



Technical Bulletin

Division of Public and Behavioral Health



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Topic: Technical Bulletin for Medical Licensees Who Release Patients Containing Detectable Amounts of Radiation

From: Medical Administrations

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To: Medical Use Radioactive Materials Licensees

Purpose:

The State of Nevada Radiation Control Program (RCP) is providing this technical bulletin to medical licensees for their information and to remind licensees of the importance of various regulatory requirements, guidance, and communications on this topic. Medical licensees should review the information for applicability to their facility and consider appropriate actions to ensure compliance with regulatory requirements. This technical bulletin contains some information specific to the release of patients following therapeutic treatment of Iodine-131 (I-131) but the processes and regulatory requirements are also applicable to other types of therapies, including implants, and medical administrations that involve the release of patients containing detectable amounts of radiation.

Medical licensees are encouraged to review the regulations, guidance, and communications and consider appropriate actions to ensure the adequacy of: 1) their radiation protection program, 2) records for the release of individuals containing detectable amounts of radiation, and 3) written instructions provided to released patients. Licensees should review the records of released patients to ensure the records include: those required by 10 CFR 35.75 and 10 CFR 35.2075; and as applicable, an evaluation of the patient's release destination; ALARA instructions; an evaluation of the patient's ability to comply with the ALARA instructions; the documented basis for releasing the patient (i.e., patient-specific calculations); and an evaluation of potential doses to infants and young children or other members of the public.

Nevada Administrative Code (NAC) 459.3062 adopts by reference Title 10 of the Code of Federal Regulations (CFR) Part 35. 10 CFR 35.75 allows licensees to release individuals containing unsealed radioactive material or implants containing radioactive material if the radiation dose to any other individual is not likely to exceed 500 milliRem (mRem); and it requires licensees to maintain a record of the basis for authorizing the release of these individuals. 10 CFR 35.75 also requires licensees to provide released individuals with written instructions on how to maintain doses to other individuals to levels that are As-Low-As-Reasonably-Achievable (ALARA), if the dose to any other individual is likely to exceed 100 mRem.

The U.S. Nuclear Regulatory Commission (NRC) has issued guidance on compliance with 10 CFR 35.75. This guidance can be found in Appendix U, "Model Procedures for Release of Patients or Human Research Subjects Administered Radioactive Material" of NUREG-1556, "Consolidated Guidance About Medical Licensees," Volume 9, Revision 2. Appendix U contains guidance for providing patients with written instructions on how to maintain doses to other individuals to levels that are ALARA and maintaining records to document the release of patients. Appendix U also provides guidance for documenting the basis for releasing patients based upon:


- The administered activity;
- Measured dose rate; or
- Patient-specific dose calculations.

NRC Information Notice 2003-22, "Heightened Awareness for Patients Containing Detectable Amounts of Radiation from Medical Administrations" was issued December 9, 2003. This informational notice reminds authorized users to: 1) emphasize to patients the importance of following the written release instructions for keeping doses to other individuals ALARA; 2) evaluate the patient's capability to follow recommended written instructions to determine if release is advisable; and 3) provide patients with information about triggering radiation monitoring equipment installed in public

locations for increased public security. Supplement 1 to this informational notice issued on July 29, 2009, contains additional information for medical-use licensees to consider regarding instructions and information provided to individuals who are released in accordance with 10 CFR 35.75.

NRC Regulatory Issue Summary 2008-11, "Precautions to Protect Children Who May Come in Contact with Patients Released after Therapeutic Administration of Iodine-131," was issued May 12, 2008. This regulatory issue summary informs licensees that contamination of infants and young children with saliva from treated patients could result in significant doses to the child's thyroid and potentially raise the risk of radiation-induced thyroid cancer. This guidance recommends that licensees consider not releasing patients administered I-131 whose living conditions may result in unnecessary exposure of infants and young children. Enclosure 1 of this regulatory issue summary contains guidance and additional instructions for protecting children who may be in contact with patients released after therapeutic administrations of I-131.

NRC Regulatory Issue Summary 2011-01, "NRC Policy on Release of I-131 Therapy Patients Under 10 CFR 35.75 to Locations Other Than Private Residences" was issued January 25, 2011. This regulatory issue provides information for medical licensees who may need to release patients to destinations that are not a private residence. Releasing patients to hotels or motels is not expressly prohibited by 10 CFR 35.75. However, the NRC strongly discourages this practice because it can result in radiation exposure to members of the public which are not ALARA. Licensees must consider the destination (private home, hotel, dormitory, etc.) to which a patient will be released and potential exposures to others to assure instructions compliant with 10 CFR 35.75 are provided to the patient. Licensees are reminded they are required to maintain a record of the basis for authorizing the release of a patient.



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