

June 12, 2008

MEMORANDUM TO: John Kinneman, Director
Division of Nuclear Materials Safety, Region I

FROM: Cynthia Flannery, Acting Branch Chief **/RA/**
Medical Safety and Events Assessment Branch
Division of Materials Safety and State Agreements

SUBJECT: RESPONSE TO TECHNICAL ASSISTANCE REQUEST, DATED
NOVEMBER 28, 2007, UNIVERSITY OF VIRGINIA, LICENSE
NO. 45-00034-26, AND MEDSTAR GEORGETOWN MEDICAL
CENTER, LICENSE NO. 08-30577-01

Issue:

In a technical assistance request (TAR) dated November 28, 2007, (ML071680002 and ML072140256), Region I requested assistance in determining whether patient release to a hotel was permissible under 10 CFR 35.75. The Region also requested information on additional instructions to be provided to patients released to hotels. This TAR is requested due to Region I inspections of the University of Virginia (UVA) and Medstar Georgetown Medical Center, Inc. (Georgetown). The inspections determined that the licensees knowingly released Iodine-131 (I-131) therapy patients to hotels after they received treatment.

Action Approved:

The licensees acted in accordance with existing NRC regulations and guidance at the time that the patients were released. In the future, NUREG-1556, Vol. 9, Appendix U will be revised or interim guidance will be developed that will incorporate guidance for release of radiotherapy patients to hotels.

Background:

In June and August of 2007, NRC's Region I Office performed separate inspections at UVA and Georgetown. During the inspections it was determined that each licensee knowingly released I-131 therapy patients, in accordance with the dose limits of 10 CFR 35.75, who planned to stay at a hotel. The inspection at UVA discovered that two patients, who were sisters, were treated on the same day for cancer using I-131. Both patients agreed to sleep alone, avoid mass transit, avoid sharing a bathroom, and minimize contact with others. Based on these agreements, the licensee used an occupancy factor of 0.125 to support release from the hospital, and calculated a maximum public dose of 223 millirems and 308 millirems from each sister, respectively.

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The licensee also indicated that the sister receiving the higher dosage of I-131 stayed at the hospital for the first four hours after dosing, awaiting dosing and release of her sister. Therefore, the licensee concluded that the maximum dose to a member of the public from this sister would have been further reduced. The patients (sisters) indicated to the hospital staff that they planned to stay at a hotel after they were released from the hospital, due to the patients' concerns with being able to keep their children off their laps. UVA gave the sisters their standard written instructions regarding what they should do upon leaving the hospital. However, the instructions given were not specific to staying at a hotel. According to a UVA nurse, the sisters appeared to already have obtained additional instructions pertinent to reducing exposure to members of the public (e.g., notifying the hotel to remove linens so they could bring their own to use and remove, asking the hotel not to clean their room, and having food brought in by one of the husbands). These instructions led them to consider staying at a hotel. UVA did not know the source of the additional instructions the sisters received, but thought the instructions, if followed, would keep exposures to hotel staff or other guests far below the 500 millirem (mrem) release criteria limit specified in 10 CFR 35.75.

During the Georgetown inspection, Region I discovered that Georgetown was aware of certain I-131 therapy patients that stayed at hotels after being released from its hospital. Georgetown asked each iodine ablation patient to fill out a questionnaire to determine when the patient might be released from the hospital and the environment to which the patient would be released. One of the patients indicated in her questionnaire that she lived in a residential hotel with her husband and would be sharing the bathroom with him. Georgetown decided to release this patient to the residential hotel because her exposure rate at one meter was less than 7 mR/hr (4.9 mR/hr @ 1 meter), which is the dose rate for I-131 at which a patient can be released in accordance with 10 CFR 35.75 as described in NRC Regulatory Guide 8.39 "Release Of Patients Administered Radioactive Materials." (Note that Georgetown referenced Regulatory Guide 8.39, but this Regulatory Guide was superseded by NUREG-1556, Vol. 9 "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses"). In the questionnaire, the second patient indicated that he was staying at a hotel, since he had a small child at home. For the stay at the hotel, he indicated that he would not be sharing the bed or bathroom with anyone else; therefore the dose assessment determined that the maximum dose to any member of the public would be 91 mrem. Therefore, this patient was released to a hotel. Georgetown provided each patient with written instructions for limiting doses to others and additional instructions, specific to staying at a hotel, were provided to the second patient. Georgetown did not provide additional instructions to the first patient because the patient resided at the hotel and her exposure rate at one meter was less than 7 mR/hr.

Discussion:

In addition to these two licensees, NRC learned that releasing patients from a hospital to go to a hotel or other temporary accommodation is not an uncommon practice. For example, in 2007, several newspaper articles were published regarding concerns with releasing radioiodine therapy patients from hospitals after treatment. One specific article indicated that patients released, after radioiodine therapy, were staying at hotels or other temporary accommodations in order to minimize the risk of exposing their families (especially small children) to radiation.

The newspaper articles also mentioned that one of the concerns with radiotherapy patients being released from a hospital is that members of the public may be exposed to radiation depending on the patients' activities (e.g., staying at a hotel, using public transportation).

10 CFR 35.75 provides that a licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual is not likely to exceed 5 mSv (0.5 rem) (i.e., 500 mrem). The regulation does not limit the location to which the individual must be released. In 1997, NRC amended its regulations concerning the criteria for release of patients administered radioactive material to base the criteria for patient release upon potential dose to other individuals exposed to the patient. Neither the Supplementary Information accompanying the proposed rule, 59 FR 30724 (June 15, 1994) or the final rule, 62 FR 4120 (January 29, 1997) address the release of patients to hotels. However, the Supplementary Information indicates that dose to all individuals was considered during the development of this rule. The information provided in the Supplementary Information indicates that the dose-based limit of 500 mrem was considered an acceptable dose limit for any member of the public and that the dose to an individual in real circumstances probably would not approach 500 mrem.

In summary, the regulations do not prohibit the release of a patient to a hotel if the patient meets the criteria for release specified in 10 CFR 35.75 that the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (500 mrem). The dose-based limit of 500 mrem is considered to be an acceptable limit to any member of the public. Guidance regarding additional instructions to be provided to patients released to hotels is expected to be developed.

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