SUMMARY OF DISCUSSION
Meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) Held in Rockville, Maryland on September 25-26, 1997

Prepared for
Office of Nuclear Regulatory Research
by ICF Incorporated
under Contract NRC-04-95-065

4/17/98

Abstract

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) is formed under the Federal Advisory Committee Act of 1972. The function of the Advisory Committee is to advise the NRC staff on issues and questions that arise on the medical use of byproduct material. The Committee provides counsel to the staff, but does not determine or direct the actual decisions of the staff or the Commission. On September 25-26, 1997, the ACMUI held a public meeting, in accordance with the rules and regulations of the Federal Advisory Committee Act and the Nuclear Regulatory Commission. The meeting was announced in the Federal Register on September 5, 1997.

The agenda for the public meeting of the ACMUI primarily addressed the revision of 10 CFR Part 35, the NRC's regulations governing the medical use of byproduct material. The topics relating to Part 35 included the 1979 Medical Policy Statement, the requirement for a Quality Management Program, the requirements for a Radiation Safety Committee, the requirements for training and experience, and the requirements for patient notification and the related definition of reportable events. NRC staff also provided a description of the status of Part 35 rulemaking and guidance.

The purpose of this document is to provide a succinct summary of the views expressed in the meeting.

Contents

Contents (continued)

List of Participants

Committee Members:

Judith Anne Stitt, M.D.
Chairman

Daniel F. Flynn, M.D.
Radiation Therapy

John Graham
Health Care Management

Andrew Kang, M.D.
Food and Drug Administration

William B. Nelp, M.D.
Nuclear Medicine/Research

Dennis P. Swanson, M.S., B.C.N.P.
Radiopharmacy

Louis K. Wagner, M.D.
Medical Physics/Nuclear Medicine

Theresa Walkup, C.M.D.
Medical Dosimetry

Jeffery F. Williamson, Ph.D.
Medical Physics/Radiation Therapy

ACMUI Invited Guests:

Naomi Alazraki, M.D.
Nuclear Medicine

Manuel Cerqueira, M.D.
Cardiology

Ruth McBurney
State Regulatory Agencies

Cathy Ribaudo
Radiation Safety

James R. Anderson
Patient Rights

List of Participants (continued)

Also Present:

Donald A. Cool, NRC
Director, Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Cathy Haney, NRC
Designated Federal Officer

Chip Cameron, NRC

Diane Flack, NRC

Donna-Beth Howe, NRC

Sam Jones, NRC

Marjorie Rothschild, NRC

John Szabo, NRC

Barry Siegel, M.D., NRC Consultant

PART I. INTRODUCTION

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

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

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

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

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

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

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

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

The NRC staff initially considered proposing a modality approach to the Part 35 rule. The modality approach would place all requirements for a given type of treatment into a single section of the regulation, including who or what organization is licensed; what type of license is issued; necessary technical requirements, such as surveys and calibration; training and experience requirements; event recording and reporting requirements; and the quality management objectives. The NRC staff began by addressing the following modalities:

(1) Low-dose unsealed materials (diagnostic nuclear medicine);
(2) High-dose unsealed materials (nuclear medicine therapy);
(3) Low-dose sealed source applications;
(4) Teletherapy;
(5) High-dose rate remote afterloaders;
(6) Gamma stereotactic radiosurgery; and
(7) Emerging technologies.

This list is not viewed as all-inclusive. Additional categories may be developed, depending on the breadth of the areas to be covered, and the similarity of requirements in a given area.

Development of rule text alternatives, including draft guidance documents, is being done using a "Working Group" and "Steering Group" approach. State participants are taking part in both the Working Group and Steering Group.

The meeting was convened by the Designated Federal Officer pursuant to a notice in the Federal Register dated September 5, 1997. The agenda also was approved by the Designated Federal Officer. It included the following topics pertaining to the revision of 10 CFR Part 35:

Update on the Revision of 10 CFR Part 35;

1979 Medical Policy Statement;

Discussion of the Requirement for a Quality Management Program;

Discussion of the Requirements for a Radiation Safety Committee;

Discussion of Requirements for Training and Experience;

Discussion of Requirements for Notification of Patient and Related Definition of Reportable Events; and

Status Report on Rulemaking and Guidance.

The staff had not selected any alternatives prior to the meeting, and additional options could be (and were) discussed during the meeting.

A transcript of the meeting was prepared pursuant to 10 CFR §7.13 and is available at the NRC's Headquarter's Public Document Room, 2120 L Street, N.W., Washington, D.C. 20555-0001.

PART II. REVISIONS TO THE MEDICAL POLICY STATEMENT

A. Background

1. History and Purpose of the Medical Policy Statement

The purpose of the Medical Policy Statement (MPS or "the Policy Statement"), first drafted in 1979, was described to the ACMUI as defining the role the NRC would play in regulating the medical uses of radioisotopes. The Policy Statement was intended to implement the Atomic Energy Act's mandate to protect public health and minimize danger to life and property, while also recognizing that physicians have the primary responsibility for the protection of patients. The MPS is intended to serve as a guideline for NRC regulations under Part 35.

The discussion began with a recapitulation of the ACMUI's discussion of the MPS at its previous meeting. The MPS had been recognized as important to the entire process of revising the Part 35 regulations, and it had been suggested that rather than change the MPS, the regulations should be modified to conform to the MPS. The rationale expressed in the Federal Register notice in 1979 when the MPS was first promulgated was summarized, although it was noted that the rationale may no longer be current. In 1979, the NRC had stressed that it had the authority to regulate the radiation safety of patients; that it wanted to work closely with professional groups in designing voluntary guidance for practitioners to limit unnecessary patient radiation exposure; and that it had recognized that physicians have the primary responsibility for their patients, and that although the NRC might set limits for the higher risk areas in order to insure patient safety it also recognized that too much regulation might result in poorer health care.

2. Past Experience with the Medical Policy Statement

A member reminded the ACMUI that in its previous meeting it had decided as a group that the MPS was of utmost importance and that everything else done in the context of Part 35 would follow from the MPS.

Another member immediately suggested that consideration of a new alternative for the MPS, stating that "NRC's role is to assure that the physician's prescription is accurately delivered to the correct patient," be dropped. Under the current MPS, this member calculated, over the past 20 years over 400 million cobalt-60 teletherapy treatments had been given to patients, while NRC's misadministration records indicated that there had been 7 misadministrations out of the 400 million treatments. Voluntary standards adopted by the medical community were already addressing the issue, in the view of this member.

A third member noted that the 1979 MPS had been promulgated as a result of an incident that had occurred. In this member's opinion, the MPS had opened the door for the NRC to intrude into the practice of medicine, although the member recognized that the NRC did not consider that it was intrusive. Members of the medical community had wanted the MPS to be reviewed, and in that review the key issue was whether the options for the revised MPS allowed or precluded regulatory instrusion into medicine.

B. Review of Options

1. Option 1: Status Quo: Retain the current text of the Medical Policy Statement:

"1. The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.
2. The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.
3. The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine."

a. Arguments in favor

The ACMUI did not make explicit arguments in favor of the option.

b. Arguments against

As noted above, members of the ACMUI argued that under the 1979 MPS the NRC had intruded in some cases into the practice of medicine.

c. *Discussion of NRC's proposed pros and cons*

The ACMUI did not explicitly discuss NRC's proposed pros and cons for the option.

2. Option 2: ACMUI recommended option, revised 9/97:

The ACMUI concentrated its discussion on Option 2, which originated in the April 1997 meeting of the ACMUI as its own recommendation.

"1. The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.
2. The NRC will regulate the radiation safety of patients only where justified by the risk to patients and only where the voluntary standards or compliance with these standards are inadequate. Assessment of the risks justifying such regulations will reference comparable risks and comparable voluntary standards and modes of regulation for other types of medical practice.
3. The NRC will not intrude into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine."

a. Discussion concerning Option 2

The ACMUI held an extensive discussion of the statement in Option 2 that would require NRC to assess risks in other types of medical practices and consider whether the risks from the use of byproduct materials in medicine are comparable. Referencing comparable risks and comparable modes will be very difficult, in the opinion of one member, who opposed the idea.

Another member, however, argued that it would be very valuable to have a disinterested third party that is neither from the NRC or the regulated community perform such a study.

A member noted that many high risk procedures performed in medicine that can result in an outcome of death for the patient are completly unregulated. No regulation comparable to that of radiation exists in any other area of medicine.

An invited guest noted that many diagnostic procedures are of very low risk compared to other activities undertaken by cardiologists. Therefore, it is unnecessary to deal with the risks for diagnostics in any way, and concentration should be placed on the therapeutic activities.

Another invited guest noted that the purpose of the ACMUI Option 2 statement about risk was to provide a cure for the ambiguity in the Atomic Energy Act that provides a wide range of regulatory discretion. The statement was intended to require the NRC to consider how the risks of radiation medicine compare with the risks of other parts of medicine. Such an assessment would help to ensure the best allocation of societal resources.

In contrast, a member noted that such comparisons could be difficult or ambiguous, and argued that instead the MPS should help to disassociate the NRC from both radiation therapy and other areas of medicine.

A member argued that it is clear that NRC possesses the authority under the Atomic Energy Act to regulate the medical uses of byproduct material. In licensing the possession and use of byproduct material, NRC establishes the limits within which physicians exercise professional discretion. The issue, in this member's opinion, is one of policy: to what extent should the protection of the patient be considered in NRC's regulation of the medical use of byproduct material? In that context, in the opinion of another member, NRC should view those hazards in the context of comparable risks and comparable modes for other types of medical practice. Furthermore, as a third member concluded, the involvement of the practice of medicine is why the area of patients is different from the other areas in which NRC regulates to protect the safety of the general public.

c. Discussion of NRC's Proposed Pros and Cons

i. Pros

One member noted that Option 2 maintains the risk-based aspect of the original Policy Statement. The participant went on to remark that this option is consistent with the effort to make all of Part 35 risk-based.

The same member went on to remark that this option, while looking to other medical practices for guidance on risk analysis, properly separates the medical use of byproduct material from other medical practices, thus allowing for the proper evaluation of the special risks that accompany radioactive medicine. Finally, like the Status Quo option, this option emphasizes the primary role physicians play in the protection of their patients.

Another member spoke out in favor of the practice of relating risk analysis from other fields of medicine to risk judgments in nuclear medicine. The participant noted that the regulatory atmosphere would be greatly clarified by a major risk study that would evaluate the linkage between risks in medicine, not including radiation, and risks in the medical uses of byproduct material. However, the member noted that the study should be conducted by a disinterested third party, not by the regulated community or the NRC.

ii. Cons

One member argued strenuously that the con stating that implementation of Statements 2 and 3 could be in conflict when the level of risk justifies intrusion, is in fact an attempt to justify more instrusion. In this member's opinion, the suggestion of intrusion reflected an mindset on the part of NRC that should be changed. Another member argued that the cons identified by NRC were in fact pros.

Members noted that Option 2 had been adopted by ACMUI to require NRC to go through a process to quantitatively justify regulations intruding into the practice of medicine by looking at serveral questions: Is there a realistic risk? Are standards inadequate? Are standards not being followed on a large scale instead of reacting to single events? However, the qualification in Statement 2 might be violated and considered to justify imposition of restraints that would be in conflict with Statement 3. Therefore, the order of the statements in the draft Option 2 of the MPS was identified as a con.

Conclusion and Recommendation:

One member suggested that Option 2 be modified in the following manner: Statement 3 should be moved upward and renumbered as Statement 2, "the NRC will not intrude into medical judgements affecting patients in other areas traditionally considered to be the practice of medicine." The ACMUI moved that this recommendation be sent to the Commission. The ACMUI further recommended that Statement 2 under Option 2, which now would become Statement 3, should read "The NRC will regulate the radiation safety of patients only where justified by the risk to the patients, and only where voluntary standards or compliance with those standards are inadequate. Assessment of the risks justifying such regulations will reference comparable risks and comparable voluntary standards and modes of regulations for other types of medical practice."

3. Option 3:

"1. The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.
2. The NRC will regulate the radiation safety of patients only where justified by the risk to patients, and only where voluntary standards or compliance with these standards are inadequate.
3. The NRC will continually strive to minimize involvement in medical judgements affecting patients and into other areas traditionally considered to be a part of the practice of medicine."

a. Arguments in favor

Not discussed.

b. Arguments against

Not discussed.

c. Discussion of NRC's Proposed Pros and Cons

Not discussed.

4. Option 4:

"1. The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.
2. The NRC will regulate the radiation safety of patients consistent with the risk posed by the radioactive materials. In regulating the radiation safety of patients, NRC's role is to ensure that the physician's prescription is accurately delivered to the correct patient.
3. The NRC will not intrude into the medical judgment forming the basis of the physician's prescription."

a. Arguments in favor

None.

b. Arguments against

One member suggested that Option 4 should be dropped from consideration. A comparision of teletherapy treatments (about 400 million since the late 1970s) and misadministrations (about 7 in the same period) suggests that current practices are ensuring that the treatement is delivered to the correct patient. The member concluded by noting that several voluntary measures have been adopted by many radiation oncology departments that minimize the potential for a patient to receive an incorrect treatment.

Another member expressed concern over Statement 2 of this option, that regulation levels shall be "consistent with the risk posed by the radioactive materials." The problem with

this Statement, the commentator continued, is that it is not performance-based, and that even a material that is being properly handled, albeit a risky material, will not escape regulation. The member concluded by noting that the potential for the NRC to intrude on every aspect of the physician's nuclear medicine practice was very strong under this option. This opinion was seconded by another member who noted that of all the options presented at the meeting, Option 4 had the largest potential to increase the regulatory burden.

c. Discussion of NRC's Proposed Pros and Cons

Not discussed.

C. Preferred Options

The Advisory Committee on the Medical Uses of Isotopes reiterated its recommendation to the NRC that the statement of general policy to guide regulation of the medical use of isotopes should be changed.

The ACMUI recommended that the policy be revised to state:

1. The NRC will continue to regulate the medical ueses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.

2. The NRC will not intrude into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.

3. The NRC will regulate the radiation safety of patients only where justified by the risk to the patients, and only where voluntary standards or compliance with these standards are inadequate. Assessment of the risks justifying such regulations will reference comparable risks and comparable voluntary standards and modes of regulation for other types of medical practice.

PART III. CROSS-CUTTING ISSUES

The ACMUI was asked to consider five topics that are pertinent to all modalities, and therefore either might be addressed in generic sections of the regulations devoted to general administrative or technical requirements, rather than in modality-specific sections, or at a minimum need to be addressed in a similar way throughout the rules. The five cross-cutting issues are:

(1) Radiation Safety Committee;

(2) Quality Management Program;

(3) Patient notification;

(4) Threshold for a reportable event; and

(5) Training and experience requirements.

Each is addressed in the following sections. For each cross-cutting issue, the summary of the discussion by the ACMUI has been organized according to the following outline:

- "Background" first outlines NRC's original purpose for the requirements, as explained in the meeting, and then describes the group's discussion of its experience with the requirement and its assessment of whether it does or does not meet the purpose;

- "Key Current Problems/Advantages" summarizes the basic views of the group toward the requirement or issues raised by it;

- "Review of Options" describes the ACMUI's discussion of the regulatory options presented by NRC. For each option, the arguments for and against the option by ACMUI members are summarized. When invited guest or other persons spoke about a particular option, their views also are presented. The ACMUI's views on the pros and cons of the options developed by NRC are presented, when they can be determined. Finally, any alternative options discussed by the ACMUI are described, along with the ACMUI's views on them.

Finally, when a clearly preferred option was identified by the ACMUI, it is described.

Cross-Cutting Issue 1. Radiation Safety Committee

A. Background

1. History and Purpose of the Radiation Safety Committee Requirement

The ACMUI began its discussion of the Radiation Safety Committee (RSC) by reviewing the possible alternatives. The first is to maintain the status quo, which requires an RSC for all modalities in a medical institution. The second alternative is that an RSC is required for a medical institution in all modalities with the exception of the diagnostic, low dose, sealed and unsealed byproduct material uses. Thirdly, an RSC is not required for any medical licensee. Finally, the fourth alternative is that an RSC is not required, but the licensee will be required to establish and implement a program for administrative and technical oversight of the radiation safety program.

There was also some discussion about the requirements for the quarterly review of the exposure records and the annual reviews of the ALARA Program. It was clarified that these requirements were intentionally removed with the rationale that they were already covered in 10 CFR Part 20. The NRC has decided not to duplicate requirements in both Part 20 and Part 35; instead if an activity is currently required by Part 20, it will not be duplicated in Part 35.

2. Past experience with the Radiation Safety Committee requirement

The ACMUI did not explicitly address past experience with the RSC requirement. However, several members stated that it is important to reduce the prescriptive nature of the RSC requirements.

B. Key Current Problems/Advantages to Radiation Safety Committee Identified by Participants

One member of the ACMUI expressed the opinion that RSCs should be required for medical institutions because they are instrumental in supporting the administration and Radiation Safety Officer (RSO). The member suggested another option, which requires the retention of the RSC, but allows the institution to develop its own policies and procedures relative to how that RSC operates. The member stressed the importance of retaining the concept of an RSC, but suggested eliminating many of the prescriptive requirements on the way in which the RSC conducts its business. The member went on to state that it is important to maintain RSCs to ensure that the administration of an institution is not completely dominated by the opinion of the RSO.

Several of the members agreed that it is necessary to more clearly define the term "medical institution." The members also discussed whether a medical institution would ever be likely to be limited to only diagnostic use of low dose material. Finally, a member questioned whether it would be sensible to have a RSC in a medical institution, but to exclude diagnostic nuclear medicine from membership on it. An invited guest stated that any institution that is providing high risk procedures definitely should have an RSC.

One of the members suggested that the question at hand is not whether an RSC is needed, but whether the current mode of medical practices is such that a Federal law is necessary to keep this check in place with a high level of confidence.

Another member voiced the opinion that there does not appear to be any difference between Option 4 and Option 2 if the definition of the concept of RSC is not maintained. Otherwise an RSC can be whatever a given institution specifies, as in Option 4.

One member also suggested that the RSC should remain flexible and reflect the size of the facility with which it is associated. For example, an RSC at a large institution may have a larger membership and more stringent requirements.

The ACMUI also discussed the issue of the composition of the RSCs. One member stated there should be specific requirements for specific individuals and suggested the following language, "membership must reflect the scope of operations respective to the use of byproduct materials within the institution and include the radiation safety officer and a representative of the management."

C. Review of Options

1. Option 1: Status Quo -- A Radiation Safety Committee (RSC) is required for all modalities in a medical institution.

The group did not explicitly discuss Option 1. However, in a general discussion of this issue, members agreed that specific RSC requirements for all modalities in a medical institution would be too prescriptive.

2. Option 2: RSC required for medical institution and all modalities, except diagnostic low dose sealed and unsealed byproduct material uses.

a. Arguments in favor

Several members supported Option 2 and the NRC's recognition of diagnostic nuclear medicine as low risk. One member argued in favor of Option 2, stating that any institution that conducts high risk procedures using radioactive materials or radiation delivery needs an RSC. The member stated that RSCs are also necessary to support the RSO and to ensure that there is a acceptable level of awareness regarding radiation safety on the part of the administration and the physicians practicing at the institution. Another member agreed and added support for Option 2, stating that this is one of the rare occasions when a Federal regulation is necessary.

Another member supported this option with the modification that institutions that have exclusively diagnostic low dose sealed and unsealed byproduct use do not need to have an RSC.

b. Arguments against

Option 2, as stated, was described as being worded incorrectly because it implied that the RSC would not have purview over 35.100 and 35.200 activities. Instead, the option should

read that an RSC is not required if a facility is only licensed to conduct 35.100 and 35.200 activities.

Another concern raised by several of the members is that the text of Option 2 implies that the Committee would not look at diagnostic low dose sealed and unsealed byproduct use, which was not the intent.

Several members argued against Option 2, and stated that more flexibility was necessary, especially in the make up and membership of these committees. These members were opposed to unnecessary requirements, such as committee size and formal meeting requirements.

One of the members made a motion to accept Option 2 with the clarification that institutions with only diagnostic low dose sealed and unsealed byproduct material are not required to have an RSC.

c. Discussion of proposed pros and cons

The ACMUI did not explicitly address the NRC's pros for Option 2. Implicitly, however, many of the members recognized that the option provides for involvement of executive management and communication between disciplines and departments.

The ACMUI did not explicitly address the NRC's cons for Option 2. Implicitly, however, several members noted that an RSC may not be necessary for effective radiation safety management at small medical institutions.

3. Option 3: RSC not required for any medical licensee

The ACMUI did not explicitly discuss Option 3.

4. Option 4: RSC not required, but licensees required to establish and implement a program for administrative and technical oversight of radiation safety

a. Arguments in favor

One member argued in favor of Option 4, as a performance-based alternative that requires a licensee to establish policies and procedures relative to the operation of the radiation safety committee to oversee the use of licensed material.

One participant supported Option 4, but expressed the concern that inspectors may have to be educated on how to evaluate performance-based issues properly.

Another participant also supported Option 4, but suggested that the requirement for a committee be tied to the scope of the license. This participant argued that facilities with a broad scope license should be required to have a RSC.

b. Arguments against

One member of the group argued against Option 4, because it specifically states that an RSC is not required. The member noted that an RSC requirement is necessary and the program established by this option for the administration and technical oversight of radiation safety is not sufficient to ensure radiation safety.

c. Discussion of NRC's proposed pros and cons

Not discussed.

5. Support for another alternative

a. Proposed alternative(s)

One member suggested another possible option, which requires the retention of the RSC, but allows the institution to develop their own policies and procedures relative to how that RSC operates.

Another member suggested a combination of Options 2 and 4 which would require that "membership must reflect the scope of operations respective to the use of byproduct materials within the institution, and include the Radiation Safety Officer and a representative of management other that the Radiation Safety Officer."

D. Preferred Options

The ACMUI recommended that a RSC be required for a medical institution and all modalities, with the exception of diagnostic low dose sealed and unsealed byproduct material uses.

Cross-Cutting Issue 2: Quality Management Program

A. Background

1. History and purpose of the Quality Management Program requirement

To initiate the discussion, the ACMUI reviewed NRC's purpose for the Quality Management Program (QMP) and its focus on patient safety. Based on the Commission's Staff Requirements Memorandum (SRM) of March 30, 1997, potential revisions to the QMP should focus on three issues: confirming patient identity, requiring written prescriptions, and verifying dose.

2. Past experience with the Quality Management Program requirement

Some members believed that maintaining records and written directives have been helpful practices to ensure that the prescription is accurately delivered. Members indicated that this was especially useful for institutions whose practices needed some improvement. One member stated that these regulations had been helpful to institutions whose practices needed improvement, but had been burdensome on other institutions where patient safety had not been in question. Other members stated that performing audits had provided their institutions with no measurable benefit, because these audits had not revealed precursor events or problems that the institution was unaware of.

B. Key Current Problems/Advantages of Quality Management Program Identified by Participants

The general feeling among the members was that QMP requirements intruded into the practice of medicine. Many members stated that the current QMP contained requirements that would be practiced by physicians regardless of any regulatory requirement to do so. These members argued that either through common practice standards or legal requirements such as tort law, institutions would retain records of administrations and conduct audits as necessary.

Members believed that some of the functions performed under the current regulations did not meet the objectives of the Quality Management Program. One member asserted that the objective for performing audits and maintaining recordable events was to assist the licensee in identifying precursor events. This member stated that performing audits did not identify precursor events.

Some members believed that maintaining separate records of administrations was a useful practice, because it helped assure patient confidentiality by eliminating the need for NRC to view a patient's file. Other members indicated that maintaining separate records would be useful in the case where an institution needed to improve its practices.

C. Review of Options

Members did not explicitly address each option; rather they reviewed the requirements included in all of the options to determine which option best met their preferences. Arguments in favor or against the options are implicitly drawn from the members' statements about the requirements contained in each option. The members discussed Option 2 at length.

1. Option 1: Status Quo -- Maintain Current Requirements in §35.32.

a. Arguments in favor

Most members were opposed to retaining the current option. Several members indicated that they supported the provision to require maintenance of recordable events. One member asserted that some level of record keeping would be optimal to assist the regulating agency in performing its function. This member pointed out that maintaining records of these events outside of patient files would help to assure patient confidentiality as well as facilitate any sort of review process by NRC. One member stated that requiring the retention of the written record would provide NRC with the ability to enter an institution and determine that safe practices were being followed.

b. Arguments against

Members found several elements of the current QMP to be unnecessary to ensure patient safety. A majority of members were opposed to the requirements to conduct audits, and to submit modifications of the QMP to NRC. A number of members also felt that regulations should not dictate that institutions retain records, although members believed that retaining records in itself was not objectionable. In general, members were inclined to believe that many of the requirements currently mandated by the QMP would occur in practice by physicians, regardless of any regulatory requirement, out of common practice standards and other legal (though not necessarily regulatory) requirements.

Members voiced several arguments against requiring audits. One member stated that this function was a standard procedure, undertaken regularly by the Radiation Safety Officer and therefore did not need to be a regulatory requirement. A second member stated that institutions spend a great deal of time on audits which provide little or no benefit to the institution. This member added that audits were not used as the primary mechanism to identify errors or misadministrations, and that requiring an institution to conduct them was not a useful expenditure of resources. Another member stated that the purpose of the audits had been to assist institutions in the detection of precursor events, but that this mechanism had not proved effective at doing so. One member commented that the number of therapy administrations at a given institution is currently so small that auditing these administrations is unnecessary. There are few enough administrations that practitioners are aware of each one and would certainly be aware of any errors. A unanimous vote confirmed that members were opposed to including a provision requiring audits in the revisions to the QMP.

Members also were opposed to the provisions requiring licensees to submit revisions to their QMPs to the NRC. There was little discussion of this requirement but members quickly voted that there should be no provision for this in the revisions to the QMP.

Many members were opposed to including a requirement to maintain records in the revised QMP. A number of members stated that their institutions would keep records regardless of whether it was a regulatory requirement. Several members asserted that although retaining records was a reasonable and necessary requirement, it is not in the purview of NRC. One member argued that retaining records would lead to periodic audits. Another member pointed out that retaining records did not contribute towards ensuring patient safety. This member indicated that any elements of the QMP that did not directly address patient safety concerns should be eliminated from the revised QMP. Another member pointed out that licensees retain records in case of any future legal action.

Members did not reach a consensus in their discussion of maintenance of records. Several members indicated that these records should not be maintained in light of the group's statement against the requirement to conduct audits. These members believed that maintaining these records would encourage audits. One member stated that NRC could review patient records if necessary, and that no special recordkeeping requirement was necessary for recordable events.

c. Discussion of proposed pros and cons

The ACMUI did not explicitly address NRC's proposed pros and cons for this option. Implicitly, members agreed that this option's requirement for a written QMP would provide confidence that byproduct material would be administered as intended by the authorized user. Members agreed that this option did not reduce regulatory burden to licensees and was not performance based.

2. Option 2: Only require a written QM program

a. Arguments in favor

Many members agreed that Option 2 best reflected their preferences for QMP regulatory requirements. One member pointed out that this option best reflected the Agency's attempts to render Part 35 a more performance-based rule. This member stated that the purpose of the QMP under a performance-based rule would be to ensure that byproduct material is administered as intended by the authorized user. If this was the case, neither NRC nor the licensee would need to follow any additional procedures.

One member stated a preference for this option because the requirements contained in it were dose based. This member believed that tieing the requirement to prepare a written directive on the size of the dose rather than on the procedure to be performed allowed flexibility to include emerging technologies in this regulation.

Although the requirement that any unintended deviation be identified and evaluated and appropriate action taken caused some argument from members, several members argued in favor of including this provision. One member indicated that this provision would serve as a good feedback mechanism for institutions to be made aware of any misadministrations, which would assist them in improving their program.

b. Arguments against

One member suggested that the phrase "unintended deviation" in the draft rule text needed to be defined. Other members supported this suggestion, providing examples of situations in which NRC might perceive an "unintended deviation" which would be considered more of an acceptable and addressable variation to medical practitioners. One member argued that requiring an "unintended deviation" to be identified and evaluated would be the equivalent of requiring an audit, which this member stated was unnecessary from a patient safety perspective. Some members hoped to improve this provision by changing the phrasing from "any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken," to "any unintended deviation from the written directive is documented and evaluated." These members thought that changing the phrasing of this requirement would help to prevent any requirement to perform audits implicit in the word "identified," and prevent any misinterpretation of the phrase "appropriate action," which was not defined.

Several members thought that the requirement to verify the patient's or human research subject's identity "by more than one method" was prescriptive and unnecessary. These members believed that the objective of this statement could be achieved by requiring verification of identity without calling for multiple methods to be used.

c. Discussion of NRC's proposed pros and cons

Members did not explicitly address NRC's proposed pros and cons for this option. Implicitly, members agreed that this option was performance based, would provide assurance through written directives that byproduct material was delivered as intended by the authorized user, and was dose-based. Members agreed that if records were not maintained, it would increase on-site inspection time.

3. Option 3: Require written QM program, retention of each written directive and a record of each dosage requiring a written directive, and perform audits

a. Arguments in favor

No arguments were made in support of this option, although members agreed that modifications to the QMP should not be submitted to NRC.

b. Arguments against

The arguments against Option 1 also apply to Option 3.

c. Discussion of NRC's Proposed Pros and Cons

Members did not explicitly address NRC's proposed pros and cons for this option. Members agreed that this option would provide assurance through written directives that byproduct material was administered as intended, and that licensees should not be required to submit modifications to their QMPs to NRC.

4. Option 4: Require written QM program, retention of each written directive and a record of each dosage requiring a written directive, and maintain a record of recordable events

a. Arguments in favor

Some members argued in favor of a requirement to maintain recordable events. One member asserted that some level of record keeping would be optimal to assist the regulating agency in performing its function. This member pointed out that maintaining records of these events outside of patient files would help to assure patient confidentiality as well as facilitate any sort of review process by NRC. One member stated that requiring the retention of the written record would provide NRC with the ability to enter an institution and determine that safe practices were being followed.

b. Arguments against Option 4

Some members argued against a requirement to maintain recordable events. Several members indicated that these records should not be maintained in light of the group's statement against the requirement to conduct audits. These members believed that maintaining these records would encourage audits. One member stated that NRC could review patient records if necessary, and that no special record keeping requirement was necessary for recordable events.

c. Discussion of NRC's Proposed Pros and Cons

Members did not explicitly address NRC's proposed pros and cons for this option. Members agreed that this option would provide assurance through written directives that byproduct material was administered as intended by the authorized user and would not require licensees to submit modifications of their QMPs to NRC. Some members agreed that this option would continue the requirement to maintain recordable events. Members agreed that on-site inspection time would increase if records were not maintained.

5. Support for another alternative

Members supported a modified version of Option 2.

D. Relationship to other programs

There was no discussion of this issue in relationship to other programs.

E. Preferred Options

The ACMUI recommended that the rule only require a written quality management program.

Cross-Cutting Issue 3: Patient Notification of Reportable Event

A. Background

1. History and purpose of the reportable event requirement

Part 35 currently makes the licensee responsible for notifying the NRC of a misadministration. Under the current rule, in case of a misadministration the NRC must be notified, the referring physician must be informed, and the patient or responsible relative must be notified, unless the referring physician believes that patient notification would be harmful.

A written report must be submitted within 15 days after discovery of a misadministration. The report must include the licensee's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; actions taken to prevent recurrence; whether the licensee notified the patient or the patient's responsible relative or guardian, and if not, why not; and if the patient was notified what information was provided. The report must not include the patient's name or other information that could lead to their identification. The licensee must notify the referring physician and the patient of the misadministration within 24 hours after its discovery, unless the referring physician either notifies the licensee that he will inform the patient or that, based on medical judgment, the patient should not be notified. If the patient is notified, the licensee must either furnish the patient a copy of the report that was submitted to the NRC or another brief description of the event and its potential consequences to the patient. Records of misadministration must be retained for five years.

A NRC staff member started the discussion by reviewing the American Medical Association's (AMA) Principles of Medical Ethics. The NRC staff member stated that two specific AMA ethical principles are directly related to the issue of patient notification. The first, which AMA calls principle number three, is that physicians shall respect the law and rights of patients and the second, which the AMA refers to as principle four, is that physicians shall guard patient confidences within the constraints of the law. The NRC staff member continued by noting that these principles entail that the duty of confidentiality is not absolute and that the confidential nature of physician-patient relationship must yield when disclosure is necessary, as determined by legal requirements, to protect an individual or society as a whole. The regulatory history of the patient notification rule was briefly discussed. It was noted that the Commission

first included the patient notification requirement in the first proposed rule on misadministration reporting in 1973 and 1978. The requirement was also included in the statements of consideration for the final misadministration rule. The Commission believed that the patient notification rule was necessary to protect patients. It was also noted that the Commission did acknowledged that the rule does, to a certain degree, affect the nature of the physician's obligation to protect his or her patient. However, in the Commission's view, there was nothing in the rule that would detract from or impair a physicians ability to protect his or her patient. In fact, the Commission believed the rule was consistent with the AMA's standards.

2. Past experience with the reportable event requirement

A member asked if any data existed that indicated a history of failure by licensees to notify patients following a reportable event. The member wanted to know whether any events in the past had justified the need for the patient notification requirement. A NRC staff member responded by discussing an incident at Riverside Hospital where nearly 400 patients received teletherapy misadministrations over a two-year period. Due to an absence of a regulatory requirement to notify the patients of the misadministration, the affected patients were not contacted until NRC had finished investigating the incident. NRC responded to this incident by creating a requirement for patient notification following a reportable event. The rule was structured to resemble the rule that requires public and occupation worker notification following exposure to radiation. The NRC staff member indicated that NRC feels patients should by privy to reportable events in order to allow the patient to make timely decisions about their health care or remedial care.

Several members continued to discuss the misadministration incident at Riverside. One member reported that the incident involved a systematic error where patients received overdoses over a period of time. Another member asked whether the failure by the Riverside licensee to notify patients affected by a misadministration was intentional; an attempt to cover-up the incident. Further, the member asked whether this case represented a precedence in failure to notify patients after a misadministration or whether similar events had occurred prior to this case.

A NRC staff member responded that, at the time of the incident, patient notification requirements were non-existent; licensees were not required to notify NRC of any reportable events involving patients. However, after learning of the incident, NRC believed the patients involved in the incident had a right to be notified of the misadministration. To answer a member's earlier question, the NRC staff member stated that NRC was unable to determine whether the Riverside incident was unique at the time due to the absence of any reporting requirements.

Another empirical example of systematic overdosage was given by a member. This incidence took place in Puerto Rico. Many of the patients in this case came to the licensee directly and left inadequate contact information. The member noted that the licensee in this case claimed that notification of patients after the fact was difficult due to insufficient contact information. However, the member reported, other physicians familiar with the incident felt this was not the case, notification of all the patients was possible if enough effort was expended. A NRC staff member replied by stating that in fact the patients in this case had been notified.

One member thought that notification of misadministrations involving patients that mistakenly received radiation treatment was already covered by Part 20. The member argued that in these cases the patients were not covered by a written directive and thus were effectively members of the general public. Another member remarked that this point had been discussed extensively and people erroneously subject to radiation exposure are considered patients. Therefore, these people, like all radiation patients, are covered by Part 35. A NRC staff member remarked that this situation is addressed in the "wrong patient rule."

Another member believed that the reason physicians wanted patients, involved in radiation treatments, to be covered by Part 35 and not Part 20 was that it preserves the physician's option to use medical judgment and not tell the patient of a misadministration if such a choice is deemed appropriate.

The members endorsed the need for patient notification of misadministration based upon medical judgment, and not a regulatory requirement.

B. Key Current Problems/Advantages with Patient Notification Identified by Participants

The major question raised in this discussion was whether there should be a Federal requirement to notify the patient of a misadministration or whether standard procedures of physicians are sufficient to ensure proper patient care. The ACMUI generally agreed that patient notification should be based strictly on medical judgment, rather than a regulatory requirement.

C. Review of Options

1. Option 1: Status Quo -- In the case of a misadministration the NRC must be notified, the referring physician must be informed, and the patient or responsible relative must be notified unless the referring physician believes patient notification would be harmful.

b. Arguments against

One member felt Option 1, the status quo, gives the referring physician exclusive power to decide whether patients receive notification following a misadministration. The member felt that Option 1 gives the referring physician, who is not a NRC license, too much discretion in patient notification decisions. The member felt that Option 5--notification decisions are based on medical judgments but not necessarily the referring physician's judgment--was preferable to Option 1. An invited guest disputed the member's interpretation of Option 1. The invited guest felt the language of Option 1 implies that if a referring physician fails to notify a patient affected by a misadministration the authorized user is required to convey the information to the patient. A member replied by stating that this is what was intended by the rule, but in practice the rule is often interpreted as giving the referring physician exclusive power during notification decisions.

2. Option 2: Licensee to Notify NRC Only

a. Arguments in favor

An invited guest would support Option 2 if all language after "...NRC must be notified" was stricken and replaced by language that stated all patient notification decisions would be based on medical practice and ethical principles. Several members supported this suggestion. One member suggested that this added language could be placed in a footnote

b. Arguments against

In response to the arguments in favor of Option 2 as expressed above, one member felt it was inappropriate to put voluntary standards of medical practice in rules since they can differ from State to State. Another member felt it was important to include conditional language in the final rule that recognized the rule differences among the States. One member expressed some frustration with this option because a licensee might be inclined to notify NRC only and ignore its ethical commitment to make patient notifications as needed. Another member was not supportive of Option 2 (as well as Option 3) because it does not require notification of the referring physician. This member, as well as several other members, felt this language could be construed by the public as an attempt by licensees to hide misadministrations from patients and their physicians.

c. Discussion of NRC's Proposed Pros and Cons

There was no explicit discussion of NRC's proposed pros and cons for this option. However, one member suggested rewording this option so that a licensee would be required to notify the NRC and that patient notification should be in accordance with the ethics of general medical practice.

3. Option 3: Licensee to Notify NRC and Referring Physician

One member felt that this option adequately protected the physician-patient relationship, without requiring any Federal regulation for patient notification.

a. Arguments in favor

An invited guest argued that this Option was better than Option 2 because it ensured that the referring physician was told of the misadministration while preserving the right to withhold the information from a patient. Otherwise, if the referring physician is never told, medical judgments cannot be exercised.

4. Option 4: Licensee to Notify NRC, Referring Physician, and Patient or Guardian

A NRC staff member pointed out that Option 4 (as well as Option 5) differed from the status quo option by replacing the term "responsible relative" with "guardian." The commenter continued by stating that this change would improve notification procedures. In some cases it is more appropriate to notify someone other than a patient's relative of a misadministration, for example in the instances where the person holding a health care power of attorney for the patient is a non-relative.

5. Option 5: Licensee to Notify NRC and Referring Physician, but Not Patient or Guardian, Unless Based on Medical Judgment There Would be Detrimental Effects on Patient Due to the Reportable Event

Several members felt the meaning of this Option needed to be clarified. A NRC staff member reported that Option 5 would require a licensee to notify NRC and the referring physician of a misadministration, but not the patient or guardian unless, based on medical judgment, the reportable event would cause detrimental effects.

a. Arguments in favor

Several members favored this option in that it gave reasonable consideration to both regulatory requirements and medical judgment. One member mentioned that this option, especially the term "detrimental effect," provided for some medical interpretation of the notification responsibility to the patient based upon the nature, severity, and potential consequences of the misadministration. In response, an invited guest remarked that this option is not consistent with notification requirements to the public and workers of unnecessary radiation exposure.

Another member was in favor of Option 5 because the decision to notify the patient would ultimately reside with the referring physician.

b. Arguments against

There were no explicit arguments against this option. Individual members offered grammatical and editorial changes to the language of the option, such as including a definition of the term "detrimental effect" and excluding any reference to Part 20.

c. Discussion of NRC's Proposed Pros and Cons for Option 5

There was no explicit discussion of NRC's proposed pros and cons for this option. However, one invited guest, citing a specific example, asked why a patient should be notified if an unintended misadministration met the criteria for a reportable event. This led to a discussion about whether there should be a Federal requirement for patient notification, or if patient notification should be solely at the discretion of the referring physician. A member responded that the whole issue of patient notification should be viewed as a medical practice issue rather than a regulatory issue. The member then noted that if the regulations were to require both NRC and referring physician notification, the patient should also be notified about the reportable event.

D. Related Topics

There was no explicit discussion of related topics for this issue.

E. Preferred Option

"The ACMUI did not support any regulation specific to patient notification. The ACMUI supported notification of the physician and/or patient in accordance with ethical medical

practice, as well as in accordance with State regulation or law, but does not support the introduction of a Federal regulation.

Cross-Cutting Issue 4: Threshold for Reportable Event

A. Background

1. History and Purpose of NRC's Goal of Capturing not only Safety-Significant Events, but also Precursor Events

The ACMUI discussed a set of questions pertaining to the best process for reporting of events to ensure that NRC is aware of potential or generic safety issues, what the thresholds for reporting should be, and how reporting requirements should be implemented. The Commission's instructions to the staff requested consideration of how best to capture not only relevant safety significant events but also precursor events. The ACMUI also considered the criteria for reporting abnormal occurrences (AO), and in particular whether the NRC should set reporting levels at a certain percentage of the AO threshold.

In reviewing the history and purpose of NRC's goal for reportable event thresholds, the staff reported that the concept arose from concerns over patient notification. After internal deliberation, the SRM directed the staff to capture precursor events. One important consideration for this instruction was a determination that the QMP did not sufficiently capture precursor events. Consequently, the proposed requirement is intended to identify generic incidents that may adversely affect either patient or public health and safety through the identification and evaluation of precursor events.

The NRC staff reported that the NRC is required to report AOs to Congress. The NRC staff also discussed the existing regulations requiring licensees to report an event to the NRC within a certain time interval. In response, the ACMUI considered it important for licensees to directly report to the NRC any events that meet the AO threshold. The members then discussed the need for a voluntary program to use the insights gained from evaluating precursor events to improve institutional QMPs.

B. Key Current Problems/Advantages Identified by Participants

The ACMUI decided to discuss precursor events and reportable events separately from the discussion of patient notification.

Precursor events

Regarding precursor events, one member questioned whether standard medical practice could or would identify such events. Other members argued that the medical profession was unlikely to understand the concept, without clearer criteria for what constituted a precursor event. Presently, only clinical judgment provides the basis for assessing whether a given deviation from normal medical procedures could potentially create an unsafe situation, and, thus, require some type of corrective action. Members felt it was, possible to characterize, but not define, precursor events.

The ACMUI members questioned whether NRC could satisfactorily define precursor events, based on the multitude and diversity of medical procedures, in order to collect the kind of information needed. One member discussed that even under the best circumstances, such as seen in therapeutic radiology, with remote afterloading, it is difficult to identify suitable precursor events. Another member cautioned the NRC against a broad-based definition, arguing that the NRC could find itself buried in an avalanche of information. A third membe, however, suggested that defining precursor events too narrowly could actually limit the quantity and quality of information collected.

One member stated that the NRC could change existing policy, without promulgating regulations, to gather precursor information. Consequently, that member recommended that the NRC adopt regulatory language for licensees to establish their own policies and procedures for reporting and evaluating precursor events. In response, the staff replied that although flexibility would not be stifled, the regulations must provide a certain level of uniformity across the industry. Without defining precursor events, the NRC would not have any assurance of uniformity.

Members argued that the single most important purpose for the requirement to report precursor events is to address, in a clear fashion, some perceived public health hazard. The staff acknowledged the NRC's intent to develop such a program, by examining institutional programs for identifying precursor events. However, the purpose of the regulation is to improve overall licensee performance.

Members suggested that the program would be more effective if NRC eliminated any enforcement provisions. Further, the group agreed that as long as the NRC acted as a clearinghouse for analyzing this information, a voluntary regulatory program would be acceptable if the criteria explicitly recognizes the need for clinical judgment in identifying precursor events.

A related concern was whether the proposed regulatory program, which would track precursor events nationally, could ever beneficially change medical procedures without incurring significant costs. The group recommended pilot program approach, in which the NRC would fund one or two professional societies to collect precursor information from licensees on a voluntary basis to determine whether the NRC might eventually identify trends and then recommend improvements.

Recordable and reportable events

In general, the discussion focused on AO and reportable events. Members noted that the existing reporting requirements only capture a very small number of events (those where the dose threshold exceeds 5 rem effective-dose equivalent (EDE) and 50 rem organ dose) because the majority of misadministrations rarely reach these dose thresholds. Another member argued that one of the negative influences of the current misadministration definition and associated reporting rules is that even the most trivial errors are presumed medically significant, when they are not.

One member suggested the adoption of a three tiered system. Tier one would be events that cause actual injury to the patient or high probability thereof; tier two would involve technical error on the part of the caregiver serious enough so that it would have generic safety

implications. It would be reported to NRC but would not necessarily be reported to the patient unless it was associated with injury to the patient. The third level would be similar to recordable events or precursor events, which would be collected by the institution and to which the institution would be required to respond, but which would not trigger action on the part of the agency.

Another member argued in favor of eliminating regulatory limits for recordable events, but supported reporting of certain events to NRC. The best approach would be a performance requirement in which the institutions would evaluate all abnormal events, but collect information on non-reportable events only on a voluntary basis. The medication error reporting program of the United States Pharmacopeia was suggested as a model voluntary reporting program.

A member of the ACMUI noted that because the current misadministration criteria do not have a lower threshold for wrong site applications, many small technical errors with no medical consequences must be reported. In addition, in some cases dose delivery errors may not be associated with any patient injury or probability of injury, when it can be compensated for in the remaining procedures.

One member suggested simplifying the somewhat confusing criteria for recordable and reportable events by specifyiing that a reportable event is an event that results in an unintended radiation dose that is equal to or greater than 5 rems EDE or equal to or greater than 50 rads to any other organ. However, another member doubted that such a definition could apply to therapy. Thus, the definition might need to be modality specific.

A member suggested that to determine the necessary thresholds, the purpose of the reportable event must be clearly defined. If it triggers a mandated action on the part of the physician toward the patient, it would be different than if it triggers only investigation or analysis of the operations of the institution. Other members suggested that in the past reports generally triggered action.

Another member suggested that the criteria for reportable event should be scaled and that the criteria should include an indication of the circumstances of the event, so that patient intervention, for example, as well as other circumstances that are not the fault of the physician are taken into account.

Finally, the ACMUI discussed the implications of describing a reportable event as one that "differs from" the prescribed dose compared to one that "exceeds" the prescribed dose. Current use of the term "differs" causes underdoses to be reported. For purposes of patient notification, "exceeds" may be more appropriate. Similarly, if reportable events trigger reactive inspection and escalated enforcement, "exceeds" may be better than "differs." The members also addressed the question of how fractions should be treated, and whether a variation from a fraction should be reported, or only a variation exceeding the criteria from an entire course of treatment.

The Committee reached a consensus that the current criteria for radiopharmaceutical misadministrations be reduced from three categories to two. The two categories are "radiopharmaceutical not requiring a written directive" and "radiopharmaceutical requiring a written directive." The Committee did not believe any changes were necessary for those not

requiring a written directive. The current misadministration definition of therapeutic radiopharmaceuticals would be changed as follows:

> "The recordable event definition for those requiring a written directive would add the "wrong radiopharmaceutical" and replace "the administered dosage differs by greater than 20 percent..." to "the administered dosage is greater than 20 percent, or an underdose of 20 percent or more that is left uncorrected in a clinically timely fashion...." (The wrong mode of transport was deleted because it did not occur in the current regulation.)

The Committee was in agreement that all the radiation therapy definitions be prefaced with the phrase "wrong site that involves unintended delivery of a dose equal to at least 10 percent of the total prescribed dose in the written directive." This was added to provide a dose threshold for wrong sites.

The ACMUI felt strongly that the reporting mechanism should be decoupled from patient reporting and should not be used by NRC as an excuse for escalated enforcement. It should be used only by NRC to identify generic problems. They also agreed that an underdosage, if it could be, and was corrected in a clinically timely manner, would not have to be reported.

C. Review of Options

1. Option 1: Thresholds for Reportable Event (Misadministration) and Recordable Event Remain as Listed in the Current §35.2, with the *Addition of a Statement in the Reportable Definition to Address* Precursor Events That Are Outside the Area Defined by the Term "Misadministration."

No explicit discussion was held on this option.

2. Option 2: Threshold for Reportable Event Is Raised to the Level of the NRC Abnormal Occurrence Reporting Criteria. In Addition, the Definition for Reportable Event Will Include a Statement to Address Precursor Events That Are Outside the Area Currently Defined by the Term "Misadministration." Threshold for Recordable Event Is Raised to the Current Threshold for "Misadministration."

No explicit discussion was held on this option.

3. Option 3: Threshold for Reportable Event Is Raised to the Level of the NRC Abnormal Occurrence Reporting Criteria. In Addition, the Definition for Reportable Event Will Include a Statement to Address Precursor Events That Are Outside the Area Currently Defined by the Term "Misadministration." (No Requirement for Recordable Event.)

Based upon the ACMUI's general discussion of the key problems and advantages of the proposed regulation, several members endorsed Option 3, with the proviso that the program be voluntary and without any enforcement by the NRC.

4. **Option 4: Threshold for Reportable Event Is Lowered to the Current Level of Recordable Event, with the Inclusion of Items Such as Wrong Patient, Route, or Dosage That Are Not Covered by the Current "Recordable Event" Definition. In Addition, the Definition for Reportable Event Will Include a Statement to Address Precursor Events. (No Requirement for Recordable Event.)**

No explicit discussion was held on this option.

5. Option 5: Thresholds for Reportable Event and Recordable Event, If Applicable, Would Be Set According to the Outcome of Discussions on Alternatives 1, 2, 3, and 4. Licensees Would Voluntarily Report Precursor Events That Are Outside of the Area Currently Defined by the Term "Misadministration."

No explicit discussion was held on this option.

6. Support for Another Alternative

One member mentioned that the NRC excluded an alternative option -- maintaining the status quo, but deleting the requirement for recordable events.

Another member strongly endorsed a voluntary mechanism for reporting precursor events. The suggested arrangement would be for a third party, such as the United States Pharmacopeia, to serve as a clearinghouse for these voluntary reports. This arrangement would allow the NRC to accomplish its goals without creating a new regulatory program.

Cross-Cutting Issue 5: Training and Experience

A. Training and Experience for an Authorized User:

1. Background

The ACMUI discussed in detail the purpose of the training and experience requirement for an authorized user. The medical consultant to the Part 35 Working Group explained that NRC was considering a paradigm shift in the training and experience approach in Part 35. Currently, for nuclear medicine, the NRC requires an extensive clinical component. The revised approach would reduce the required training and experience to the radiation safety component, and leave the clinical component to other bodies, such as hospital credentialling boards or certifying boards. An examination would be used to validate the mastery of the training. Two forms of validation would be recognized by NRC: (1) Board certification or (2) passage of an independent examination focused on radiation safety knowledge. Clinical experience would continue to be required for therapeutic uses of byproduct material, because of the close connection between hands-on experience and radiation safety for radiopharmaceutical therapy, teletherapy, and brachytherapy.

NRC staff noted that data are not readily available on the overall number of physicians who are authorized users or licensees but are not Board certified. An ACMUI member estimated that about 10 percent of radiation oncology physicians are not Board certified. The member also expressed concern that special training courses outside a medical facility may not provide a fully adequate knowledge of radiation safety.

2. Key Current Problems/Advantages Identified by Participants

An invited guest of the ACMUI, with experience in testing, suggested that the logistics of the required testing might be a problem. A relatively large number of persons might be taking such examinations in such specialities as radiology, nuclear medicine, and cardiology. In

addition, one guest noted that cardiologists, for example, in the past have not had a special Board, but have been certified by internal medicine, and questioned whether internal medicine would seek approval for a radiation safety component of their certifying examination. This guest noted that over time the requirements for Board certification, which initially included very little radiation safety, have increased the scope of the radiation safety component. In addition, determining which Boards would be acceptable could be an issue. An ACMUI member with experience proctoring written and oral examinations in radiation oncology noted that the oral examination is a clinically-oriented examination and the written examination may not reflect NRC's current views on radiation safety.

ACMUI members who prepare examination questions discussed the coverage of radiation safety on the current examinations. They suggested that periodic communication between the Boards and NRC would be useful to ensure that the examinations address the major radiation safety issues that NRC has identified, based on its nationwide experience. It was noted that in order to obtain the status of an examiner, the Boards would need, under the proposed approach, to satisfy requirements set by NRC. NRC would recognize the radiation safety exam module of the Board as adequate and certify that Board as meeting the requirements.

An invited guest noted that an approach that stresses either Board certification or passage of an examination on radiation safety would also need to address the situation of physicians who are doing research, and who may not seek Board certification.

Two advantages of the preliminary approach were identified: (1) it simplifies the training and experience requirements and can reduce disagreements about which organizations should be providing certification, and (2) it reduces the amount of training required by NRC to that which is essential to protect workers and members of the public.

Another guest of the ACMUI noted that in some situations going to lectures and reading textbooks on radiation safety is not sufficient, and experience with the practical handling of radiation in a clinical setting is necessary. However, some clinical experience provided in a preceptorship situation also may lack the desirable rigor.

An ACMUI member raised the issue of ensuring that the training and experience paradigm, primarily based on diagnostic nuclear medicine, is also correct for radiation oncology and other therapeutic uses of byproduct material. In radiation oncology, according to this member, the medical physicist puts together the radiation safety and quality assurance infrastructure used by the physician. Therefore, the assumption that the physician is the source of all direction concerning radiation safety is not correct.

3. Cross-Cutting Training and Experience Issues

The ACMUI members did not vote on the details of what the training and experience requirements should include, but their discussion suggested that they generally agreed that safe handling and use of byproduct materials was the key topic to be addressed in NRC regulations, and that NRC should not be concerned with an individual's medical competence. Clinical requirements thus would be reduced for diagnostic users of byproduct materials. Clinical requirements would be retained for therapeutic users, such as remote afterloading, because of the overlap of clinical experience and radiation safety.

One member stressed that an additional topic that should be included is medical response to incidents involving radiation safety, as a particularly important example of the overlap of clinical and radiation safety.

One member cautioned that the regulatory requirements should not be too specific, to ensure that the regulations do not need to be changed frequently to address additional therapeutic radiopharmaceuticals, for example.

4. Review of Options

a. Option 1: Status Quo (Require User to Be a Physician, Certified by a Board Specified in the Regulations, and Meet Specified Hour of Training and Experience)

i. Arguments in favor

There was no explicit argument made in favor of this option, as a whole. Members did argue, however, that the clinical requirements currently included in Part 35 for authorized users of teletherapy, brachytherapy, and remote afterloaders should be retained.

ii. Arguments against

The arguments against the current requirements are summarized above.

iii. Discussion of NRC's Proposed Pros and Cons

Not discussed.

b. Option 2: Certification plus Specified Hours of Training and Experience or Option 3: Certification plus Specified Hours of Training and Experience plus an Examination

The discussion focused on the differences between Options 2 and 3, which the ACMUI identified as an examination requirement that is included in Option 3 but is not in Option 2.

An invited guest stressed the need to work out the details of the examination requirement and the clinical requirement to ensure that the proper level of knowledge of radiation safety was required, considering differences between diagnostic and therapeutic uses of byproduct material. The ACMUI noted that the particular example it was reviewing, requirements for a diagnostic modality, did not provide a clear picture of how the requirements would be shaped for therapeutic uses. A member stressed that the requirements should not be too specific, so that they would have to be constantly modified to address new situations or radiopharmaceuticals.

Another member questioned whether, if patient safety and quality of treatment remained the regulatory endpoint, how this approach to training and experience could be successful. Secondly, this member stressed that it would be very difficult to separate the training that a radiation oncologist and a medical physicist in radiation oncology receive, which allows them to do accurate treatment calculations, treatment planning, and correctly proceduralizing treatment

delivery, from the clinical training experience that they receive. In response, however, it was pointed out that the clinical experience requirements for brachytherapy and teletherapy would remain largely unchanged.

An ACMUI member added in response that it was particularly important, therefore, to have persons actively involved in the modality developing the examinations, so that they are familiar with what the clinical decisions are and can incorporate them into the radiation safety examination.

An invited guest noted that if a separate examination is required for those individuals not seeking Board certification, a simple, possibly centralized and computerized, method of taking the examination should be provided.

An ACMUI member expressed concern about endorsing an option with respect to teletherapy and brachytherapy that might be interpreted as suggesting that radiation safety issues and the issue of clinical competence can be separated. Another member offered an amendment to Option 3 to address this concern by removing "with minimal requirements for clinical experience" and substituting the words "with appropriate modality specific requirements."

A member pointed out that Option 3 would add an examination requirement, not currently part of the regulations, for endocrinologists training to treat hyperthyroidism or thyroid cancer, and another member noted that cardiologists also might need to be examined, depending on how the Boards revise their training.

c. Option 4: M.D. Degree

i. Arguments in favor

Not discussed.

ii. Arguments against

Does not include a Board certification requirement.

iii. Discussion of NRC's Proposed Pros and Cons

Not discussed.

d. Option 5: Examination only

i. Arguments in favor

Not discussed.

ii. Arguments against

Does not include a Board certification requirement.

iii. Discussion of NRC's Proposed Pros and Cons

Not discussed.

e. Option 6: Exam and clinical experience

i. Arguments in favor

Not discussed.

ii. Arguments against

Does not include a Board certification requirement.

iii. Discussion of NRC's Proposed Pros and Cons

Not discussed.

f. Support for Another Alternative?

No members explicitly supported another alternative.

5. Preferred Option(s)

The ACMUI recommended that the training and experience requirements for an authorized user require the indivudal to be a physician who is board certified, or has completed a number of hours of appropriate modality-specific training and clinical experience, which focuses on radiation safety and has passed an exam focused on radiation safety.

B. Training and Experience for Radiation Safety Officer

1. Background

A member of the ACMUI sought information about the alternative requirements concerning who can now be a RSO under the current requirements in Part 35, which lists nine certifying boards. The list includes Board certified professional health physicists, physicians with a radiological sciences specialty certification, radiation oncology physicists, and Board certified diagnostic physicists. In addition, authorized users may be RSOs.

2. Key Current Problems/Advantages Identified by Participants

One member stressed that the responsibilities of an RSO can differ significantly depending on the size and type of institution. In a large institution, the RSO may serve alongside authorized users and medical physicists. In a very small institution, there might be only an authorized user and a medical physicist, and one of them would be the RSO. In a very small institution doing only diagnostic nuclear medicine, the authorized user is also named as the RSO. Therefore, in the opinion of one member, the level and kind of radiation safety training necessary to the the RSO, as well as the kind of training and experience needed to be the RSO rather than an AU, are very different, and the absence of such differentiation is a

problem with the current regulation. Another member noted, however, that when institutions have a number of modalities, or when the RSO lacks experience in some modalities, they can rely on assistance from nuclear medicine technologists, radiation oncology physicists, and from members of the RSC. Therefore, the regulatory requirement should be for the generic baseline qualifications for RSO.

3. Review of Options

The ACMUI's discussion of the options presented for consideration by the NRC staff focused on Option 3. One member noted, first, that it is consistent with the requirements for authorized user. Another member who supported Option 3 rejected Option 5 because of the impracticality of requiring one year of experience under an authorized RSO. A member noted that Board certifications could apply only to specific modalities, and the RSO might need to address others. However, as discussed above, it was pointed out that the requirement would be for generic radiation safety knowledge and experience and the RSO could, if necessary, obtain assistance from other personnel at the institution. Another member of the ACMUI supported Option 3 because it included an examination requirement.

One member suggested eliminating a requirement for experience with the types and forms of radioactive materials at the institution, because it was unrealistic to expect the RSO to have experience in every area or every modality within the institution. Training in the modalities was necessary, but requiring actual experience was not.

One member summarized the differences between Option 3 and the current requirement as (1) elimination of the requirement for one year of experience under an authorized RSO and (2) addition of an examination as an alternative to Board certification. It was also noted that under Option 3 the Boards would not be listed in the regulation and each would be required to demonstrate to NRC that its certification and/or examination adequately addresses radiation safety.

The members discussed the type of examination needed. The decision depended in part, in some member's opinion, on the duties of the RSO. A generic examination would test basic understanding and experience, while a modality-based examination would be needed if the ACMUI concluded that the differences among modalities required more specific knowledge and experience. That decision depended, in part, on the eventual requirements for support services for the RSO. Another member noted that the number of different modality specific examinations would need to be quite large and would create a very ungainly examination system. A member argued that modality specific examinations were unnecessary, because institutions will choose the best candidates for RSO and will ensure that necessary support is available.

4. Preferred Option

The ACMUI recommended that the RSO be board certified by a board approved by the NRC or have completed a specified number of training hours plus examination.

C. Training and Experience for Medical Physicist

1. Background

The ACMUI began its consideration of training and experience requirements for radiation physicists by noting the similarity of the requirements to those for authorized users. Instead of an M.D. degree, the physicist would be required to hold an M.S. or Ph.D. degree.

A member noted, however, that a modality specific Board certification was not possible for physicists. The most specific certifications currently available are for diagnostic physics, therapeutic (radiation oncology) physics, and nuclear medicine.

Another member noted that medical physicists are not trained for a very narrow, limited range of procedures. Their training is in designing and operating efficient treatment planning and delivery systems.

2. Key Current Problems/Advantages Identified by Participants

An invited guest obtained clarification that the proposed Part 35 would address medical physicists only in conjunction with therapy. A member of the ACMUI then noted that the identity of the Boards that offer appropriate radiation oncology physics is relatively clear. Even so, the member suggested removing their names from the revised regulation, for consistency with the balance of Part 35.

The same member voiced a concern about the close relationship between radiation safety and the competence of physicists to practice radiation oncology physics, arguing that NRC would not have the competency to examine in the latter area. Other members agreed that NRC could not do clinical testing on the physicists, with one member noting that one point of view is that safety and physicist are synonymous. As the issue was summarized by a member, NRC would like to see the medical physicist be competent because they know that the medical physicist plays an important role in radiation delivery and how well the patient is managed. However, this comes within the practice of medical physics, and might not be within the purview of the NRC.

The same member noted that a few States, including Texas, are licensing medical physicists. The member concluded that NRC should limit the scope of the testing to the equivalent scope required for authorized users, that is, radiation safety, and leave the competency of medical physics up to the practice.

The ACMUI also discussed whether Part 35 should specify particular graduate degrees. One member noted that in the future medical physics certification programs might not be "academic" types of programs. However, it was noted that the two Boards that offer radiation oncology certification have rejected undergraduate degrees as adequate preparation for medical physics.

Finally, the ACMUI discussed whether medical physicists should be required for modalities besides brachytherapy, teletherapy, high dose-rate remote afterloaders, and gamma stereotactic radiosurgery. One member strongly encouraged low dose-rate brachytherapy to also be included.

3. Preferred Option

The ACMUI believed that the medical physicist training and experience be patterned after the authorized user. The members believed that the medical physicist should have at least an M.S. degree and that there be a requirement for an exam.

D. Training and Experience for Other Categories of Professional Staff

A member of the ACMUI encouraged the NRC to include training and experience requirements for medical dosimetrists, radiation therapists, and nuclear medicine technologists, and to require them to pass Board examinations. Another member questioned what categories of staff should be included, raising in particular nursing staff. However, the members did not discuss the topic in detail or reach a conclusion or recommendation in this meeting.

PART IV. LICENSING OF MEDICAL USES OF BYPRODUCT MATERIAL

A. How Should Industry Standards and Guidance Be Used in Revising Part 35?

In a Staff Requirements Memorandum dated June 5, 1997, "Meeting with Advisory Committee on the Medical Uses of Isotopes," (Attachment A) the Commission directed four questions to the ACMUI. The ACMUI members discussed the specific items under Question 1 pertaining to industry standards: First, how should NRC determine which industry standards, including voluntary standards, are adequate to meet the NRC's regulatory responsibility for patients, workers, and public safety? Second, to what extent should NRC allow licensee flexibility in interpreting or selecting an industry standard? Third, how should the concept of quality improvement be incorporated into reliance on the industry standards and accreditation type of approach to licensing and inspection?

The ACMUI also discussed the issue of possible barriers to NRC working with professional societies to develop standards and putting them into practice. One participant suggested the Federal Advisory Committee Act as a possible barrier and expressed the concern that if the Act is applicable, the development of these standards may need to be carried out in conformance with the statute. Another member noted that a problem could arise if NRC dealt with one professional society to the exclusion of others or in some other way gave one or more societies special standing. Another member noted that the ACMUI itself could provide information based on its own knowledge about which societies are the most prominent and relevant for a given activity. A relatively small amount of research, as well as input from the regulated community, could collect the standards relevant to a particular topic.

One member commented that including the NRC in the discussions and formulation of the standards of professional groups is a way to address the appropriate use of industry standards and ensure that issues which are important to the NRC are addressed. The member argued that it is especially important for the NRC to work with professional organizations to develop training and experience requirements, which are directly related to the radiation safety of workers and patients.

A key goal, in the opinion of one member, is to ensure that regulations do not conflict with what appear to be consensus standards of the regulated community. This member stated that one of the central problems of the current regulatory system is the number of conflicts between some of the existing prescriptive guidance documents and regulations and industry standards that most institutions attempt to follow.

Several members argued that turning a standard adopted by a professional organization as a policy or recommendation into an enforceable regulation posed great difficulties. Many of the recommendations of professional organizations are given to individuals, after consideration of potentially unique circumstances, and are not mandatory. Making such standards mandatory for everyone through promulgation as a regulation can reduce flexibility. An invited guest of the ACMUI expressed the opinion that guidelines or standards approved or adopted by multiple groups, with different compositions and interests, were more significant and meaningful, and should be given more consideration by NRC. A member noted, however, that if a standard is incorporated into a regulatory enforcement model, all of the specified contents of the standard must be done, or the institution is in violation. In contrast, the regulated community considers standards as a road map or broad plan for helping to build a program that has overall good

quality. Therefore, adopting an enforcement program that has an accreditation orientation, measuring overall program quality rather than specific infractions, is an important component part of considering the use of industry standards

Another member suggested that the ACMUI may not want to specifically define industry standards, but instead allow each facility the flexibility to decide what it feels is best. The member felt that this approach would work well with the second part of the medical policy statement which says "the NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate."

A member described the way in which the Food and Drug Administration is recognizing not only U.S. but also international standards. In general, if a majority of the manufacturers of a device are following a particular standard, the FDA also tries to adopt that standard, if it meets its other requirements.

1. When Would Industry Standards Be Appropriate?

One member expressed concern over whether an industry standard should be given the status of a regulation, arguing instead that they should be guidelines. Although the member was unsure about the future structure of the Part 35 rules, making the regulation a minimum standard and a definition of the performance outcome, and allowing the use of voluntary standards to reach that outcome would be a desirable approach. Another member noted that the training and experience requirements in Part 35 currently refer to certification processes, and the certification examinations are based upon the standards of practice of the certifying organization, so a similar regulatory approach already is in use.

2. What Specific Standards Are Available?

One member noted that American Association of Physicists in Medicine (AAPM) standards are very technical, and in many ways are more prescriptive than regulations. However, those standards also contain references to the need to exercise clinical judgment and flexibility, and the need to tailor a program to a specific institution. Another member noted that several of the American College of Radiology standards, addressing low dose-rate, high dose-rate brachytherapy, could be looked at in parallel by NRC. A third member noted that over the recent past the therapeutical radiology societies, particularly radiation oncology, have developed standards that would be adequate for use by NRC.

B. What External Professional Standards Currently Guide Practitioners in Addressing Issues That Are Covered Under the Rule?

One member suggested that the ACMUI identify and solicit input from the most prominent and relevant professional societies. Through this process the group could obtain a limited number of documents which are relevant to the revision of Part 35.

Another member suggested that because professional societies have differences in their compositions and interests the NRC may want to give more weight to evaluating those professional standards which are supported by multiple societies.

A member concluded the discussion by noting that one fundamental role of the ACMUI is to continue to remind the NRC that there is a practice of medicine; there are voluntary standards and groups that review standards; and there has to be an overriding concern about the risk to the patient, worker, public safety before any regulation is promulgated.

PART V: DEVELOPMENT OF REGULATORY GUIDANCE

A. What Revisions to Regulatory Guidance Are Anticipated?

A member expressed the concern that a variety of unanticipated issues such as occupancy factors and contact factors, used for calculations, had found their way into the final regulatory guide, causing the document to become very prescriptive regarding patient release.

1. How Will Risk-Informed, Performance-Based Criteria Be Preserved?

The ACMUI did not explicitly discuss how risk-informed, performance-based criteria will be preserved.

2. Process for Developing Regulatory Guidance

One member suggested that the staff's draft of Part 35 be written in modular form, breaking the document into sections such as brachytherapy and teletherapy. This member proposed that while an individual was working on the draft for these modular sections, he or she could simultaneously develop the draft of the regulatory guide. Following this strategy the committee member hoped to avoid possible confusion on how to meet the regulation in the future. Along these lines several of the members stressed the importance of having a draft guidance document available for review with the proposed rule and a final guidance document available for use with the final rule.

B. Can Regulatory Guidance Potentially Undermine Benefits of Revisiting Part 35?

One member was concerned about the discrepancy between the proposed and final regulatory guides. The regulatory guide that was reviewed by the ACMUI contained a two compartment model to evaluate I-131 elimination and retention and the final regulatory guide included a three compartment model. The member argued that it does not make sense and is unclear how this alteration became part of the regulatory guide after public comment.