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NUCLEAR REGULATORY COMMISSION 92 OCT 26 P1:23

10 CFR Part 35

PUBLIC MEETING ON THE QUALITY MANAGEMENT PROGRAM AND MISADMINISTRATIONS RULE:
Meeting Notice

AGENCY: Nuclear Regulatory Commission

ACTION: Notice of meeting and request for comment

SUMMARY: The Nuclear Regulatory Commission (NRC) will convene a meeting with the American College of Nuclear Physicians (ACNP) and the Society of Nuclear Medicine (SNM) and other professional organizations within the medical community having an interest in the implementation of the Quality Management Program and Misadministrations Rule (the Rule), to provide an explanation of the Rule language and the information collection and reporting requirements imposed by the Rule. This will include a discussion of 10 CFR Part 35, Sections 35.2, 35.32, and 35.33; Regulatory Guide 8.33; contractor guidelines for reviewing submitted Quality Management (QM) programs; and the interim inspection guidance and enforcement policy. Time will be made available for comments and discussion by representatives of other professional organizations participating in the meeting. Following this, the ACNP will describe their Practice Audit Program and how it might fit into the implementation of the requirements of the Rule.

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DATES: The meeting will be held between 8:30 a.m. and 5:30 p.m., on November 9, 1992.

ADDRESS: Marriott Airport - Dulles
333 West Service Road
Chantilly, Virginia 22021

COMMENTS: Submit comments to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

FOR FURTHER INFORMATION, CONTACT: Larry W. Camper, Office of Nuclear Material Safety and Safeguards, MS 6-H-3, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone (301) 504-3417.

SUPPLEMENTARY INFORMATION: On August 12, 1992, the Commission voted unanimously to override the Office of Management and Budget's (OMB's) disapproval of the information collection requirements associated with the Rule. In a letter dated August 14, 1992, to James B. McCrae, Jr., of OMB, James M. Taylor, Executive Director for Operations, NRC, stated that the NRC would hold a public workshop with the medical community and other interested parties, to assure that there is a mutual understanding as to the intent of the Rule, especially the information collection requirements, and to discuss effective implementation.

In addition to the ACNP and SNM, other professional organizations, such as those representing hospital administrators, physicians, physicists, dosimetrists, technologists, and other related professionals that may be affected by the Rule, are being invited and will participate in a discussion outlining implementation of the rule.

The NRC staff will discuss the definitions and requirements of the Rule with emphasis on clarifying any misunderstandings that may exist with regard to the information recordkeeping and reporting requirements of the Rule. Inspection guidance in the form of a temporary instruction and interim field notes has been prepared along with a interim revision to the enforcement policy for the Rule. The performance-based inspection program and enforcement policy will be presented to the meeting participants and comments will be invited for consideration before the staff finalizes the guidance for submission to the Commission. There will be time for questions and answers throughout the meeting.

The staff, in a letter dated September 8, 1992, informed ACNP that there would be an opportunity during this meeting to discuss ACNP's Practice Audit Program and its potential utility for satisfying some or all of the requirements of the Rule. Representatives of ACNP will make this presentation during the afternoon session. Additionally, there will be a period during the afternoon session where other organizations can make remarks about similar self-auditing or voluntary quality assurance programs within their respective organizations.

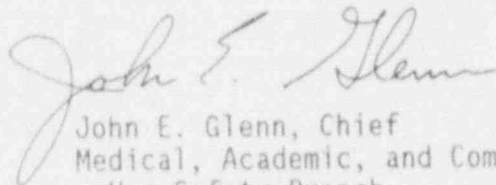
CONDUCT OF THE MEETING:

John E. Glenn, Ph.D., will chair the meeting. Dr. Glenn 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 "COMMENTS" heading). Comments must be received by November 4, 1992, to ensure consideration at the meeting. The transcript of the meeting will be kept open until November 16, 1992, for inclusion of written comments.
2. Persons who wish to make oral statements should inform Mr. Camper, in writing, by November 4, 1992. 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 will be based on the order in which requests are received. In general, oral statements should be limited to approximately 5 minutes. Oral statements must 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. Camper, (301) 504-3417, between 9 a.m. and 5 P.M. EST, on November 5, 1992.

3. 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 23, 1992.

4. Seating for the public will be on a first-come, first-served basis.



John E. Glenn, Chief
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

DATE: OCT 16 1992