Radioactive Materials Unit
Minnesota Department of Health
625 Robert Street North
PO Box 64975
St. Paul, Minnesota 55164-0975

Date: August 14, 2007

To: Medical licensees with diagnostic and therapeutic use of I-131

From: Radioactive Materials Unit

Subject: Violations of written directives for use of I-131

Information Notice 2007-08

The Minnesota Department of Health (MDH) is issuing this Information Notice to underscore the requirements in 4731.4408 regarding the administration of sodium iodide (Iodine-131) in dosage greater than 30 microcuries (1.11 MBq) requiring a written directive signed and dated by an authorized user. This Notice is being issued to emphasize the need for administering technologists to verify the existence of written directive and/or the dosage with an authorized user to administration of sodium Iodide I-131. In addition, this notice is being issued to remind licensees of their responsibility under 4731.4407 to instruct the supervised individual in written directive procedures and to require supervised individuals to follow the instruction of the supervising authorized user.

The NRC has identified a number of events caused primarily by failure to recognize that dosages greater than 30 microcuries of sodium iodide (I-131) require a written directive and should have been verified against a prescribed dosage in a written directive. These events could have been prevented if procedures for checking dosages against a prescribed dosage contained in a written directive had been established and followed. There have been eleven administrations without a written directive. Five of these were prescribed dosages less than 30 microcuries of sodium iodide-131 (two of these included verbal orders), one was for a different radionuclide (I-123), one had no prescribed dosage, and one for greater than 30 microcuries was only made verbally.

Cases in which no written directive was issues:

Pharmacy Errors:

- A contaminated pipette in the radiopharmacy raised the desired dosage of 20 microcuries to 0.9 millicurie (mCi). The dosage was correctly labeled as 0.9 mCi. The nuclear medicine technologist misread the 0.9 mCi on the label as 9 microcuries and administered the dosage.

- The radiopharmacy prepared a dosage of 980 microcuries instead of the prescribed dosage of 15 microcuries. The dosage of 980 microcuries was administered to a patient by a technologist at the medical facility without verification of the dosage. This mistake could have been prevented by verifying the dosage and recognizing that a written directive is required for all sodium iodide I-131 administrations exceeding 30 microcuries.

- The authorized user gave a verbal order for 2.0 millicuries without providing the required written directive. The nuclear pharmacy inadvertently prepared and sent a 2.8 millicurie dosage, which was administered by the technologist at the medical facility.

Verbal order:

- The technologist misunderstood the verbal orders of the authorized user and ordered 500 microcuries of sodium iodide I-131 instead of 5 microcuries. The patient was administered 535 microcuries instead of 5 microcuries. The technologist did not verify the existence of a written directive which is required for all sodium iodide I-131 administrations exceeding 30 microcuries.

Miscommunication/misunderstood request or written order:

- The technologist misunderstood the referring physician's request and administered 3 millicurie of I-131 rather than the intended 25 microcuries. Approval of the dosage was not obtained from the authorized user prior to administration.

- The authorized user intended to prescribe 12 millicuries but wrote 12 microcuries on the prescription by mistake. The technologist did not realize that the authorized user had written 12 microcuries and ordered and administered a dose of 12 millicuries which the technologist thought was what the authorized user had intended. The administration did not comply with the written directive, and therefore constituted a medical event. This event was caused by the failure to compare the dosage with the authorized user's written instruction and lack of communication between the technologist and the authorized user.

Wrong patient:

- The individual received a 2 millicurie I-131 dosage instead of the intended 200 microcuries I -131 dosage because the patient incorrectly responded affirmatively to being the patient that was supposed to receive the I-131 dosage.

No order:

- The technologist administered a 4 millicurie dosage that was left over from a pervious "no show" patient without a written directive under the assumption that the prescribing physician would complete the written directive at a later time. After administering the 4

millicurie dosage, the technologist discovered that the authorized user had intended to prescribe 150 millicuries.

Failure to Follow a Written Directive:

- Two different medical events resulted in administered dosages of 5.2 millicuries and 15 millicuries instead of the prescribed 2 millicurie dosages. One was attributed to lack of attention to detail and the other to failure to follow procedures.

- The technologist confused the dosages of three patients who were scheduled to receive I-131 treatments on the same day and administered 100 millicuries to a patient who was scheduled to receive 17.3 millicurie.

The Advisory Committee on the Medical Use of Isotopes (ACMUI) has developed four suggestions that the medical community may consider to improve compliance with MDH regulations.

- Licensees are required to have a written directive before the administration of greater than 30 microcuries of I-131 and to provide instructions in written directive procedures to supervised individuals. MDH suggests that licensee's reemphasize these requirements to their staff to ensure that the staff is aware of the need for a written directive before administrating these dosages. Licensees should also remind staff that verbal orders are only acceptable under specific situations, and even then, must be followed up with a written directive in accordance with 4731.4008.

- Licensees are required to determine and record the activity of each dosage before medical use in 4731.4422. MDH recognizes that the licensees are not required to perform a direct measurement of a unit dosage in a dose calibrator prior to administration if it is received from a drug manufacturer or commercial nuclear pharmacy. However, MDH believes that it is a good standard of practice to make direct measurements of therapeutic dosages in dose calibrators. They also suggest that licensees have a written directive readily available when determining the dosage to verify and ensure that the dosage conforms to the written directive.

- As required by 4732.4409, the licensee must have written procedures to provide high confidence that the patient's identity is verified before each administration. MDH suggests that licensees evaluate their identity verification procedures to prevent patient misidentification. Although not required by the regulations, MDH strongly suggests that licensees consider confirming positive patient identification by two separate methods prior to dosage administration. MDH suggest following a patient identification procedure similar to that required for a blood administration or radiation therapy treatment.

- MDH suggests that licensees seek to improve communication between the authorized users and the individuals performing the administration. The authorized users should consider reviewing plans for the treatment with the administering technologists. In addition, licensee's management should foster a culture at the licensee's facility that

encourages technologists to freely ask questions of the authorized users regarding written directives.

MDH medical licensees must ensure that their staff fully understand and adhere to the requirements contained in the *Radioactive Materials Rules,* Chapter 4731. This Notice conveys suggestions and, as such, are not requirements for the administration of I-131. MDH believes consideration of these suggestions will improve compliance with the regulations and minimize the likelihood of medical events. This Notice requires no specific action or written response.