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

November 1, 1995

MEMORANDUM TO: Ronald R. Bellamy, Chief
Nuclear Materials Safety Branch, RI

FROM: for Larry W. Camper, Chief
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: TECHNICAL ASSISTANCE REQUEST REGARDING NEW ENGLAND MEDICAL CENTER (BOSTON, MA) AMENDMENT REQUEST TO EXEMPT THE LICENSEE FROM THE REQUIREMENTS OF 10 CFR 35.410 AND 35.415 FOR PATIENTS WHO HAVE PERMANENT IMPLANTS AND REMAIN CONFINED TO THE CENTER FOR ADDITIONAL CARE SUBSEQUENT TO IMPLANTATION OF A PERMANENT RADIATION THERAPY SOURCE

I am responding to your technical assistance request (TAR) dated March 14, 1995, regarding an amendment application from the New England Medical Center in Boston, Massachusetts (Attachment 1). The licensee is requesting exemption from 10 CFR 35.410 and 35.415 for patients who have permanent implants and remain confined in the care of the licensee, subsequent to radiation therapy, for additional procedures which are not under the jurisdiction of U.S. Nuclear Regulatory Commission. The staff's review included the discussion provided in the TAR as well as the accompanying letters from the licensee dated December 15, 1994 (Item 1 only) and July 26, 1994 (Item 3 only). The staff has concluded that, once the patient is released from confinement pursuant to 10 CFR 35.75, and does not require confinement to a private room under 35.415(a)(1), the regulations in 10 CFR 35.410 or 35.415 are no longer applicable. This assumes, of course, that all requirements of 10 CFR 35.410 and 35.415 have been met up to the point where confinement is no longer required.

Specifically, the licensee requests exemption from 10 CFR 35.410 and 35.415 for patients with permanent implants that are sutured in place and for which the radiation levels measure much less than 1 mR/hr at 1 meter from the patient. The licensee further states that such a patient exhibits no threat to his or her care takers from either a dislodged source or external radiation exposure. The staff recognizes that, for much of the interaction with the patient, the radiation exposure to another individual is minimal. Furthermore, there is only a limited possibility of anyone other than the patient coming in contact with a permanently implanted source which is, as indicated, sutured in place and, as such, is unlikely to become dislodged.

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ATTACHMENT 2

NRC Information Notice (IN) No. 94-09 dated February 3, 1994 (Attachment 2), states that, "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," as is otherwise required in 10 CFR Part 20. Additionally, the IN confirms that patient waiting rooms and hospital rooms do not need to be controlled for patients meeting the release criteria in 10 CFR 35.75.

Licensees should be reminded that 10 CFR 35.415(a)(5) requires that a licensee provide implant patients with "radiation safety guidance that will help to keep radiation dose to household members and the public as low as reasonably achievable before releasing the individual [in accordance with 10 CFR 35.75] if the individual was administered a permanent implant" (emphasis added). According to the October 31, 1986, "Statements of Consideration" for 10 CFR Part 35, 10 CFR 35.415 was modified to require licensees to provide such guidance in response to comments that the release of patients pursuant to 10 CFR 35.75 may cause unnecessary radiation dose to members of the public. Hence, the patient guidance should still be provided upon the patient's release from confinement for radiation safety purposes, either from specified radiation safety controls within the facility or from the facility. As a practical matter, since the licensee's question essentially proposes "release" of the patient prior to transfer of the patient to the recovery room, the licensee may want to consider providing guidance to these patients prior to surgery. If instructions have not been given prior to surgery, the licensee should continue following 10 CFR 35.410 and 10 CFR 35.415 restrictions until the instructions have been given to the patient.

Attachments: 1. TAR dtd 3/14/95
2. IN No. 94-09

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