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PR 35
53FR39745

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35
Quality Assurance Subcommittee of the Advisory Committee on the Medical Uses of Isotopes; Meeting Notice and Request for Comments

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of meeting and request for comments.

SUMMARY: The Nuclear Regulatory Commission (NRC) will convene a meeting of the Quality Assurance Subcommittee (QA Subcommittee) of the Advisory Committee on the Medical Uses of Isotopes to assist in the consideration of amendments to NRC regulations that apply to the medical use of byproduct material. The amendments would require medical use licensees to implement quality assurance programs, and would revise misadministration reporting requirements. Public comments on the issues discussed in this notice are welcome in writing prior to the meeting, and at the meeting.

DATE: Monday, November 7, 1988, at 9:00 a.m.

ADDRESS: Holiday Inn, 8120 Wisconsin Ave., Bethesda, MD.

COMMENTS: Comments must be received by October 31, 1988 for consideration at the meeting. Comments received after this date will be considered if it is practicable to do so, but assurance of consideration cannot be given except as to information received on or before this date.

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~~ADDRESSES:~~ Submit comments to Secretary, U.S. Nuclear Regulatory Commission, Washington, DC, 20555. ATTN: Docketing and Service Branch. Submit requests to make oral statements to Norman L. McElroy, Office of Nuclear Material Safety and Safeguards, 6H3, U.S. Nuclear Regulatory Commission, Washington, DC 20555. insert para. p 1

FOR FURTHER INFORMATION CONTACT: Norman L. McElroy, Office of Nuclear Material Safety and Safeguards, (301) 492-3417 or Dr. Anthony N. Tse, Office of Nuclear Regulatory Research, (301) 492-3797, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

SUPPLEMENTARY INFORMATION:

Background

On October 2, 1987 (52 FR 36942), the NRC published a proposed rule that would require its medical use licensees to implement certain quality assurance steps to reduce the chance of misadministrations in medical use. Public comments indicated that, although these proposed steps may reduce the chance of misadministrations, the imposition of the prescriptive steps as regulatory requirements may interfere with the practice of medicine because the proposed rule may not provide sufficient flexibility for clinical practice.

In a public meeting held on January 26, 1988, members of NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI), heard public comment and made the following general recommendations for regulating the medical use of byproduct material:

- Adopt a regulatory approach to quality assurance programs similar to that taken for ALARA (as low as reasonably achievable) programs. Require the licensees to submit their own quality assurance program as a part of their license application. These programs would be reviewed by the NRC and used as the basis for enforcement if they were not followed.

- Work with the Department of Health and Human Services and existing groups such as professional organizations, professional colleges, and the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) to assist in developing uniform and compatible voluntary standards.

- Endorse existing and developing voluntary standards that meet regulatory needs. Develop these standards into regulatory requirements after a pilot study testing their practicality, impact on patient care, cost, and benefits.

- Support a pilot study prior to adopting any other medical regulations resulting from changes and new technologies in patient care.

- Explore new ways for NRC to provide information to the medical community to ensure wide distribution of safety information and regulatory concerns. Continue to participate in regional and national meetings to provide health and safety and quality assurance information.

- Use performance-based approaches to rulemaking instead of prescriptive-based approaches.

On April 7, 1988, members of the medical community, including members of the ACMUI, briefed the Commission on their concerns regarding the proposed rule. They suggested that a pilot program may be useful in identifying whether certain quality assurance procedures would interfere with clinical practice. Also, they stated that, under existing NRC regulation of the medical use of byproduct material (10 CFR Part 35), the definition of the term "misadministration" is unclear and that reporting requirements are confusing.

The Commission directed the staff to continue the rulemaking initiative, stating that the staff should: (1) prepare for public comment a new proposed rule with performance-based basic quality assurance requirements, and a revision, if needed, of the misadministration definition and reporting requirements, (2) prepare a regulatory guide with prescriptive QA steps that would be acceptable to the NRC staff in implementing the performance-based QA rule, and (3) conduct a pilot program to evaluate the effectiveness of the specific measures in the regulatory guide.

The staff was also directed to continue its analysis of public comments received in response to an advance notice of proposed rulemaking on comprehensive quality assurance (October 2, 1987; 52 FR 36949), and make a recommendation to the Commission on that project at a later date.

Comments

To help develop the new proposed rule, regulatory guide, and pilot program, the Quality Assurance Subcommittee of the ACMUI has been formed.

The NRC would like to invite public comments on the issues set forth below. Public comments should be submitted to the NRC under the heading ADDRESSES. Copies of the comments will be forwarded to the Subcommittee for consideration. The Subcommittee will report its recommendations to the ACMUI for review and transmittal to the Commission.

Regarding the proposed rulemaking, public comment in response to the following questions is requested: (1) What types of performance-based QA criteria should be specified in the regulations to avoid, detect, and correct simple human errors in medical use? (2) What are the problems associated with the current definition of the term "misadministration" and reporting requirements specified in 10 CFR Part 35? What alternatives are available?

Regarding the regulatory guide, public comment is requested on the following questions: (1) What types of prescriptive basic QA steps should be included in the guide? (2) Do you have a set of QA steps that have been demonstrated to help can avoid, detect, and correct simple human errors? If so, what are they?

In the pilot program, selected volunteer hospitals and clinics (which are NRC or Agreement State licensees) would implement the proposed basic QA steps, report to the NRC the benefits and impacts of the procedures, and recommend ways to improve the procedures. The NRC would appreciate public comment on the following questions: (1) How many hospitals or clinics are needed to participate in the pilot program? What characteristics, such as size (large or small), population served (rural or urban), and ownership (private or public), should be used when selecting participating hospitals? (2) What information should the

participants collect during the test period? (3) What criteria should be used for evaluation of the pilot program results?

Other comments and information that may be helpful in developing the proposed rule, regulatory guide, and pilot program are welcome.

NRC and Agreement State licensees that may like to participate in the pilot program are invited to contact Dr. Tse (see "FOR FURTHER INFORMATION").

Conduct of the Meeting

Vincent Collins, M.D., will serve as Chairman of the Subcommittee and will chair the meeting. Dr. Collins will conduct the meeting in a manner that will facilitate the orderly conduct of business.

The following procedures apply to public participation in the meeting.

1. Persons may submit written comments by sending a reproducible copy to the Secretary of the Commission (see "ADDRESSES" heading). Comments must be received by October 31, 1988 to ensure consideration at the meeting. The transcript of the meeting will be kept open until November 15, 1988 for the inclusion of written comments.

2. Persons who want to make oral statements should inform Mr. McElroy in writing by October 14, 1988. Statements must pertain to the topics at hand. The Chairman will rule on requests to make oral statements. Opportunity for members of the public to make oral statements, within the time available, will be based on the order in which requests are received. In general, oral statements should be limited to approximately 5 minutes. Oral statements may be supplemented by detailed

written statements for the record. Rulings on who may speak, the order of presentation, and time allotments may be obtained by calling Mr. McElroy at (301)492-3417 between 9:00 a.m. and 5:00 p.m. EST on Friday, October 21, 1988.

3. At the meeting, questions from attendees other than Subcommittee members, consultants, and NRC staff will be permitted at the direction of the Subcommittee chairman.

4. The transcript, minutes of the meeting and written comments will be available for inspection, and copying for a fee, at the NRC Public Document Room, 2120 L Street NW., lower level, Washington, DC 20555 on or about November 19, 1988.

5. Seating for the public will be on a first-come/first-served basis.

The meeting will be held in accordance with the Atomic Energy Act of 1954, as amended (primarily section 161a), the Federal Advisory Committee Act (5 U.S.C. App) and the Commission's regulations in Title 10, Code of Federal Regulations, Part 7.

Dated at Washington, DC, this 7TH day of October 1988.

For the Nuclear Regulatory Commission.

Andrew L. Bates
Advisory Committee Management Officer