

March 1, 2007

TO: All Affected Ohio Radioactive Material Licensees.

OHIO INFORMATION NOTICE 2007-02 REPORTABLE MEDICAL EVENTS INVOLVING
PATIENTS RECEIVING DOSAGES OF SODIUM
IODIDE IODINE-131 LESS THAN THE
PRESCRIBED DOSAGE BECAUSE OF
CAPSULES REMAINING IN VIALS AFTER
ADMINISTRATION

PURPOSE

The Ohio Department of Health, Bureau of Radiation Protection (BRP) is issuing this information notice (IN) 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. However, suggestions contained in this IN are not new Ohio requirements; therefore, no specific action or written response is required. NRC provided this IN to the Agreement States for their information and for distribution to their medical licensees as appropriate.

DESCRIPTION OF CIRCUMSTANCES

In September 2006, one licensee performed administrations incorrectly on two separate occasions. In each case, only one sodium iodide I-131 capsule was administered to the patient, rather than the two capsules containing the total dose. Consequently, the patients did not receive the dosages prescribed in the written directives. Before these events, the licensee had received the total prescribed dose of I-131 in a single capsule. In the case of these two events, instead of the expected single capsule, the commercial radiopharmacy dispensed two capsules containing the prescribed dose. The licensee measured the radioactivity in each vial containing capsules, before administration, to ensure the proper dosage amount. When the content of each of the vials was emptied, for administration, one of the two capsules remained in the vial. Each vial was placed back into its shipping container and returned to the pharmacy. Each of the two patients was released, having received only a portion of the prescribed dosage.

Over the last 10 years, there have been 12 reported events of this type (i.e., events in which patients were administered dosages of sodium iodide I-131 that were less than the prescribed dosages, because capsules remained in vials after administration). In some of these cases, the patients were administered one of multiple capsules contained in a single vial. In other cases, patients were administered two of three capsules, where two capsules were placed in one vial by the commercial pharmacy, and the third capsule was placed in a separate vial.

There were a few instances where the errors were discovered shortly after the patients had been released, and the patients returned to the licensees to receive the remaining portions of the prescribed dosages. Notwithstanding that in these cases the patients returned to receive the remaining portions of the prescribed dosages, NRC concludes that the total dose, for purposes of determining whether the medical event reporting criteria had been met, is the dose received by the patients at the time when they were released from the licensee's control (i.e., following administration of the first capsule). Since, at the time of the patients' release, the delivered dosages differed from the prescribed dosages by more than 20 percent and the thyroid dose reductions resulting from the reduced dosages exceeded the 0.5 sieverts (50 rem) to an organ, the events required reporting as medical events under OAC rule 3701:1-58-101.

DISCUSSION

Ohio regulations, in OAC rule 3701:1-58-25, do not require licensees 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 into 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 OAC Chapter 3701:1-50, "Packing and Transportation of Radioactive 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 for storage and control of licensed material in OAC Chapter 3701:1-38, "General Radiation Protection Standards for Sources of Radiation."

CONTACT

This IN requires no specific action or written response. If you have any questions about the information in this notice, please contact Mark Light, Supervisor, Medical Inspection and Licensing at 614-644-2727.