DOCKET NUMBER PROPOSED RULE PR-30, 31, 32 et al. (7)
(50 FR 30616)

Lynchburg General-Marshall Lodge Hospitals

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DOCKETED USNRC

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OFFICE OF SECRETARY DOCKETING & SERVICE BRANCH

September 20, 1985

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Attention: Docketing and Service Branch

Dear Sirs:

I have read and given considerable thought to the proposed rules published in the Federal Register, volume 50 number 144 dated July 26, 1985. I would ask that you expand on your proposed rules for section 35.44 dealing with authorized visiting users of radioisotopes, as this would apply to my personal situation.

We operate under Nuclear Regulatory Commission license number- 45-02207-02. I am the only physician who in reality uses the cobalt unit on a daily basis. As you can see from our license, there are other individuals named as authorized users. When I am on vacation or away at a meeting, a radiation oncologists is usually hired from elsewhere in the state, as there is no other radiation oncologist in the city of Lynchburg. The other users on our license are general radiologists who have chosen not to practice radiation oncology since I arrived in Lynchburg in 1977.

Since 1977 I have participated in the education and training of residents in radiation oncology at the Medical College of Virginia, and more recently, at the University of Virginia also. As is customary in many fields of medicine, I have had, on occasion, the chief resident or a senior resident in radiation oncology cover my practice while I am away for a few days. By the nature of the license at the Host Institution, these senior or chief residents are not specifically listed by name on that institution's license. Because of this, your proposed regulations (and my present license) make it difficult to use these physicians since they are not specifically listed. Because I have been participating in their training, I am quite familiar with their capabilities and would only extend this invitation for locum tenens work to someone in whom I have sufficient confidence of their ability. While they are here working for me, they are in contact with their training institution (about 100 miles away) in the event any decisions need to be discussed with their preceptors. If I am to be away from my practice for any length of time (more than a week) I will usually also have a board certified radiation oncologist cover my practice part of the time. Due to the nature of the practice of radiation oncology in the state of Virginia, it is not always possible to obtain a board certified radiation oncologist. A mixture of coverage from the chief residents, senior residents, and fully boarded physicians has become most appropriate. Please keep in mind that our radiation safety officer and one or more of the other users listed on our license are usually present within the city, but there can be no guarantee of this.

I feel that my approach to this in the past has been very reasonable and it has proved to be a very satisfactory working relationship. I believe that by viture of the status

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of these individuals at either the Medical College of Virginia or the University of Virginia that they should be allowed to cover my practice in my absence under these terms. There is no problem with the sixty day maximum as we have rarely exceeded thirty days of such usage in a given year. I would ask that you reply by letter to this request indicating whether it meets with your approval.

Thank you very much.

Sincerely,

Peter R. Hulick, M.D.

PRH:rwf
cc: File
Enclosure ✓

assure that exposures remain ALARA considering the few program adjustments typically made during any single year. More time between reviews might not permit the committee to make timely recommendations for reducing unnecessary worker, public, or patient exposure by, for example, changing space allocation, purchasing new equipment, or changing procedures.

Section 35.33 Requirement for authority and statement of responsibilities.

To ensure that material is used safely, the Radiation Safety Officer and Radiation Safety Committee need a clear statement of their duties from management so that questions about authority, responsibility, and jurisdiction do not keep these individuals from acting.

Section 35.34 Visiting authorized user.

The uninterrupted provision of medical care occasionally requires a visiting authorized user to work for a host licensee when its permanent staff may be unable to do so. This was allowed in the past by a standard license condition. If the licensee had a copy of another licensee's NRC license that listed the visitor as an authorized user, the visitor could work under the license for sixty days each year without requesting a license amendment. The scope of this concept has been expanded to allow NRC licensees to employ Agreement State authorized users. Because the visiting authorized user's training and experience has been reviewed for health and safety consideration by a regulatory agency, this short-term authorization will not pose an undue risk to public health and safety. The purpose of written permission is to assure that the required records have been reviewed and found complete.

When exercising this privilege, host licensees should identify each individual method of use authorized by their license, each individual method of use authorized by the visitor's license, and each individual method of use that the visitor will be allowed to do at the host facility. Note that in some cases the Agreement States' groups, schedules, or subparts do not correspond to those of the NRC. The visitor can only do those procedures authorized by *both* licenses.

Section 35.35 Mobile nuclear medicine service administrative requirements.

Mobile nuclear medicine service has been limited to diagnostic medical use because the inherent hazard of therapeutic amounts of byproduct material makes it unsuitable for use in locations where the licensee might not have clear and direct control over personnel, facilities, or equipment. The Commission will continue, on a case-by-case basis, to authorize provision of low level radiopharmaceutical therapy by mobile nuclear medicine services. These licensees are required to have a letter of permission from the management of each client to assure that the client management is aware of and in agreement with the medical use of byproduct material within the facility.

Mobile service may not be provided to licensed clients because, in case of a spill or dose rates above regulatory limits, the responsibility for corrective action may be clouded.

Section 35.36 Radiation safety program changes.

This section allows the licensee to make changes in the radiation safety program that was described in the application if the changes are within the requirements of the regulation. The purpose of this authorization is to allow the licensee to respond to changes in staff levels, available equipment, or patient load that may require reallocation of floor space, or to make changes that may be necessary for patient care, administrative, radiation safety, or economy needs. Before implementing any change, the licensee must make a record of safety matters that were considered when planning the change. The record will be used during unannounced inspections to determine whether the licensee has made changes that are contrary to the regulations, license conditions or orders, and during termination surveys to provide an indication of every area where material was used.

The Commission notes that this change in the current licensing process under which *all* radiation safety program changes must be approved by license amendment, recognizes that, in the end, public health and safety is based on three features: (1) NRC regulates who may use byproduct material for medical use by listing authorized users on the license; (2) NRC regulates the degree of hazard, balanced with medical needs, by only allowing certain chemical and physical forms for medical use; and (3) NRC regulates where byproduct material may be used to allow for unannounced inspections of licensee radiation safety programs. This proposal would retain those regulatory features by requiring licensees to receive a license amendment before using material for new clinical methods of use not permitted by the license; before permitting new authorized users to use material; before receiving more material or different kinds of material than permitted by the license; and before using material at locations not listed on the license. These are major changes in a licensee's radiation safety program for which a license amendment would still be required (see § 35.17). Under this proposal all other changes (such as selecting replacement equipment, re-arranging the nuclear medicine clinic, switching from one service contractor to another, or switching to an alternative equipment quality assurance procedure) would be minor changes.

The Commission would appreciate comments on this major/minor dividing line or threshold. Is this dividing line clear and complete? Are there other features that should be considered as major changes, or are some of these major changes really not important to health and safety? Is there some other dividing line, either fixed or flexible, that would clarify which changes are really not important to health and safety and may therefore be made by the licensee? Alternatively, should the Commission continue to require licensees to submit all radiation safety program changes for agency approval?

Section 35.37 Records and reports of misadministrations.

The proposed Part 35 retains the misadministration definitions and reporting and recordkeeping requirements of the current Part 35. A discussion of these requirements appears at 45 FR 31701, published May 14, 1980.

Although the Commission has not revised its misadministration reporting and recordkeeping requirements, it would like to take this opportunity to ask for public comment on these requirements based on the experience gained since the requirements were first published in final form five years ago. For both diagnostic and therapeutic misadministrations, are the current requirements adequate to protect the public health and safety or should they be made more or less stringent? Should the regulations require prompt notification of the patient who received the misadministration? Do the regulations provide the public with a clear notice of the Commission's role when there is misadministration? Should the Commission take enforcement action against licensees who misadminister by product material or radiation to patients? If so, what type of enforcement action should be taken?

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, 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 § 35.30(b)(2).

(5) The Committee must 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) Be responsible for monitoring the institutional program to maintain individual and collective doses as low as reasonably achievable;

(2) 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, the Radiation Safety Officer, or Qualified Teletherapy Calibration Expert before submitting a license application or request for amendment or renewal;

(3) Review on the basis of safety and approve or disapprove each proposed method of use of byproduct material;

(4) Review on the basis of safety, and approve with the advice and consent of the Radiation Safety Officer and the management representative, or disapprove procedures and radiation safety program changes;

(5) Review quarterly, with the assistance of the Radiation Safety Officer, occupational radiation exposure records of all personnel working with byproduct material;

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

(7) Review annually, with the assistance of the Radiation Safety Officer, the byproduct material program; and

(8) Establish a table of investigational levels for occupational dose that, when exceeded, will initiate investigations and considerations of action by the Radiation Safety Officer.

§ 35.33 Requirement for authority and statement of responsibilities.

(a) A licensee shall provide the Radiation Safety Officer, and at a medical institution the Radiation Safety Committee, sufficient authority and organizational freedom to:

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide solutions; and

(3) Verify implementation of solutions.

(b) A licensee shall establish in writing the authorities, duties, responsibilities, and radiation safety activities of the Radiation Safety Officer, and at a medical institution the Radiation Safety Committee.

§ 35.34 Visiting authorized user.

(a) A licensee may permit any visiting authorized user to use licensed material for medical use under the terms of the licensee's license for sixty days each year if:

(1) The visiting authorized user has the prior written permission of the licensee's management and, if the use occurs on behalf of an institution, the institution's Radiation Safety Committee;

(2) The licensee has a copy of a Commission or Agreement State license that identifies the visiting authorized user by name as an authorized user for medical use; and

(3) Only those procedures for which the visiting authorized user is specifically authorized by a Commission or Agreement State license are performed by that individual.

(b) A licensee need not apply for a license amendment in order to permit a visiting authorized user to use licensed material as described in paragraph (a) of this section.

(c) A licensee shall retain copies of the records specified in this section for two years after the visiting authorized user's last use of licensed material unless the visiting authorized user has been listed as an authorized user on the licensee's license.

§ 35.35 Mobile nuclear medicine service administrative requirements.

(a) The Commission will only license mobile nuclear medicine service in accordance with Subparts D, E and H of this part and § 31.11 of this chapter to serve clients who do not have a Commission or Agreement State license for the materials listed in those Subparts.

(b) Mobile nuclear medicine service licensees shall retain for the duration of service a letter signed by the management of each location where services are rendered that authorizes use of byproduct material.

§ 35.36 Radiation safety program changes.

(a) A licensee may change the radiation safety procedures and equipment that are used to meet regulatory requirements and that were described in the application for license, renewal, or amendment. The licensee may also receive, use, and store licensed material (except teletherapy sources) in areas of use that were not identified in the application for license, renewal, or amendment.

(b) A licensee shall retain for the duration of the license a record of each change. The record must include the effective date of the change, a copy of the old and new radiation safety procedures, equipment descriptions, or area floor plans, the reason for the change, a summary of radiation safety matters that were considered before making the change, the signature of the Radiation Safety Officer, and the signatures of the affected authorized users and of management or, in a medical institution, the Radiation Safety Committee's chairman and the management representative.

§ 35.37 Records and reports of misadministrations.

(a) When a misadministration involves any therapy procedure, the licensee shall notify by telephone the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter. The licensee shall also notify the referring physician of the affected patient and the patient or a responsible relative (or guardian), unless the referring physician agrees to inform the patient or believes, based on medical judgment, that telling the patient or the patient's responsible relative (or guardian) would be harmful to one or the other, respectively. These notifications must be made within 24 hours after the licensee discovers the misadministration. If the referring physician, patient, or the patient's responsible relative or guardian cannot be reached within 24 hours, the licensee shall notify them as soon as practicable. The licensee is not required to notify the patient or the patient's responsible relative or guardian without first consulting the referring physician; however, the licensee shall not delay medical care for the patient because of this.