ENVIRONMENTAL ASSESSMENT
FOR AMENDMENTS TO 10 CFR PART 35
"MEDICAL USE OF BYPRODUCT MATERIAL" AND
PETITION FOR RULEMAKING
"REVISION OF DOSE LIMIT FOR MEMBERS OF THE
PUBLIC EXPOSED TO HOSPITALIZED PATIENTS"
(PRM-20-24)
FINDING OF NO SIGNIFICANT IMPACT

1. Background

The Nuclear Regulatory Commission (NRC) is amending its regulations for the medical use of byproduct material. The NRC has examined the issues surrounding its medical use program, and has undertaken a comprehensive revision of Part 35. The revision is one component of the Commission's overall program for revising its regulatory framework for medical use. The overall goals of this program are to focus NRC regulation of medical uses of byproduct material on those medical procedures that pose the highest risk, to make the regulatory requirements more risk-informed and performance-based, and to reduce the prescriptive nature of some of the current requirements. The rule is intended to provide greater flexibility to licensees in providing high confidence that the byproduct material or radiation from byproduct material will be administered as directed by an authorized user physician, while also providing for protection of patients and the public. In addition, as a result of the development of new medical uses involving byproduct material, certain portions of the existing regulations in Part 35 need to be updated or expanded.

NRC's Medical Use Program includes uses of byproduct material in medical diagnosis, therapy, and research. Currently, there are approximately 1,700 NRC licenses authorizing the medical use of byproduct material under 10 CFR Part 35. In addition, there are approximately 4,200 State licenses in Agreement States authorizing the medical use of byproduct material. The Commission recognizes that physicians have the primary responsibility for the diagnosis and treatment of their patients, and recognizes that nuclear pharmacists have the primary responsibility for the preparation of radioactive drugs. The Commission's regulations are predicated on the assumption that properly trained and adequately informed physicians and pharmacists will make decisions that are in the best interests of their patients.

The major features of the amendments address: (1) restructuring of Part 35 to incorporate all of the requirements that are specific for a modality into the same subpart; (2) revisions to the requirement for a Radiation Safety Committee to require only licensees for two or more different types of uses of byproduct material under Subparts E, F, and H, or two or more types of units under Subpart H to establish a Radiation Safety Committee, and to provide licensees more flexibility in carrying out the responsibilities for the radiation safety program; (3) requirements for written directives to provide high confidence that the physician's prescription is administered in accordance with the physician's directions and to focus on those requirements that are essential for patient safety; (4) reporting of medical events; (5) reduction of requirements in Part 35 that are in other parts of 10 CFR, particularly Part 20; (6) reduction in the number and type of licensing actions required under Part 35; (7) revision of the training and experience requirements for authorized users, Radiation Safety Officers, authorized nuclear

pharmacists, and authorized medical physicists to focus more on radiation safety; (8) reductions in recordkeeping and/or reporting requirements when there would be no health and safety impact; and (9) revisions to the decay-in-storage provisions of Part 35.

2. Need for the Amendment

The rulemaking action addressed the following issues concerning 10 CFR Part 35:

First, amendments to Subpart B - General Administrative Requirements, Subpart C - General Technical Requirements, and to Subparts D through H are needed to reduce the prescriptive nature of certain requirements of Part 35, which result in costs to licensees without commensurate health and safety benefits. Although licensees currently can seek to adopt exemptions or alternatives to some prescriptive requirements through license amendment, such licensing amendment actions are costly both to the licensee and to NRC.

Second, amendments to Subparts D through H are needed for certain established medical uses, such as high dose-rate brachytherapy, low dose-rate brachytherapy, pulsed dose-rate brachytherapy, and gamma stereotactic radiosurgery. Regulation of these technologies currently is primarily through license conditions.

Third, amendments to Part 35 are needed to provide for the licensing of new medical uses in a timely manner. Currently, new medical uses must be licensed through case-by-case reviews in which the applicant or licensee must submit a request for an exemption for medical uses that are not specifically addressed in Part 35.

Fourth, the regulations in 10 CFR 35.2 regarding thresholds for "misadministrations" are not entirely dose based. Also, new medical uses are not addressed under the current criteria, and the current requirements do not address "patient intervention" or provide a threshold for wrong treatment site. Further, the Commission directed the staff to consider changing the nomenclature from "misadministration" to "medical event."

Fifth, regarding training and experience, Subpart J includes requirements for clinical experience in all modalities, even though diagnostic procedures present a lower overall risk than that presented by therapeutic procedures. Therefore, NRC requirements for clinical experience may not be necessary for most diagnostic procedures.

Sixth, the regulations permit medical use licensees to hold byproduct material with a physical half-life less than 65 days for decay-in-storage, if it holds the byproduct material for decay before disposal in ordinary trash for a minimum of ten half-lives. Licensees now must obtain a license amendment exempting them from the requirements of § 35.92 for materials with longer half-lives or to hold material for less than ten half-lives.

Finally, a Petition for Rulemaking (PRM-20-24) received by the Commission requests a revision from 1mSv (0.1 rem) to 5mSv (0.5 rem) of the public dose limit for specified visitors of radiation therapy patients who are not released in accordance with §35.75.

In its Staff Requirements Memorandum (SRM)-COMSECY-96-057, "Materials/Medical Oversight (SDI 7)," dated March 20, 1997, the Commission directed the NRC staff to revise 10 CFR Part 35, the NRC's regulations for 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, the Commission directed the NRC staff to consider the following:

(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 medical events, but also precursor events that could lead to a medical event;

(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 staff identified the following issues that also needed to be addressed:

(1) Radiation Safety Committee (RSC) requirements;

(2) Threshold for reportable events; and

(3) Training and experience requirements for authorized users, Radiation Safety Officers, authorized nuclear pharmacists, and authorized medical physicists.

3. Alternatives

The following alternatives were considered in this rulemaking:

Alternative One: Status quo.

Continue 10 CFR Part 35 without revision. Deny PRM-20-24 and retain the 1mSv (0.1 rem) public dose limit for visitors of radiation therapy patients on the basis that there are sufficient provisions within 10 CFR

20.1301(c) to allow case-by-case use of the 5mSv (0.5 rem) annual dose limit for visitors of radiation patients.

Alternative Two: Comprehensive revision of Part 35.

Promulgate comprehensive amendments that focus NRC regulation of medical uses of byproduct material on those medical procedures that pose the highest risk, restructure the regulatory requirements into more risk-informed, performance-based standards, and relax or eliminate certain prescriptive requirements currently contained in Part 35. Promulgate new requirements pertaining to low dose-rate, pulsed dose-rate, and high dose-rate remote afterloaders, gamma stereotactic radiosurgery units, and mobile remote afterloaders. Promulgate a new dose limit of 5mSv (0.5 rem) for visitors of radiation patients, as requested under PRM-20-24.

The no-action alternative is not favored because, based on the information presented to it, the Commission believes that its current regulations may be unnecessarily prescriptive and are not sufficiently risk-informed and performance-based. The Commission believes that greater flexibility can be provided, while continuing adequate protection of public health and safety.

4. Impact on the Public and the Environment

The amendments would have no significant impact on the public and the environment.

The amendments to the general administrative requirements and general technical requirements, and to Subparts D through H of Part 35, reducing the prescriptive nature of certain sections of Part 35, and deleting requirements that are covered in other parts of NRC's regulations will have no significant impact on public health and safety, occupational health and safety, or the environment. First, 10 CFR Part 20 continues to require medical licensees to develop ALARA programs; possess, use, calibrate, and check instruments; conduct surveys for contamination and ambient radiation exposure; and ensure the control of volatiles and gases. Reliance on 10 CFR Part 20 is expected to have no significant impact on public health and safety, occupational health and safety, or the environment. Second, the amendments to Part 35, reducing the overly prescriptive nature of certain requirements and making them more risk-informed and performance-based, will allow licensees greater flexibility in the development and implementation of their radiation safety programs associated with the use of byproduct materials in medicine, but the amendments are expected to result in no significant impact on public health and safety, occupational health and safety, or the environment.

The amendments to Subparts D through H that place the basis for regulation of high dose-rate brachytherapy, low dose-rate brachytherapy, pulsed dose-rate brachytherapy, and gamma stereotactic radiosurgery units into the requirements in Part 35 will codify existing license conditions. This is expected to have no significant impact on public health and safety, occupational health and safety, or the environment.

The amendments to Part 35 regarding new medical uses provide information that is needed for submission of a license application, which should result in expedited licensing for new medical uses.

This is expected to have no significant impact on public health and safety, occupational health and safety, or the environment.

The amendments to the requirements for reporting medical events would have a positive impact on public health and safety and the environment by helping to ensure that affected persons and the NRC are informed about conditions or incidents that have caused, or could cause, a medical event involving a patient or human research subject, dose to an embryo/fetus or a nursing child, worker or member of the public.

The amendments to the training and experience requirements in Part 35 focus on knowledge and experience that is integral to radiation safety. These changes are expected to have no significant impact on public health and safety, occupational health and safety, and the environment.

The amendment of § 35.92, pertaining to decay-in-storage, provides that byproduct material with a physical half-life of less than 120 days may be held for decay-in-storage before disposal without regard to its radioactivity and eliminates the requirement that such material be held for a minimum of ten half-lives. Licensees will be required to monitor the material at the surface before disposal to verify that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set at its most sensitive scale and with no interposed shielding, and to remove or obliterate all radiation labels except for material that will be handled as biomedical waste after it has been released from the licensee. These changes are expected to have no significant impact on public health and safety, occupational health and safety, or the environment.

The amendment in 10 CFR 20.1301 to permit, on a case-by-case basis, consenting adult, nonpregnant visitors to receive up to 5mSv (0.5 rem) in a year from exposure to radiation therapy patients, is expected to result in an increase in radiation exposure to the public. However, this alternative is considered acceptable, according to generally accepted radiation protection principles, such as those expressed by NRC, the National Council on Radiation Protection (NCRP), the International Atomic Energy Agency (IAEA), and the International Commission on Radiological Protection (ICRP).

Therefore, with the exception of the amendment to 10 CFR 20.1301, the rulemaking action will not lead to any increase in radiation exposure to the public, health care workers, or the environment. Revisions to the regulatory specifications to reduce the prescriptiveness of the requirements are not expected to lead to any increase in radiation exposure to the public, health care workers, or the environment, beyond the exposures currently resulting from the administration of byproduct material or radiation from byproduct material. Revisions to the requirements to focus on those requirements that are essential for patient safety will not lead to any increase in radiation exposure to the public, health care workers, or to the environment. These revisions would not increase radiation exposure because the performance-based regulations would provide for adequate protection. Reduction or elimination of duplication or overlaps between Part 35 and other parts of 10 CFR, particularly Part 20, will not lead to any increase in radiation exposure to the public, health care workers, or to the environment.

5. List of Agencies and Persons Consulted and Identification of Sources Used

The program for revising Part 35 and the associated guidance documents has involved more interactions and consultations with potentially affected parties (the medical community and the public) than is provided by the typical notice and comment rulemaking process. The NRC published an announcement

of its proposed revision of Part 35 and a request for public input on NRC's medical use program in a Federal Register notice on August 6, 1997 (62 FR 42219). In response, NRC received numerous written comments, which were reflected in the proposed rule, published on August 14, 1998 (63 FR 43516). The NRC received numerous public comments on the proposed rule, which are reflected in the final rule.

To ensure that the interests affected by the medical use rulemaking were given an early opportunity to comment on the rulemaking alternatives, the Commission convened or participated in a number of public workshops to discuss the fundamental approaches and issues to be addressed in the rulemaking. NRC participated in a Part 35 workshop held during the Organization of Agreement States' All Agreement State meetings in October 1997 and October 1998. The All Agreement States workshops were attended not only by representatives of the 30 Agreement States, but also by the public. NRC convened two facilitated public workshops, in Philadelphia, Pennsylvania on October 28, 29, and 30, 1997, and in Chicago, Illinois on November 12, 13, and 14, 1997. (See 62 FR 53249; October 14, 1997) These workshops were attended by nuclear medicine physicians; radiation oncologists; other specialists (e.g., cardiologists, radiologists); radiation safety officers; medical physicists; medical technologists; nurses; medical education and certification organizations; radiopharmaceutical interests; hospital administrators; patients' rights advocates; Agreement States; Federal agencies; and members of the public. In addition, the Advisory Committee on the Medical Uses of Isotopes (ACMUI), an NRC advisory committee, discussed the issues raised by the proposed rulemaking in its semiannual meetings in 1997, 1998, and 1999. The ACMUI meetings were open to the public. Finally, NRC staff participated in meetings with numerous groups representing physicians, pharmacists, medical physicists, technicians, and other stakeholders.

Public input also was obtained by holding open meetings of the government groups developing the revised rule language; putting background documents, options for the more significant regulatory issues associated with the rulemaking, a "strawman" draft proposed rule, and the draft proposed rule on the Internet; and convening public workshops.

In addition, the rulemaking process used a working group, steering group, and guidance consolidation team that included not only members from the NRC Headquarters offices, but also members from the regional licensing and inspection staff who are in frequent contact with NRC's medical licensees. Representatives of two Agreement States and a non-Agreement State were members of the groups developing the rule and guidance. The Agreement State representative on the working group also is a member of the Conference of Radiation Control Directors' Suggested State Regulation Committee on Medical Regulation, which is working toward parallel development of suggested State regulations. State participation in the process was intended to enhance development of corresponding rules in State regulations and provide an early opportunity for State input. In addition, it allowed the State staff to assess the potential impacts of NRC draft language on the regulation of non-Atomic Energy Act materials used in medical diagnosis, treatment, or research in the States. The meetings of the groups developing the rule text and the associated guidance were noted in the NRC meeting announcements and were open to the public. The NRC also held public workshops during the public comment period on the rulemaking, and extended the public comment period to allow additional responses to be prepared and submitted..

6. Finding of No Significant Impact

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that the amendments, if adopted, would be a major Federal action but would not significantly affect the quality of the human environment, and therefore an environmental impact statement is not required. The amendments would relax certain requirements and eliminate other procedural restrictions associated with the medical use of byproduct material. The Commission believes these amendments would provide greater flexibility in the medical use of byproduct material while continuing to adequately protect public health and safety. It is expected that this rule, if adopted, would not cause any significant increase in radiation exposure to the public or radiation release to the environment beyond the exposures or releases currently resulting from the medical use of byproduct material.