POLICY ISSUE

(NEGATIVE CONSENT)

January 4, 1994

SECY-94-001

FOR: The Commissioners

FROM: James M. Taylor
Executive Director for Operations

SUBJECT: PROPOSED STAFF ACTIONS TO PROVIDE GUIDANCE ON THE INTERPRETATION OF THE GENERAL REQUIREMENTS IN 10 CFR 20.1301 FOR RELEASE OF PATIENTS CONTAINING RADIOACTIVE MATERIAL AND CONTROL OF EXPOSURE FROM PATIENTS

PURPOSE:

To inform the Commission of the staff's plan to address the relationship between the general requirements in 10 CFR 20.1301, "Dose limits for individual members of the general public," which become effective on January 1, 1994, and the relevant specific requirements of 10 CFR Part 35. Specifically, the staff intends to issue an Information Notice (IN) that provides explicit guidance to the medical community on the interpretation of 10 CFR 20.1301 for the release of patients containing radioactive pharmaceuticals or permanent implants and the control of areas due to the presence of a patient containing radioactive material. Due to the heightened concern expressed by the medical community and the pending implementation date, there is a need to issue this IN as early as possible in January 1994.

BACKGROUND:

On May 21, 1991, the U.S. Nuclear Regulatory Commission published a final rule (56 FR 23360) that amended 10 CFR Part 20, "Standards for Protection Against Radiation." Licensees are required to implement the revised 10 CFR Part 20 by

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NOTE: TO BE MADE PUBLICLY AVAILABLE WHEN THE FINAL SRM IS MADE AVAILABLE, UPON REMOVAL OF ENCLOSURE 2

January 1, 1994. 10 CFR 20.1301(a) requires, in part, that a licensee conduct operations so that: 1) the total effective dose equivalent (TEDE) to any individual member of the public from licensed activities does not exceed 1 millisievert (mSv) (0.1 rem) in a year; and 2) the dose in any unrestricted area from external sources does not exceed 0.02 mSv (0.002 rem) in any 1 hour. Radioactive pharmaceuticals or radioactive implants are routinely administered to patients for the diagnosis or treatment of disease. A patient whose body contains radioactive material can be a source of external radiation exposure to individuals around them with potential exposure rates in excess of 0.02 mSv (0.002 rem) in an hour. NRC's current patient release criteria, adopted in 1986, are contained in 10 CFR 35.75, "Release of patients containing radiopharmaceuticals or permanent implants." The release criteria include, in part, a dose rate of 0.05 mSv/hr (0.005 rem/hr) at 1 meter, which is greater than the dose rate limit specified in 10 CFR 20.1301(a)(2). In the discussion of the proposed 10 CFR 35.75 in 1985, the Commission stated that the proposed limits provided an "adequate measure of safety for the general public, and that further reductions in public exposure are not reasonably achievable considering the cost and potential for detrimental effect from an unnecessarily long hospital confinement."

During the November 1 and 2, 1993, meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI), the issue of whether 10 CFR Part 20 or 10 CFR Part 35 should be the governing regulation for patient release was discussed. Members of ACMUI indicated that implementation of a position that the 10 CFR Part 20 limits would govern the release of patients would have a significant negative impact on medical cost and delivery of care without any significant improvement in safety. The ACMUI recommended that implementation of 10 CFR Part 20 be delayed until the conflicts with the practice of medicine are resolved because the new Part 20 will adversely impact the conduct of medical licensed activities and that resolution of these issues should include consideration of cost/benefit. The staff committed to afford the ACMUI the opportunity to discuss the impact of the implementation of the revised Part 20 at future ACMUI meetings.

DISCUSSION:

The staff does not believe there is a need to delay implementation of the revised Part 20. There is no clear difference between medical and industrial facilities with respect to storage, handling, and control of radioactive materials. The staff considers case-by-case licensee requests for exemptions to 10 CFR Part 20. In addition, the staff will forward proposed revisions of 10 CFR Parts 20 and 35, addressing patient release criteria, to the Commission, as expeditiously as possible. This will include an analysis of the staff's interim proposal that 10 CFR 35.75 be considered the controlling regulation for dose to members of the public from patients administered byproduct material.

In the interim, the staff intends to inform licensees that past practice will continue regarding radiation exposure to individual members of the public from radioactive materials administered to patients. That is, patient waiting rooms or hospital rooms need only be controlled for therapy patients not

meeting the release criteria. This allows time for the Commission to evaluate any policy changes concerning exposure of members of the general public from byproduct material administered to patients. To provide this information to licensees and address the concerns of the medical community regarding these regulations, the staff has developed a draft IN (Enclosure 1) to inform licensees of the NRC's policy for implementation of the regulations.

In a memorandum dated October 22, 1993 (Enclosure 2), the Office of the General Counsel (OGC) concluded that the NRC staff could reasonably interpret 10 CFR 20.1301(a) as not being applicable in the case of licensee's release of a patient in conformance with the criteria of 10 CFR 35.75 and other applicable requirements in Part 35. The underlying basis for this was that, where a general and a specific regulation of the Commission both address the same subject, it is reasonable to assume the Commission intended the more specific regulation to prevail in the case of a conflict unless there is evidence the Commission intended otherwise. The staff has reviewed the "Statements of Consideration" for the 1986 revision to Part 35 and the 1991 revision to Part 20 and found no evidence that the Commission intended the general requirements of Part 20 to prevail over 10 CFR 35.75. Therefore, NRC's public health and safety judgment specific to patient release under Part 35 can prevail over the potentially conflicting, more general purposes underlying the public dose limits in Part 20. Furthermore, the staff believes that continued reliance on the release criteria in 10 CFR 35.75 is commensurate with sound regulatory policy.

Under the revised Part 20, the 0.02 mSv (0.002 rem) in any one hour limit in an unrestricted area could be more controlling than the 1 mSv (0.1 rem) in a year limit for some patients. In fact, the 0.02 mSv (0.002 rem) in any one hour limit could be exceeded for many common diagnostic procedures and scenarios. In the 1991 "Statements of Consideration" for the revision to Part 20, the Commission stated that the 0.02 mSv (0.002 rem) dose rate limit specified in 10 CFR 20.1301(a)(2) provided a more readily measurable quantity than the 1 mSv (100 mrem) per year value, and can be more easily verified by short-term measurements. This verification has been used primarily to ensure that the dose rate limit of 0.02 mSv (0.002 rem) is not exceeded at the boundary of unrestricted areas, rather than applied to the exposure of an individual.

Past practice has required controlling patient waiting rooms or hospital rooms only for therapy patients not meeting the release criteria of 10 CFR 35.75. The staff also proposes continuing this practice for the interim based on the low probability of exceeding the annual dose limit in the vast majority of scenarios and the significant adverse psychological impact of separating patients from family and friends while undergoing diagnosis. Even temporary restriction of patients to private rooms under such circumstances could have a significant financial and psychological impact on patients or the public.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection.

RECOMMENDATION:

That the Commission: Note that the staff will issue the enclosed Information Notice within 10 working days of the date of this paper, unless directed otherwise by the Commission.

James M. Taylor
Executive Director
for Operations

Enclosures:
1. Draft Information Notice
2. OGC memo dtd 10/22/93

NOTE: This paper, with the exception of Enclosure 2, can be released.

SECY NOTE: In the absence of instructions to the contrary, SECY will notify the staff on Thursday, January 20, 1994, that the Commission, by negative consent, assents to the action proposed in this paper.

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555

December , 1993

NRC INFORMATION NOTICE NO. 93-XX: RELEASE OF PATIENTS WITH RESIDUAL RADIOACTIVITY FROM MEDICAL TREATMENT AND CONTROL OF AREAS DUE TO PRESENCE OF PATIENTS CONTAINING RADIOACTIVITY FOLLOWING IMPLEMENTATION OF REVISED 10 CFR PART 20

Addressees:

All U.S. Nuclear Regulatory Commission medical licensees

Purpose:

NRC is issuing this information notice to notify addressees of the Commission's intent for release of patients pursuant to 10 CFR 35.75. It is expected that licensees will review this information for applicability to their operations and distribute it to appropriate staff. The information contained in this notice does not include new NRC requirements; therefore, no specific action nor written response is required.

Description of Circumstances:

NRC's current patient release criteria, adopted in 1986, are contained in 10 CFR 35.75, "Release of patients containing radiopharmaceuticals or permanent implants." Specifically, this section states:

> (a) A licensee may not authorize release from confinement for medical care any patient administered a radiopharmaceutical until either:
>
> > (1) The measured dose rate from the patient is less than 5 millirems (mrem) per hour at a distance of one meter; or
> >
> > (2) The activity in the patient is less than 30 millicuries (mCi).
>
> (b) A licensee may not authorize the release from confinement for medical care of any patient administered a permanent implant until the measured dose rate is less than 5 millirems per hour at a distance of one meter.

In the discussion of the proposed 10 CFR 35.75 in 1985, the Commission stated that the proposed limits (30 millicuries (mCi) of activity or 6 milliroentgens per hour dose rate at 1 meter, based on the exposure rate from 30 mCi iodine-131), provided an "... adequate measure of safety for the general public, and that further reductions in public exposure are not reasonably achievable considering the cost and potential for detrimental effect from an unnecessarily long hospital confinement." Subsequently, the 1986 Statements

ENCLOSURE 1

of Consideration for the revision to 10 CFR Part 35 discuss that the release criteria, specified in 10 CFR 35.75 (30 mCi of residual activity or 5 millirems per hour (mrem/hr) dose rate at 1 meter) are based, in part, on the considerations addressed in NCRP Report No. 37, "Precautions in the Management of Patients who Have Received Therapeutic Amounts of Radionuclides." Again, the Commission reiterated that the release limit provided an adequate measure of public health and safety.

On May 21, 1991, NRC published a final rule (56 FR 23360) that amended 10 CFR Part 20, "Standards for Protection Against Radiation." Licensees are required to implement the revised Part 20 by January 1, 1994. 10 CFR 20.1301(a) requires, in part, that a licensee conduct operations so that: 1) the total effective dose equivalent to any individual member of the public from licensed activities does not exceed 1 millisievert (mSv) (0.1 rem) in a year; and 2) the dose in any unrestricted area from external sources does not exceed 0.02 mSv (0.002 rem) in any 1 hour. There has been some concern, in the medical community, that a licensee, assuming compliance with 10 CFR 35.75 and other applicable Part 35 requirements, in releasing, from confinement, a patient containing byproduct material, could be in violation of the revised Part 20, if the dose limits specified in 10 CFR 20.1301(a) are exceeded as a result of radiation emitted from a patient undergoing a medical procedure.

Discussion:

The adoption of 10 CFR 35.75 in 1986 was based on an independent NRC public health and safety judgment specific to patient release, and was neither tied to, nor designed to implement, the more general Part 20 dose limits that were later revised in 1990. When Part 20 was revised, there was no discussion in the "Statements of Consideration" on whether or how the provisions of 10 CFR 20.1301 would apply to the release of patients. Since a general and a specific regulation of the Commission both address the same subject, the staff, in consultation with the Commission, has taken an interim position that the more specific regulation prevails in this case, pending action to formally resolve the issue in response to pending rulemaking petitions.

Therefore, licensees should continue past practices regarding radiation exposure to individual members of the public from radioactive materials administered to patients, whether inpatients or outpatients. The provisions of 10 CFR 20.1301(a) should not be applied to radiation received by a member of the general public from patients released from confinement in accordance with 10 CFR 35.75 and other applicable requirements in Part 35. Furthermore, if a patient is not required to be confined, pursuant to 10 CFR 35.75, licensees are not required to limit the radiation dose to members of the public (e.g., visitor in a waiting room) from a patient to 0.02 mSv (2 mrem) in any one hour. Patient waiting rooms or hospital rooms need only be controlled for those patients not meeting the release criteria in 10 CFR 35.75.

This information notice requires no specific action nor written response. If you have any questions about the information in this notice, please contact one of the technical contacts listed below or the appropriate regional office.

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Attachments:
1. List of Recently Issued NMSS Information Notices
2. List of Recently Issued NRC Information Notices

ENCLOSURE 2

Removed to allow public release
of the rest of this paper