UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

DEC 14 1993

MEMORANDUM FOR: Richard L. Bangart, Director
Office of State Programs

FROM: Carl J. Paperiello, Director
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: RESPONSES TO QUESTIONS GENERATED AT THE AGREEMENT STATES MANAGEMENT WORKSHOP

This is in response to your memorandum dated November 17, 1993, requesting our assistance in responding to three issues discussed at the recent Agreement States Management Workshop. We offer the following information for your consideration.

Issue 1:

On April 20, 1993, NRC issued Bulletin 93-01 to require NRC medical use licensees, authorized for high-dose-rate (HDR) brachytherapy remote afterloading, to take specific actions to minimize the possibility of the loss of control of high activity brachytherapy sealed sources. The Bulletin requires that two individuals be physically present during all HDR procedures, the authorized physician user and either the brachytherapy physicist or radiation safety officer. NRC does not currently require the physical presence of any of these individuals during low-dose-rate (LDR) afterloading brachytherapy procedures, manual brachytherapy, or teletherapy.

Although NRC staff has noted that positioning of sources in brachytherapy has been a prominent source of errors leading to misadministrations in both LDR and manual brachytherapy, in most instances an authorized user has been present. We would be interested in any instances where the Agreement States are aware that the presence of an authorized user has been critical to preventing a misadministration or unintended radiation exposure to a worker or member of the public. Further, we can not believe that any Agreement State currently requires an authorized user to be physically present during every insertion or removal of sources during LDR. LDR is intended to reduce nursing exposure to radiation and can not be practical if an authorized user must be physically present on a 24 hour basis for 2 to 3 days.

Teletherapy does not involve the surgical implantation or removal of devices containing brachytherapy sealed sources, and thus, does not necessitate the constant physical presence of specially trained individuals to intervene in the event of an emergency. Authorized physician users are allowed to delegate specific tasks to supervised individuals, and in fact, teletherapy units are routinely operated safely by qualified and adequately trained supervised individuals such as physicists and technologists. For all therapy procedures, including radiopharmaceutical therapy, NRC requires that a written directive

be prepared to ensure that the radiation dose is delivered as prescribed. This necessitates involvement by the authorized physician user to identify the intended procedure, prescribed dose or dosage and other treatment parameters. In some cases, this may result in the physical presence of the authorized user when the radiation dose or dosage is actually administered to the patient.

We will consider additional requirements for therapy administrations as part of the Medical Management Plan (MMP). Therefore, we are interested in the number of Agreement States who have requirements similar to those proposed. We are also interested in successes and problems that the Agreement States have noted with the implementation of these requirements.

Issue 2:

Periodically, NRC reevaluates its training and experience criteria, to include radiation safety officers, authorized physician users, and teletherapy physicists, and its need to authorize other individuals. As part of the MMP, NRC will conduct a comprehensive review of the adequacy of the current criteria including workshops with Agreement State personnel. Specifically, each training pathway currently described in Part 35 will be reviewed to determine whether the radiation safety component is adequate to ensure that authorized individuals safely possess and use licensed material, and whether additional board certification programs or training pathways should be recognized. Additionally, a determination will be made regarding whether training and experience criteria is needed for brachytherapy physicists, and supervised individuals such as technologists and dosimetrists. The staff's review will be augmented by contract support which will include contract individuals experienced in medical nuclear medicine and radiation oncology. The contract findings may necessitate a revision to the current training and experience criteria which would be incorporated into a major revision to Part 35 scheduled for completion in late 1997.

Issue 3:

NRC issues licenses with more than one location of medical use when the licensee or applicant describes mechanisms to ensure adequate control over licensed material. The experience with Oncology Services, Incorporated, pointed out some omissions in the NRC oversight such as a policy on inspection at multiple sites. Additionally, licensees with significant changes in the size and scope of the licensed program or number of key responsible personnel may require a reevaluation of licensed activities by NRC. As part of the MMP, the staff is re-evaluating its licensing and inspection guidance and procedures in this area to ensure that licensees are exercising sufficient control over licensed facilities and are operated in a manner which protects public health and safety. This will include a revision of NRC Manual Chapter 2800, "Materials Inspection Program." It is our understanding that Agreement States vary in their requirements. Additional information regarding various Agreement State requirements on these issues would be appreciated.

If you have any additional questions regarding this information you may contact me or Janet Schlueter of this staff, at 504-2659 or 504-2633, respectively.

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