[7590-01]

NUCLEAR REGULATORY COMMISSION

10 CFR PART 35

Comprehensive Quality Assurance in Medical Use and a Standard of Care

AGENCY: Nuclear Regulatory Commission.

ACTION: Advance Notice of Proposed Rulemaking.

SUMMARY: The Nuclear Regulatory Commission (NRC) is considering amendments to its regulations that apply to the use of byproduct material for radiation therapy and diagnostic uses involving large radiation dosages. In addition to the current requirements for quality assurance, the contemplated amendments would require licensees that offer teletherapy or brachytherapy services to implement a comprehensive quality assurance program to reduce the chance of misadministrations. The NRC requests public comment on the extent to which additional radiopharmaceutical quality assurance requirements are needed, and invites advice and recommendations on several questions that will have to be addressed in the rulemaking process. The NRC is also requesting comments on some basic quality assurance program requirements set out in a proposed rule published elsewhere in this issue.

DATE: Submit comments by 12/31/87. Comments received after this date will be considered if it is practical to do so but assurance of consideration cannot be given except as to comments received on or before this date.

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ADDRESSES: Mail comments to: The Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

Deliver comments to: Room 1121, 1717 H Street NW., Washington, DC, between 7:30 am and 4:15 pm on Federal workdays.

Examine copies of comments received at: The NRC Public Document Room, 1717 H Street NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Norman L. McElroy, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 427-4108.

SUPPLEMENTARY INFORMATION:

Therapy Use of Byproduct Material

Teletherapy is the application of a beam of radiation emanating from a cobalt-60 source to a patient for a therapeutic purpose, usually curative, prophylactic, or palliative cancer therapy. (High energy x-ray machines are also used for the same purposes.) As an example, a treatment might be comprised of daily treatments of 200 rads to the tumor volume for five weeks, yielding a total tumor dose of 5000 rads.

Brachytherapy is the insertion of small sealed sources such as cesium-137, iridium-192, gold-198, or iodine-125 into the tumor volume for curative or prophylactic cancer therapy. As an example, a treatment might require insertion of 50 millicuries for 48 to 72 hours, resulting in a tumor dose of 5000 rads.

Radiopharmaceutical therapy is the administration of a radioactive drug for therapeutic purposes. The most common clinical procedure involves the oral administration of liquid or gelatin-capsuled iodine-131 as sodium iodide. For hyperthyroidism, 5 to 30 millicuries might be administered; for thyroid cancer, 70 to 200 millicuries might be administered.

Most diagnostic uses result in whole body doses of about 0.1 rem and target organ doses of about 2.0 rem. Occasionally, however, as much as 5 millicuries of iodine-131 is administered as a diagnostic dosage for patients who have been treated for thyroid cancer. If this dosage were mistakenly administered to a patient who has no thyroid disease, the thyroid dose would be several thousand rads.

NRC'S Policy Regarding the Medical Use of Byproduct Material

In a policy statement published February 9, 1979 (44 FR 8242), the NRC stated:

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

"2. The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.

"3. The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine."

The NRC has the authority to regulate the medical use of byproduct material to protect the health and safety of patients, but also recognizes that physicians have the primary responsibility for the protection of their patients. NRC regulations are predicated on the assumption that properly trained and adequately informed physicians will make decisions in the best interest of their patients.

NRC's Responsibilities in the Medical Use of Byproduct Material

The NRC draws a line between the unavoidable risks attendant to purposefully prescribed and properly performed clinical procedures and the unacceptable risks of improper or careless use of byproduct material in medicine. The NRC is obliged, as part of its public health and safety charge, to establish and enforce regulations that protect the public from the latter.

Reports of Misadministrations in Radiation Therapy

The NRC has published a study of the twenty-seven therapy misadministrations that were reported over the period November 1980 through July 1984.[1] The following NRC analysis of these events provides the basis for determining that a need exists for this rulemaking.

The specific causes of the misadministrations, detailed in Table 1, are, of course, related to the treatment modality. Nonetheless, three basic themes run through the reports: inadequate training, inattention to detail, and lack of redundancy.

[1] For a copy of this report, write to Kathleen M. Black, Office for Analysis and Evaluation of Operational Data, Nuclear Regulatory Commission, Washington, DC 20555. Ask for report AEOD/C505.

Table 1. Therapy misadministrations reported to NRC from November 1980 to July 1984

Teletherapy
Prescription
Total daily dose was delivered from each port (2)*
Oral and written prescriptions were different (1)
Boost dose of 500 rad/3 da was interpreted as 500 rad x 3 da (1)
Proper body side was not clear (1)
Treatment planning
Tumor depth was incorrectly measured (1)
Tumor depth was incorrectly recorded (1)
Dosimetrist used wrong computer program (1)
Dosimetry tables for wrong unit were used (1)
Arithmetic mistakes were made (3)
Records
Arithmetic mistakes were made (1)
Poor handwriting of numerals caused misunderstanding (1)
Physical measurements
Wedge factors were measured incorrectly (1-53 patients affected)
Application
Field blocks were not used (1)
Brachytherapy
Treatment planning
Dose rate was much higher than first estimated (1)
Application
Wrong sources were loaded in applicator (2)
Source fell out of applicator (1)
Source was improperly seated in applicator (1)
Radiopharmaceutical Therapy
Wrong radiopharmaceutical was administered (2)
Assay date on unit dosage was not read (3)
Patient was improperly identified (1)

*Numbers in parentheses indicate number of events of the type described.

Improved training of medical personnel who handle and administer byproduct material can reduce the potential for error. Thorough training should also clearly impress on each individual involved in the medical use of byproduct material that a clear communication of concepts and quantities as well as systematic checks for revealing mistakes early in the process are both essential for the delivery of quality care. All information integral to the process, whether specific to the patient or to the clinic, should be carefully examined for clarity, applicability, and correctness. Each individual involved in the process should be strongly encouraged to ask for clarification if there is any unclear or unexpected step or if an expected step is missing.

Inattention to detail is often the medium in which a misadministration event germinates. NRC recognizes that this problem is not specific to the medical use of byproduct material. Computerized radiation therapy treatment planning may reduce the chance of mistakes in sealed source treatment planning, and "record and verify" systems that check teletherapy unit orientations and settings may reduce the chance of mistakes in teletherapy administration. But even these systems must ultimately rely on quantities that are initially measured, recorded, and entered into memory by individuals.

Lack of redundancy means that there exists no independent mechanism for detecting errors. An independent verification requires examination by a second individual of each data entry, whether a physical measurement or a number copied from a table of values, as well as a check of arithmetic operations for correctness. Redundancy requires that two separate systems produce the same result. For purposes of planning radiation therapy, the best method of early detection of mistakes may be a simple independent

check. Independent verification may also need to be incorporated into procedures for measuring radiation parameters, using those measurements for treatment planning, and applying radiation to patients. In radiation therapy or any other endeavor, an independent outside auditor can detect mistakes in both process design and process application as well as cite areas where a change in the process might reduce the chance for future error.

These observations have led the NRC to some general conclusions regarding quality assurance.

The radiation therapy process should be planned with the realization that individuals are likely to make mistakes. Some simple aids may include using tables and graphs that are clearly titled and easy to read, and use of a uniform written prescription format. NRC inspections have revealed that about ten percent of teletherapy unit calibrations and spot-checks are incomplete. Checklists could be used to assure completeness.

Independent verification must be made integral to the design of the radiation therapy process. All entries and calculations in a treatment plan should be checked by an individual who did not construct the treatment plan. Each patient's chart should be reviewed weekly to check for accumulated dose and implementation of prescription changes. A quality assurance program for the teletherapy unit should include a periodic check of the teletherapy unit output and an occasional detailed examination of the complete teletherapy process, including physical measurements, by an outside expert with an eye towards systematic errors and system improvements.

A program that requires a physical measurement of the dose or amount of radioactivity actually administered to the individual patient would provide assurance that the given dose is the same as the prescribed dose. Such measurements are now done for radiopharmaceutical therapy and occasionally for some teletherapy cases, but because of expense or unavailability of equipment are not commonplace in sealed source therapy.

Reports of Diagnostic Misadministrations That Result in Doses in the Therapy Range

The NRC has also published a report on misadministrations of diagnostic dosages of iodine-131 that lead to doses in the therapy range.[2] The report was a review of fourteen recent misadministration events in which patients were administered one to ten millicuries of iodine-131 with a resulting thyroid dose of several thousand rads. Many of the events demonstrated that the physician authorized user failed to review the medical history of the referred patient to determine the suitability of a particular clinical procedure. In many cases the referring physician, who is not a nuclear medicine expert, and the nuclear medicine technologist, who is not a medical expert, determine which radiopharmaceutical should be administered. Furthermore, in some events technologists unfamiliar with the clinical procedure prescribed by the authorized user mistakenly administered a dosage that was not requested. It is apparent, therefore, that whenever radiopharmaceuticals capable of producing therapy doses are used, clear nomenclature, independent verification, and adequate training are essential.

[2]For a single copy, submit a request for report number AEOD/N701 to the address in footnote 1.

Earlier NRC Efforts

This is not the first time the NRC has examined the matter of quality assurance in the medical use of byproduct material. In 1979 the NRC issued some basic quality assurance requirements for teletherapy (see 10 CFR 35.632 and 10 CFR 35.634). This rulemaking was precipitated by the inaction of a single licensee. The output of a teletherapy unit was incorrectly calculated and the licensee made no physical measurements to determine whether the calculation was correct. This inaction resulted in cobalt-60 teletherapy being misadministered to 400 patients. The 1979 rule addressed the circumstances surrounding that event but did not critically examine the entire radiation therapy process.

Voluntary Initiatives

The Commission is aware of voluntary initiatives to improve quality assurance. A notable example is the Patterns of Care study managed by the American College of Radiology. In addition to comparing prescriptions, methods of applying radiation, and survival rates for certain diseases at various therapy facilities across the nation, methods of calculating and measuring applied dose rates are examined for accuracy. Such an examination can detect whatever procedural flaws may be present as well as determine the precision and accuracy of day-to-day service.

It is NPC's position that voluntary programs alone may not provide adequate assurance of public health and safety. Serious misadministrations continue to occur. The NRC would be remiss in its responsibilities were it to fail to thoroughly examine all avenues available to reduce unnecessary exposure from licensed material.

Summary

The NRC believes many misadministrations could reasonably be avoided if certain quality assurance steps were included in the radiation therapy process.

Other Actions

The NRC recognizes that the medical use of byproduct material is a complex field, and that preparing regulations to reduce the likelihood of misadministrations must be done carefully. However, the NRC cannot allow the complexity of medical use to prevent it from taking regulatory action when patients are harmed by the incorrect application of byproduct material. The NRC has balanced these competing desiderata by preparing two rulemaking actions for contemporary publication.

This Advance Notice of Proposed Rulemaking (ANPR) will provide the foundation for a comprehensive quality assurance program requirement that will address each source of error that can lead to a misadministration. The NRC elected to prepare the ANPR because of the complexity of medical use. Elsewhere in this issue of the Federal Register, the NRC has published a Notice of Proposed Rulemaking (NPR) that provides the foundation for a basic quality assurance program that addresses some simple sources of error that have come to light under NRC's misadministration reporting program.

The NRC believes this two-pronged approach to the problem of misadministrations provides the best balance between the need to assure public health and safety without inadvertently interfering in the delivery of quality medical care.

Effect on the Agreement States Program

Many States, known as Agreement States, have assumed responsibility for regulating certain radioactive materials within their respective borders by agreement with the NRC. (This kind of agreement is authorized by the Atomic Energy Act.) They issue licenses for the use of byproduct material, and currently regulate about 5,000 medical licensees. Because the NRC will request the Agreement States, as a matter of compatibility, to implement regulations equivalent to those that it implements on this matter, state regulatory agencies are asked to comment.

Request For Comments

The NRC has prepared the following questions to elicit comments on methods of preventing misadministrations. Comments need not be confined to these questions alone; discussion of other related topics or alternatives is welcome if the commenter believes this will help to resolve issues related to this rulemaking.

Quality Assurance

General

The following questions apply to the provision of all types of medical use:

1. How can the Commission most effectively implement requirements for comprehensive quality assurance? The Commission has the authority to adopt existing national standards. The Commission, in concert with medical experts, could identify and adopt by rulemaking the key elements in a quality assurance program. The Commission could impose a performance requirement under which licensees would be required to implement a quality

assurance program that would provide absolute assurance that there would be no misadministrations. What other mechanisms should be considered?

2. Should the definition of misadministration in 10 CFR 35.2 be changed? Is it clear and complete? Is the definition sufficiently broad to include all appropriate activities? Is it so broad as to include inappropriate activities? Is the term "misadministration" appropriately descriptive of the activities? Should some more descriptive term be used?

3. The NRC knows of one instance in which radiation was administered to a patient without a request from the primary care physician. Should the NRC require that the authorized user actively consult with the primary care physician before prescribing radiation or deciding that radiation is not needed? How can the chance of miscommunication be reduced? What improvements can be made in terminology, prescription format, and orders?

4. What methods should be considered to provide assurance that the patient to whom radiation is administered is the patient for whom radiation was intended?

5. What current standards exist to ensure the adequacy and uniformity of training of all individuals who participate in the administration of radiation to patients? Should NRC require certification or prescribe specific training criteria for technologists, dosimetrists, and others who participate in the application of radiation to patients, or should NRC have a performance requirement that requires licensees to provide each individual whatever training is necessary? In either case, how can NRC ensure the adequacy and consistency of this training throughout the radiation therapy community? Should the NRC require licensees to

administer written examinations to workers and evaluate them before allowing the workers to participate in radiation therapy? Should periodic retraining and re-examination be required?

6. What other regulatory, certifying, accrediting, or inspecting organizations examine medical quality assurance programs? Describe the purpose, objectives, and rigor of these examinations.

7. Should the NRC require physicians to provide patients, upon request, a record of the radiation dose prescribed and/or given? What information should or should not be provided?

8. Apart from increased NRC oversight, what changes in industry practice or standards could improve the quality of performance and minimize human error?

Teletherapy and Brachytherapy

The following questions apply to the provision of teletherapy and brachytherapy services.

1. What performance criteria could be adopted to assure appropriate care, minimize the chance of human error, and mitigate the consequences of potential error?

2. To assure adequacy of continued experience, some organizations recommend that certain surgical or test-tube procedures only be performed if the practitioner has a sufficient case-load to assure that dexterity and familiarity with the procedure are retained. Should NRC require that licensees have a certain minimum case-load to assure that their employees retain their expertise in pe forming radiation therapy clinical and quality assurance procedures?

3. What fraction of licensees already have a quality assurance program? What are its key elements?

4. The Regulatory Flexibility Act requires that regulatory agencies examine the cost of compliance with regulations. How much does a quality assurance program cost per patient or per year? What fraction of staff time, including physicians, physicists, dosimetrists, technologists, and nurses, is currently budgeted for quality assurance work?

5. Are there complete model quality assurance programs already available that address every step of the radiation therapy process, or will model programs have to be developed? Should physical measurements, redundant calculations, or both be required to assure that the dose given is the same as the dose prescribed? What other areas are, or should be, covered in a complete quality assurance program?

6. Are the staff and equipment that are needed to implement a complete quality assurance program available in the marketplace, or would new training programs and equipment development be needed?

7. Computers are used in radiation therapy to calculate dose distributions and to control the operation of equipment. How could quality assurance of software accuracy and validity be improved? Should licensees be required to verify them? How can user skill and knowledge of the inherent assumptions and limitations of a computer program be assured? Should additional quality assurance requirements be developed to ensure that users understand the algorithms on which the programs are based?

8. What additional methods are available for reducing the frequency or impact of human error?

Radiopharmaceutical Therapy

The NRC requires that licensees use only certain radiopharmaceuticals for specified therapy clinical procedures, measure the radioactivity in radiopharmaceutical dosages before administration, and have a measurement quality assurance program for the dose calibrator used to make that measurement. These requirements appear to encompass the steps in a radiopharmaceutical therapy physical quality assurance program. However, the NRC invites public comment on this position.

There have been cases in which, due to procedural failure, a radiopharmaceutical other than that intended has been ordered and administered. Many of these cases began with miscommunication between the referring physician and the licensee. Some began with miscommunication between the physician's authorized user and the nuclear medicine technologist. The NRC expects that all licensees have procedural requirements for clear statements of prescription and verification before administration of any pharmaceutical. The NRC would appreciate suggestions on methods to assure that the clinical procedure (including radiopharmaceutical, dosage, and route of administration) intended by the authorized user is prescribed, and that the prescribed clinical procedure is the clinical procedure that is performed. The NRC has observed several cases of miscommunication of the referring physician's request. What improvements can be made to minimize such errors? Are there special needs regarding patient identification in radiopharmaceutical therapy that go beyond the information regarding patient identification that was requested in question 4 of the General subsection?

Standards of Care

The following questions apply to the medical use of byproduct material.

1. Is there a clear, generally accepted standard of care that the NRC can adopt? If yes, please describe it. If not, please describe a standard that NRC could adopt. Is a standard needed if NRC has comprehensive prescriptive requirements?

2. What effect would such a standard or comprehensive, prescriptive requirements have on provisions of radiation therapy care?

3. What kinds of penalties should be imposed on licensees, their employees, or both, if the standard or the comprehensive, prescriptive requirements are not met? Should penalties be imposed on employees? Should NRC's Enforcement Policy (see 10 CFR Part 2, Appendix C) be changed, and if so, how?

List of Subjects in 10 CFR Part 35

Byproduct material, Drugs, Health facilities, Health professions, Incorporation by reference, Medical devices, Nuclear materials, Occupational safety and health, Penalty, Radiation protection, Reporting and recordkeeping requirements.

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Dated at Washington, DC, this 29th day of September, 1987.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,
Secretary of the Commission.