

The licensee subsequently administered the intended treatment without incident. The radiation oncologist did not anticipate any immediate adverse effects to the patient because of the treatment to the wrong site. He was not certain of the potential for any long-term effects as a result of the misadministration.

The NRC contracted with a medical consultant to evaluate the medical data associated with the July 10, 2001, misadministration and assess any probable deterministic effects to the exposed patient. The consultant agreed with the licensee's assessment. With regard to long-term effects, the NRC's consultant concluded that the misadministration may be at the threshold of late central nervous system injury and may produce symptoms. The consultant further opined that long-term follow up was indicated for the patient and that the patient was eligible for inclusion in the Department of Energy's Office of Epidemiology and Health Surveillance voluntary life-time morbidity study. The licensee conducted medical follow up of the patient to identify and respond to potential adverse medical consequences resulting from the misadministration in December of 2001. However, during an attempt to follow up on the patient in June 2002, the licensee lost contact with the patient.

The licensee notified the patient's referring physician, who was also the attending neurosurgeon, immediately after the event. The radiation oncologist informed the patient of the event the following day and subsequently provided a copy of the report submitted to the NRC.

Cause or Causes—This misadministration was caused by human error, in that the licensee staff failed to verify that the treatment plan used was for the patient being treated. Contributing factors included: (1) The patient's name was not on each page of the computer-generated treatment plan; (2) the clipboard obscured the patient's name on the first page of the treatment plan; and (3) the licensee treated two patients with similar treatment plans.

Actions Taken To Prevent Recurrence

Licensee—Based on the cause and contributing factors of the misadministration, the licensee immediately implemented measures to ensure that patient-specific parameters are confirmed and verified prior to initiation of treatment. The measures included: (1) Independent verification of the treatment plan to ensure that it corresponds to the couch on the Gamma Knife unit; (2) labeling each page of the

computer treatment plan with the patient's name; (3) placing the treatment plan in the standard pink-colored patient-specific binder; (4) ensuring that the outside of patient-specific binders have large lettering indicating the patient's name; (5) ensuring that all patient-specific binders contain all medical information for the patient; (6) use of clipboards to hold verification forms that do not cover up the patient's name at the top of the forms; and (7) training of applicable staff regarding the cause and contributing factors of the misadministration and the measures to ensure that patient-specific parameters are confirmed and verified prior to initiation of treatment.

NRC—The licensee was cited for violations that included failure to verify that the treatment parameters implemented were for the patient being treated.

This event is closed for the purpose of this report.

02-3 Extremity Exposure in Excess of Regulatory Limits at Pacific Radiopharmacy, Limited, in Honolulu, Hawaii

Date and Place—March 26, 2002; Pacific Radiopharmacy, Limited, Honolulu, Hawaii.

Nature and Probable Consequences—During a routine, unannounced inspection conducted by the NRC on March 6, 2002, an inspector observed a radiopharmacist drawing 3700 megabecquerels (MBq) (100 millicurie (mCi)) bulk doses of technetium-99m (Tc-99m) utilizing a vial shield without a shielded top. The inspector observed that the radiopharmacist used his left index finger to hold the vial containing the Tc-99m in the shield when he inverted the vial to draw a dose. After questioning the individual, the inspector determined that this was the individual's routine practice. The inspector then informed the licensee that this practice may contribute to unnecessary exposure to the individual's finger and that the licensee should perform an evaluation to determine if the individual's extremity monitor (finger badge) was indicative of the actual dose received as a result of this handling practice. Following the inspection, a licensee consultant calculated the exposure to the individual's left index finger to be 7000 mSv (700 rem) for calendar year 2001. The exposure was reported to the NRC Operations Center on March 26, 2002. In addition, the licensee's consultant calculated the exposure to the individual's left index finger to be 1400 mSv (140 rem) from January 1, 2002, through March 13, 2002. The exposure

was reported to the NRC Operations center as a 30 day report on March 28, 2002. The radiopharmacist's extremity exposure was chronic and not acute, occurring over the entire calendar year. The inspector viewed the individual's left index finger and did not identify any visible skin reddening.

Cause or Causes—Licensee management and the Radiation Safety Officer failed to effectively train Pacific Radiopharmacy employees on NRC requirements for the safe handling of radionuclides and failed to provide effective oversight of its radiation safety program.

Actions Taken To Prevent Recurrence

Licensee—The licensee has obtained additional vial shields with shielded tops, placed them at the second drawing station, and has required the radiopharmacist to use them. The licensee also reviewed the adequacy of the radiation safety officer's oversight of the radiation safety program, determined it to be inadequate, and has replaced the radiation safety officer with another individual. The new radiation safety officer conducts unannounced inspections of the radiopharmacy to ensure compliance with their procedures requiring the use of vial shields with shielded tops during dose drawing procedures.

On March 29, 2002, the NRC issued Confirmatory Action Letter (CAL) 4-02-003 to the licensee associated with the extremity exposure in excess of regulatory limits. On April 8, 2002, the licensee responded to the CAL with corrective actions which included: (1) Removing the radiopharmacist from working with radioactive materials throughout the remainder of calendar year 2002; (2) contracting with a local consultant to provide safety training, conduct random unannounced audits, and provide Radiation Safety Officer (RSO) services; and (3) replacing its current RSO with the new consultant and requiring the RSO to attend quarterly board meetings to provide safety reports to the board.

NRC—In addition to issuance of CAL 4-02-003, NRC staff also met with licensee representatives in a Predecisional Enforcement Conference on October 10, 2002, to discuss the inspection findings. Enforcement action is currently pending.

This event is closed for the purpose of this report.

Agreement State Licensees

The NRC determined that the following events, which occurred at Agreement State licensed facilities