part 35 rulemaking in five separate SRMs. The purpose of this attachment is to provide the Commission with sufficient information on any outstanding issues in those SRMs and to close them.

SRM-SECY-98-128 Proposed Rule: Revision of 10 CFR Part 35, Medical Use of Byproduct Material

This SRM provided Commission approval to publish the proposed rulemaking in the Federal Register, subject to the comments provided in the SRM. These comments required staff to provide the Commission with additional information when the draft final rule was forwarded to the Commission or revise the rulemaking package. When completing the proposed rulemaking package, we either revised the Statements of Consideration for the rule to request public comments on specific issues or revised rule text prior to publishing the proposed rule. The following discussion provides information on any open items associated with the SRM.

Radiation Safety Committee

The Commission asked that we solicit specific comment on the proposed changes which impact the Radiation Safety Committee (RSC) and the licensee's effectiveness in carrying out radiation protection programs. A summary of the public comments on this topic can be found in Attachment 7, Supplementary Information Section III, Section 35.24, of this Commission Paper.

Training and Experience

The Commission briefing of the proposed rule included a discussion of the proposed increase in the number of hours of training and experience required for authorized user status for treatment of hyperthyroidism and thyroid carcinoma. The SRM directed staff to provide a more thorough explanation of the basis for raising the number of training hours for each category of use where the hours were increased in the FRN. As a result of public comment, the number of hours of training and experience required for authorized user status for treatment of hyperthyroidism and thyroid carcinoma is status quo with the current rule. However, the final rule contains an increase in the number of training hours for one group of users: authorized users of unsealed byproduct material that requires a written directive (§ 35.300). The basis for raising the hours can be found in Attachment 7, Supplementary Information Section III, of this Commission Paper.

The Commission also asked that we provide more detailed information, in the final rule package, on the FTE effort that would be required to implement the proposed third party examination process for the adequacy of licensee training and experience and that we solicit specific public comments on the need for this additional regulatory layer. Based on public comments, we have not included the requirement for the third party examination in the draft final rule. The basis for this decision can be found in Attachment 7, Supplementary Information Section III, of this Commission Paper.

Calibration of Brachytherapy Sources

The Commission asked that the requirement for calibration of all brachytherapy sources by the licensee before initial use should be revised to allow calibration by the manufacturer traceable to NIST or other recognized bodies. Such calibration would be an acceptable means of meeting the requirement in the proposed rule, unless the staff could provide evidence that there have been problems with the manufacturer's calibration. We were also asked to seek specific public comments on this area of the proposed rule. We revised the requirement in § 35.432 to address manufacturers' calibrations prior to issuing the proposed rule. A summary of the public comments on this requirement can be found in Attachment 7, Supplementary Information Section III, Section § 35.432, of this Commission Paper.

Recordkeeping Requirements

The Commission asked staff to continue to review the proposed recordkeeping requirements to determine if there are any that could be deleted, and, if so, specifically solicit comment on those requirements. As a result of public comments and revisions to some regulatory requirements, some recordkeeping requirements have been deleted, while others have been revised to eliminate some elements of the recordkeeping requirements. A summary of the public comments on recordkeeping requirements can be found in Attachment 7, Supplementary Information Section III, Subpart L, of this Commission Paper.

SRM-SECY-98-263 Proposed Rule: Revision of 10 CFR Part 35, Medical Use of Byproduct Material

In SECY-98-263 Proposed Rule: Revision of 10 CFR Part 35, Medical Use of Byproduct Material, we asked for Commission direction on whether the public comment period for the proposed rule should be extended and whether a risk assessment should be performed in support of this rulemaking.

In the related SRM, the Commission approved Option 2B in the Paper and requested that the staff provide additional information on the need to perform a risk assessment. Specifically, the Commission directed the staff to extend the comment period for the proposed rule and the final rule due date for 30 days, but not to perform a formal risk assessment. The Commission asked that we include a discussion of the risk assessment as an option and provide the pros and cons for this option when the proposed final rule is submitted to the Commission. The pros and cons for performing a risk assessment are listed below.

Pros and Cons of Whether a Risk Assessment is Needed

Pros:

1. Risk assessment would provide additional information on the basis and need for revising regulations.

2. Responsive to comments made by stakeholders.

   Some stakeholders believe that Part 35 should be developed using a "risk-based" approach rather than a "risk-informed" approach. Commenters believe that NRC had not adequately assessed the risk of the various modalities for medical use because a formal risk assessment was not done. Three major comments were made on the need for a risk assessment: (1) NRC had not fully accounted for the low risk in diagnostic nuclear medicine; (2) relative risk must be considered because risk can occur from both action and inaction in medicine; and (3) NRC should perform a risk assessment, with stakeholders involved in the selection of the methodology, and publish the results for comment before it proceeds with any revision of its medical use program.

3. Responsive to written request from Organization of Agreement States to "extend the comment period for the ongoing revision of 10 CFR Part 35 to allow for the development of the risk analysis and the rule accordingly" (November 6, 1998).

Cons:

1. If the decision is made to perform a risk assessment, the publication date for the final rule would be significantly delayed. This would not be beneficial to many licensees since the draft final rule provides regulatory relief to licensees using unsealed byproduct material under §§ 35.100 and 35.200. The rule also codifies requirements for remote afterloaders and gamma stereotactic radiosurgery units.

2. NRC resource intensive. We estimate that a formal risk assessment, with significant stakeholder involvement, could require up to 10 FTE over a 5-year period and several million dollars for an outside contractor to perform the risk assessment. These resources are not included in the present budget submission or in the Operating Plan.

3. Not responsive to comments from Agreement State representatives at the 1998 All Agreement States Workshop on Part 35 and stakeholders.

Conclusion:

The staff believes that no additional risk assessment should be performed.

SRM: Briefing on Part 35

The Commission's SRM of April 23, 1999, requested that, in addition to the current patient notification language, the staff consider, and provide the pros and cons of revising the patient notification provisions to require: (1) verbal notification of the patient (or the individual's responsible relative or guardian) of the medical event while retaining the current caveat regarding referring physician discretion on patient notification; (2) written documentation of the medical event in the patient's file; and (3) written certification by the referring physician to the NRC that the patient was notified, unless discretion was exercised, as part of the event report submitted to NRC.

Discussion

The difference between this alternative and the draft final rule text in § 35.3045, "Report and notification of a medical event" would be deletion of paragraph (f). That paragraph would require a licensee to furnish individuals notified of medical events with a written report consisting of either the report submitted to NRC or a brief description of the event and the consequences as they may affect the patient. Thus, our discussion below sets forth the pros and cons of deleting the requirement for the licensee to provide a written report to the patient.

As part of our consideration of this alternative, we have interpreted the Commission's intent in the third part of the alternative as requiring the licensee, rather than the referring physician, to certify that the patient was notified of the medical event. This interpretation avoids the issue whether such a requirement should be imposed on an individual (the referring physician), who in all likelihood is neither an NRC licensee nor an individual otherwise subject to NRC reporting requirements (e.g., Section 206 of the Energy Reorganization Act of 1974).[1] Therefore, we have provided pros and cons of requiring the licensee, rather than the referring physician, to make the certification to the NRC.

Enclosure 1 contains regulatory text that could be used in the final rule to incorporate the approach described above. The regulatory text is identical to that proposed by staff in the draft final rule text with the exception of paragraph (f). Note, we have used the term "medical record" in the rule rather than the term "patient's file" because this is the term more commonly used in medicine and law to describe the collection of documents or other information pertaining to the physical or mental examination of or treatment administered to anyone. These records include, but are not limited to, patient histories, examination results, test results, records of drugs prescribed, dispensed, or administered, records of surgical or other medical procedures, and reports of consultations and hospitalizations.

[1] In addition, in some medical administrations, there may be no referring physician (i.e., the authorized user physician prescribes the administration of byproduct material and there is no referral from another physician).

Pros

- Is more consistent with medical policy goals of (1) avoiding or minimizing NRC intrusion into the practice of medicine, and (2) recognizing that physicians have the primary responsibility for the protection of their patients and that they will act in the best interest of their patients. (Reference 1)

- Places greater reliance on the physician-patient relationship, in which physicians are to provide patients with complete and accurate information (and in which patients have the right to obtain copies of their medical records). (Reference 2)

- Is consistent with SRM direction to revise Part 35 to be risk-informed, i.e., a requirement to provide the patient with copy of written report to NRC (or other written report) may unduly magnify, in the patient's eyes, an event that could be of minimal safety significance. (Reference 3)

- Is consistent with aspects of another Federal patient notification requirement, specifically, in "The Mammography Quality Standards Reauthorization Act" of 1998 (Pub. L. No. 105-248), under which notification (not specified as oral or written)[2] of a patient and referring physician may be required for certain events (i.e., when a patient has received mammography from a facility whose quality is found to be "so inconsistent with quality standards as to present a risk to individual or public health"). (Reference 4)

- Is responsive to commenters from medical community who objected to the requirement to provide the patient (or responsible relative) with a written report.

Cons

- Does not ensure that patients will be fully informed of a medical event (unless that information would be harmful to them), and therefore, patients may not receive information, viewed necessary by NRC, to make informed medical care decisions. (Reference 5)

- Is not consistent with other NRC requirements, in 10 CFR 20.2205 and 19.13(d), requiring licensees to provide to an individual a copy of the licensee's written report to NRC or other report of radiation exposures to that individual. (Reference 6)

- May not effectuate the specific Commission determination that patients have a right to fully know when they have been involved in a medical event unless that information would be harmful to them. (Reference 7)

- Is unduly prescriptive (i.e., requirement for written documentation of the medical event in

[2]However, a written report of the mammography results must be sent directly to the patient if the patient's physician is not available or if there is no such physician. Whether or not such a physician is available or there is no physician, a summary of the written report of mammography results must be sent directly to the patient. 42 U.S.C. § 263b(f)(1)(G)(ii)(III)-(IV).

the patient's file) as compared to the current rule (10 CFR 35.33(b) and proposed rule (10 CFR 35.3045(h), which do not dictate where the required record of a medical event be made.

- Does not recognize the right of individuals to know information about themselves which is contained in records both inside and outside the Federal sector, unless they have obtained their medical records. (Reference 8)

- May weaken protection of patients, articulated by the Commission as a basis for the misadministration rule (45 FR at 31702; May 14, 1989), due to the deletion of the requirement that a copy of the written report to NRC, or other written report, be provided to the patient.

- Does not account for inconsistent or incomplete adherence by physicians to the AMA Code of Medical Ethics provision for physicians to provide patients with complete and accurate information. (Staff has previously provided copies of professional medical journal articles on this subject to the Commission.)

- AMA threshold for informing patients of physicians' mistakes ("significant complications" to the patient) may not capture NRC "medical events." (Reference 9)

References

1. "Medical Use of Byproduct Material; Draft Policy Statement," 63 FR 43580, 43584-85 (August 13, 1998); "Regulation of the Medical Uses of Radioisotopes; Statement of General Policy," 42 FR 8242 (February 9, 1979).

2. American Medical Association Council on Ethical and Judicial Affairs, "Code of Medical Ethics," Fundamental Element 1.

3. COMSECY-96-057 "Materials/Medical Oversight (DS1 7), March 20, 1997.

4. 42 U.S.C. § 263b(h)(2)(1998).

5. "Quality Management Program and Misadministrations," 56 FR 34104, 34117 (July 25, 1991).

6. “Basic Quality Assurance Program, Records and Reports of Misadministrations or Events,” 55 FR 1439, 1444 (January 16, 1990); "Misadministration Reporting Requirements," 45 FR 31701, 31702 (May 2, 1980).

7. Basic Quality Assurance Program, Records and Reports of Misadministrations or Events, 55 FR 1439, 1444 (January 16, 1990), "Misadministration Reporting Requirements," 45 FR 31701, 31702 (May 2, 1980).

8. 55 FR 1444; 45 FR 31701.

9. "AMA Council on Ethical and Judicial Affairs, "Code of Medical Ethics," Current Opinions with Annotations at xxxix, 120, 125 (§ 8.12), 1996-1997.

Enclosure 1

Draft Alternative Rule Language

Differences between the draft final rule are marked to facilitate review.

§ 35.2045 Records of medical events.

(a) A licensee shall retain a record of medical events reported in accordance with § 35.3045 for 3 years.

(b) The record must include--

(1) The licensee's name;

(2) Names of all the individuals involved;

(3) The affected or potentially affected individual's social security number or other identification number of one has been assigned;

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

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

(6) The actions, if any, taken or planned to prevent recurrence.

§ 35.3045 Report and notification of a medical event.

(a) A licensee shall report any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in --

(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 delivered differs from the prescribed dose by 20 percent or more;

(ii) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(iii) 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 radioactive drug containing byproduct material;

(ii) An administration of a radioactive drug containing byproduct material 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 mode of treatment; 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 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

(b) A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct

material results or will result in an unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(c) The licensee shall notify by telephone the NRC Operations Center[3] no later than the next calendar day after discovery of the medical event.

(d) 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 --

(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, if any, on the individual(s) who received the administration;

(vi) What actions, if any, have been taken or are planned to prevent recurrence; and

(vii) Certification that ~~Whether~~ the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not; ~~and~~

~~(viii) 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.

(e) 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.

~~(f) If the individual was notified under paragraph (e) of this section, the licensee shall also furnish a written report to the individual within 15 days after discovery of the medical event. A licensee may send 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.~~

(f)~~(g)~~ 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.

(g)~~(h)~~ A licensee shall retain a record of a medical event in accordance with § 35.2045.

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[3] The commercial telephone number of the NRC Operations Center is (301) 951-0550.

ATTACHMENT 5

CRCPD SR-6 Committee Concerns

The Conference of Radiation Control Program Directors, Inc., SR-6 Committee plans to recommend to the States that they adopt more restrictive requirements than those in Part 35. The revised Part G, "Medical Uses of Radionuclides," of the Suggested State Regulations (SSR) will contain the rule text required to maintain compatibility with Part 35 but will also contain the more restrictive requirements. Any variances will be denoted by the bracketing of text and explanations in the rationale. In addition, the supporting rationale for the revision will recommend that the States adopt the more restrictive rule text.

Specific areas where the SR-6 Committee believes the rule should be more restrictive are listed below in order of the importance the Committee has placed on them:

Area 1 - Training and experience requirements for use of I-131 in quantities greater than 30 microcuries (§§ 35.392 and 35.394).

The SR-6 Committee intends to recommend that the States not adopt either § 35.392 or § 35.394 (80 hours of training plus casework) (currently codified, with minor differences, as §§ 35.932 and 35.934). The Committee plans to recommend that the States require individuals using iodine in quantities requiring a written directive to meet the training and experience requirements in § 35.390 (700 hours plus casework).

The Committee believes that radioiodine is the most radiotoxic radionuclide currently in use in medicine, and poses the greatest radiation risk to ancillary personnel and the general public. They stated that iodine misadministrations are the most common type of therapy misadministration, and that these misadministrations pose a greater biological radiation risk to the patient (based on the larger number of organs which receive unnecessary high exposures) and the public than a sealed source therapy misadministration does. Because of this, the Committee believes that authorized users of iodine therapy doses should not be held to lesser training and experience requirements than diagnostic users of radioiodine or any other diagnostic doses for which a written directive is required. They also believe their approach addresses the stakeholder comments recommending that the regulating agencies assure users are adequately trained in the medical use of byproduct material commensurate with the risk involved.

Note: Comments on this section of the proposed rule are summarized in the draft Federal Register Notice, Supplementary Information Section, Sections III and IV, General Training and Experience.

Area 2 - Need for a reporting requirement for unintended doses to an embryo/fetus or a nursing child (§ 35.3047).

The SR-6 Committee intends to recommend that the States not adopt the requirements in § 35.3047. Committee members believe that the reporting threshold should be 5 mSv

(500 mrem) as is currently required in § 20.2203(a)(2)(iv). In their opinion, the reporting requirement in § 35.3047 establishes a de facto approval on the part of the NRC to allow doses of 50 mSv (5 rem) to the embryo/fetus and nursing child. They do not believe the 5 mSv (500 mrem) limit in Part 20 will negatively impact the practice of diagnostic nuclear medicine because, based on information provided by radiologists and physicists, the majority of diagnostic nuclear medicine procedures will not result in a dose in excess of 5 mSv (500 mrem) to the embryo/fetus or nursing child. Therefore, the SR-6 Committee plans to allow Section D.1203, Aii(4) of the Suggested State Regulations, which requires the licensee to report exposures to an embryo/fetus or nursing child which exceed 5 mSv (500 mrem), to remain and prevail.

Note: Comments on this section of the proposed rule are summarized in the draft Federal Register Notice, Supplementary Information Section, Section III, § 35.3047.

Area 3 - Criteria for releasing individuals containing unsealed byproduct material or implants containing radioactive material (§ 35.75).

The Sr-6 Committee continues to be concerned by the current patient release rule's waiver of regulatory responsibility on the part of the licensee. They are also concerned with the number of radiation alarms at landfills that have been "tripped" by articles contaminated with radioactive materials after the individual is released from the licensee's facility and the State resources which must be expended in responding to these alarms. As a result, the Committee believes the rule should address the licensee's continued responsibility for the contaminated articles.

As a result, the SR-6 Committee plans to recommend that the States incorporate the following rule text into their regulations in this area. (Marked text in paragraphs (c) and (e) identifies where SSR text in this paragraph differs from the draft final rule text in § 35.75.)

Excerpts from draft SSR Part G, Sec.G.27.

(c) *The authorized user shall sign,* and the licensee shall maintain, a record of the basis for authorizing the release of an individual, in accordance with § 35.2075(a).

(e) Notwithstanding G.27a, the licensee may be held responsible for the proper disposal of any individual's radioactive waste discovered in a solid waste stream that can be traced to the licensee.

Note: Comments on this section in the proposed rule are summarized in the draft Federal Register Notice, Supplementary Information Section, Sections III and IV, § 35.75.

Area 4 - Safety precautions associated with brachytherapy treatments (§ 35.415).

The SR-6 Committee plans on allowing a patient receiving implant therapy to be in the same room as a nonradiation therapy patient only if the licensee documents that the public dose limits at a meter are met (Part D of the SSR). Currently, they do not intend to allow the housing of more than one unsealed source therapy patient in the same room (as is approved in the draft § 35.315). They plan to keep the requirement to survey both after implantation of brachytherapy sources and after the administration of unsealed therapy doses.

The SR-6 Committee plans to recommend that the States incorporate the following rule text into their regulations in this area.

Excerpts from draft SSR Part G, Sec. G.45 - Safety Precautions.

a. For each patient receiving implant therapy, a licensee shall:

i. Not place the patient in the same room with a patient who is not receiving radiation therapy unless the licensee can demonstrate compliance with the radiation dose limits for individual members of the public as specified in Part D of these regulations at a distance of 1 meter from the implant;

iii. Authorize visits by individuals under 18 years of age only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer;

iv. Promptly after implanting the sources, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with Part D of these regulations and retain for 3 years a record of each survey that includes the time and date of the survey, a sketch of the area or list of points surveyed, the measured dose rate at several points expressed in microsieverts (mrems) per hour, the instrument used to make the survey, and the initials of the individual who made the survey;

Note: 1. Comments on this section of the proposed rule are summarized in the draft Federal Register Notice, Supplementary Information Section, Section III, § 35.415.

2. The draft final Part 35 allows the licensees to quarter patients or human research subjects who are both undergoing a brachtherapy treatment and who cannot be released in accordance with § 35.75 to be quartered in the same room. It does not contain a dose limit for either patient.

3. The draft final Part 35 does not contain a requirement for the licensee to survey the dose rates in contiguous restricted and unrestricted areas. General requirements for surveys are contained in Part 20.

ATTACHMENT 6

SUMMARY MINUTES
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

MARCH 24-25, 1999

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) held a meeting in Rockville, Maryland on March 24-25, 1999. A briefing book, with background information for the issues under discussion, was provided to the ACMUI members in advance of the meeting, and is available through the Public Document Room.

ACMUI members present at the meeting:

Judith Ann Stitt, M.D., Chair

Manuel Cerqueira, M.D.
Nikita Hobson
Ruth McBurney, M.S., CHP
Dennis P. Swanson, M.S., B.C.N.P
John Graham (3/24 only)
Andrew Kang, M.D.
William B. Nelp, M.D. (3/25 only)
Louis K. Wagner, Ph.D.

Invited guests present at the meeting:

Bruce Bower, M.D., representing endocrinology perspectives
Larry Holder, M.D., representing nuclear medicine perspectives
Richard Vetter, Ph.D., representing Radiation Safety Officer perspectives
Jeffrey F. Williamson, Ph.D., representing medical physicists perspectives

Nuclear Regulatory Commission staff present at the meeting:

Cathy Haney, Section Leader, Rulemaking and Guidance Branch (RGB), IMNS, NMSS and Chair of the Part 35 Working Group (Designated Federal Official for the Committee)
Donald Cool, Ph.D., Director, Division of Industrial and Medical Nuclear Safety, NMSS
Robert Ayres, Ph.D., Materials Safety and Inspection Branch, INMS, NMSS

Part 35 Working Group Members present at the meeting:

Marjorie Rothschild, Office of the General Counsel
Penny Lanzisera, Region 1
Diane Flack, RGB
Sam Jones, RGB
Tony Tse, RGB
Tom Young, Region III
Barry Siegel, M.D., medical consultant to the Part 35 Working Group

OPENING REMARKS

Ms. Cathy Haney officially opened the meeting at 9:05 a.m. with general comments on the meeting agenda and the function of the ACMUI. Ms. Haney stated that she had reviewed the

Committee members' financial and employment interests, and had not identified any conflict of interest with items to be considered during the meeting. Ms. Haney stated that any ACMUI member who becomes aware of a potential conflict of interest during the course of the meeting should inform her or Dr. Judith Stitt. Ms. Haney noted that the meeting was announced in the Federal Register on March 3, 1999.

Donald A. Cool, Ph.D., made opening remarks to the Committee. Dr. Cool discussed the importance of the Part 35 rulemaking to the Commission as an effort to move in the direction of more risk-informed and performance-based regulations. He also expressed thanks to three members of the Committee whose terms are ending later in 1999, Dr. Stitt, Mr. Dennis Swanson, and Dr. William Nelp.

PREVIOUS ACMUI SUBCOMMITTEE RECOMMENDATIONS

Ms. Haney updated the Committee on the activities of the Part 35 Working Group since the ACMUI diagnostic and therapeutic subcommittee meetings in February 1999. She asked the Committee members to review the minutes of the subcommittee meetings to ensure that the minutes adequately captured the recommendations of the subcommittees. She indicated that the Working Group had incorporated most of the recommendations of the subcommittees into the revised draft final rule that was provided to the ACMUI in advance of this meeting (hereafter referred to as "draft final rule"). In a few cases, the Working Group wanted further information or dialogue with the Committee about certain recommendations.

TIMELINE FOR REVISION OF 10 CFR PART 35 AND ASSOCIATED ACTIVITIES

Ms. Haney summarized the Part 35 rulemaking activities leading up to the present meeting. She also explained that following this meeting the NRC staff and the ACMUI would brief the Commission on the draft final rule. Following the briefing, the rule would be revised to incorporate any ACMUI recommendations, unless the Commission had previously stated a position that was not consistent with the ACMUI recommendations, e.g., patient notification. This version of the rule would then be provided to the other NRC offices for review and concurrence. Comments from the other NRC offices would be returned by early May. She indicated that the final rulemaking package was due to the Commission by June 1999. Finally, she indicated that during the summer and fall of 1999, the Part 35 Working Group expects to focus on finalizing the guidance document associated with Part 35 (NUREG 1556) and the Medical Policy Statement.

REVIEW OF KEY ISSUES IN PART 35 WORKING GROUP'S DRAFT FINAL RULE

Ms. Haney explained that the Working Group had identified specific issues where they would like ACMUI review and comment. This review would assist the Working Group in finalizing the draft final rule for Commission consideration & approval and in writing the Statements of Consideration.

Section 35.292, Training for imaging and localization. (Note that this section was changed to 35.290 in version being forwarded to the Commission)

Ms. Haney indicated that the training and experience requirements in the proposed rule were focused on radiation safety. The duration of the training and experience program needed for individuals to become authorized users (AUs) for imaging and localization studies (§ 35.200) was significantly reduced from the current rule (1,200 hours to 120 hours). In addition, requirements for an examination in radiation safety and a preceptor affirmation of competence was added to the training requirements for AUs, as well as for the authorized nuclear pharmacist (ANP), authorized medical physicist (AMP), and Radiation Safety Officer (RSO).

Ms. Haney explained that the examination requirement was not included in the draft final rule, but a provision was added for NRC to review and approve training programs. She also explained that the duration of the training program for use of byproduct material for imaging and localization studies (§ 35.200) was increased from 120 hours to 700 hours. (The training and experience requirements in the proposed rule are presented in Attachment 1. The training and experience requirements in the draft final rule are presented in Attachment 2.)

A physician member of the public expressed concern that the training and experience requirements for this category of AUs had been increased since the last public meeting. Ms. Haney explained that the classroom and laboratory training (80 hours) and supervised practical experience (40 hours) would be considered a component within the 700 hours so the actual increase was 580 hours. Dr. Cerqueira stressed that it was important to ensure that the required hours of training could be done concurrently (i.e., 120 within the 700).

Dr. Siegel suggested that eliminating the words "in basic radionuclide handling techniques" would help to clarify that the requirement for 700 hours includes the 120 hours (80 hours of didactic and 40 hours of handling [80/40 split]). Mr. Swanson suggested that the specificity of 80 hours and 40 hours within the 700 hours was too prescriptive, and recommended instead that the requirement be made more flexible by saying "700 hours of training and experience applicable to the medical use of unsealed byproduct material." Dr. Siegel argued that this would provide insufficient information to training organizations on the breakdown between classroom training and practical work experience. Mr. Swanson then modified his recommendation to specify 700 hours of training "that includes 120 hours of training in the following areas: (1) didactic and (2) supervised practical experience."

Ms. McBurney suggested that specifying an 80/40 split in the 120 hours would allow Agreement States to make a determination on the adequacy of the alternate training program. Mr. Graham suggested that without such specification, the entire 120 hours could be provided in a classroom. Dr. Siegel agreed with Mr. Graham and suggested retaining the 80/40 specification.

Dr. Williamson also agreed with the split. Dr. Wagner suggested that the requirement say “at least 80 and at least 40." Mr. Swanson moved to leave the proposed final rule language as written, retaining the 80/40 split, that is to leave (c)(1) and (c)(2) of this section with respect to the required hours, unchanged.

Motion 1.1: Leave § 35.292(c)(1) and (c)(2), with respect to the required hours, unchanged.

Vote: 6 in favor, none opposed.

Mr. Swanson expressed concern about the requirements for “supervised practical experience under an authorized user.” He recommended instead that the reference should be to “experience under the preceptor,” since in some cases, such as a centralized nuclear pharmacy, the work would not be done under the supervision of an authorized user. He also questioned whether supervision was the same as preceptorship. Dr. Siegel suggested that the program director would be providing the supervision, while possibly delegating some of the responsibility for training to other persons.

Dr. Vetter supported the requirement for a preceptor. He was concerned that too narrow a restriction would make it impossible for an individual to go elsewhere to obtain specific elements of training. Dr. Wagner suggested that the requirement might be for supervised practical experience approved by a preceptor. Dr. Cerqueira also expressed concern that a cardiologist might obtain clinical training and experience in an Accreditation Council for Graduate Medical Education (ACGME) program, but go outside for didactic training. In that case, the clinical preceptor would have little authority or supervision over the outside program and two preceptor signatures might be needed. Ms. Haney explained that the preceptor will be required to certify that the individual is competent to function independently as an AU and, therefore, two signatures would not be needed.

Dr. Williamson supported revising the definition of preceptor in §35.2. Dr. Siegel thought that changing § 35.292(c)(2) to specify “under the direction of a preceptor” would be sufficient, because the preceptor would be taking the overall responsibility of ensuring that the individual had mastered the necessary material, and “direction” rather than “supervision” is a looser term. Mr. Graham asked if a medical physicist or pharmacist could serve as a preceptor, and was referred to the requirement that the preceptor must meet either §35.292 or § 35.390, which means he or she must be an AU. Dr. Cerqueira recommended using the term “preceptor authorized user” in §35.292(c)(2) and (c)(3) for clarity.

Mr. Swanson suggested that the term “radioactive drug” in the introductory statement to § 35.292 should be retained. Ms. Haney explained that the term radiopharmaceutical did not include biologics, and therefore “radioactive drug” was more appropriate. However, she noted, the FDA definition of radioactive drug could not be used because Part 35 only addresses use of byproduct material. Mr. Swanson noted that in some contexts, even in Part 35, the term should not be limited to byproduct material. For example, the 700 hours of training and experience received by an individual should not be limited to byproduct material because it could include accelerator-produced material, such as thallium. He also noted that in other contexts, use of the broad term “radioactive drug” may not be appropriate unless it is modified by “containing byproduct material.”

Mr. Graham moved to revise § 35.292(c). He moved that the phrase "in basic radionuclide handling techniques" be deleted and the term "radioactive drugs" be substituted for the term "unsealed byproduct material" in the introductory sentence of (c). He also moved that the word "direction" be substituted for the word "supervision" and the term "authorized user" be replaced with the term "preceptor authorized user" in paragraph (c)(2).

Dr. Vetter was concerned that nuclear pharmacists and RSOs may come to an institution having already had their didactic training, and, therefore, the preceptor could not have "directed" that training. Dr. Wagner noted that it is a question not only of direction, but also of approval of the training. Mr. Graham argued that the preceptor does not have to direct all the training, but only must be satisfied that all the training is acceptable. Dr. Cerqueira was concerned that the certifying preceptor could not always verify competence in any training received outside the program. Therefore, more than one preceptor statement might be necessary for individuals who do not obtain board certification, but instead seek AU status via the alternative pathway. Dr. Siegel noted that even medical boards do not require multiple program directors to attest to satisfactory completion of training. Dr. Wagner noted that the rule language should be revised to state: "under the direction of a preceptor" rather than "under the direction of the preceptor." This change would clarify that the preceptor who signs the certification does not need to direct all of the training. Secondly, he recommended replacing the phrase "under the direction of" with the phrase "approved by" to add flexibility.

Drs. Cerqueira and Siegel discussed the likelihood that an individual would plan his or her training in advance and use training programs approved by NRC or whether he or she would receive training in different places at different times. Dr. Siegel suggested an individual using a non-traditional approach could seek advance NRC approval. Dr. Cerqueira questioned if a mechanism existed for such approval. Ms. Haney noted that ACMUI assistance would be requested in approving training programs. She also asked whether NRC needed to approve the 120 hours of classroom and laboratory training and the balance of the 700 hours. Dr. Siegel believed that NRC does need to approve the entire 700, just as it would for an ACGME-approved program.

Mr. Graham argued that an individual should have the flexibility of obtaining training under the direction of multiple preceptor AUs. He moved to amend the pending motion to delete the term "authorized user physician" as preceptor and instead use the term "preceptor authorized user."

Motion 1.2:

1. Section 35.292(c), introductory sentence - The phrase "in basic radionuclide handling techniques" should be deleted and the term "radioactive drugs" should be substituted for the term "unsealed byproduct material."
2. Section 35.292(c)(2) - The word "direction" should be substituted for the word "supervision" and the term "authorized user" be replaced with the term "preceptor authorized user."
3. Section 35.292(c)(3) - The phrase "an authorized user" should be replaced with the phrase "preceptor authorized user" and the word "physician" should be deleted.

Vote: 7 in favor, none opposed.

Section 35.392, Training for use of sodium iodide I-131 for which a written directive is

required. (Note that this section was divided into 35.392 and 35.394 in the version being forwarded to the Commission.)

Mr. Swanson expressed concern that an individual who is authorized under § 35.392 for the use of I-131 could prepare I-131 capsules with only 80 hours of training. Dr. Siegel pointed out that the individual could not prepare the capsules because they are neither an ANP nor an AU under § 35.292. He indicated that an individual licensed under § 35.392 can only use a drug that is received from an organization licensed under § 32.72 or prepared by an ANP or an AU who meets the requirements in § 35.292. Dr. Siegel indicated that an AU who only meets the requirements of § 35.392 cannot direct anything be done to a drug received from a § 32.72 supplier. Mr. Swanson then moved that § 35.300(b) be amended to say: "who meets the requirements specified in §§ 35.292, 35.390, or an individual under the supervision . . . "

Ms. McBurney noted that the Conference of Radiation Control Program Director's, Inc., (CRCPD) working group developing State regulations had expressed concern to her about inconsistency between the training and experience requirements in §§ 35.292 and 35.390. They were concerned that the draft final training requirements for individuals that would like to use I-131 for treatment of hyperthyroidism and thyroid cancer were insufficient. Dr. Bower noted that I-131 dosages are administered orally, and have a low risk profile. It was also noted that the training and experience requirements in the proposed rule would have resulted in increased training requirements for an individual who would like to be authorized to administer only I-131 for hyperthyroidism or thyroid cancer. Finally, it was noted that the endocrinology community did not think the increase was warranted in light of their impeccable safety record under the current 80 hour training requirement.

Motion 2: Modify § 35.300(b) to state: "who meets the requirements specified in §§ 35.292, 35.390, or an individual under the supervision . . . "

Vote: 7 in favor, none opposed.

Intravascular Brachytherapy

Dr. Cerqueira suggested that intravascular brachytherapy should be classified under § 35.1000, "Other medical uses of byproduct material or radiation from byproduct material," as an emerging technology. Ms. Haney noted that intravascular brachytherapy is currently addressed under the requirements for brachytherapy, and that the draft final rule does not explicitly classify intravascular brachytherapy as an emerging technology. She explained that the training and experience requirements for intravascular brachytherapy will be addressed after the completion of the Part 35 rulemaking, and in the meantime will be handled on a case-by-case basis.

Dr. Cerqueira made a motion that intravascular brachytherapy, for the prevention of restenosis in the vascular system, be classified as an emerging technology, pending the results of the ongoing Food and Drug Administration (FDA)/broad trials. Mr. Graham suggested that the implications for intravascular brachytherapy would be better understood if the topic was addressed as part of a broader discussion of Subpart K. Ms. McBurney moved to table the motion.

Motion 3: Table the motion to discuss intravascular brachytherapy for prevention of restenosis

in the vascular system until discussion of Subpart K.

Vote: 6 in favor, Dr. Cerquiera opposed, believing it appropriate to discuss at this time.

General Discussion - Training and Experience Requirements - Alternative Pathway Chart (Attachment 2)

The Committee reviewed the chart that summarized the training and experience requirements for the alternative pathway to obtain status as an AU, ANP, AMP, or RSO (Attachment 2).

Ms. McBurney expressed concern over the training requirements for an AU that would like to use sodium iodide I-131 for hyperthyroidism and thyroid carcinoma. Dr. Wagner suggested, and Dr. Siegel agreed, that explicitly stating that the requirements pertained only to oral administration of I-131 would be desirable.

Motion 4: Approve the training and experience requirements - Alternative Pathway (Attachment 2).

Vote: 7 in favor, none opposed.

Section 35.24, Authority and responsibility for the radiation protection program.

Radiation Safety Committee (RSC)

Ms. Flack explained under § 35.24(b) that an RSC is required if the institution has two or more different types of uses of byproduct material under Subparts E, F, and H. The ACMUI therapy subcommittee had suggested inserting "or." Ms. Flack asked whether the different types of uses would have to be in different Subparts, or whether an RSC should be required if there are different types of machines that are included in the same subpart, e.g., is an RSC needed if a licensee only has a remote afterloader and a teletherapy unit.

Mr. Graham explained that an RSC should not be required if there was only one type of use. Ms. Haney noted that “type of use” is used to reference use of byproduct material as specified in §§ 35.100, 35.200, 35.300, 35.400, 35.500, 35.600, and 35.1000. As proposed in the draft final rule, if a licensee only used unsealed byproduct material in quantities that required a written directive (§ 35.300), it would not be required to have an RSC. However, a licensee that used unsealed byproduct material in quantities that require a written directive (§ 35.300) and manual brachytherapy (§ 35.400) would be required to have an RSC.

Dr. Williamson noted that two units under § 35.600 would not be covered by the term “types of use.” Dr. Wagner suggested adding a reference to two or more units under § 35.600, so that even two of the same type of units would require a RSC. Dr. Williamson advocated making the criterion two or more uses under § 35.600. Dr. Stitt suggested that the distinction between “units” and “uses” should be clear.

Mr. Graham moved that § 35.24(b) be amended to read that licensees authorized for two or more different types of uses of byproduct material under Subparts E, F, or H or two or more types of units under Subpart H should be required to have an RSC. Dr. Siegel suggested that

uses under Subpart K should also be included. Ms. Haney said that the need for an RSC under Subpart K should be addressed on a case-by-case because it could involve a low risk activity. Ms. McBurney moved to modify the motion to state "two or more uses under E, F, and H."

Motion 5.1: That § 35.24(b) be amended to state "Subparts E, F, and H or two or more types of units under Subpart H."

Vote: 7 in favor, none opposed.

Dr. Siegel commented that the RSC's duties should be clarified, to specify that the RSC is not just responsible for the activities that mandate the RSC, but also for all other activities involving the use of byproduct materials in the institution. For example, he explained, if an RSC is required because both Subpart E and Subpart H activities are permitted by the license, the intent is that Subpart D activities at the institution would also be covered by the RSC. Mr. Graham moved to change § 35.24 to read: "establish a radiation safety committee to oversee all uses of byproduct material permitted by the licensee."

Motion 5.2: That § 35.24 be amended to "establish a radiation safety committee to oversee all uses of byproduct material permitted by the licensee."

Vote: 7 in favor, none opposed.

Temporary Radiation Safety Officer (RSO)

Ms. Flack noted that the Working Group is revising § 35.24 to allow multiple temporary RSOs. The Committee made no specific comments on this item.

Section 35.27, Supervision.

Ms. Flack stated that the Working Group considered it important to retain the requirements in § 35.27. Mr. Graham noted that ultimately the chief executive officer is responsible for the actions of everyone who is carrying out any activity that is in any way covered by the hospital's license. He indicated that the draft final rule is correct - licensees are responsible for the acts and omissions of the supervised individual. The Committee had no other comments on this item.

Section 35.40, Written Directives.

Ms. Flack asked the Committee to review § 35.40(b) that lists the information that must be included in written directives. Dr. Williamson recommended that the rule should be revised to state that a written directive for gamma stereotactic radiosurgery include the treatment site, total dose, and number of gamma stereotactic shots for each anatomically distinct treatment site. Other specifications, such as gamma angles and coordinates, should be placed in the treatment plan description. In addition, the written directive should specify number of target coordinate settings, not the target coordinate settings themselves. Dr. Stitt agreed.

Dr. Siegel asked whether the term "anatomically distinct treatment site" was consistent with the definition of treatment site in § 35.2. Dr. Williamson clarified that "distinct" in treatment planning

means that the dose contribution from site one is not considered in planning the dose to site two. Dr. Stitt agreed that the language was consistent and would not be burdensome. Dr. Williamson also stated that, to the best of his knowledge, the gamma stereotactic radiosurgery device is only used for single fraction radiosurgery.

Dr. Siegel asked if § 35.40(b) should specify route of administration. Dr. Vetter pointed out that § 35.392 already specifies oral administration, although for sources of I-131 other than sodium iodide, the route of administration should be specified. Mr. Swanson argued that under (b)(1), the written directive could contain a dosage but not the identity of the radiopharmaceutical. Dr. Siegel explained that a form would generally be used to identify the radiopharmaceutical as I-131 sodium iodide. Mr. Graham was unwilling to rely on a form, and argued in favor of adding the radiopharmaceutical name to the minimum requirements for a written directive. The Committee determined that the rule should be modified to address these concerns. Specifically § 35.40(b)(1) should be revised to state: "for an administration of a radiopharmaceutical: the radiopharmaceutical, dosage, and route of administration." The Committee also agreed that the balance of the list of items to be included in the written directive was acceptable.

Dr. Williamson noted that for remote afterloading brachytherapy, the written directive must include the radionuclide, treatment site, dose per fraction, number of fractions, and total dose. He did not believe the requirements for a low dose-rate (LDR) remote afterloader were appropriate, since the logistics of loading the sources, and doing the treatment planning before the treatment is complete, are identical to the requirements for manual brachytherapy. He believed the requirements should be modified to group the requirements for manual brachytherapy with the requirements for pulsed dose-rate (PDR), medium dose-rate (MDR), and LDR remote afterloaders. Dr. Stitt agreed.

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

Ms. Haney indicated that the definition for prescribed dosage, as specified in the proposed rule, did not preclude the AU from prescribing a dosage range. In addition, the requirements for written directive in § 35.40 do not preclude an AU from prescribing a dosage range. She also indicated that § 35.63 provides for a 20% deviation between the prescribed and administered dosage.

Dr. Siegel suggested that the rule allow the AU to prescribe a dosage range. He went on to state that if the dosage is specified as a range, the administered dosage must fall within that range. Whereas if the dosage is specified as a single number, the administered dosage should be within 20% of the prescribed dosage. Dr. Vetter questioned whether such a broad latitude would be wise from a radiation safety perspective. Dr. Siegel noted that a physician has latitude to prescribe a dosage range.

Dr. Wagner questioned whether the requirement that administered dosages be within 20% of the prescribed dosage was limited to administrations that require a written directive. He believed a 20% range was acceptable for diagnostic dosages but might not be acceptable for therapeutic doses or dosages. Dr. Williamson noted that the practice was not to prescribe dose ranges when using sealed therapy sources. Typically, the radiation oncologist specifies a single dose. Dr. Williamson was concerned that allowing AUs to specify a range would cause an increase in treatment delivery errors. Dr. Stitt agreed that a specific dose was desirable for

therapeutic uses, although flexibility for diagnostic uses made sense.

Mr. Swanson moved to amend § 35.63(d) to allow a licensee to administer dosages that do not differ from the prescribed dosage by more than 20% or dosages that fall within the prescribed dosage range, unless otherwise directed by the AU.

The Committee discussed at length whether a dosage range should be allowed for unsealed byproduct material that requires a written directive. Dr. Wagner moved to make the distinction according to whether or not a written directive is required.

Mr. Swanson argued that this approach directly interfered with the practice of medicine and implied a level of accuracy and dosage determinations with unsealed byproduct material that does not exist. Dr. Wagner agreed that the issue is defining the boundary between radiation safety and interference with good medical practice. Dr. Williamson was concerned that by allowing a range for certain modalities, an incentive could be created for practitioners to abandon time-honored practices of prescribing a single number in order to avoid potential problems of regulatory enforcement.

Dr. Wagner sought to clarify the motion. He wanted to specify that ranges should not be allowed for the medical use of byproduct material where a written directive is required. Drs. Wagner and Siegel noted examples of situations in which a 20% range could be too narrow. In some cases, administrations could fall outside this range but still be within acceptable medical limits.

Ms. Haney summarized the motion as follows:

Motion 6: NRC regulations should reflect the following:

1. An authorized user may prescribe a dosage range for material administered under §§ 35.100, 35.200, and 35.500.
2. An authorized user may not prescribe a dosage range for material administered under §§ 35.300, 35.400, and 35.600.
3. Administered activities can deviate from a prescribed dosage by 20%.

The Committee decided not to address the issue of a dose range for material used under §§ 35.400 or 35.600.

Vote: Motion withdrawn.

Motion 7: Amend § 35.63(d) to state that unless otherwise directed by the AU, a licensee shall not use a dosage if (a) the dosage differs from the prescribed dosage by more than 20% or (b) the dosage does not fall within the prescribed dosage range.

Vote: 7 in favor, none opposed.

Section 35.3045, Reports of medical events.

Ms. Flack summarized the requirements for medical event reporting, noting that the Working Group revised the requirement to exclude reporting of events that occur as a result of patient

intervention, unless a physician determines that the event resulted in permanent function damage to an organ or a physiological system. Ms. Flack also explained that wrong treatment site now involves a dose to the skin or an organ or tissue, other than the treatment site, that exceeds 50 rem to an organ or tissue or 50% of the dose expected from the administration.

Dr. Williamson suggested that the Working Group completely revise the definition of medical event to say it is "an administration of byproduct material in which a technical error on the part of the care giver or device malfunction results in a dose that . . ." Ms. Haney noted that the phrase "technical error" would need to be defined. Drs. Stitt and Wagner agreed that it would be difficult to define "technical error." Dr. Siegel noted that even with the proposed definition, patient intervention would need to be defined. Dr. Stitt concluded that the proposed final rule was a definite improvement over the current requirements.

Mr. Swanson requested that the Statements of Consideration contain a clear statement that subcutaneous infiltration of a dose that was put into a vein is not considered wrong route of administration.

Ms. Haney requested comments on the phrase "or is expected to result." She explained that the Working Group used the abnormal occurrence reporting policy, which used similar language, in developing the rule text. Mr. Graham and Dr. Siegel suggested using the phrase "results or will result" rather than the phrase "or is expected to result." Dr. Stitt agreed with this approach.

Dr. Wagner noted that the phrase "dose to the skin" could mean dose to a point on the skin or dose to all or a large area of the skin as an organ. He moved that all references to "skin, organ, or tissue" be revised to reference "tissue" only.

Motion 8: In § 35.3045, references to "skin, organ, or tissue" should be revised to reference "tissue" only.

Vote: 7 in favor, none opposed.

The Committee agreed, by consensus, to accept the remainder of the editorial rule changes to this section.

Mr. Swanson moved that the Committee go on record as opposing the patient notification requirements in §§ 35.3045 and 35.3047. Dr. Stitt agreed with the statement that the ACMUI does not support any regulation for required notification of physicians and patients, because the requirement is redundant to existing State laws and medical ethics. Ms. Hobson also noted the possible cruelty in notifying patients unnecessarily and frightening them if negative effects of the event were not anticipated. Ms. Haney noted that the Commission believes the requirement to notify patients recognizes the right of individuals to know information about themselves and provides the opportunity for patients to consult with their personal physicians to make timely decisions about their health care. Drs. Stitt and Siegel noted that providing the patient with a copy of the official letter citing Federal regulations harms the physician-patient relationship. Mr. Graham moved to modify the motion to add that notification is redundant to existing State laws and medical ethics.

Motion 9: ACMUI reaffirms that it does not support any regulation requiring notification of physicians and patients as this is redundant to existing State laws and medical ethics.

Vote: 6 in favor, none opposed, 1 abstention. Ms. McBurney abstained, on the grounds that NRC's reasons for retention of the requirement may be valid, and because she was not an official Committee member during the initial discussion.

Dr. Siegel proposed adding the words "if any" to paragraphs (d)(1)(v), (vi) and (vii). Dr. Stitt agreed, since in some cases there will be no effect on the patient; no improvements are necessary in the program; and no actions need to be taken. The Committee approved the change.

Section 35.3047, Report of a dose to an embryo/fetus or a nursing child.

Ms. Flack indicated that the Working Group had not made any changes to the draft final rule since the subcommittee meetings. However, it has been considering whether the requirement should be removed from the Part 35 rulemaking and instead become the subject of a Part 20 rulemaking that would apply to all NRC licensees. She also indicated that the majority of the Working Group members believed that the reporting threshold for reports should be 50 mSv (5 rem) rather than 5 mSv (500 mrem). Ms. Flack noted that based on information contained in a recent study (Joy R. Russell, et al.,"Radiation absorbed dose to the embryo/fetus from radiopharmaceuticals," *Health Physics Journal*, 73:5 (November 1997) pp. 756-769), a 5 mSv (500 mrem) level could result in a large number of reports being submitted to NRC. Dr. Siegel noted that if the Agreement States adopted the rule, the number of reports would be substantially larger because of gallium and thallium use. Ms. Haney noted that representatives from the CRCPD SR-6 Committee indicated to her that they preferred the 5 mSv (500 mrem) level.

Ms. McBurney moved that the requirement be placed in Part 20.

Motion 10: The reporting requirements for unintended exposures to an embryo/fetus or nursing child that are currently in § 35.3047 should be moved to Part 20.

Vote: 7 in favor, none opposed.

Dr. Siegel stated that the 5 mSv (500 mrem) limit could impact use of byproduct material in diagnostic nuclear medicine. He indicated that a number of nuclear medicine procedures could approach the 5 mSv (500 mrem) limit and would impose either a de facto pregnancy testing requirement or a de facto diversion of women of childbearing age away from needed nuclear medicine procedures. Dr. Wagner stressed the importance of the issue, arguing that the 5 mSv (500 mrem) level would lead to a great amount of patient anxiety and stress. He agreed that the rule would require pregnancy testing for a large number of diagnostic nuclear medicine patients. He supported the 50 mSv (5 rem) reporting level. Mr. Graham moved that the ACMUI endorse the subcommittee recommendation that the reporting threshold be 50 mSv (5 rem).

Motion 11: The reporting threshold in § 35.3047 should be 50 mSv (5 rem).

Vote: 7 in favor, none opposed.

Dr. Wagner noted that the only action a physician can do to protect the nursing child is to properly notify and instruct the mother about the precautions to be taken to minimize exposure to the child. He moved that the notification requirements in § 35.3047, that pertain to a nursing child, be restricted to events in which the mother was not properly instructed in accordance with § 35.75 prior to release from the facility.

Motion 12: The reporting requirements in § 35.3047 should be limited to only those events where the mother was not properly instructed in accordance with § 35.75 prior to release from the facility.

Vote: 6 in favor, none opposed, 1 abstention. Ms. McBurney abstained, on the grounds that NRC's reasons for retention of the requirement may be valid, and because she was not an official Committee member during the initial discussion. (Mr. Graham no longer present.)

Dr. Siegel proposed adding the words "if any" to paragraphs (d)(1)(v) and (vi). The Committee agreed.

Mr. Swanson moved that the ACMUI state that it does not support any regulation requiring notification of physicians, mothers, or pregnant women as this is redundant to existing State laws and medical ethics.

Motion 13: ACMUI does not support any regulation requiring notification of physicians, mothers, or pregnant women as this is redundant to existing State laws and medical ethics.

Vote: 5 in favor, none opposed, 1 abstention. Ms. McBurney abstained, because NRC's reasons for the requirement may be valid. (Mr. Graham no longer present.)

Dr. Siegel suggested and Dr. Wagner moved that the language on unintended permanent functional damage be added.

Motion 14: The following phrase should be included with regards to the embryo/fetal reporting requirement in § 35.3047(a): "Has resulted or will result in an unintended permanent functional damage to an organ or a physiological system, as determined by a physician."

Vote: 6 in favor, none opposed (Mr. Graham no longer present).

Dr. Siegel raised the question of how the phrase "specifically approved in advance by the authorized user" will be interpreted, when a dose is given to a patient based on the belief that she is not pregnant, especially during the period when pregnancy is undetectable. Ms. Haney requested advice on what the Statements of Consideration should say on this subject. Dr. Wagner noted that if the threshold is placed at 500 millirem, a large number of reports would be generated concerning doses to individuals within the first two weeks after conception. Dr. Williamson expressed concern that the medical community will be forced to give pregnancy tests to every woman of childbearing age who receives a diagnostic procedure. Dr. Wagner noted that even pregnancy tests would not be effective early in the pregnancy. The Committee concluded that the Statements of Consideration should acknowledge that there is no need to report an exposure to an embryo/fetus if the exposure occurred while the pregnancy was not medically detectable.

The meeting recessed at 5:33 p.m. on March 24, 1999.

The meeting reconvened at 8:08 a.m. on March 25, 1999.

REVIEW OF ISSUES RAISED BY NRC GENERIC ASSESSMENT PANEL

Dr. Bob Ayres explained that the NRC Generic Assessment Panel had two issues requiring ACMUI advice. First, an Agreement State licensee had used an ultasound device to place iodine-125 (I-125) seeds in a patient's prostate. The ultrasound device did not have the necessary resolution to image the ends of the implant needle. As a result, 31 seeds were placed in the patient's bladder. Dr. Williamson suggested that the problem was a failure of the device quality assurance program, noting that there are standard tests that are done to ensure contrast resolution. Dr. Holder thought the problem was due to inadequate operator training. Specifically, operators should know what they are looking at and be obligated to not proceed if they cannot see properly. Dr. Siegel asked if this event was considered to be a misadministration or an example of malpractice. If a physician performed the actions, he suggested, it might be malpractice and not require NRC involvement. Dr. Ayres said it was a misadministration, since the intended dose was not given. He asked ACMUI to advise whether NRC should describe this event to its licensees as a generic issue. Ms. McBurney did not believe it was a generic issue since this was the only instance known to have occurred. Dr. Cerqueira thought that it was a malpractice issue and no NRC action was needed. Dr. Stitt indicated that the staff needed to provide additional, more detailed information to the ACMUI prior to any further action.

Second, an Agreement State licensee was giving written instructions to I-125 prostate implant patients that directed the patients to strain their urine for at least the first few days, after source implantation, to capture any I-125 seeds. The instructions directed the patient to return the seeds to the hospital. The licensee indicated that the purpose of the instructions was to ensure that the patient is receiving the "correct dose." Dr. Ayres indicated that the Generic Assessment Panel was concerned that patients would not handle the seeds properly. He requested ACMUI advice on actions, if any, that should be taken by NRC. Dr. Williamson thought that it could be within the medical purview of the physician to ask that the seeds be counted, but he believed the patient should be instructed to then flush them down the toilet rather than collecting and retaining them or transferring them to someone else. Dr. Nelp thought the instruction given to the patient was a matter of medical practice and ACMUI or NRC involvement was not needed. No further recommendations were made.

CONTINUED REVIEW OF KEY ISSUES IN WORKING GROUP'S DRAFT FINAL PART 35 RULE

Section 35.2, Definitions.

Ms. Rothschild questioned whether the duties of the AU, ANP, AMP, and RSO should be placed in the rule or in the guidance document. The Committee agreed that the list of duties should be placed in the guidance rather than in the rule, provided the list did not place any additional requirements on the individuals.

The Committee agreed with the following actions:

1. The definition of diagnostic clinical procedures manual and reference to it should be deleted from the rule.

2. MDR remote afterloaders should be defined.

3. The definition of prescribed dosage should be revised to state: "the quantity or range of radiopharmaceutical activity, as documented in . . ."

4. Ms. Haney and Drs. Stitt and Williamson should develop a definition of manual brachytherapy.

5. The term "radioactive drug" rather than "radiopharmaceutical" should be used generically in the rule. They noted some places where it may be necessary to use the phrase "radioactive drug containing byproduct material."

6. The definition for a unit dosage should be revised to reference dosages prepared "by or under the supervision" of an ANP or AU. The definition should also clearly state that a unit dosage is a dosage intended for medical use, without subsequent manipulation, in a single patient."

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

The Committee was asked whether NRC should only review and approve the procedures required in Subpart H as part of the license or amendment process. Mr. Swanson and Dr. Siegel noted that Subpart K should require a more detailed review of procedures for an emerging technology. Dr. Williamson supported the change, but asked why it was necessary for NRC to review the procedures required by Subpart H. Ms. Haney explained that at present only one procedure is required by Subpart H (full calibrations and spot checks).

Drs. Wagner and Williamson suggested that the review of procedures was unnecessarily burdensome and resulted in a situation where the licensee could only change a protocol by a license amendment. Ms. McBurney noted that Agreement States prefer the review to be done by the license reviewer rather than by an inspector.

Dr. Cerqueira moved that NRC should not require license applicants to provide any procedures, including Subpart H procedures, to NRC for review prior to NRC issuance of the license or amendment and, therefore, should not tie licensees to those procedures via license conditions. Dr. Wagner noted that the real issue was whether licensees must follow the procedures unless they apply for and receive a license amendment that allows use of a revised procedure. He suggested the motion should say that the licensee is free to amend the procedures as needed, without prior approval.

Motion 15: ACMUI believes that NRC should not require license applicants to provide any procedures (including Subpart H procedures) to NRC for review prior to NRC issuance of the license (or amendments) and therefore should not tie licensees to these procedures via license conditions.

Vote: 5 in favor; 1 opposed, 1 abstention. Ms. McBurney opposed because States and many licensees want review of procedures. Dr. Nelp abstained because he disliked how the motion was phrased.

Section 35.60, Possession, use and calibration of instruments to measure the activity of unsealed byproduct materials.

The Committee agreed with the proposed revisions to § 35.60. Mr. Swanson recommended that the identity and serial number of any radionuclide standards used in calibrating the instruments be included in the recordkeeping requirement in § 35.2060.

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

Dr. Siegel noted that § 35.63 needed to be revised to address the issue of tritiated and carbon-14 compounds used in research, which may be obtained from a manufacturer who is not a § 32.72 licensee, radiopharmacist, or AU, but whose activity cannot be directly measured by a licensee without altering the dosage. Dr. Stitt suggested additional work by the Working Group to address the issue.

Section 35.400, Use of sealed sources for manual brachytherapy.

The Committee agreed with the addition of the phrase “in accordance with an effective investigational device exemption application accepted by the FDA” in § 35.400. The ACMUI believed this phrase addresses use of sources not listed in the Sealed Source and Device Registry.

Section 35. 410, Safety Instructions.

The Committee agreed with the revision to § 35.410 that requires an AU to be notified if a

patient or human research subject has a medical emergency or dies.

Section 35.432, Calibration measurements of brachytherapy sealed sources.

The Committee agreed with allowing a licensee to accept a manufacturer's calibration of manual brachytherapy sources.

Subpart H, Use of a Sealed Source in Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

The Committee agreed with limiting Subpart H to photon-emitting devices.

Section 35.600, Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.

The Committee agreed with the addition of the phrase "in accordance with an effective investigational device exemption application accepted by the FDA" in § 35.600. The ACMUI believed this phrase addresses use of sources not listed in the Sealed Source and Device Registry.

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

Dr. Williamson noted that the requirements for qualified individuals to be present during initiation and ongoing treatments with MDR and HDR afterloaders should not be identical. He believed that requirements for MDR, LDR, and PDR remote afterloaders should be similar.

The Committee reached agreement on the following items:

1. The draft final language in § 35.615 for "an authorized medical physicist and an authorized user or an individual under the supervision of the authorized user who has been trained to remove the applicators in the event of an emergency, to be immediately available during continuation of all patient treatments," during initiation and ongoing treatments with an MDR afterloader provides needed flexibility.

2. Only a physician designee is needed at the initiation of a treatment with a PDR remote afterloader.

3. Paragraph (b) should be revised to delete the requirement to "immediately" shield the radioactive source for gamma stereotactic radiosurgery, because time is needed to withdraw the patient.

Section 35.632, Full calibration measurements on teletherapy units.
Section 35.633, Full calibration measurements on remote afterloader units.
Section 35.635, Full calibration measurements on gamma stereotactic radiosurgery units.

The Committee agreed with the requirements for calibration in §§ 35.632, 35.633, and 35.635.

Section 35.642, Periodic spot-checks for teletherapy units.
Section 35.643, Periodic spot-checks for remote afterloader units.
Section 35.644, Periodic spot-checks for low dose-rate remote afterloaders.
Section 35.645, Periodic spot-checks for gamma stereotactic radiosurgery units.

The Committee agreed with the removal of the redundancies in §§ 35.642, 35.643, 35.644, and 35.645. Dr. Williamson recommended changing the check on source transfer tubes from quarterly to annually. He also recommended NRC clarify whether LDR remote afterloader licensees need to possess a calibration system if they rely on the manufacturer's calibrations.

Section 35.657, Therapy-related radiosurgery units.

The Committee suggested that Dr. Williamson review the requirements in § 35.657 directly with the Working Group.

Preparation of Commission Briefing Materials

The Committee members developed a list of issues that they wished to bring to the attention of the Commission and identified the members of the Committee who would present particular parts of the briefing.

10 CFR Part 32, Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material.

Mr. Swanson noted that Part 32 contains similar requirements to the current Part 35. In particular, § 32.72, "Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35," requires that the licensee have instrumentation to measure the radioactivity of drugs and have procedures for use of the instrumentation. Mr. Swanson made a motion that, following completion of the Part 35 rulemaking, the NRC review § 32.72 and make it consistent with the requirements in the final Part 35.

Motion 16: Subsequent to publication of the final Part 35 rule, NRC should review Part 32 for items of consistency.

Vote: 6 in favor, none opposed.

ACGME and NRC Approval of Training Programs

Dr. Cerqueira indicated that only the nuclear medicine program, as described in the ACGME Directory, meets the requirements to be ACGME accredited. The description of the radiology program is general; the cardiology program does not specify details about the hours of training; and the endocrinology program does not specify requirements.

Dr. Cerqueira was concerned that all cardiology, radiology, and endocrinology programs will have to apply to NRC for approval. He noted that there are over 400 cardiology training programs. He was uncertain how quickly programs could make the necessary changes to the ACGME Directory. Dr. Holder suggested that all of the 400 programs would not involve nuclear

cardiology and so only a portion of them would seek approval. Dr. Siegel argued that programs, such as radiology, would be able to make the necessary changes in the program description within the two-year rule implementation period.

Mr. Swanson suggested that the cardiology and endocrinology societies should seek information on what would be involved in obtaining ACGME approval of the nuclear cardiology and nuclear endocrinology programs. Dr. Siegel noted that programs have cross-departmental training, so potentially cardiologists or endocrinologists could obtain the necessary training as part of a radiology or nuclear medicine program, as an elective in their cardiology or endocrinology training. The necessary training could be an elective component of an ACGME-approved training program, rather than an essential component of all programs, but the requirements of the program would need to be specified for that elective.

At 12:17 p.m. Ms. Haney adjourned the meeting.

SUMMARY OF MOTIONS

Motion 1.1: Leave § 35.392(c)(1) and (c)(2), with respect to the required hours, unchanged.
Vote: 7 in favor, none opposed.

Motion 1.2:
1. Section 35.292(c), introductory sentence - The phrase “in basic radionuclide handling techniques” should be deleted and the term “radioactive drugs” should be substituted for the term “unsealed byproduct material.”
2. Section 35.292(c)(2) - The word “direction” should be substituted for the word “supervision” and the term “authorized user” be replaced with the term “preceptor authorized user.”
3. Section 35.292(c)(3) - The phrase “an authorized user” should be replaced with the phrase “preceptor authorized user” and the word “physician” should be deleted.

Vote: 7 in favor, none opposed.

Motion 2: Modify § 35.300(b) to state "who meets the requirements specified in §§ 35.292, 35.390, or an individual under the supervision . . . "
Vote: 7 in favor, none opposed.

Motion 3: Table the motion to discuss intravascular brachytherapy for prevention of restenosis in the vascular system until discussion of Subpart K.
Vote: 6 in favor, Dr. Cerquiera opposed, believing it appropriate to discuss at this time.

Motion 4: Approve the training and experience requirements - alternative pathway (chart)
Vote: 7 in favor, none opposed.

Motion 5.1: That § 35.24(b) be amended to state “Subparts E, F, and H or two or more types of units under Subpart H.”
Vote: 7 in favor, none opposed.

Motion 5.2: That § 35.24 be amended to “establish a radiation safety committee to oversee all uses of byproduct material permitted by the licensee.”
Vote: 7 in favor, none opposed.

Motion 6: NRC regulations should reflect the following:
1. An authorized user may prescribe a dosage range for material administered under §§ 35.100, 35.200, and 35.500.
2. An authorized user may not prescribe a dosage range for material administered under §§ 35.300, 35.400, and 35.600.
3. Administered activities can deviate from a prescribed dosage by 20%.

Vote: Motion withdrawn.

Motion 7: Amend § 35.63(d) to state that unless otherwise directed by the AU, a licensee shall not use a dosage if (a) the dosage differs from the prescribed dosage by more than 20% or (b) the dosage does not fall within the prescribed dosage range.
Vote: 7 in favor, none opposed.

Motion 8: In §35.3045, references to "skin, organ, or tissue" should be revised to reference "tissue" only.

Vote: 7 in favor, none opposed.

Motion 9: ACMUI reaffirms that it does not support any regulation requiring notification of physicians and patients as this is redundant to existing State laws and medical ethics.

Vote: 6 in favor, None opposed, 1 abstention. Ms. McBurney abstained, on the grounds that NRC's reasons for retention of the requirement may be valid, and because she was not an official Committee member during the initial discussion.

Motion 11: The reporting threshold in § 35.3047 should be 5 rem.

Vote: 7 in favor, none opposed.

Motion 12: The reporting requirements in § 35.3047 should be limited to only those events where the mother was not properly instructed in accordance with § 35.75 prior to release from the facility.

Vote: 6 in favor, none opposed, 1 abstention. Ms. McBurney abstained, on the grounds that NRC's reasons for retention of the requirement may be valid, and because she was not an official Committee member during the initial discussion. (Mr. Graham no longer present.)

Motion 13: ACMUI does not support any regulation requiring notification of physicians, mothers or pregnant women as this is redundant to existing State laws and medical ethics.

Vote: 5 in favor, none opposed, 1 abstention. Ms. McBurney abstained, because NRC's reasons for the requirement may be valid. (Mr. Graham no longer present.)

Motion 14: The following sentence should be included with regards to the embryo/fetal reporting requirement in § 35.3047(a), "Has resulted or will result in an unintended permanent functional damage to an organ or a physiological system, as determined by a physician."

Vote: 6 in favor, none opposed (Mr. Graham no longer present).

Motion 15: ACMUI believes that NRC should not require license applicants to provide any procedures (including Subpart H procedures) to NRC for review prior to NRC issuance of the license (or amendments) and therefore should not tie licensees to these procedures via license conditions.

Vote: 5 in favor; 1 opposed, 1 abstention. Ms. McBurney opposed because States and many licensees want review of procedures. Dr. Nelp abstained because he disliked how the motion was phrased.

Motion 16: Subsequent to publication of the final Part 35 rule, NRC should review Part 32 for items of consistency.

Vote: 7 in favor, none opposed.

Attachment 1

Proposed Rule - August 1998
Training and Experience Requirements
Alternative Requirements to Certification by Board Approved by NRC

	Structured Educational Program		Other
	Didactic (hrs)	Practical (hrs)	
35.100, Unsealed - uptake, dilution, excretion	40	20	Physician, preceptor, exam
35.200, Unsealed - imaging and localization	80	40	Physician, preceptor, exam
35.300, Unsealed - written directive required	80	40	Physician, preceptor, exam, 5 cases
35.400, Manual brachytherapy	200	500	Physician, preceptor, exam, 1 yr ACGME program, 2 yrs clinical experience
35.500, Sealed sources for diagnosis	8		Physician, Dentist, Podiatrist
35.600, Therapeutic medical devices	200	500	Physician, preceptor, exam, 1 yr ACGME program, 2 yrs clinical experience
RSO	200		Preceptor, exam, 1 yr or AU
AMP			Preceptor, exam, MS, 2 yrs
ANP	700		Preceptor, exam

Attachment 2
TRAINING AND EXPERIENCE REQUIREMENTS - Alternative Pathway

	Requirements*
§ 35.290 - Training for uptake, dilution, and excretion studies *(Written Directive is not required - § 35.100)*	- 40 hours classroom and laboratory - 20 hours supervised practical
§ 35.292 - Training for imaging and localization studies *(Written Directive is not required - § 35.200)*	- 80 hours classroom and laboratory - 40 hours supervised practical - 580 hours supervised experience in a clinical environment
§ 35.390 - Training for use of unsealed byproduct material *(Written directive is required - § 35.300)*	- 80 hours classroom and laboratory - 40 hours supervised practical - 580 hours supervised experience in a clinical environment - 3 cases each use category requested
§ 35.392 - Training for use of sodium iodide I-131 for which a written directive is required	- 80 hours classroom, laboratory and supervised practical - 3 cases each use category requested
§ 35.490 - Training for use of manual brachytherapy sources (§ 35.400)	- 200 hours didactic - 500 hours practical - 3 years ACGME program
§ 35.590- Training for use of sealed sources for diagnosis (§ 35.500)	- 8 hours classroom and laboratory
§ 35.690 - Training for use of remote aferloader units, teletherapy units, and gamma stereotactic radiosurgery units (§ 35.600)	- 200 hours didactic - 500 hours practical - 3 years ACGME program

§35.50 - Radiation Safety Officer	- OPTION 1
	  - 200 hours didactic
	  - 1 year supervised experience
	- OPTION 2
	  - Authorized user for type of use

§35.51 - Authorized Medical Physicist	- MS - 2 years experience
§ 35.55 - Authorized Nuclear Pharmacist	- 700 hours structured educational program

* Training must be in NEC or A/S approved program. An AU under §§ 35.290, 35.292, 35.390, 35.392, 35.490, 35.690 must be a physician. An AU under § 35.590 may be a physician, dentist, or podiatrist. An AU, AMP, and ANP must also have a preceptor statement.