J. Davis AA73-1
PDR
C.5
McElroy

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

March 11, 1985

MEMORANDUM FOR: Chairman Palladino
Commissioner Roberts
Commissioner Asselstine
Commissioner Bernthal
Commissioner Zech

FROM: John E. Zerbe, Director
Office of Policy Evaluation

SUBJECT: COMMENT ON PROPOSED REVISION OF 10 CFR PART 35, "MEDICAL USE OF BYPRODUCT MATERIAL" (SECY-84-485)

We have reviewed SECY 84-485 and offer for your consideration the following comments.

BACKGROUND

In June, 1983, the Commission reviewed a staff proposal (SECY-83-62) to consolidate medical radiation safety requirements and allow for greater flexibility under the license. The Commission approved the consolidation of provisions from existing regulations, standard license considerations, regulatory guides, and branch policy positions; directed that pre-licensing review of physicians' qualifications and applicants' operating procedures be continued; and called for staff's clarification of how it would implement the proposed requirements while continuing to ensure safety. (Memorandum from SECY to the EDO, June 23, 1983.)

The proposed revision of 10 CFR Part 35 described in SECY-84-485 is a response to the Commission's June, 1983 directive. Staff has coordinated revision of the rule with NRC regional staff and the Agreement States; both of these groups find the revision generally acceptable, with some exceptions as discussed below.

OPE believes that the revised proposed rule complies with the Commission's directive in offering a comprehensive and consistent statement of regulatory requirements having safety significance. The substantial improvement in

Contact:
Joan Aron
63-43302
Clyde Jupiter
63-43295
Neill Thomasson
63-43302

readability should enhance licensee understanding of the regulations, and the more uniform requirements should enable more efficient use of regulatory resources and facilitate inspections. Thus, we support its publication for comment.

However, we identify below some issues raised by the Agreement States, by NRC Regional Offices, and by OPE which you might wish to discuss with staff, Agreement State representatives, and representatives of medical and professional groups at the meeting which is scheduled for March 20, 1985. Based on the discussion at the meeting, the Commission may wish to have staff include in the rulemaking notice specific requests for comments on these issues, to assure they are adequately addressed and resolved. We also identify a couple of issues that might be raised at the meeting but which we would recommend be deferred to a separate discussion.

SUGGESTED ISSUES FOR DISCUSSION AT THE PART 35 MEETING

Should NRC review all licensee modifications of procedures, rather than just the major ones?

The staff's proposed revision indicates (SECY-84-485, Enclosure 1, Section 35.36, p. 30) that the proposed rule would allow:

> 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 Agreement States oppose the proposed change, arguing that an effective regulatory program to assure public health and safety requires review of all modifications of procedures, and not merely those which a licensee may consider major. The States believe that many licensees lack the requisite expertise to differentiate between major and minor changes or, even for minor changes, to make an adequate review of their safety significance. The Agreement States are not confident that their inspectors can review and evaluate licensee changes in the field as adequately as in the office, where support resources are available; hence, they believe some inspections would be deficient. Further, since their licensees are inspected less often than

once a year, their inspectors would be likely to confront several changes upon each visit. The Agreement States believe too that, if NRC were to revise its requirements to eliminate review of minor changes, the States would be under pressure from the medical industry to conform. The Agreement States' views on this issue are particularly important, since they license more hospitals and physicians than NRC. Some NRC staff in Region III support the States' views.

NRC staff does not believe the revision will have the impact envisioned by the Agreement States. The staff notes that the Agreement States would not be required to follow NRC's lead in permitting flexibility in the revision of procedures. Further, staff points out that the States have an argument to counter industry pressure to conform to NRC practices insofar as the States rely on greater oversight before changes are made (usually without license fees) and do not levy civil penalties for violations (as NRC does). The NRC staff also believes it would be available to respond to the States' technical concerns and to provide assistance in conducting safety evaluations. The staff believes that licensees would not have difficulty in differentiating between major and minor changes since major changes (e.g., new users, kinds and permissible amounts of byproduct material, and location of equipment) are listed in the regulations. Also, new revisions of regulatory guides dealing with the preparation of applications for medical programs and for teletherapy programs will provide guidance on items that should be considered before changes are made. (See Enclosure 1, "License Application, Issuance, and Authority and Responsibility" pp. 7-8.)

Does the proposed rule provide an appropriate balance between regulatory flexibility and prescriptive measures?

The proposed rule collates information drawn from various regulatory instruments, including rules, regulatory guides and branch technical positions, and provides a single source of regulatory requirements to ensure consistency and ease of inspection. Some may view codifying provisions now in regulatory guides or branch technical positions (e.g., training requirements) as being more prescriptive than envisaged by the Commission's Policy and Planning Guidance. However, we believe the proposed rule strikes a reasonable balance between flexibility and prescription for physician and medical institution licensees.

Should physician licensees be required to have a formal ALARA review program similar to that to be required for medical institution licensees?

Staff believes that physician licensees do not need a formal annual review of their radiation safety programs. The staff justifies its formal ALARA reporting program only for medical institutions on the basis that, in private practice, the safe use of byproduct material does not usually depend on the coordination of several administratively separate departments. (See

Enclosure 1, p. 27.) Region III staff disagrees with this position, advocating that all licensees should be required to have a formal ALARA reporting program. We note that in specifically requiring a formal ALARA program only at institutions, ALARA could be construed by physician licensees as unimportant. The goal of ALARA public and worker exposure for individual physician licensees as well as institutional licensees could be clarified by stating that, although private physicians are not required to have a formal ALARA review program, it is expected that they would continue to be alert to possibilities of eliminating unnecessary radiation exposure.

ISSUES WHICH MAY ARISE AT THE PART 35 MEETING BUT WHICH MIGHT BEST BE DISCUSSED SEPARATELY

Are the training requirements for physicians too prescriptive (or too lax)?

The proposed regulations specify the precise number of hours of different types of training required of various classes of practitioners and applicant physicians who apply for a license. However, the rule also permits an NRC license examiner to allow credit for knowledge, training, and skills developed through experience or demonstrated by means other than the prescribed requirements. The issue of training is somewhat controversial; e.g., Congressman Bevill has suggested that the agency review its rules on training for the medical use of isotopes so as to protect the public health and safety. The staff has received proposed alternative training and experience criteria from several organizations, including the American College of Cardiology, the American College of Radiology, the American College of Nuclear Physicians and the Society of Nuclear Medicine, and has scheduled a meeting in May of the Advisory Committee on the Medical Uses of Isotopes to discuss the matter. All interested parties will be able to comment. The staff has not addressed these proposals in this paper. Thus, we believe that further discussion on this matter should await the outcome of the Advisory Committee meeting.

Should the revised rule continue to require that misadministration of diagnostic and therapeutic radiation doses be reported as specified?

In approving the final rule on misadministration reporting, (SECY-80-26, April 2, 1980), the Commission indicated that it wished to reexamine the misadministration recordkeeping and reporting requirements (proposed to be placed in 10 CFR §§35.41-35.45) after they had been in place for about three years. Among other things, the requirements provide for NRC medical licensees to keep records of all misadministrations of radioactive material, to promptly report therapy misadministrations to the NRC and to the patient's referring physician and, with certain safeguards, to the patient, and to report diagnostic misadministrations quarterly to the NRC and to the referring physician. In October, 1982, the Commission disapproved a staff recommendation (SECY-82-388) to withdraw the Medical Misadministration

Reporting Requirements to be contained in the proposed 10 CFR §§35.42, 35.43 and 35.45. To our knowledge, there is not now a request that this regulation be modified. As the misadministration subject is complex, we believe that any reconsideration of the reporting requirements should be taken up as a matter separate from the more straightforward matter of Part 35 codification.

cc: H. Plaine
S. Chilk
W. Dircks
J. Davis
J. Taylor