

September 30, 1997

RADIATION SAFETY COMMITTEE

NOTE

Following Commission approval of the staff's program to revise 10 CFR Part 35 and associated guidance documents, the NRC staff initiated development of draft rule language, using a modality-based approach. As directed by the Commission, the staff has developed alternatives, with draft rule text, for the more significant issues associated with the regulation of the medical use of byproduct material. These alternatives to regulation in specific areas are intended to help focus the discussion during the NRC's public meetings and the meetings with medical professional societies during the Fall of 1997 and to assist the staff in developing the proposed rule language. The alternatives represent a broad range of possibilities and are being provided to stimulate input from members of the public in an effort to encourage all interested parties to provide input into the development of the revised regulation. The NRC staff has not selected any alternative at this time, and is open to additional alternatives which might be proposed that are consistent with the guidance provided by the Commission.

PART 35 - RADIATION SAFETY COMMITTEE

Summary of Alternatives

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

ALTERNATIVE 1

Status quo: A Radiation Safety Committee (RSC) is required for all modalities in a medical institution.

Pros

1. Licensee familiarity and continuation of established radiation safety programs.
2. Provision for communication between disciplines & departments in a single committee, with a radiation safety focus.
3. Requirements for approvals via multidisciplinary view points in a team approach.
4. Radioactive material use and users are under licensee personnel/peer review and accountability.
5. Provisions for direct involvement of executive management (resource allocation, corporate policy, and interdepartmental coordination).
6. A committee of varied representation is granted significant latitude and authority to develop & implement an appropriate radiation safety program & direct personnel.

Cons

1. Need for RSC is not based on risk of modality.
2. May not be necessary for effective radiation safety management at small medical institutions.
3. Radiation safety is not directed solely by an individual(s) (e.g., Radiation Safety Officer) whose role is independent of the authorized user role and interests.

Current Rule Text

Each medical institution licensee shall establish a Radiation Safety Committee to oversee the use of byproduct material.

(a) Each Committee must meet the following administrative requirements:

(1) Membership must consist of at least three individuals and must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. Other members may be included as the licensee deems appropriate.

(2) The Committee must meet at least quarterly.

(3) To establish a quorum and to conduct business, at least one-half of the Committee's membership must be present, including the Radiation Safety Officer and the management's representative.

(4) The minutes of each Radiation Safety Committee meeting must include:

(i) The date of the meeting;

(ii) Members present;

(iii) Members absent;

(iv) Summary of deliberations and discussions;

(v) Recommended actions and the numerical results of all ballots; and

(vi) ALARA program reviews described in Section 35.20(c).

(5) The Committee must promptly provide each member with a copy of the meeting minutes, and retain one copy for the duration of the license.

(b) To oversee the use of licensed material, the Committee must:

(1) Review recommendations on ways to maintain individual and collective doses ALARA;

(2)(i) Review, on the basis of safety and with regard to the training and experience standards in subpart J of this part, and approve or disapprove any individual who is to be listed as an authorized user, an authorized nuclear pharmacist, the Radiation Safety Officer, or a teletherapy physicist before submitting a license application or request for amendment or renewal; or

(ii) Review, pursuant to Section 35.13 (b)(1) through (b)(4), on the basis of the board certification, the license, or the permit identifying an individual, and approve or disapprove any individual prior to allowing that individual to work as an authorized user or authorized nuclear pharmacist;

(3) Review on the basis of safety, and approve with the advice and consent of the Radiation Safety Officer and the management representative, or disapprove minor changes in radiation safety procedures that are not potentially important to safety and are permitted under Section 35.31 of this part;

(4) Review quarterly, with the assistance of the Radiation Safety Officer, a summary of the occupational radiation dose records of all personnel working with byproduct material;

(5) Review quarterly, with the assistance of the Radiation Safety Officer, all incidents involving byproduct material with respect to cause and subsequent actions taken; and

(6) Review annually, with the assistance of the Radiation Safety Officer, the radiation safety program.

[51 FR 36951, Oct. 16, 1986, as amended at 59 FR 61782, Dec. 2, 1994]

ALTERNATIVE 2

A RSC is required for a medical institution and all modalities, with the exception of diagnostic low dose sealed and unsealed byproduct material uses.

Pros

1. Risk based.
2. Licensee familiarity and some continuation of established radiation safety programs.
3. Provisions for communication between disciplines & departments in a single committee, with a radiation safety focus.
4. Requirements for approvals via multidisciplinary view points in a team approach.
5. Radioactive material use and users are under licensee personnel/peer review and accountability.
6. Provide for direct involvement of executive management (resource allocation, corporate policy, and interdepartmental coordination).
7. A committee of varied representation is granted significant latitude and authority to develop & implement an appropriate radiation safety program & direct personnel.

Cons

For institutions with an RSC:

1. An RSC may not be necessary for effective radiation safety management at small medical institutions.
2. Radiation safety is not solely directed by an individual(s) (e.g., Radiation Safety Officer) whose role is independent of the authorized user role and interests.

For diagnostic low-dose sealed and unsealed byproduct material uses:

1. No provisions for licensee to establish interdepartmental/interdisciplinary communication &/or a committee with emphasis on radiation safety.
2. No collegial consensus assisting/representing executive management in oversight of radiation safety issues.
3. Radiation safety is dependent upon only the RSO and executive management oversight.

4. Current broad scope licensees & regulatory provisions for use & approvals (facilities & use) will undergo significant change.
5. Decreased potential for executive management involvement in the radiation safety program.

Draft Rule Text

Section 35.XX Radiation Safety Committee

Each medical institution licensee shall establish a Radiation Safety Committee to oversee the use of byproduct material, with the exception of diagnostic low-dose sealed and unsealed byproduct material use.

(a) Each Committee must meet the following administrative requirements:

(1) Membership must consist of at least four individuals and must include an authorized user of each type of use permitted by the license(s), appropriate modality-specific physicist(s) (if applicable), the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. Other members may be included as the licensee deems appropriate.

(2) To establish a quorum and to conduct business, at least one-half of the Committee's membership must be present, including the Radiation Safety Officer and the management's representative.

(3) The committee must meet at least quarterly.

(4) The licensee shall prepare and maintain records of the Committee meetings in accordance with §35.2022.

(b) To oversee the use of licensed material, the Committee must:

(1) Review, on the basis of safety and with regard to the training and experience, and approve or disapprove any individual who is to be listed as an authorized user, authorized nuclear pharmacist, the Radiation Safety Officer, or an authorized modality-specific physicist, before submitting a license application or request for amendment or renewal; or

(2) Review, pursuant to Section 35.13, on the basis of the board certification, the license, or the permit identifying an individual, additional training and experience requirements, as applicable, to approve or disapprove any individual prior to allowing that individual to work as an authorized user, nuclear pharmacist, or physicist;

(3) Review on the basis of safety, and approve with the advice and consent of the Radiation Safety Officer and the management representative, or disapprove minor changes in radiation safety procedures, provided the changes do not affect the standard of safety established in applicable NRC regulations;

(4) Review quarterly, with the assistance of the Radiation Safety Officer, all incidents involving byproduct material with respect to cause and subsequent actions taken; and

(5) Review the radiation safety program at least annually, with the assistance of the Radiation Safety Officer.

ALTERNATIVE 3

A RSC will not be required for any medical licensee.

Pros

1. Supports a performance-based approach and acknowledges the low risk of sealed and unsealed low-dose byproduct material uses.
2. Licensee directs the structure and management of their own radiation safety program

Cons

1. Not risk based.
2. No provisions for licensee to establish interdepartmental/interdisciplinary communication &/or a committee with emphasis on radiation safety.
3. No collegial consensus assisting/representing executive management in oversight of radiation safety issues.
4. Radiation safety is dependent upon only the RSO and executive management oversight.
5. Current broad scope licensees & regulatory provisions for use & approvals (facilities & use) will undergo significant change.
6. Decreased potential for executive management involvement in the radiation safety program.

ALTERNATIVE 4

A RSC will not be required, but medical licensees will be required to establish and implement a program for administrative and technical oversight of radiation safety.

Pros

1. Consistent with a risk-informed, performance-based approach to regulations.
2. Provisions for direct involvement of executive management (e.g., resource allocation, corporate policy, and interdepartmental coordination).
3. Licensee is granted significant latitude and authority to develop & implement an appropriate radiation safety program.

Cons

1. Radiation safety is dependent only upon executive management oversight.
2. Resources devoted to management oversight of the radiation safety program may, at times, be impacted by the need to devote management resources to other program areas within the facility.

Draft rule text

To oversee the use of licensed material, the licensee must establish a program that will do the following:

(a)(1) Approve or disapprove any individual who is to be listed as an authorized user, an authorized nuclear pharmacist, the Radiation Safety Officer, or a teletherapy physicist before submitting a license application or request for amendment or renewal; or

(2) Approve or disapprove any individual prior to allowing that individual to work as an authorized user or authorized nuclear pharmacist;

(b) Approve or disapprove minor changes in radiation safety procedures that are not potentially important to safety and are permitted under Section 35.31 of this part;

(c) Review all incidents involving byproduct material with respect to cause and subsequent actions taken; and

(d) Review annually, with the assistance of the Radiation Safety Officer, the radiation safety program.

(e) Provide a mechanism for interdepartmental/interdisciplinary communication.

Radiation Safety Committee Overview

Key Items for Consideration	Alternative 1	Alternative 2 with RSC/ without RSC	Alternative 3	Alternative 4
Risk basis		x/x		x
Licensee familiarity and continuation of established radiation safety programs with minimal or no impact on corresponding regulatory oversight	x	x/_		
Provisions for communication between disciplines & departments in a single committee with a radiation safety focus	x	x/_		
Approvals via multidisciplinary view points in a team approach	x	x/_		
Radioactive material use and users are under licensee personnel/peer review and accountability	x	x/_		
Provisions for direct involvement of executive management (resource allocation, corporate policy, and interdepartmental coordination)	x	x/_		x
A committee of varied representation is granted significant latitude and authority to develop & implement an appropriate radiation safety program & direct personnel	x	x/_		
May not be necessary for effective radiation safety management at small medical institutions	x	x/_		
Collegial consensus representing executive management in oversight of radiation safety issues	x	x/_		
Radiation safety and initial authorized user approval directed by Radiation Safety Committee	x	x/_		
Radiation Safety is dependent upon only the RSO and executive management oversight	x	_/x	x	
Licensee directs the structure of their own radiation safety program		_/x	x	x