(MBq) (5 millicurie [mCi]) of thallium–201 (a radiopharmaceutical not regulated by NRC) for a myocardial perfusion study was mistakenly administered 148 MBq (4 mCi) of Sr–89 (which is regulated by NRC). Based on the misadministration of the Sr–89, the licensee estimated that the patient received 250 centigray (250 rads) to the surface of the bone. The RSO reported that no action was taken to mitigate the consequences of the dose (i.e., administration of calcium as a blocking agent) because the patient had a preexisting heart condition which could have been exacerbated by administering calcium. The licensee also stated that medical experts were contacted to assist in an assessment of potential health effects to the patient. In addition, the licensee reported that with the exception of emergency procedures, it had voluntarily suspended all nuclear medicine procedures involving the intravenous administration of radiopharmaceuticals and had initiated an internal review of the misadministration.

On August 10, 1994, NRC issued a Confirmatory Action Letter to confirm the licensee's actions as stated above.

Cause or Causes—The cause of the misadministration was attributed to the administering technologist's failure to verify the isotope as well as the dosage (by reading the label on the syringe) prior to injection.

Actions Taken To Prevent Recurrence

Licensee—Corrective actions initially proposed by the licensee included the following: (1) Physically separating diagnostic unit dosages from therapeutic radiopharmaceutical dosages in the licensee's hot lab; (2) packaging unit dosages received from a local radiopharmacy in different containers, according to isotopes; and (3) retraining technologists in requirements for identifying radiopharmaceuticals prior to injection.

NRC—Two NRC inspectors conducted a special safety inspection on August 10–12 and 17–19, 1994, to review the circumstances associated with the misadministration and to review the licensee's corrective actions. In addition, NRC contracted a medical physician consultant to assist in its evaluation of the potential consequences of the patient's radiation exposure. The consultant stated that there were no adverse health effects to the patient.

An Enforcement Conference was held with the licensee on November 30, 1994, to discuss an apparent violation involving the failure of an individual working under the supervision of an authorized user physician to follow the licensee's written radiation safety procedures. Additional concerns discussed during the conference included the licensee's use of an informal labeling system for unit radiopharmaceuticals which was identified as a potential programmatic weakness. The licensee presented information during the conference which supported its view that the error which led to the August 9, 1994, misadministration was an isolated failure rather than a programmatic problem.

Based on its review of information developed during the inspection and information provided during the Enforcement Conference, NRC concluded that the misadministration was the result of an isolated failure. A Notice of Violation was issued on December 29, 1994, for a violation involving the failure of an individual working under the supervision of a physician authorized user to follow the licensee's written procedures for verifying a radiopharmaceutical dose prior to administration to a patient. The violation was categorized as a Severity Level IV violation.

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94–23 Medical Brachytherapy Misadministration at North Memorial Medical Center in Robbinsdale, Minnesota

One of the AO reporting guidelines notes that a therapeutic exposure to any part of a body not scheduled to receive radiation can be considered an AO.

Date and Place—August 3, 1994; North Memorial Medical Center; Robbinsdale, Minnesota.

Nature and Probable Consequences—On August 15, 1994, a licensee informed NRC that a patient received 1380 centigray (cGy) (1380 rads) to a wrong treatment site during a brachytherapy treatment for metastatic lung cancer.

On August 3, 1994, a catheter was inserted into the patient's bronchus and a ribbon containing 20 seeds of iridium–192 having a total activity of 673.4 megabecquerel (18.2 millicuries) was then inserted into the catheter and moved to the proper treatment location. The treatment plan was intended to deliver a prescribed dose of 2000 cGy (2000 rads) to the intended target. The treatment began at 11:15 a.m. on August 3, 1994, and continued until its scheduled completion at 10:15 a.m. on August 4, 1994.

At about 7 p.m. on August 3, 1994, a nurse informed the physician that the visible portion of the catheter appeared to be protruding approximately 25.4 to 30.5 centimeters (10 to 12 inches) from the patient's nose. This was a significantly greater protrusion than previously observed, indicating that the catheter had moved from its initial placement. The nurse secured the catheter in place with additional tape. The physician stated that, based on the information available to him at that time, he determined that the catheter and ribbon had moved but that the tumor was receiving some radiation dose and therefore he continued the treatment. The iridium-192 seeds were removed on August 4 as planned. On August 4, 1994, a staff radiologist read the portable x-ray film taken on August 3, 1994, and indicated that the iridium implant was not seen.

Due to catheter displacement, the tumor dose was significantly reduced and estimated to be 620 cGy (620 rads) or 31 percent of the intended dose. The remaining dose of 1380 cGy (1380 rads) was delivered to an unintended site.

The patient was notified of the event by the treating physician on August 4, 1994, and again by another physician on August 17, 1994. The referring physician was informed by the treating physician on August 4, 1994.

An NRC medical consultant was retained to perform a clinical assessment of this misadministration. The medical consultant concluded that it is improbable that the patient will experience any long term consequences as a result of the exposure to the unintended treatment site.

Cause or Causes—The licensee has determined that the catheter movement caused a misadministration of the intended dose. Two possible explanations for the catheter movement could be the following: (1) Failure to properly secure the catheter in place with tape; or (2) nasal discharge decreasing the adhesive capability of the tape.

Action Taken To Prevent Recurrence

Licensee—The licensee's corrective actions include: amending the nursing staff procedure so that the attending physician will be contacted if there are further questions; directing nurses to follow the standing protocol for obtaining an administrative consult; providing additional inservice training; documenting the final length of the catheter in the patient chart; and documenting the catheter position on each visit to the patient's room.

NRC—NRC conducted a safety inspection from August 15 through September 7, 1994, to review the circumstances of the misadministration. One apparent violation and one area of concern were identified. An Enforcement Conference was held with