

schools and developing museum resources and programs in support of State and local school curricula;

(3) supporting museums in assessing, conserving, researching, maintaining, and exhibiting their collections, and in providing educational programs to the public through the use of their collections;

(4) stimulating greater collaboration among museums, libraries, schools, and other community organizations in order to share resources and strengthen communities;

(5) encouraging the use of new technologies and broadcast media to enhance access to museum collections, programs, and services;

(6) supporting museums in providing services to people of diverse geographic, cultural, and socioeconomic backgrounds and to individuals with disabilities;

(7) supporting museums in developing and carrying out specialized programs for specific segments of the public, such as programs for urban neighborhoods, rural areas, Indian reservations, and State institutions;

(8) supporting professional development and technical assistance programs to enhance museum operations at all levels, in order to ensure the highest standards in all aspects of museum operations;

(9) supporting museums in research, program evaluation, and the collection and dissemination of information to museum professionals and the public; and

(10) encouraging, supporting, and disseminating model programs of museum and library collaboration.

The Director is also authorized to enter into contracts and cooperative agreements with appropriate entities to strengthen museum services.

## II. Current Actions

One of the core duties of the Institute of Museum and Library Services, as stated in its strategic plan, is to create and sustain a nation of learners by building the capacity of libraries and museums. This goal will be accomplished in part by promoting access to learning and information resources held by museums and libraries through electronic linkages. IMLS is seeking assistance in developing specific plans to collect information from the U.S. library, museum and archive communities to assess their digitization readiness and technological capacity. A great deal of information has been collected on the Internet access of libraries for internal and public access. The information IMLS collects should build on but not

duplicate existing or ongoing collections.

*Title:* Technology and Digitization Survey.

*OMB Number:* None.

*Agency Number:* 3137.

*Frequency:* One time.

*Affected Public:* Museums, libraries, archives and State Library Administrative Agencies.

*Number of Respondents:* 6366.

*Estimated Time Per Respondent:* 1 hour.

*Estimated Time Per Respondent:* 1 hour.

*Total Burden Hours:* 6366.

*Total Annualized capital/startup costs:* 0.

*Total Annual Costs:* \$247,080.

*Contact:* Comments should be sent to the Office of Information and Regulatory Affairs, Attn.: OMB Desk Officer for Education, Office of Management and Budget, Room 10235, Washington, DC 20503 (202) 395-7316.

Dated: April 29, 2004.

**Rebecca Danvers,**

*Director of Research and Technology.*

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## NUCLEAR REGULATORY COMMISSION

### Report to Congress on Abnormal Occurrences Fiscal Year 2003; Dissemination of Information

Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438) defines an abnormal occurrence (AO) as an unscheduled incident or event which the U.S. Nuclear Regulatory Commission (NRC) determines to be significant from the standpoint of public health or safety. The Federal Reports Elimination and Sunset Act of 1995 (Public Law 104-66) requires that AOs be reported to Congress annually. During fiscal year 2003, 14 events that occurred at facilities licensed or otherwise regulated by the NRC and/or Agreements States were determined to be AOs. The report describes five medical events at facilities licensed by the NRC. Three events involved patients undergoing therapeutic brachytherapy treatments, one event involved an unintentional therapeutic dose of sodium iodide (I-131) to an embryo/fetus, and one event involved a diagnostic overexposure of a minor. The report also discusses nine AOs at facilities licensed by Agreement States. Agreement States are those states which have entered into a formal agreement with the NRC pursuant to

Section 274 of the Atomic Energy Act (AEA) to regulate certain quantities of AEA material at facilities located within their borders. Currently, there are 33 Agreement States. Seven Agreement State events were medical events (five therapeutic and two diagnostic), one Agreement State event involved overexposure to a radiographer, and one Agreement State event involved overexposure to members of the public from a damaged gauge. As required by Section 208, the discussion for each event includes the date and place, the nature and probable consequences, the cause or causes, and the action taken to prevent recurrence. Each event is also being described in NUREG-0090, Vol. 26, "Report to Congress on Abnormal Occurrences, Fiscal Year 2003." This report will be available electronically at the NRC Web site <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/>.

### Nuclear Power Plants

During this period, no events occurred at U.S. nuclear power plants that were significant enough to be reported as AOs.

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### Fuel Cycle Facilities (Other Than Nuclear Power Plants)

During this period, no events occurred at U.S. fuel cycle facilities that were significant enough to be reported as AOs.

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### Other NRC Licenses (Industrial Radiographers, Medical Institutions, etc.)

The NRC determined that the following events which occurred at facilities, licensed or otherwise regulated by the NRC, during this reporting period were significant enough to be reported as AOs:

03-01 Intravascular Brachytherapy (IVB) Medical Event at the Queen's Medical Center in Honolulu, Hawaii

*Date and Place*—October 9, 2002; the Queen's Medical Center; Honolulu, Hawaii.

*Nature and Probable Consequences*—A patient undergoing IVB treatment for cardiac stenosis received an underdose to the intended treatment site, but a dose above the AO criterion to an unintended site. This medical event occurred because the strontium-90 (Sr-90) source contained in the device's source train (catheter) did not reach the intended treatment site. The patient undergoing IVB was prescribed treatment of 18.4 Gray (Gy) (1,840 rads)

to the left anterior descending (LAD) artery to prevent scar tissue blockage. Sixteen Sr-90 seeds with a total activity of 2.224 gigabecquerel (GBq) (60.11 millicuries [mCi]) were positioned in the patient using fluoroscopy. Because the radiation oncologist and cardiologist believed that they could see the proximal and distal markers of the source train on the fluoroscopy monitor, the physicist did not perform a survey to ensure that the source train was in the patient's chest.

After the end of the treatment, the radiation oncologist was unable to retrieve all of the Sr-90 radioactive sources. After a second attempt to retrieve the sources failed, the oncologist pulled the treatment catheter from the patient and placed it in the bailout box. The bailout box is an acrylic box approximately 12 inches (in) by 10 in by 6 in with a hinged acrylic lid. Acrylic is used because of its shielding properties to attenuate the beta radiation from the catheter system. While inspecting the catheter, the oncologist discovered a kink at the location wherein the distal seed and marker became lodged. The kink was attributed to the patient's anatomy (small curves in the blood vessel, branching off the aorta where the catheter was inserted). A review of the cinematography images revealed that only one Sr-90 seed reached the intended treatment site while 5 seeds were positioned in the beginning LAD and 10 seeds were outside the cinematography field of view. Instead of receiving the intended 18.4 Gy (1,840 rads), the LAD received approximately 1.25 Gy (125 rads). The remaining dose was delivered to an unintended section of the LAD and aorta. No adverse effects due to this medical event are expected.

**Cause or Causes**—This medical event was caused by human error as the licensee did not perform a survey to verify that the radioactive sources were in the proper location. The patient's anatomy was a contributing factor in that there were curves in a small blood vessel branching off the aorta.

#### **Actions Taken To Prevent Recurrence**

**Licensee**—Based on the cause and contributing factors of the medical event, the licensee modified its procedures to require additional documented verification of the position of the markers by the radiological technologist and medical physicist in addition to the required verification by the radiation oncologist and cardiologist.

**NRC**—On November 13, 2002, the NRC issued a Notice of Violation to the licensee for the failure to follow the

manufacturer's operation procedures for the IVB device as specified in its license.

This event is closed for the purpose of this report.

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**03-02 Dose to Fetus at Community Hospital of Anderson in Anderson, Indiana**

**Date and Place**—August 8, 2003; Community Hospital; Anderson, Indiana.

**Nature and Probable Consequences**—On August 8, 2003, the Community Hospital of Anderson reported that a 35-year-old female patient was administered 1.1 GBq (29.8 mCi) of sodium iodide-131 (I-131) for the treatment of hyperthyroidism. At the time of the therapy, the patient was unaware that she was pregnant and, as a result, an unintentional dose to her embryo/fetus was delivered. On August 25, 2003, the patient's gynecologist informed the hospital and the patient that she had been approximately 15 weeks pregnant at the time of the therapy.

The NRC staff contracted with a medical consultant to review the possible deterministic effects of the dose to the embryo/fetus as a result of the event. The medical report indicated that the total effective dose equivalent (whole body) to the embryo/fetus was approximately 0.074 Gy (7.4 rads) and the committed dose equivalent to the embryo/fetal thyroid was approximately 278 Gy (27,800 rads). The licensee anticipated that the fetal thyroid would be ablated. The NRC medical consultant, contracted to review this event, also anticipated that the fetal thyroid would be ablated.

**Cause or Causes**—The event appeared to be an isolated occurrence. The root cause of the event was determined to be human error. Although the authorized physician user and the chief technologist asked the patient on several occasions, prior to the administration of the I-131 dosage, if she were pregnant or believed that she could possibly be pregnant, the patient denied the possibility of pregnancy. Due to other preexisting medical conditions and consultations by other physicians informing the patient that she was unable to conceive, the patient believed that she could not become pregnant and declined taking a pregnancy test prior to the I-131 therapy. Further, the hospital staff, knowing that the patient was also a physician on staff at the hospital, did not pursue a pregnancy test because they believed that the patient was aware of her pregnancy status.

#### **Actions Taken To Prevent Recurrence**

**Licensee**—The licensee conducted a thorough investigation of the event, including identification of the root cause. The root cause of the event was identified as human error by the patient. The event appeared to be an isolated occurrence. No further actions were deemed necessary to prevent recurrence.

**NRC**—The NRC conducted an inspection on August 26 and 27, 2003, with continued in-office review through September 30, 2003. The inspectors determined that the licensee made the required notifications to the patient, referring physician, and the NRC. No violations of NRC requirements were identified.

This event is closed for the purpose of this report.

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**03-03 IVB Medical Event at Washington Hospital Center in Washington, DC**

**Date and Place**—May 6, 2003; Washington Hospital Center; Washington, DC.

**Nature and Probable Consequences**—A patient undergoing IVB treatment of two areas within the right coronary artery for the treatment of restenosis was prescribed a dose of 23 Gy (2,300 rads) to each treatment site. Some difficulty was experienced in inserting the catheter to the first treatment site, but in the judgment of the treatment team, the catheter appeared to be inserted properly. Fluoroscopy was used to guide insertion and to position the source train. Upon completion of the first treatment, the catheter was moved to the second treatment position, as planned. When the source train was sent out for the second treatment, resistance was met and this time the catheter was replaced. The second treatment was successfully given.

In documenting the treatment, the licensee reviewed the films taken during the treatment and printed a copy of the films for the patient's record. During this documentation, the medical physicist noted that the source markers were not in the right position and suspected that the treatment area was not covered for the first treatment given. The radiation oncologist and interventional cardiologist reviewed the films and determined that the source train was approximately 40 millimeters (mm) (1.6 in) away from the intended treatment site. Therefore, the 23 Gy (2,300 rads) dose was delivered to an unintended treatment site.

The NRC contracted a medical consultant to review the medical event and assess the probable deterministic

effects of the treatment to the wrong area of the patient's coronary artery. The medical consultant concluded that the dose to the normal segment of the right coronary artery reported in this case was well below the tolerance dose for coronary arteries and no effect was expected other than fibrosis of the right coronary artery vessel wall.

**Cause or Causes**—This medical event was caused by human error, in that the licensee did not properly visualize the placement of the source train due, in part, to a lapse in time in the fluoroscopy performed during the treatment and the inherent inability to differentiate between the proximal and distal markers of the source train. In addition, a kink in the catheter may have prevented the source train from traversing to the correct area of the right coronary artery.

#### *Actions Taken To Prevent Recurrence*

**Licensee**—The licensee immediately implemented measures to further enhance source positioning verification prior to initiation of future treatments. The measures included verification of fluoroscope calibration and reinstruction of the treatment team to fully appreciate the movement of both ends of the source train at the site prior to treatment. Further, the licensee recommended to the device manufacturer that they redesign the proximal and distal markers to make them more radiographically distinct from each other and from the guiding catheter marker.

**NRC**—No violations of NRC requirements were identified. The NRC issued Information Notice 2003-09 describing medical events resulting from source positioning errors and is in the process of reviewing all events related to IVB since inception of this technology.

This event is closed for the purpose of this report.

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**03-04 Iodine-125 (I-125)**  
Brachytherapy Seed Medical Event at Guthrie Healthcare System in Sayre, Pennsylvania

**Date and Place**—May 24, 2001 (identified on June 12, 2003); Robert Packer Hospital (part of Guthrie Healthcare System), Sayre, Pennsylvania.

**Nature and Probable Consequences**—In 2001, a patient received a permanent brachytherapy implant using I-125 seeds as treatment for prostate carcinoma. The authorized user prescribed a dose of 144 Gy (14,400 rads) to the prostate. The implant was performed under ultrasound guidance

using 18 needles and 50 radioactive sources, as prescribed in the written directive. In June 2003, the patient returned for consultation regarding additional treatment after a diagnostic test indicated that the prostate cancer may have returned. A computerized tomography (CT) scan taken May 27, 2003, revealed that many of the seeds were not in the prostate but in adjacent tissue where they would have been ineffective in the treatment. The CT scan showed the array of seeds approximately 3 centimeters from the prostate. A review was then conducted of the May 2001 CT scan performed shortly after the initial implant procedure. This CT scan showed the array of I-125 seeds in the same location as in the May 2003 CT scan. The seed configuration resulted in a negligible dose to the prostate and a dose of 60 to 80 Gy (6,000 to 8,000 rads) to an adjacent structure, the penile bulb. The probable deterministic effects to the patient are being determined by NRC medical consultants. The patient and the patient's referring physician were notified of the event.

**Cause or Causes**—The cause of this event is under investigation by the licensee.

#### *Actions Taken To Prevent Recurrence*

**Licensee**—This event occurred in 2001 and involved an entirely different radiation oncology team than is currently employed by the licensee. The current radiation oncology team uses a different prostate implant protocol than was used in 2001. Reviews of the licensee's current prostate implant program by both the NRC and an independent physics consultant indicate that treatments performed since October 2002 have been accurate.

**NRC**—The NRC staff conducted a special safety inspection on June 19, 2003. Subsequent to this inspection, the licensee (Guthrie Healthcare System) began to audit other prostate implants performed in 2001 and identified additional cases of possible treatment errors. On July 28, 2003, the NRC issued a Confirmatory Action Letter (CAL) specifying actions the licensee agreed to perform, including evaluation of the root cause of the events and performance of an audit of past and current prostate implants. The NRC conducted a second special inspection on August 14, 2003. As of the date of this report, the licensee has reported a total of 21 possible medical events and is continuing the actions required by the CAL. It appears that the treatment errors may have been less extreme for the additional 20 cases reported by the licensee. An NRC medical consultant is

currently evaluating these cases. NRC staff will consider enforcement options upon the completion of the licensee's and NRC's investigations.

This event is considered open for the purpose of this report.

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**03-05 Diagnostic Medical Event at Deaconess Hospital, Evansville, Indiana**

**Date and Place**—March 28, 2003; Deaconess Hospital; Evansville, Indiana.

**Nature and Probable Consequences**—A nine-year-old patient, who had been prescribed a dosage of 0.148 MBq (4  $\mu$ Ci) in an I-131 capsule for a thyroid uptake study, instead received 15.6 MBq (421  $\mu$ Ci) of I-131 in liquid form. Because the patient was unable to swallow the capsule, the technologist placed a telephone request to a local commercial radiopharmacy for liquid I-131; however, the technologist erroneously ordered 15.6 MBq (421  $\mu$ Ci) of I-131 for the patient. The licensee identified the error while reviewing related paperwork on April 2, 2003. The referring physician, the patient, and the patient's family were informed of this event on April 3, 2003. The intended thyroid dose was approximately 0.13 Gy (13 rads), but the NRC's contracted medical consultant estimated that the patient received a thyroid dose of 13.7 Gy (1,370 rads) and an effective dose equivalent of 0.42 Gy (42 rads).

According to the medical consultant, no acute radiation effects were anticipated to any organ, since no organ (except the thyroid) received more than 0.01 Gy (1.0 rad). The 13.7 Gy (1,370 rads) dose will not cause radiation thyroiditis. The medical consultant also stated that there was insufficient data on juveniles to be reassured that a radiation dose in excess of 13.7 Gy (1,370 rads) to the thyroid would have no long-term consequences, given the increased radiosensitivity of the thyroid glands of children.

**Cause or Causes**—This medical event was caused by human error in ordering the correct dosage.

#### *Actions Taken To Prevent Recurrence*

**Licensee**—Corrective actions include (1) develop and use a standardized order form for liquid I-131 that will be faxed to the local nuclear pharmacy as written confirmation of the dosage ordered; (2) modify the computerized unit dose manager system to prevent an inappropriate dosage of I-131 from being entered into the computer system; (3) provide the local nuclear pharmacy with typical dosage ranges used by the licensee, which will be put into the nuclear pharmacy's computer and used as a secondary check to verify that the dosage ordered is appropriate for the

study or treatment to be performed; and (4) provide in-service training to the nuclear medicine technicians regarding the medical event.

**NRC**—On August 29, 2003, a Notice of Violation was issued for a violation that included the failure to order the correct quantity of I-131 as directed by the authorized user, to have a written directive dated and signed by an authorized user prior to the administration of the 15.6 MBq (421  $\mu$ Ci) I-131 dosage, and to administer a dosage within 20% of the prescribed dosage range for a thyroid uptake study using I-131.

This event is considered closed for the purpose of this report.

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#### Agreement State Licensees

The NRC determined that the following events, which occurred at Agreement State licensed facilities during this reporting period, were significant enough for reporting as AOs: AS 03-01 IVB Medical Event at Union Memorial Hospital in Baltimore, Maryland

**Date and Place**—May 22, 2003, Union Memorial Hospital; Baltimore, Maryland.

**Nature and Probable Consequences**—During a cardiac brachytherapy procedure conducted at the licensee's facility, a malfunction of the drive mechanism occurred with an IVB device containing a phosphorous-32 source with an activity of 3.48 GBq (94 mCi). The malfunction occurred during the treatment of the third of three patients. The first two treatments were completed without incident. The treatment of the third patient was initiated with the dummy source successfully reaching the proper dwell position (confirmed visually via fluoroscopy) and returning to the cartridge. The active source was then advanced into the catheter, but when the source movement light continued to blink well after the anticipated transit time, the licensee initiated a fluoroscopic view of the treatment site. The source was not observed in the fluoroscopic field of view, so the licensee assumed a machine malfunction had occurred and initiated emergency procedures. Radiation surveys were performed, which confirmed that the source had stopped inside the patient. The indicator light on the console continued to indicate that the source was in transit even after the licensee confirmed the source was in the patient and not at the treatment site. The licensee was unable to retract the source to its shielded position using the machine interrupt,

the system stop button, or the handwheel. At that point, the attending physician removed the catheter and source from the patient and accidentally dropped them on the operating room floor. After the power cord was removed from the wall receptacle, the source retracted into its shielded position. The licensee stated that it took approximately 45 to 60 seconds to remove the source from the patient. The manufacturer's representative present during the treatment indicated that this period was 60 to 90 seconds. The licensee estimated a worst case dose to the wall of the patient's artery as approximately 10.38 Gy (1,038 rads) based on a 60-second exposure time. The source delivery unit was taken to the licensee's "hot" laboratory after the event and the daily quality assurance (QA) checks were performed in the physics and clinical modes. The unit passed both QA checks. The manufacturer's representative present during the procedure immediately notified the manufacturer's technical center. The device was returned to the manufacturer for evaluation and a new device was provided to the licensee.

**Cause or Causes**—This medical event was caused by equipment malfunction. The manufacturer was able to simulate a similar type of failure on two occasions and is focusing on a timer chip as the possible cause of the malfunction. The manufacturer believes that a hardware problem and not the device's software caused the failure. The State of Maryland ruled out human error as the cause of the drive mechanism malfunction.

#### Actions Taken To Prevent Recurrence

**Licensee**—Corrective actions included the implementation of revised procedures regarding dosimetry, emergency response, and notification of incidents. Training for the revised procedures was completed on November 12, 2003. The licensee also revised its annual Radiation Safety Training Program to ensure compliance with pertinent State regulations and revised procedures.

**State Agency**—The State of Maryland conducted an investigation, and the State concurs with the licensee corrective actions that included implementation of revised procedures and an annual emergency exercise.

This event is considered closed for the purpose of this report.

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AS 03-02 Industrial Radiography Occupational Overexposure at a Temporary Jobsite in Ghent, Kentucky

**Date and Place**—On November 12, 2002, the Kentucky Radiation Health & Toxic Agents (KRHTA) Branch was notified, by the licensee, that for the month of October 2002, a radiographer's total annual occupational dose was exceeded while working at a temporary jobsite near Ghent, Kentucky.

**Nature and Probable Consequences**—The licensee reported an overexposure to a radiographer of 314 mSv (31.4 rem). A 3.81 terabecquerel (TBq) (103 Ci) Ir-192 source was being retracted after an exposure. The radiographer who had entered the area was in the area for approximately 3 minutes before realizing the source was not fully retracted. Upon realizing that the source was not fully retracted, the radiographer immediately left the area, extended the source, and then retracted it to the housed position. The radiographer's dosimetry was sent for processing and results indicated a whole body exposure of only 48.6 mSv (4.86 rem). However, the licensee, with assistance from the source manufacturer's Radiation Safety Officer (RSO), completed a reconstruction of the whole body exposure to the radiographer. The final result indicated an exposure of 300 mSv (30 rem) whole body from the event. This exposure was added to the radiographer's year-to-date exposure of 14 mSv (1.4 rem), for a total yearly whole body exposure of 314 mSv (31.4 rem). Discussions with the KRHTA Branch, along with independent calculations, confirmed the 300 mSv (30 rem) event exposure. The licensee stated that the thermoluminescent dosimeter (TLD) and operating ratemeter were in the radiographer's pocket, an area that did not reflect true whole body exposure, and the alarm ratemeter was never heard in an alarming condition.

**Cause or Causes**—This event was caused by inadequate operating procedures for the exposure device, improper placement of the TLD in the radiographer's pocket (rather than on his body), improper storage of the alarm ratemeter in his pocket (rather than on his body), and failure to survey the exposure device upon completion of the radiograph.

#### Actions Taken To Prevent Recurrence

**Licensee**—The licensee's corrective actions included revision of the operating procedure for retracting the source into the exposure device, personnel training on the revised procedure and proper wearing of dosimetry devices, and annual refresher training on proper operation and responses of survey instrumentation. Additionally, the radiographer involved will receive an additional 40 hours of

radiation safety training prior to returning to work in radiography, and will be evaluated at least once a month for the next year.

**State Agency**—The KRHTA Branch conducted an onsite investigation and concurred with the licensee's dose assessment and identification of the causes of the event. The licensee was issued a Notice of Violation and has provided corrective actions to the Commonwealth of Kentucky.

This event is closed for the purposes of this report.

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AS 03-03 Diagnostic Medical Event at Rush Copley Medical Center in Aurora, Illinois

**Date and Place**—July 28, 2003; Rush Copley Medical Center; Aurora, Illinois.

**Nature and Probable Consequences**—The Illinois Emergency Management Agency received a call on July 29, 2003, from a nuclear medicine technician at Rush Copley Medical Center in Aurora, Illinois. The technician reported that a patient who was to receive 148 MBq (4 mCi) of thallium-201 (Tl-201) for a heart test instead received 148 MBq (4 mCi) of I-131 on July 28, 2003. The patient had been admitted the day before the event with an order for a treadmill heart stress test to be performed. The patient remained hospitalized at the facility until discharged after July 30, 2003.

The circumstances of the event, as reported by the technician, are that both the exterior lead container and the syringe were labeled as containing a diagnostic unit dose of Tl-201. Although the injection occurred the previous day, it was not determined that I-131 was involved until the morning of July 29, 2003. Service engineers were called to the site on both days to inspect the gamma cameras used after attempts to image the patient failed. The reason became evident when a gamma camera flood source that had been made from what was thought to be the remaining Tl-201 material in the syringe from July 29 showed peaks consistent with I-131, rather than the expected Tl-201. The syringe had been assayed by the medical center before injection. The assayed amount showed the dose to be within the prescribed range for a typical 148 MBq (4 mCi) Tl-201 diagnostic administration.

On Friday, July 25, 2003, the nuclear pharmacy received an order for five unit dose syringes of I-131 for the Veterinary Service Center (VSC) and two unit dose syringes of Tl-201 for Rush Copley Medical Center. When the computer generated orders and associated labels were segregated, one of the

prescriptions for the Tl-201 was mistakenly substituted for I-131. The pharmacist did not realize the error and the I-131 dose (syringe) and its container were labeled with one of the Tl-201 labels generated for the original order. On Monday, July 28, 2003, the pharmacy facility manager noted that only four I-131 prescriptions had been filled for VSC. Assuming the I-131 dose had not been filled with the others the previous Friday, July 25, 2003, he filled an additional syringe with I-131 to complete the order for VSC.

The medical center estimates that a small amount of residual activity remained adhered to the walls of the syringe. Therefore, it estimates the amount of injected I-131 to be 148 MBq (4 mCi). Based on the package insert information for this material and assuming that an injected sodium iodide solution of I-131 results in a radiation absorbed dose similar to oral administration and that the patient had normal thyroid function (25% uptake), the dose to the patient's thyroid is approximately 51.95 Gy (5,195 rads).

The medical center technician indicated that the patient involved had been contacted by the referring physician, onsite oncologists, and the medical center's administrator and lawyer and was informed as to what had happened at the initial time of discovery of the event. Later, a copy of the medical center's report to the agency was also provided to the patient. The medical center offered to perform routine blood analysis throughout the year to monitor any changes in thyroid activity. The patient had been advised as to the potential health effects of the medical event during that time and the need for routine followup testing. The patient has not returned to the medical center for any additional testing, diagnosis, or consultation.

The medical center's oncologist indicated that it is very unlikely that any medical changes will be noted in the patient because the dose administered is only slightly larger than that typically ordered for whole body scans using I-131. Blood tests were taken immediately following the discovery of the event. Those tests suggest that the patient was hypothyroid as a preexisting condition to admittance.

**Cause or Causes**—The medical event was caused by the mislabeling of the I-131 unit dose syringe. Other factors that led to the medical event include improper segregation of the prescriptions at the pharmacy and lack of a second means of verifying proper completion of the order.

#### *Actions Taken To Prevent Recurrence*

**Licensee**—The pharmacy ceased dispensing therapeutic quantities of I-131 in unit dose syringes. Therapeutic doses of I-131 will only be dispensed in capsule form. This will preclude the possibility of a unit dose of diagnostic material being mistakenly filled with a quantity of therapeutic material. Additional corrective actions included (1) retraining of pharmacists, (2) implementation of a dual verification system for all prescriptions received, (3) implementation of a triple check system for dispensing compounds, and (4) testing a new bar code system for tracking all prescriptions.

**State Agency**—On July 30, 2003, the State agency sent an investigator to the medical center and the nuclear pharmacy to observe licensed activities and to review the circumstances of the event. During those onsite visits, preliminary information reported by the medical center and pharmacy was confirmed. The pharmacy was cited for failure to properly fill the prescription as ordered by the physician. The State agency is holding this action item open pending enforcement action and will include a review of the corrective actions taken during the next routine inspection. The agency does not expect any additional significant information to be received or other notable action to be taken outside of the enforcement process.

This event is considered closed for the purpose of this report.

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AS 03-04 High Dose-Rate Afterloader (HDR) Medical Event at Saint Joseph's Hospital in Houston, Texas

**Date and Place**—June 9, 10, and 11, 2003; Saint Joseph's Hospital; Houston, Texas.

**Nature and Probable Consequences**—A cancer patient undergoing therapeutic radiation treatment for breast cancer received a superficial skin dose of 70 Gy (7,000 rads) to a circular area approximately 10 mm (0.4 in) in diameter. This error occurred using an HDR device. Deeper absorbed doses of 34 Gy (3,400 rads), 15 Gy (1,500 rads), and 10 Gy (1,000 rads) have been estimated at depths of 10 mm (0.4 in), 20 mm (0.8 in), and 30 mm (1.2 in), respectively. These deeper doses were absorbed by the subcutaneous fat and muscle of the lower left chest wall. The patient had a slight erythema of the skin which measured 5 to 10 mm (0.2 to 0.4 in) in diameter approximately 2 weeks after the radiation therapy injury.

The incorrect placement of the source in the catheter was detected on June 11, 2003, between treatment fractions 5 and

6. The patient and referring physician were notified of the treatment error and the facts involved with this treatment. The patient elected to continue treatment with a modified treatment plan after the source location was corrected. A new plan was generated representing a composite of the unintended dose to the skin of the lower left chest wall and the intentional dose prescribed in the original treatment plan.

The attending physician, who was present during treatment, followed the patient's progress for any needed medical intervention due to exposure to the HDR source. The patient's erythema of the skin failed to heal and developed into an ulceration. The ulceration was surgically excised by the referring physician. After excision, the area fully healed within a period of approximately two months. The patient continues to be monitored by the referring physician.

**Causes or Causes**—During the setup of the HDR unit with the approved treatment plan, the source was instructed to stop at the 20th position from the catheter tip. The 20th stop resulted in the source stopping at 20 cm (7.9 in) from the catheter tip instead of the planned 20 mm (0.8 in) from the catheter tip. This was due to failure to correct the default value step size from 10 mm to 1 mm (0.4 in. to .04 in) as specified in the treatment plan. This failure was a human error in the copying of the treatment plan into the device's control console after the initial QA test. After the QA test the physician requested that the plan instruction be copied into a new plan, after the initial QA films had been approved. This procedure is required as the device manufacturer does not have a separate QA mode that allows QA without recording the QA tests as a fractional treatment.

#### **Actions Taken To Prevent Recurrence**

**Licensee**—The facility instituted a policy of comparing the console instructions to the approved QA record prior to each treatment fraction. In addition the medical physicist has made two suggestions for product improvement (1) the addition of a physics QA mode to allow the physicist to test a treatment plan without having it recorded as a treatment fraction to the patient; and (2) the placement of a display on the operator's console that graphically displays the actual position of the source within the catheter. Presently, the source position must be deduced by multiplying the current dwell step by the step size.

**State Agency**—The licensee's comments and suggested product

improvements were forwarded to the manufacturer's regulatory affairs office. The licensee was cited for failure to verify that the specific details of the administration were in accordance with the treatment plan and the written directive. Escalated enforcement actions were taken against the licensee.

This event is closed for the purposes of this report.

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**AS 03-05 Overexposure at Monsanto Chemical Plant in Luling, Louisiana**  
**Date and Place**—June 28, 2003, to July 10, 2003; Monsanto Chemical Plant; Luling, Louisiana.

**Nature and Probable Consequences**—The licensee notified the Louisiana Office of Environmental Services on July 10, 2003, that a radiation overexposure had occurred to members of the public due to a loss of control of a 37 GBq (1 Ci) cesium-137 (Cs-137) source that became dislodged from a damaged fixed gauge. The licensee stated that on June 29, 2003, a Monsanto maintenance technician noticed that the gauge's handle mechanism had broken off and fallen to the floor. The technician picked up the broken pieces and placed them on the Monsanto Planner's desk. The Planner was not present. The Planner returned to work on July 1, 2003, but did not discover the pieces until July 10, 2003. The Planner thought the parts were the gauge's locking mechanism and went to the area where the fixed gauge had been mounted and realized that the gauge's source was missing. After realizing that the parts contained the unshielded Cs-137 source, the licensee evacuated the building and secured the area. On July 11, 2003, a representative from a consulting company arrived on-site to perform an area survey, retrieve the source from the Planner's desk, and place the source in a secure storage area. The licensee requested that the manufacturer evaluate the failed gauge and conduct an assessment of the remaining gauges. On July 19, 2003, a representative from the device manufacturer removed the source from the Monsanto plant.

It was determined that the Planner occupied the desk for approximately 50 to 60 hours and received a whole body dose of approximately 400 mSv (40 rem). This determination was based on an analysis of the Planner's schedule and work habits together with the radiation dose rate of the source. The technician who carried the source to the Planner's desk received an extremity dose of approximately 18,000 mSv (1,800 rem) to the hand. Reenactments were performed to estimate the

exposures to 100 individuals employed by the plant. The estimates were determined by the time spent and proximity to the source. The highest exposure was estimated to be 740 mSv (74 rem) and the next highest exposure 180 mSv (18 rem). Altogether, 42 nonradiation workers exceeded the 1 mSv (0.1 rem) exposure limit to members of the general public. The workers are considered to be members of the public, and not radiation workers, because they are not exposed to radiation from licensed radioactive material as a normal part of their work. Others may have also been exposed at lower levels. Blood tests were performed for seven individuals, but revealed no cell changes. No one has shown signs of sickness or erythema.

The licensee contacted the Radiological Emergency Assistance Center/Training Site (REAC/TS) in Oak Ridge, Tennessee, and requested its assistance in having a cytogenetic blood study performed for the Planner. The licensee reported that it appears that vibration of the gauge caused the source holder and the attached source to fall. Surveys of the relevant areas and wipe tests on the source did not reveal any source leakage.

**Cause or Causes**—Monsanto believes the cause of the incident was corrosion of the epoxy that holds the source in place. However, the end plate was held in place by one tack weld and the vibration of the gauge could have contributed to the gauge becoming dislodged.

#### **Actions Taken To Prevent Recurrence**

**Licensee**—The decision has been made to take this type of device out of service and replace it with a newer model. Until the devices are removed from service, weekly visual inspections on the devices will be performed. The Planner and Monsanto engineers/technicians were trained only to recognize the radiation posting on the device. Now the safety training includes pictures of the device, its components, and the radioactive capsule.

**State Agency**—The licensee was cited for two violations. One violation was for the exposure of a nonradiation worker in excess of 1 mSv (0.1 rem) in a year, and the other was for creating a radiation area in an unrestricted area that exceeded 0.02 mSv (0.002 rem) in any one hour. The event was referred to the State of Louisiana's Enforcement Section.

This event is closed for the purpose of this report.

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AS 03-06 Brachytherapy Medical Event at University Hospitals of Cleveland in Cleveland, Ohio

*Date and Place*—May 13, 2003; University Hospitals of Cleveland; Cleveland, Ohio.

*Nature and Probable Consequences*—On May 22, 2003, the Ohio Department of Health notified the NRC Operations Center of an apparent brachytherapy medical event at University Hospitals of Cleveland. The licensee reported a radiation treatment to the wrong target area during a brachytherapy prostate procedure using 59 I-125 seeds, each containing 13 MBq (0.351 mCi) for a total activity of 765 MBq (20.71 mCi). The treatment resulted in a distribution of seeds in areas other than prescribed.

An unintended area of the prostate gland received approximately 1.4 Gy (140 rads) due to seeds implanted outside of the intended cancer cell site. The licensee determined that 31% of the bladder received 72 Gy (7,200 rads) and 3% of the rectum received 72 Gy (7,200 rads).

*Cause or Causes*—Unusual anatomical aspects of the seminal/prostate vesicle under ultrasound hampered the physician's ability to correctly place the seeds fully within the intended preplan margins. In addition, seed visualization on fluoroscopy was suboptimal.

#### *Actions Taken To Prevent Recurrence*

*Licensee*—Faculty and staff will increase efforts to identify unusual prostate anatomical features during the preplanning process; specifically, they will continue to cross-check and verify seed position in relation to underlying anatomy. Corrective actions taken by the licensee include (1) the introduction of stabilization needles to assist in keeping the prostate fixed relative to the base plate, the ultrasound probe, and surrounding tissues during the localization and the seed deposition process and (2) the use of a more radio-opaque seed to facilitate positive location during procedures viewed under fluoroscopy. The patient and referring physician were notified of the medical event.

*State Agency*—The Ohio Department of Health performed an investigation of the event.

This event is closed for the purpose of this report.

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AS 03-07 Diagnostic Medical Event at Christus Santa Rosa; San Antonio, Texas

*Date and Place*—June 11, 2003; Christus Santa Rosa; San Antonio, Texas.

*Nature and Probable Consequences*—A patient received 85.1 MBq (2.3 mCi) of I-131 instead of the prescribed dosage of 11.1 MBq (0.3 mCi) of I-131. The licensee discovered the error when the patient returned after 48 hours for a scan. The physician's written order requesting a thyroid scan for thyroiditis was misunderstood by the technologist as a request for a "whole body image" instead of a "thyroid up-take and scan". As a result, the technologist ordered the wrong dose for the prescribed procedure. Both the referring physician and the patient have been informed of the error.

*Cause or Causes*—The medical event was caused by human error. The wrong dosage was administered to the patient because the written order for the I-131 procedure was misread by the administering technologist.

#### *Actions Taken To Prevent Recurrence*

*Licensee*—The licensee implemented revised procedures mandating that a physician review all prescriptions requiring the use of I-131 and concur on the correct dosage.

*State Agency*—The State accepted the licensee's report and corrective actions as appropriate.

This event is closed for the purpose of this report.

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AS 03-08 Therapy Medical Event at Marian Medical Center in Santa Maria, California

*Date and Place*—April 25, 2002; Marian Medical Center; Santa Maria, California. This event was not determined to be an AO until the preparation of the FY 2003 report.

*Nature and Probable Consequences*—A patient was prescribed a therapeutic dose to the thyroid of I-131 with an activity of 296 MBq (8 mCi) but was erroneously administered 3,700 MBq (100 mCi) of I-131 instead. The error was discovered immediately and was reported to the RSO and the referring physician. After consultation, the RSO and referring physician prescribed suppressive and hydration therapy to the patient immediately in order to minimize the patient's absorbed dose. The suppressive therapy blocked the thyroid from absorbing the total dose and the hydration therapy was given to accelerate the excretion of the radioactivity from the body.

The dose to the patient was calculated to be 0.03 Gy (3 rads) to the whole body and 38.7 Gy (3,870 rads) to the thyroid. No adverse health effects are expected.

*Cause or Causes*—The State found that the medical event occurred due to human error. Two I-131 capsules had

been delivered that day for two patients who were to receive iodine therapy. The capsule containing 3.7 GBq (100 mCi) was given to the first patient. The error was recognized before the second patient was treated; therefore, the second I-131 capsule was never administered. The technologist failed to check the labeling and did not verify the dose using a dose calibrator.

#### *Actions Taken To Prevent Recurrence*

*Licensee*—Corrective actions included (1) counseling the technologist to review the labels on the vial and to check the dose in the dose calibrator before administration, (2) providing in-service training to technologists on proper procedures, (3) implementing new procedures requiring the doctor to check the label to ensure the patient will be administered the correct dose, and (4) administering I-131 to no more than one patient daily.

*State Agency*—The State has reviewed and accepted the licensee's corrective actions.

This event is closed for the purposes of this report.

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AS 03-09 Gamma Stereotactic Radiosurgery Device Medical Event at Bayfront Medical Center, Inc., in St. Petersburg, Florida

*Date and Place*—Between August and October 2002; Bayfront Medical Center; St. Petersburg, Florida.

*Nature and Probable Consequences*—On October 31, 2002, the Florida Bureau of Radiation Control was notified that 10 patients undergoing Gamma Stereotactic Radiosurgery (gamma knife) had received a dose or doses at least 50% greater than prescribed. The prescribed treatments ranged from 12.2 to 24 Gy (1,220 to 2,400 rads) at the 50% isodose curve; however, the delivered doses to the patients ranged between 19.2 and 38.4 Gy (1,920 and 3,840 rads) at the 50% isodose curve, which is 60% greater than the treatment prescribed. The patients were diagnosed with a variety of brain disorders (vascular diseases, tumors, and functional targets such as selected nerves). A treatment plan was developed and reviewed by the physicist, and the doses were administered using a gamma knife device. On October 30, 2002, while performing a routine QA, the RSO discovered that the physics parameters in the treatment planning file had an incorrect calibration factor. Further investigation identified that the system had an older calibration date which resulted in the incorrect information that the sources had 60% less activity. The medical events were discovered during a review of all patient files.



The medical events were reported to two authorized users and three referring physicians. Notification of the medical event was provided to nine of the patients or patients' responsible guardians and they were subsequently provided a copy of the report pertinent to that patient. The authorized user does not anticipate any change in the patient's condition from the additional exposure. The licensee's authorized users noted that these doses are still within the published literature. During the notifications it was discovered that one of the patients had died as a result of the patient's disease. The licensee's authorized users stated that this patient was given palliative treatment for four metastatic lesions that were not close to any critical structure. The patient died approximately 2 months after the treatment, which was the typical period of life expectancy for a patient with this type and stage of disease.

**Cause or Causes**—The State was not able to identify how the calibration date was changed in the treatment planning software physics protocol file. However, it is the licensee's responsibility, through an effective quality management program, to ensure that the treatment is administered with high confidence as directed by the authorized user.

#### **Actions Taken To Prevent Recurrence**

**Licensee**—The licensee has revised its quality management program to include additional daily checks to verify that the expected dose rate agrees with the dose rate shown on the treatment planning software physics protocol output to within 1%. The gamma knife manufacturer issued a notice dated November 4, 2002, to all customers utilizing the treatment planning system specific to the gamma knife used to treat these patients. The notice requested customers to check the physics protocol and to run tests to verify dose calibration factors after any treatment planning system service or software reinstallation.

**State Agency**—The State conducted an onsite investigation that included interviews with licensee personnel involved and a representative from the device's manufacturer on November 12–13, 2002. In the licensee's medical event report, the licensee indicated the device manufacturer installed a peripheral printer on August 26, 2002. The licensee's report also indicated that on this date the source calibration information was changed. During the investigation the manufacturer stated that it was unable to recreate the occurrence. Telephone interviews were conducted with service personnel from

the device manufacturer. The State also consulted with an independently contracted physicist with experience specific to the gamma knife and its treatment planning system to determine the state of the equipment. It was determined that the licensee's quality management program did not routinely verify calibration information as compared to treatment planning dose rates. State actions for this case are still pending.

This event is closed for the purpose of this report.

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Dated at Rockville, Maryland this 28th day of April 2004.

For the Nuclear Regulatory Commission

**Annette L. Vietti-Cook,**

*Secretary of the Commission.*

[FR Doc. 04-10045 Filed 5-3-04; 8:45 am]

BILLING CODE 7590-01-P

## **NUCLEAR REGULATORY COMMISSION**

[Docket No. 50-029]

### **Yankee Atomic Power Company, Yankee Atomic Power Station (Rowe); Notice of Receipt and Availability for Comment of License Termination Plan**

The Nuclear Regulatory Commission (NRC) is in receipt of and is making available for public inspection and comment the License Termination Plan (LTP) for the Yankee (Rowe) Atomic Power Station (Yankee-Rowe) located in Franklin County, Massachusetts.

Yankee Atomic Electric Company (YAEC, or the licensee) informed the NRC by letter dated February 27, 1992, that Yankee-Rowe was permanently shut down and that decommissioning would commence. YAEC submitted a decommission plan on December 20, 1993, which included an environmental report. The decommissioning plan was approved by Order on February 14, 1995, and the plant is undergoing dismantlement under 10 CFR 50.59.

In accordance with 10 CFR 50.82(a)(9), all power reactor licensees must submit an application for termination of their license. The application for termination of license must be accompanied or preceded by an LTP to be submitted for NRC approval. If found acceptable by the NRC staff, the LTP is approved by license amendment, subject to such conditions and limitations as the NRC staff deems appropriate and necessary. YAEC submitted the proposed LTP for Yankee-Rowe by applications dated November 24, 2003, December 10, 2003, December 16, 2003, January 19, 2004, January 20,

2004, February 2, 2004, February 10, 2004, and March 4, 2004. In accordance with 10 CFR 20.1405 and 10 CFR 50.82(a)(9)(iii), the NRC is providing notice to individuals in the vicinity of the site that the NRC is in receipt of the Yankee-Rowe LTP, and will accept comments from affected parties.

An electronic version of the Yankee-Rowe LTP may be viewed through the NRC ADAMS system at accession numbers ML033450398, ML033530147, ML041110261, ML040280024, ML040280028, ML040280031, ML040280036, ML040280140, ML040330777, ML040420388, ML041100639, and ML040690034, or at the Yankee Atomic Power Company site closure Web site, <http://www.yankee.com/siteclosure/index.htm>.

Comments regarding the Yankee-Rowe LTP may be submitted in writing and addressed to Mr. John B. Hickman, Mail Stop T-7-F27, Decommissioning Directorate, Division of Waste Management and Environmental Protection, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-3017 or e-mail [jbh@nrc.gov](mailto:jbh@nrc.gov).

Dated in Rockville, Maryland, this 22nd day of April, 2004.

For the Nuclear Regulatory Commission.

**Claudia Craig,**

*Chief, Reactor Decommissioning Section,  
Decommissioning Directorate, Division of  
Waste Management and Environmental  
Protection, Office of Nuclear Material Safety  
and Safeguards.*

[FR Doc. E4-997 Filed 5-3-04; 8:45 am]

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## **NUCLEAR REGULATORY COMMISSION**

### **Sunshine Act Meeting**

**DATES:** Weeks of May 3, 10, 17, 24, 31, June 7, 2004.

**PLACE:** Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

**STATUS:** Public and closed.

**MATTERS TO BE CONSIDERED:**

**Week of May 3, 2004**

*Tuesday, May 4, 2004*

9:30 a.m.—Briefing on Results of the Agency Action Review Meeting (Public Meeting). (Contact: Bob Pascarella, (301) 415-1245).

This meeting will be webcast live at the Web address, <http://www.nrc.gov>.