

**SUMMARY OF DISCUSSION
Facilitated Public Workshop on
NRC's Medical Rulemaking Initiative
Held at All Agreement States Meeting
Los Angeles, California
October 18, 1997**

**Sponsored by
Organization of Agreement States and
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Abstract

The Organization of Agreement States sponsored a facilitated workshop presented by the Nuclear Regulatory Commission (NRC) at the All Agreement States Meeting held in Los Angeles, California on October 18, 1997, to consider possible revisions to 10 CFR Part 35, the NRC's regulations governing the medical use of byproduct material. The workshop included State participants in the All Agreement States meeting as well as members of the public. The NRC staff presented the workshop with alternatives for the most significant issues associated with the medical use of byproduct material, including the radiation safety committee; the quality management program; training and experience for authorized users, radiation safety officers, and medical physicists; the threshold for reportable events; and patient notification of reportable events. In addition, the workshop discussed how Part 35 could be restructured into a risk-informed, more performance-based regulation; revisions to NRC's 1979 Medical Policy Statement; and several other issues. The purpose of this document is to provide a succinct summary of the broad range of viewpoints expressed in the workshop.

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PART I. INTRODUCTION

In its "Staff Requirements Memorandum (SRM)-COMSECY-96-057, Materials/Medical Oversight (DSI 7)," dated March 20, 1997, the Nuclear Regulatory Commission directed the NRC 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 Commission directed the NRC staff 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 needs.

The NRC staff initially proposed 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 quality improvement and 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 an NRC "Working Group" and "Steering Group" approach. State participants are taking part in both the Working Group and Steering Group.

To ensure that the interests affected by the medical use rulemaking as well as members of the public have an early opportunity to comment on the rulemaking and policy issues and to discuss these issues with one another and the NRC, the NRC convened several facilitated public workshops, including the workshop addressed in this summary. The workshops are intended to foster a clearer understanding of the positions and concerns of the affected interests, as well as to identify areas of agreement or disagreement. However, the workshop process was not intended to develop a consensus agreement of the participants.

The facilitated public workshop conducted at the All Agreement States meeting had a predefined scope and agenda focused primarily on alternatives prepared by the NRC staff for the more significant issues associated with the regulation of the medical use of byproduct material. These alternatives were intended to help focus the discussion and to assist the staff in developing the text of the proposed rule. The five "cross-cutting issues" addressed in the workshop were: (a) the quality management program; (b) training and experience for authorized users, nuclear pharmacists, radiation safety officers, and medical physicists; (c) the radiation safety committee; (d) patient notification of reportable events; and (e) the threshold for reportable events. In addition, alternative recommendations for revision of NRC's 1979 Medical Policy Statement were discussed. The staff had not selected any preferred alternatives prior to the workshop, and additional options could be (and were) presented during the workshop.

In addition to the following summary of the All Agreement States workshop, held in Los Angeles, California on October 18, 1997, a transcript of the workshop is available to the public in NRC's Headquarters Public Document Room, 2120 L Street, N.W., Washington, D.C.

PART II. PRELIMINARY DISCUSSION:
How to make Part 35 a more "risk-informed, performance-based" rule:

The workshop began by addressing the question of how to make Part 35 a more "risk-informed, performance-based" rule. The Agreement State participants raised a number of points concerning, in particular, the issues surrounding how to take risk into account in addressing the medical use of byproduct materials.

One State participant stressed that the risk of particular types of procedures, such as gamma stereotactic radiosurgery, had to be considered in the context of alternative procedures, which could be more dangerous to the patient, more costly, or less effective medically. Another State participant noted that medical risks needed to be considered in the context of other radiation risks addressed by regulations. For example, the participant contrasted the 100 millirem limit for public exposure found in Part 20 with the special 500 millirem standard in Part 35 applying to the release of patients and the 25 millirem standard applicable to low-level radioactive waste disposal sites. The workshop participants discussed the special circumstances applicable with respect to each.

Workshop participants also addressed the available tools for measuring and assessing risk. One Agreement State participant noted that certain models for estimating risk were, in his opinion, questionable, and that selection of a linear rather than a non-linear no-threshold model could affect results. Another participant stressed that the low number of incidents available for analysis made statistical assessment of risk very difficult. Another participant stressed that defining the arena of risk to be discussed was very important. The Agreement State participants discussed whether addressing risk to patients was an appropriate regulatory objective. Risk to the public and occupational risk, they generally agreed, were both clearly appropriate subjects for regulation, in their role as protectors of public health and safety. One participant argued that it was necessary to look at risk more broadly than just risk from byproduct materials. In his view, States had to consider the combined risk of byproduct material, x-rays, NORM, NARM, and machine-produced radiation, especially in the context of occupational exposure. Some other Agreement State participants argued that the patient risk arena should be reserved to the risk-benefit decisions of the physician. A member of the public, urged NRC to conduct a comprehensive risk analysis for medical regulation, following the guidelines of the Presidential/Congressional Commission on Risk Analysis and Risk Management.

A member of the public, speaking as both a physician and a physicist, argued that NRC should bear in mind that the amounts spent on avoiding risk in one area will lead to risks in other areas, because funds are not available to enhance safety in that area. This participant urged NRC to provide a demonstration that the amounts spent on regulation of byproduct materials in medicine were providing a commensurate savings in life, and argued that given the past ratio of medical procedures involving byproduct materials (about 250 million since 1936) and radiation deaths from nuclear medicine (one known death in the same period) such a showing could not be made. This participant also argued that NRC should consider the risk to patients who are not treated with the appropriate modality. These patients would either be treated by a less appropriate procedure or would not be treated, because the costs of complying with the regulations made the appropriate modality unavailable.

One Agreement State participant contended that the use of a modality approach in Part 35 would be incompatible with a more risk-based approach. Modalities would be delineated by convenient dividers such as types of equipment or processes being used, not by risk. Another Agreement State participant noted, however, that diagnostic procedures generally present a significantly lower risk of harm than therapeutic procedures.

Other Agreement State participants argued that if the personnel involved are properly trained in the use of radioactive material and in radiation safety, then differences in risk to patients occur as a result of medical determinations concerning the potential benefits to the patient balanced against the potential harm to the patient.

The workshop participants did not make any summary remarks on the issue of risk.

PART III. REVISIONS TO THE MEDICAL POLICY STATEMENT

A. Background

The purpose of the Medical Policy Statement (MPS or "the Policy Statement"), first drafted in 1979, was described to the workshop as defining the role the NRC would play in regulating the medical uses of radioisotopes. The 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 workshop began its consideration of the MPS by examining whether it needed to be changed. That subject, in turn, led the workshop to discuss current problems in the field, training and experience requirements, and the proper scope of regulation.

Workshop participants cited both problems and advantages with the current MPS. Some participants who expressed concern about the current MPS indicated that it allowed too much regulatory encroachment on the practice of medicine. In the opinion of one participant, the MPS had not precluded regulations under Part 35 that were very prescriptive. Another participant commented that numerous mechanisms were in place to ensure quality control in the use of radioisotopes in medicine, including training requirements and numerous forms of quality management.

One Agreement State participant argued that many problems in the practice of nuclear medicine arise because physicians are not sufficiently involved in the administration of particular modalities and in patient procedures. Some States are requiring the physician's presence at certain types of procedures. California, for example, requires the physician to be present for therapeutic administration of radiopharmaceuticals. Another participant suggested that requirements for minimum levels of physician involvement in certain procedures were necessary. The participant conceded that nuclear medicine may be a low risk practice area, especially in diagnostic uses, but hoped that NRC would call for some form of specially qualified physician involvement in interpretation of diagnostic tests.

Participants who saw advantages in the current MPS indicated that the level of regulation provided by the NRC is appropriate. One participant stated that NRC's regulations did not interfere with medical practice. Another participant agreed that NRC's current regulations provided an adequate level of oversight of medical procedures involving radioisotopes without intruding into the practice of medicine. Agreement State participants placed particular emphasis on regulation of radiation safety. One participant emphasized that a number of mechanisms besides regulation exist to ensure patient safety, citing both medical and legal mechanisms, such as practice guidelines and standards promulgated by the Society of Nuclear Medicine or the American College of Radiology, and competence and malpractice issues as addressed by the State Board of Medicine or the legal system. Another participant thought that an important element in ensuring patient safety would be encouraging the State medical boards to take action against their member physicians. The participant stated that this did not occur in his own State.

B. Options and Discussion

The workshop participants were informed that NRC was considering the following alternatives for revisions to the MPS. The workshop participant's discussion of the options appears under each option.

1. Option 1: Status Quo

- 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 judgements affecting patients and into other areas traditionally considered to be a part of the practice of medicine.**

Few participants commented on this option. One participant supported this option but wanted to switch the second and third paragraphs. Other participants, as noted above, argued that NRC's regulatory framework had been, and in the future could be, properly developed under the existing MPS. The participants who found fault with the existing regulatory framework, as too prescriptive and an intrusion into the practice of medicine, did not clearly specify whether the contents or the implementation of the MPS contributed to the problems they identified. One Agreement State participant argued that it was important that a physician who intends to perform high-dose procedures has clinical experience in order to ensure the patient's safety from overexposure. The participant believed that radiation safety included assurance that physicians were competent in patient selection, prescription of the dose and interpretation of results. If the MPS had to be changed to cover some clinical aspects of physician training and experience, then the participant supported such a change.

2. Option 2: ACMUI-recommended 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 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 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.**

Participants who supported this option did so because it did not encourage NRC regulation of the practice of medicine. One public participant strongly supported this option because it states that "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." This participant believed that this would ensure that NRC would not regulate medical practice, which the speaker felt was adequately regulated by existing practices, including voluntary standards, within the medical community. The same participant also mentioned the relatively low risk of most procedures involving the use of radioisotopes, particularly in diagnostic applications, and the high level of benefit provided to the patient through such procedures. The participant supported this option because it called for the risks of these procedures to be viewed in light of the risks of other procedures.

An Agreement State participant added that some States might support this option because of State laws. This participant pointed out that the third paragraph of this option, which provides that NRC "will not intrude into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine," was a strong statement against interference in the practice of medicine.

Comments against this option were directed at the second paragraph, which provides for assessment of comparative risk levels of various medical procedures. Some participants were uncertain of NRC's ability to evaluate these risks, while others felt that such an assessment would need to reflect a wide variety of possible situations. One participant commented that a comparative consideration of acceptable risks would reveal a great deal of variation in what was considered acceptable in different medical settings, and therefore this option would require some mechanism for judging appropriate risk. One participant commented that such a scheme would need to take into account a situation in which a trade-off would be made between more radiation, and therefore increased risk, and better health benefits resulting from the higher risk procedure.

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.**

Few participants mentioned this option in the discussion. Two participants who did support this option recommended switching the second and third paragraphs. No negative points were made about this option.

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.**

Participants who supported this option did so because it stated specifically the areas in which NRC would regulate medical use of radioisotopes. One participant supported this option because it would provide for a regulatory role for NRC without allowing regulations to intrude into medical practice areas. This participant specifically mentioned the second paragraph, which provides a role for the NRC in ensuring "that the physician's prescription is accurately delivered to the correct patient." Another participant asserted that the primary function of the regulatory agency should be to regulate the delivery of the prescription. This option calls for NRC to ensure accurate delivery of the physician's prescription.

Several participants drafted an alternative option that reads as follows:

- 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. 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 medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.**

No clear preference was expressed for any of the options, but certain participants indicated preferences in the name of their States:

- Illinois, California, and Arizona supported Option 2.
- Pennsylvania supported Option 4.
- Georgia supported Option 3.

PART IV. CROSS CUTTING ISSUES

Workshop participants were asked to consider several 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 crosscutting issues discussed in the workshop were:

- Radiation Safety Committee;
- Quality Management Program;
- Training and experience requirements;
- Threshold for a reportable event; and
- Patient notification.

Each is addressed in the following sections. For each crosscutting issue, the summary of the discussion by the workshop participants 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 workshop's discussion of its experience with the requirement, its assessment of whether the current requirement does or does not meet the purpose, and any key current problems or advantages of the status quo.
- "Options" lists the alternatives presented to the workshop participants for revisions to Part 35.
- "Discussion" provides a summary of the workshop participant's discussion. When the workshop participants directly addressed particular regulatory alternatives, the views pro and con for that alternative are summarized.

Finally, when a clearly preferred option was identified by the workshop participants, it is described. In many cases the participants did not reach a conclusion concerning its preferred option because the workshop covered a number of topics in approximately half a day's discussion.

Cross Cutting Issue 1. Radiation Safety Committee

A. Background

The purpose of the Radiation Safety Committee (RSC) was explained, first, as ensuring that all necessary persons, including authorized users of radionuclides, the Radiation Safety Officer, representatives of hospital management, nurses, and other appropriate persons, take part in the radiation safety program. The NRC envisions RSCs as a forum for increased management participation at all levels of radiation safety management. The second purpose of the RSC is to recognize that there are many disciplines within the hospital that are involved with the radiation aspect of medical care. RSCs ensure that radiation safety management is not limited to the nuclear medicine or the radiation oncology department. RSCs get employees from all staff levels actively involved in radiation safety management.

B. Options

The workshop participants were informed that NRC is considering the following alternatives for revisions to the RSC requirements:

- 1. Option 1: Status Quo -- A Radiation Safety Committee (RSC) is required for all modalities in a medical institution.**
- 2. Option 2: RSC required for medical institution and all modalities, except diagnostic low dose sealed and unsealed byproduct material uses.**
- 3. Option 3: RSC not required for any medical licensee.**
- 4. Option 4: RSC not required, but medical licensees will be required to establish and implement a program for administrative and technical oversight of radiation safety.**

C. Discussion

The workshop participants' discussion of the RSC revolved around two key issues (1) whether an RSC plays a valuable role in all medical institutions, regardless of size and use of radioactive material, or is unnecessary and/or overly burdensome for some institutions or for some low-risk procedures; and (2) whether the current RSC requirements in Part 35 are too prescriptive and should be relaxed.

A majority of the participants in the workshop argued that the RSC requirements should recognize some differences between large and small institutions and/or between low and high risk procedures. The majority agreed that an RSC plays a necessary role in broad-based facilities. However, participants asserted that it is largely unnecessary at smaller, typically diagnostic facilities. These speakers favored Option 2 because it provides a more flexible approach and acknowledges the low risk of sealed and unsealed low-dose byproduct material. Participants also spoke of the diminished benefits of requiring a RSC at smaller facilities, because low-dose procedures may frequently take place in an office or clinic setting.

A physician from the public, who is a current RSC member and a former RSC chairman at a broad-scope facility, explained that the RSC can make it possible for a medical institution to practice nuclear medicine, to carry on research, with a minimum need for the State agency or the NRC to be involved with the small details. The regulatory agencies can simply have broad oversight because the RSC is well suited for detailed management and quality control.

The workshop discussion concentrated on Options 2 and 4. A participant from an Agreement State supported Option 2 but would not make an exception for the diagnostic uses of byproduct material. He argued that even diagnostic uses can easily be mismanaged and need the oversight of a body like an RSC. A public participant advocated a revision that fell between Options 1 and 2, allowing local management the key role of determining which modalities should be covered by the RSC. Another participant contended that it would be better for the RSC to be required with exemptions permitted (as with Option 2), than for the regulatory agencies to be faced with the issue of justifying why a particular facility needed a RSC (as with Option 4). One participant from an Agreement State argued that Option 4 likely would be more time-intensive for licensing staff that would be required to make judgment calls concerning what was or was not an acceptable program. Development of criteria would help, but the criteria would have to be in the rule, rendering Option 4 significantly like Option 2. Another participant, who agreed that performance standards would have to be stated clearly in the rule for Option 4 to work, expressed concern that the regulatory agencies would end up regulating by guidance.

Other participants supported Option 4, especially if it was accompanied by guidance. One participant opposed a prescriptive rule on RSCs, while agreeing that it might be simpler to enforce. A physician from the public spoke in favor of Option 4, arguing that different facilities have different needs and that Option 4 takes these differences into account, allowing for tailor-made radiation safety management. This option would provide all the benefits of RSCs and still allow programs to be developed that fit each individual facilities' needs.

The workshop participants identified a number of components of the current rule that they found too prescriptive. Participants generally supported the lessening of prescriptive requirements for smaller, typically diagnostic facilities. They argued that regulations place an unnecessary burden on small facilities that conduct few procedures per year but still are required to conduct quarterly meetings. One physician spoke of the burden for small facilities posed by the current RSC requirements, which dictate the composition of the RSC, how often it must meet, a schedule by which it must produce minutes of each meeting, and when it must do its ALARA review. To make the proposed regulations less burdensome on small facilities, one participant recommended allowing RSCs at smaller facilities to meet every six months rather than quarterly.

One participant from an Agreement State argued that the RSC requirements should become more prescriptive, in the sense that they should require the RSC to include a radiologist so that the radiation safety efforts of the institution are comprehensive. Another Agreement State participant explained that the Agreement State might be more inclined to support a particular option if they were given greater flexibility under that option.

Cross Cutting Issue 2: Quality Management Program

A. Background

To initiate the discussion, the workshop participants 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.

B. Options

The workshop participants were informed that NRC is considering the following options for revisions to the QMP requirements:

- 1. Option 1: Status Quo -- Maintain current requirements in §35.32.**
- 2. Option 2: Only require a written QMP.**
- 3. Option 3: Require written QMP, retention of each written directive and a record of each dosage requiring a written directive, and perform audits.**
- 4. Option 4: Require written QMP, retention of each written directive and a record of each dosage requiring a written directive, and maintain a record of recordable events.**

C. Discussion

Participants from Agreement States and from the public agreed that the status quo has not addressed the problem of misadministrations. They agreed that the rule should be developed with a fresh look at the problem of misadministrations, not with the thought that the QMP is the problem. Several Agreement State and public participants contended that modifying the current requirements for a QMP would not solve the misadministration problem.

A participant from an Agreement State requested clarification of the proposed written QMP. It will likely be a document that is retained at the facility, available for inspection but not submitted as part of the application. The participant argued that this was tantamount to a "trap to cite the facility because they really don't know whether they have an adequate program until the inspector gets out there and tells them it's wrong." Instead he supported something like Option 2, "that just calls for the objectives that they're to address with it, rather than being very prescriptive."

Another Agreement State participant referred other participants to an alternative requirement developed by a Conference of Radiation Control Program Director's Inc., working group. The working group's version is substantially similar to a version of Option 2 such that is not very prescriptive.

A participant from an Agreement State contended that the responsibility for quality management should be with the medical facility, not with a regulatory agency. The workshop facilitator explained that this view was in line with an additional option that had been developed informally and dubbed Option 5. Under this option there would be no QMP and quality would be ensured through some other mechanism.

Several participants from Agreement States argued that Option 5 would be preferable to Option 2 and the other options because those options involve a written plan. They contend that misadministrations cannot be addressed with a written QMP; a solution must address the variety of ways miscommunication, misunderstanding, or a lack of training contribute to the occurrence of misadministrations. These, participants explained, are the primary means by which they see misadministrations occurring.

A physician from the public explained that the professional community has been opposed to the rule because they do not think it addresses the problem. She referred to a California policy which requires that the authorized user physician be present when a therapeutic dose is being given. There apparently has been a significant reduction in misadministrations under this requirement. She argued that physician presence and training of the technicians had been the key to reduction of misadministrations in a State where there is "no requirement for anything written."

Other participants from Agreement States and the public agreed that it was sensible to require physician presence when a therapeutic dose is administered. Several added that the definition of an "authorized user" has been weakened, particularly in a diagnostic setting. This has meant that individuals without appropriate qualifications may well be in a position to administer radioactive material. Several participants argued that this situation makes a significant contribution to the problem of misadministrations.

A physician from the public told participants of a proposed rulemaking expected in November that he believed would alleviate the NRC of the need to solve the problem at hand. The Health Care Financing Administration (HCFA) rulemaking was expected to "define three levels of physician supervision for imaging modalities." He explained that physicians would be required to be in the facility, if not in the room, where a dose was being administered in diagnostic nuclear medicine.

In other comments, participants from Agreement States argued that any QMP should be referred to in some way other than "quality management," as that term has developed a negative connotation for many.

Cross Cutting Issue 3: Training and Experience

A. Background

Workshop participants asked the NRC to clarify the intended responsibilities of the authorized user. Several workshop participants from Agreement States questioned the role of the authorized user on the license compared to the role of other physicians who are not the authorized user but use radioactive materials in limited situations. One example was diagnostic nuclear physicians practicing therapy or using I-131. Participants argued that under the proposed changes to Part 35, these physicians would now need to satisfy significant training and experience requirements in order to qualify as an authorized user and continue to do what they are currently doing. Participants also questioned whether these physicians are uniformly qualified to safely perform the procedures they currently perform.

These participants thought that the potential responsibilities could range from areas generally covered under radiation safety (receipt and handling of radioactive materials) to activities generally included in the handling of patients (selecting the patient, describing the dose and interpreting the results of the test). If an authorized user were to be responsible for the latter activities, some members would expect the physician to be board certified and to have met a specific number of hours of training and experience, including some specific radiation safety training.

After some discussion of the physician's role, the NRC clarified for the workshop that one approach under consideration was to separate the clinical component of an authorized user's training and experience from the radiation safety component. The NRC would focus on ensuring that all authorized users were competent in the safe handling of byproduct materials, and would leave the matter of competency to practice medicine, including patient selection, reading scans, and so forth, to the certification boards, medical societies and other existing mechanisms for assuring medical competence. After this clarification, the workshop participants continued to discuss the intended role of the authorized user and the relationship between the authorized user's role and the training and experience requirements.

B. Options

The workshop participants were informed that NRC was considering the following alternatives for the training and experience requirements for authorized users:

- 1. Option 1: Status Quo (Require user to be a physician and certified by a board specified in the regulations, or meet specified number of hours of training and experience)**
- 2. Option 2: M.D. plus Board Certification or specified hours of training and experience (with a change in the number of hours to focus on radiation safety with minimal requirements for clinical experience)**
- 3. Option 3: M.D. plus Board Certification or specified hours of training and experience and an exam (with a change in the number of hours to focus on radiation safety with minimal requirements for clinical experience)**

4. Option 4: M.D. degree only
5. Option 5: M.D. plus Exam
6. Option 6: M.D. plus Exam plus Clinical Experience

The workshop participants discussed training and experience in the context of these alternatives and also during the discussion of the QMP.

C. Discussion of Training and Experience Requirements for Authorized Users

The workshop participants were divided on the question of whether Part 35 training and experience requirements could focus exclusively on the radiation safety component of an authorized user's training and experience or whether issues such as patient selection and reading scans should be considered by the NRC under the training and experience requirements. One participant believed that, from the patient's perspective, the physician's role in all aspects of the diagnostic procedures is essential, which suggested that the NRC should address the requirements for more than the safe handling of byproduct material. For example, one participant would support Options 2 and 3, which use certification to address clinical training, or specified hours of training for authorized users with significant patient involvement or organ doses above 2 rem, but Options 4, 5, and 6 for authorized users involved in lower dose or diagnostic procedures or if the authorized user were not the individual responsible for maintaining the radiation safety procedures. Another participant argued that the workshop's support, during discussion of the MPS, for moving the NRC farther away from the practice of medicine, suggested that a sole focus on radiation safety was appropriate. This participant stated that training and experience in the handling of byproduct material would be applied to the authorized user and anyone else handling radiation, both in diagnosis and therapy. Continuing, the participant questioned whether the certification boards examined candidates on radiation safety issues. This information was needed before the group could determine whether Options 2 or 3 would be acceptable for the purpose of assuring authorized user competence in radiation safety. The participant doubted, however, whether radiation safety was part of certification, which was intended to test clinical competency.

A public participant, who was a nuclear medicine physician, expressed a contrary opinion. This participant stated that quality care in nuclear medicine includes both radiation safety and clinical competency however, Part 35 currently contains provisions that can be interpreted as interfering in the practice of medicine. The speaker stated that the quality of patient care was adequately addressed by State medical licensing laws, certification boards, and hospital procedures for credentialing and allowing privilege to practice. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) oversees the integrity of these processes. The participant did raise a concern about misinterpretation of NRC requirements for licenses. Apparently hospitals sometimes misunderstand NRC issuance of licenses to authorized users as competence to perform procedures in nuclear medicine rather than ability to handle byproduct materials safely. Consequently, physicians may be credentialed or have privileges in areas where clinical competency in all procedures has not been demonstrated. The JCAHO is addressing this problem by requiring that initial privileging and reprivileging, usually every two or three years, include quality assurance, prescription of the dose, and interpretation, as well as continuing medical education (CME) or training and a statement of demonstrated current clinical competency to perform procedures. This participant also noted that using CME

to police competency was undercut when States and/or hospitals allowed the definition of specialty to be stretched so that a physician could continue to practice in a specialty by taking courses related to the specialty but not in the specialty itself. The participant noted that this is a problem, particularly in nuclear medicine. As a result, physicians could go years without taking a CME course that pertains to their practice. A physician who is more than two or three years past residency should not be given automatic privilege to perform all possible procedures. The participant suggested that JCAHO needs to tighten up CME requirements. Furthermore, the JCAHO, State licensing boards, and hospitals need to be educated to properly oversee competency to practice nuclear medicine. These processes, in addition to changes in Part 35, hold the key to maintaining the highest standards of radiation safety and other aspects of quality patient care. This approach to fixing the systems can be done using existing institutions at little or no additional cost.

Two other members of the workshop from Agreement States expressed reservations about reliance on certifying organizations. One participant commented that the JCAHO did not accredit two thirds of the hospitals in Iowa. Another member stated that some State regulators did not believe the boards of medicine or physician professional organizations have or would be able to limit the practice of medicine in those fields to those who were really qualified.

Another workshop participant expressed displeasure with the NRC's apparent withdrawal from requiring that an authorized user prescribe dosages or interpret the results of procedures. This participant was concerned that a hospital could get a license by putting forward any M.D. as an authorized user. This participant's State agency would want to ensure that all physicians are well qualified and trained. For example, all physicians who are not board-certified in radiology must take a radiation safety exam. The NRC might consider this approach to its radiation safety training requirements.

Another workshop member stated that he had received a letter from a physician who wanted approval to use radioactive material (patient selection, prescription, administration and evaluation) based solely on the possession of a medical degree, board certification and license to practice in the State. The physician thinks that no other requirements should be imposed. The participant apparently argued that the mammography certification model might be appropriate here, that is, clearly separating the physician's role in selecting the patient and evaluating the results from that of the technician who handles the machine, positions the patient and administers the radiation.

Another workshop member commented that the broad experience of the workshop members tended to muddle the discussion, because they were aware of seeing physicians in many different roles that they feel ought to be covered. For example, a physician who is a radiation safety officer (RSO) might need different training from one who is surrounded by a large staff of health physicists and medical physicists. The speaker also thought that the authorized user and RSO functions should be separate because the qualifications of the authorized user and RSO should be defined.

One participant questioned how the NRC would handle "grand-fathering" physicians if new training and experience requirements were imposed. This was an important consideration to the participant.

One participant questioned whether the NRC was the only entity that would give the exam proposed in several of the options. The NRC staff responded that other options were also possible, for example, the NRC might approve another organization's exam. The participant was concerned that the Agreement States might be responsible for providing these exams if adopted by the NRC. The participant stated that creating and validating a new exam would be costly in comparison to seeking out existing exams that were validated and acceptable to the NRC.

One workshop participant stated that if an authorized user were required to be present during procedures using byproduct materials, then the training and experience requirements for other staff could be less than would be necessary if there were no physician present when radioactive materials were being handled and used. If this latter case were anticipated, the workshop would need to look at the training and qualifications of support for radiation safety purposes. One workshop member stated that he was unaware of physicians handling radioisotopes, such as eluting generators on a regular basis, performing surveys or handling waste. While some physicians might administer doses of radioisotopes, they rarely prepare the doses. In addition, the participant was unaware of physicians making mistakes involving administering the incorrect dose or selecting the wrong patient. Based on these observations, the participant believed that the training and experience of the technologists, rather than the authorized users, should be the group's focus. Similarly in the case of radiopharmaceuticals, the doses are prepared by others than the physicians, yet the training and experience of these individuals (presumably radiopharmacists) are not being addressed. The requirements should emphasize those who handle radioisotopes on a regular basis. Another participant agreed with this call to ensure that the training and experience regulations focus on the people who are doing the actual work with radioisotopes because the existing guides might not be adequate.

Responding to this position, another workshop participant argued that physicians do indeed handle radioactive material and inject patients frequently even if State regulators do not see it. Physicians need to know how to handle radioactive materials. A physician may perform common tasks when the technologist is not available. The workshop member believed that the NRC should restrict itself to credentials in quantitative radiation protection plans rather than medical qualifications. The member suggested that the NRC assure that physicians are capable of "intelligently handling, calculating and supervising radioactive material." The level of education to demonstrate this competence should be uniform regardless of the hazard posed by the material, because the same basic radiation science, dosimetry and radiation safety apply to any amount of radioactive material. To comply with Part 20 standards, a physician needs basic skill in quantitative radiation science.

One workshop member expressed discomfort, as a license reviewer, with the need to find a physician unqualified because of management's anxiety presumably in making judgements about medical qualifications. The member thought that telling a physician that he or she could not practice because of having failed a radiation safety exam would make regulators equally uncomfortable. A solution would be to keep licensing personnel out of the role of evaluating the qualifications of physicians, if possible. One workshop member stated that under every State's malpractice law, the physician is ultimately responsible for quality of medical practice, so the issue of whether the physician or technologist is responsible is answered in court as the physician.

One participant questioned whether the term physician was intended to refer only to Medical Doctors, or was used generically, so that a Doctor of Osteopathy (D.O.) would be included within the definition. The NRC responded that the term "physician" was meant to apply broadly to include professionals such as D.O.s. Another workshop member stated that an authorized user should not be defined as a "physician" because under some State laws other professionals, such as osteopaths, chiropractors and podiatrists are covered under the term "physician."

D. Discussion of Training and Experience Requirements for Other Professionals

The discussion of training and experience requirements for other professions only included medical technologists. During the discussion of how to define the responsibilities and related requirements for authorized users, one workshop member noted that, although the errors that the training requirements aimed at addressing were actually more likely to be made by technicians, the training requirements for radiation technicians were not being addressed. Similarly, although the doses are prepared at radiopharmacies and are not prepared in hospitals and clinics, radiopharmacists are not being addressed. The point was that, rather than focussing on the radiation safety training of the physician, the radiation safety training should be on those who handle radioactive materials on a daily basis. Another workshop member agreed that the workshop should look more closely to assure that those who do the work itself are adequately trained. The current rules do not adequately address this issue.

A representative of nuclear medicine technologists stated that the role of the technologist entailed more than safely handling radioactive materials, rather it was to provide the physician with information to better treat the patient. The success of the entire diagnostic process correlated with the education and training of the technologist and physician. The National Association of Medical Technologists (NAMT) along with the American Society of Radiologic Technologists (ASRT), support certification and licensure for technologists, and support legislation to mandate that States require technologists using ionizing radiation to have licenses, which, in turn, would require education standards. The groups did not favor the NRC setting standards for training and education for technologists because the NRC does not have the experience in deciding how many hours of biochemistry, physiology and anatomy that a technologist needs to take, and the NRC does not do this for physicians. The member noted that two credentialing boards in nuclear medicine (the American Registry of Radiologic Technologists (ARRT) and the Nuclear Medicine Technology Certification Board (NMTCB) currently accredit schools if they provide the requisite training in radiation safety, handling of radiopharmaceuticals and anything else that goes into nuclear medicine.

One workshop participant confirmed that a minority of States already have required technologist certification. The member noted that the Conference of Radiation Control Program Directors (CRCPD) was planning on discussing minimum training and experience qualification criteria for technologists and planned to suggest State regulations to address what was a long-recognized problem. The experience of States with programs would be solicited in preparing rules. Another workshop member added that his State has testing for technologists, recognizing the tests provided by the two aforementioned credentialing boards, and adds a requirement for continuing education to maintain certification. Another member agreed that technologist training and continuing education were important in his State, but argued that even when technologists were responsible for an error, the physician needed to be closely involved in the operation to assure safety. Another State is in the process of developing a consensus group to recommend

minimum training and education requirements. At the conclusion of this discussion of State activities, the technologist representative supported recognized national tests, such as those of the ARRT and NMTCB, and would support State tests depending on how they were structured.

One workshop participant whose State also requires certification of technologists endorsed the importance of certification and continuing education requirements. This approach also enables State regulators to fix blame when a mistake has been made and it is the technician who is at fault. The physician and technologist make an important team, and both need to be held accountable for what they do. Another participant noted that State requirements for initial and continuing education of technologists relate to the issue of whether the physician needs to be present.

Cross Cutting Issue 4: Threshold for Reportable Event

A. Background

The workshop participants were asked to consider the threshold for reportable events. This issue involved not only how best to capture relevant safety significant events but also, pursuant to the Commission's instructions to the staff, how to capture precursor events -- events or practices that are or could be precursors to misadministrations. With respect to safety significant events, the participants were asked to consider alternatives to the criteria for reportable events (misadministrations), including whether NRC should set reporting levels at a certain percentage of the Abnormal Occurrence (AO) threshold.

AOs must be reported to Congress, although the thresholds for defining such events are specified by NRC. AO criteria cover the whole range of NRC regulation. With respect to the medical use of byproduct material currently, an AO event occurs when the following conditions are met:

- a. Results in a dose that is (1) equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow, to the lens of the eye, or to the gonads, or (2) equal to or greater than 10 Gy (1000 rad) to any other organ; AND
- b. Represents either (1) a dose or dosage that is at least 50 percent greater than that prescribed in a written directive or (2) a prescribed dose or dosage that is (i) the wrong pharmaceutical, (ii) delivered by the wrong route of administration, (iii) delivered to the wrong treatment site, (iv) delivered by the wrong treatment mode, or (v) from a leaking source(s).

"Misadministration," as it is currently defined in §35.2, involves some of the same criteria as an AO (e.g., involving the wrong pharmaceutical, the wrong route of administration, or differing from the prescribed dosage or dose by certain percent). However, misadministrations generally are defined as dosages or doses differing by more than 20 percent of the prescribed dosage or dose, in some cases; 10 percent in some cases; and 30 percent in some cases, rather than the 50 percent difference defining an AO. Misadministrations must be reported to NRC.

"Recordable event," as it is currently defined, also involves some of the same criteria, but involves differing dosages or doses (e.g., differing by more than 10 percent in some cases and 15 percent in other cases from the prescribed dosage or dose). All recordable events must be evaluated as part of the licensee's QMP and corrective action taken. Records must be retained for review by NRC during audits and inspections.

B. Options

The workshop participants were informed that NRC was considering the following alternatives for revising the reporting threshold requirements:

- 1. Option 1: Status Quo -- 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."**
- 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."**
- 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.)**
- 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.)**
- 5. Option 5: Thresholds for reportable event and recordable event, if applicable, would be set according to the outcome of discussions on Options 1, 2, 3, and 4. Licensees would voluntarily report precursor events that are outside of the area currently defined by the term "misadministration."**
- 6. Option 6: ACMUI Alternative-- modified version of Option 1. The existing misadministration reporting thresholds would be retained under this option, but the requirement to document recordable events would be eliminated.**

As a subsidiary issue, the term "misadministration" would be changed.

C. Discussion

The workshop participants concentrated their discussion on the question of how to identify precursor events. The discussion began with a working definition of precursor event as an event that would have programmatic implications for nuclear safety, either at the facility where it was identified or at other facilities of the same type. The goal was to identify information that would be useful to avoid potentially significant problems.

An Agreement State participant suggested that mechanisms already existed, without a rule change, to provide information to licensees about potential problems before they occur. Other organizations such as health physics societies and medical associations provide information to licensees about misadministrations, events and their root causes. This participant, who supported the status quo option on reporting thresholds, opposed adding additional requirements for reporting significant precursors.

Several participants requested additional clarification on what would constitute a precursor. One State participant suggested that a precursor resembled a near miss of noncompliance with a regulation. This participant reported that the State was sometimes notified by licensees of such near misses, and he believed that such situations should be recorded and publicized.

Another Agreement State participant argued that unless misadministrations exceeded certain levels or occurred more than once, even the radiation regulatory agency did not need to be informed. This participant argued that if the physician involved believed that a significant misadministration had occurred then the agency should be notified. Otherwise, corrections could be made in terms of total dose without involvement of the agency, and such corrections were matters of medical judgment. A second participant, who agreed that the State agency might not need to be informed of all events, stressed that the facility management, including the radiation safety organization, should be informed. The State agency could confirm that such reporting was occurring, and the corrective actions that were being taken, during periodic inspections. Another participant agreed, noting that the use of precursor events by management in nuclear power plants was proving very effective, and that a similar process was appropriate for medical institutions. Another participant noted, however, that clinics and private practice situations might not have the same levels of internal scrutiny and quality control.

Several workshop participants suggested that a requirement to send information about precursors to regulatory agencies could actually inhibit their identification. On the other hand, however, they supported programs to identify precursors to the facility management, so that they can be addressed by the facility. The effectiveness of that process could be inspected by the NRC or Agreement States. Reporting to NRC or the Agreement States would not be helpful unless a mechanism existed to share the information across the industry.

A member of the public and a medical physicist noted that numerous event reporting requirements already existed under which medical institutions documented problem areas and conducted audits of potential problem areas. Many of these were required by the JCAHO. NRC was encouraged to avoid duplicating already existing programs with requirements concerning precursors. Another public participant, a physician, argued that information about problems or potential problems already is transferred very quickly within the medical community. Reporting

to NRC or Agreement States, in this participant's opinion, does not enhance the information transfer, and could lead to embarrassing situations for the patients involved.

Should nomenclature be changed from "misadministration" to medical event" or comparable terminology?

The workshop did not discuss the suggestion that the terminology be changed to "medical event" from "misadministration."

Cross Cutting Issue 5: Patient Notification

A. Background

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 misadministrations must be retained for five years.

B. Options

The workshop participants were informed that NRC was considering the following alternatives for revising the patient notification requirements:

- 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.**
- 2. Option 2: Licensee to notify NRC only**
- 3. Option 3: Licensee to notify NRC and referring physician**
- 4. Option 4: Licensee to notify NRC, referring physician, and patient or guardian**
- 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**

As a subsidiary issue, the term "responsible relative" would be changed to "guardian."

C. Discussion

The workshop's discussion of this topic was intermingled with the discussion of reporting thresholds and precursor events. One Agreement State participant argued in favor of reducing the scope of the reporting requirement, requiring only that errors and problems be reported to the radiation regulatory agency, and the agency, either NRC or an Agreement State.

A State participant identified a potential problem with a notification system in which the licensee notifies the State and also certifies to the State that the patient has been notified. This participant had experienced a situation in which patients had not been notified, despite the verbal assurances of the licensee that notice had been given them.

The Agreement State participants also confirmed that legal requirements for patient privacy affecting patient notification procedures could be different from State to State and different from requirements under the Federal Privacy Act.

A State participant pointed out that the HCFA was addressing patient notification, and therefore NRC should investigate the HCFA requirements.

A member of the public and health physicist argued that medical standards of practice and tort law were the two mechanisms that should address notices to patients, and that Federal or State legal requirements for patient notification were unnecessary and inappropriate. Another member of the public also argued that questions of quality assurance and patient notification should be left to medical institutions and physicians. This participant, a physician and medical physicist, agreed that tort law and the risk management practices of medical institutions would address patient notification adequately.

PART V. FORMAT OPTIONS/STRUCTURE OF RULE

The proposed changes to the format and contents of Part 35 were described to the group. Part 35 currently contains three general sections, devoted to general information such as definitions and licensing; general administrative requirements on radiation safety and quality management; and general technical requirements such as calibration, surveys, storage, and similar topics. The next six sections address uptake, dilution, and excretion studies; imaging and localization; radiopharmaceuticals for therapy; sources for brachytherapy; sealed sources for diagnosis; and teletherapy. Each of these contains specific technical requirements for that modality. However, all of the currently existing modalities are not addressed in these sections. The next section addresses training and experience, including requirements not only for the modalities in the preceding sections but also for some additional modalities. The final section addresses enforcement.

The workshop participants were informed that in place of this structure the NRC anticipates structuring the revised Part 35 to include a general administrative section, a general technical section, and then several modality-specific sections. The modalities currently under consideration are

- (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.

Training and experience requirements for a particular modality would be consolidated with the pertinent technical requirements for that modality. Three separate sections would follow addressing recordkeeping, reporting, and enforcement.

The workshop participants did not, in general, oppose the concept of using a modality approach. The topic, however, was not discussed in detail.

PART VI. INDUSTRY GUIDANCE AND STANDARDS

A public participant representing nuclear medicine physicians in California argued that NRC and Agreement States should require evidence of mastery of quantitative radiation protection science and experience before permitting a physician to become an authorized user. No lower qualifications than those of the Accreditation Council for Graduate Medical Education (ACGME) should be accepted. On the question of whether physicians have the medical qualifications to practice nuclear medicine, NRC and Agreement States should rely entirely on the decisions of the practice privilege committees, the JCAHO, and State boards of medicine.

PART VII. DEVELOPMENT OF REGULATORY GUIDANCE

A public participant representing nuclear medicine physicians in California expressed concern that even if the revised Part 35 regulations were excellent, NRC's guidance and licensing practices might be inappropriately prescriptive. This participant questioned the need for, and the contents of, recent draft guidance for manufacturers, physicians, and pharmacies and for the patient discharge rule. Therefore this participant suggested that Agreement States should not be required to adopt any of the revised Part 35 or any of its accompanying regulatory and licensing guides.

PART VIII. AGREEMENT STATE ISSUES

A public participant representing nuclear medicine physicians in California argued that NRC's regulations in Part 35 on medicine and pharmacy practice should not be items of adequacy or compatibility under the Atomic Energy Act for Agreement States. This participant argued that the Part 35 standards should be adopted voluntarily, if at all, by Agreement States. Such voluntary adoption would be more likely to occur, according to the participant, if the revised Part 35 standards reflected a consensus between NRC and the professional and regulatory stakeholders.