Radioactive Materials Unit
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Date: March 23, 2007

To: Medical Licensees

From: Radioactive Materials Unit

Subject: I-131 Capsules Left In Vials

Information Notice 2007-03

REPORTABLE MEDICAL EVENTS INVOLVING PATIENTS RECEIVING DOSAGE OF IODINE-131 LESS THAN THE PRESCRIBED DOSAGE BECAUSE OF CAPSULES REMAINING IN VIALS AFTER ADMINISTRATION

The Minnesota Department of Health (MDH) is issuing this information notice to alert addressees about events in which patients were administered dosages of sodium iodide, iodine-131 (I-131), that were less than the prescribed dosages, because of sodium iodide I-131 capsules that remained in vials, containing multiple capsules, after administration. These occurrences resulted in medical events because the patients did not receive the prescribed dosages. It is expected that recipients will review the information for applicability to their facilities and consider actions, as appropriate to avoid similar problems.

MDH regulations in 4731.4422 do not require licensee to perform a direct measurement of a unit dosage in a dose calibrator before administration, if the unit dosage is corrected for decay based on the activity determined by an appropriately licensed manufacturer, preparer or licensee (e.g., commercial pharmacy). However, as a measure for prevention of these types of medical events, a licensee could assay the vial containing I-131 capsules, after administration of the dosage, to assure that no capsules remain in the vial. To keep occupational doses as low as reasonably achievable, assay measurement of the vial post-administration is preferred over visual verification of the content of the vial.

Precautions can also be taken before administration, and include reviewing the packing slip before administration, to verify the number of capsules shipped by the pharmacy. Further, assaying the activity before administration could identify that the total dose was not in the vial and that missing capsule(s) may, for example, have been placed in another vial of the shipment.

Besides resulting in a medical event, another negative consequence of a capsule remaining in a vial is that the licensee may incorrectly mark and label the vial for transport back to the commercial radiopharmacy. For example, the vial may be placed back in to the original

container and shipped back to the commercial pharmacy with the marking and labeling of a package that is assumed to be empty, when in fact, it is not. This could result in a violation of the requirements in 4731.0402, “Transportation of Licensed Material.” Another example of an adverse consequence of a capsule remaining in the vial is that this might result in the inadvertent disposal of the vial containing I-131 in “non-radioactive” waste. This could lead to a violation of the requirements for waste disposal, or the requirements of storage and control of licensed material.