As a result of the incorrect angles of exposure, the treatment site received only part of the prescribed dose and adjacent tissue received a higher does than intended. The licensee estimates a dose of 300 cGy (300 rad) to the unintended site. Under normal conditions, the unintended site would have received approximately 20–50 cGy (20–50 rad).

The treatment angles were corrected on the patient's chart, and the radiation dose was modified to compensate for the reduced dosage delivered in the initial treatments. The patient was informed and no adverse medical effects are expected.

The patient was notified verbally on July 26, 1994 and in writing as required by 10 CFR 35.33. According to the medical consultant, there will be no medical consequences as a result of the misadministration.

Cause or Causes—The error occurred because the simulated gantry angles had not been converted to the treatment unit gantry angles, and gantry angle conversion factors were not included in the licensee's treatment chart checks conducted by the technologists.

The root causes of the problem were discussed with the licensee on September 1, 1994, during an Enforcement Conference. The causes appeared to be the following: (1) Written procedures were not developed to address gantry angle conversions; (2) the technologists did not have an adequate understanding of the informal gantry angle conversion procedures; (3) the informal gantry angle conversion procedure was not part of the licensee's annual refresher training program; (4) technologists did not fully understand their responsibilities to resolve discrepancies in a treatment plan; and (5) gantry angle conversion factors were not included in the licensee's treatment chart checks conducted by the technologists.

Action Take To Prevent Recurrence

Licensee—The licensee's corrective actions included: (1) Revising the simulation data form to include a specific location to document the converted gantry angles; (2) initialing all angle conversions by the person performing the conversion, and having a second individual independently verify the conversions prior to treatment; (3) instructing the technologists to review all treatment information and to resolve any discrepancy prior to continuing treatment; (4) performing all future gantry angle conversions by the licensee rather than by the licensee's simulation contractor; and (5) conducting a review

of past treatment plans back to 1988, with emphasis on those which did not identify any additional errors.

NRC-NRC Region III conducted an inspection on August 1, 1994, to review the circumstances surrounding the misadministration (Ref. 2). NRC also retained a medical consultant to review the case. An Enforcement Conference was held on September 1, 1994, to discuss the inspection findings and actions taken by the licensee. On September 20, 1994, NRC Region III issued a Notice of Violation with a Severity Level III (Severity Levels I through V range from the most significant to the least significant) violation with no civil penalty assessed. The licensee's corrective and preventive actions will be reviewed during the next NRC inspection of the licensed program.

94–17 Sodium Iodide Misadministration at St. Joseph Mercy Hospital in Pontiac, Michigan

The following information pertaining to this event is also being reported concurrently in the **Federal Register**. Appendix A of this report notes that administering a diagnostic dose of a radiopharmaceutical differing from the prescribed dose by more than 50 percent in which the event results in adverse health effects worse than expected for the normal range of exposures prescribed for the diagnostic procedure can be considered an abnormal occurrence.

Date and Place—July 26, 1994; St. Joseph Mercy Hospital; Pontiac, Michigan.

Nature and Probable Consequences— On July 27, 1994, the licensee reported to NRC that a misadministration occurred involving a patient receiving the wrong radiopharmaceutical for a diagnostic procedure.

The patient's referring physician requested a thyroid scan which involves administration of a standard prescription at St. Joseph Mercy Hospital of a 9.25 megabecquerel (MBq) (0.25 millicurie [mCi]) sodium iodide– 123 (I–123) capsule. However, the licensee administered a 92.5 MBq (2.5 mCi) I–131 capsule. The amount of activity that was administered is normally used following removal of the thyroid to examine a patient for the spread of cancer from the thyroid through the body.

NRČ retained a medical consultant to review the case. The medical consultant concluded that the resultant unnecessary dose to the patient's thyroid would result in a low, but finite, probability of hypothyroidism developing in the future. Also, there is a lifetime probability of developing radiation-induced thyroid cancer of 10 percent, including a risk of fatal thyroid carcinoma of approximately 1 percent. The licensee has arranged for the patient to be seen by a endocrinologist, and for repeat thyroid imaging with I–123 to be performed several months after the misadministration.

The patient was notified in person by the Radiation Safety Officer on July 27, 1994. Subsequently, the patient was also given a written report that was dated August 5, 1994.

Čause or Causes—Part of the cause of the misadministration was the lack of the treating physician's involvement in the patient's examination prior to the I-131 administration. The administrative staff and technologists failed to have the examination clarified by a treating physician with the referring physician prior to administration of the I-131. Causal factors for this event also included the failure of licensee management to ensure implementation of the licensee's written Quality Management Program. Contributing factors also appear to include deficiencies in training, and a failure to follow through on matters.

Action Taken To Prevent Recurrence

Licensee—The licensee took the following corrective actions: (1) Held a training session which included the Radiation Safety Officer, treating physicians and technologists; (2) instituted a limit on the number of individuals who will be involved in the use of I–131; and (3) required a written directive to be filled out and signed by a treating physician.

NRC—NRČ Region III conducted an inspection on August 1, 1994, to review the misadministration (Ref. 3). A Conformatory Action Letter (CAL) was issued to the licensee on August 2, 1994, which described the commitments made by the licensee as to which actions will be taken prior to the administration of I–131. An Enforcement Conference was held on August 24, 1994, to discuss the inspection findings and actions taken by the licensee in response to the CAL. In October 1994, NRC proposed an

In October 1994, NRC proposed an \$8,000 fine against the licensee for violations of NRC requirements involved in a diagnostic procedure using radioactive iodine at the hospital. The violations involve: (1) Failure to have signed written directives by an authorized user prior to administration of I–131 in quantities greater than 1.11 MBq (0.03 mCi) on July 26, and in two previous instances where the I–131 was the intended radiopharmaceutical; (2) failure to have a clinical procedure for the proper administration of I–131 for