

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

August 26, 2019

NRC INFORMATION NOTICE 2019-06: PATIENT SKIN CONTAMINATION EVENTS
ASSOCIATED WITH I-131
METAIODOBENZYLGUANIDINE DURING
NEUROBLASTOMA TREATMENTS

ADDRESSEES

All U.S. Nuclear Regulatory Commission (NRC) medical-use licensees and NRC master materials licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.

PURPOSE

The NRC is issuing this information notice (IN) to alert addressees of potential patient contamination risks associated with therapeutic treatments with iodine-131 (I-131) meta-iodobenzylguanidine (MIBG). The NRC expects that recipients will review the information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. Information contained in this IN does not constitute new NRC requirements; therefore, no specific action or written response is required. The NRC is providing this IN to the Agreement States for their information and for distribution to their medical licensees, as appropriate.

DESCRIPTION OF CIRCUMSTANCES

In the past five years, the NRC has been notified of two events in which patients have had skin toxicities caused by I-131 skin contamination from leaks associated with a therapeutic treatment using I-131 MIBG. In 2018, an infusion line leaked, and approximately 221 millicuries (mCi) of the 834 mCi, the intended dosage, contaminated the patient's bed linens. The leak was identified at completion of the procedure and likely occurred at the connector. During the treatment, the patient was disconnected from the infusion pump and allowed to go to the lavatory. The port line was disconnected at the connector and may not have been properly reconnected. After the leak was discovered, at the completion of the treatment, the patient's clothes were immediately changed, and the bed linens were removed; however, the patient's skin was not decontaminated. Two days later, the patient reported discomfort and was found to have an erythematous lesion that degenerated into a moist desquamation the following day. The dose to the patient's skin was estimated to be 55,000 centigray (cGy) (rads) to a 15cm² area of skin.

In 2013, the NRC was notified that a patient being treated with one Curie of I-131 MIBG for neuroblastoma had his catheter start to leak a day following treatment. Urine contaminated the patient and bedding. Upon discovery, the patient's skin was immediately cleaned, the catheter removed, and the patient's clothing and sheets changed. Six weeks later, a physician examining the patient noted skin irritation on the patient's inner thighs and buttocks consistent with radiation injury. The estimated dose to the patient's skin was approximately 1,000 cGy.

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DISCUSSION

These medical events show the importance of the development and implementation of effective practices and procedures to prevent leaks and spills from causing significant patient skin contamination. Identification of significant contamination on the skin is challenging with this therapy because the patient becomes a significant source of gamma radiation that interferes with standard contamination surveys and monitoring techniques. In addition, low level I-131 contamination of patient, clothing, and bed linens is expected from the patient's perspiration, saliva, or other bodily fluids. Therefore, licensees should have procedures for the identification and decontamination of skin contamination from leaks or spills to minimize exposure to the patient's skin in order to prevent risk of adverse effects should a leak or spill event occur.

Potential actions licensees may take to minimize the risk of skin contamination and unintended skin dose to the patient include:

- (1) Use absorbent pads with a membrane under the port line, tube, and infusion pump line, if they pass over the patient or the patient's bed. In the event of a leak in the delivery system, the absorbent pads will absorb and reduce the quantity of material that may contaminate the patient and facilitate clean-up.
- (2) After the treatment is completed, remove the patients clothing and bedding to a low background area and survey them to assure that they are not contaminated above expected values. Significantly contaminated clothing and bedding indicates that the patient may have been contaminated from a leak or spill, and that decontamination procedures should be implemented.
- (3) Develop processes and procedures to minimize interruptions during the infusion process to reduce the probability that the port line will need to be disconnected. Consider development of a procedure to address patient fluid management prior to and during infusion. A catheter may be employed, and the use of absorbent pads with the catheter line would be prudent, as a precaution for line leakage.
- (4) Patient-specific decontamination procedures and radiation safety incident response procedures should be developed. I-131 MIBG exhibits an affinity for bonding to the skin; thus, a shower with mild soap may not prove overly effective for decontamination. Any decontamination practices and procedures developed should consider the overall health and age of the patient.

CONTACT

This information notice requires no specific action or written response. Please direct any questions about this matter to a technical contact listed below or the appropriate regional office.

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Note: NRC generic communications may be found on the NRC public Web site,
<http://www.nrc.gov>, under NRC Library/Document Collections.

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*concurred via email

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