NATIONAL INDIAN GAMING COMMISSION

Notice of Approval of Class III Tribal Gaming Ordinances and Revocation of Class III Tribal Gaming Ordinance

AGENCY: National Indian Gaming Commission.

ACTION: Notice.

SUMMARY: The purpose of this notice is to inform the public of class III gaming ordinances approved by the Chairman of the National Indian Gaming Commission.

FOR FURTHER INFORMATION CONTACT: The NIGC at (202) 632–7003, or by facsimile at (202) 632–7066 (not toll-free numbers).

SUPPLEMENTARY INFORMATION: The Indian Gaming Regulatory Act (IGRA) 25 U.S.C. § 2701 *et seq.*, was signed into law on October 17, 1988. the IGRA established the National Indian Gaming Commission (the Commission). Section 2710 of the IGRA authorizes the Commission to approve class II and class III tribal gaming ordinances. Section 2710(d)(2)(B) of the IGRA as implemented by 25 CFR § 522.8 (58 FR 5811 (January 22, 1993)), requires the Commission to publish, in the **Federal Register,** approved class III gaming ordinances. Section 522.12 of the Code of Federal Regulations requires the Chairman to publish all class III gaming ordinance revocations.

The IGRA requires all tribal gaming ordinances to contain the same requirements concerning ownership of the gaming activity, use of net revenues, annual audits, health and safety, background investigations and licensing of key employees. The Commission, therefore, believes that publication of each ordinance in the **Federal Register** would be redundant and result in unnecessary cost to the Commission. The Commission believes that publishing a notice of approval of each class III gaming ordinance is sufficient to meet the requirements of 25 U.S.C. § 2710(d)(2)(B). Also, the Commission will make copies of approved class III ordinances available to the public upon request. Requests can be made in writing to: National Indian Gaming Commission, 1441 L Street, N.W., 9th Floor, Washington, D.C. 20005.

The Chair has approved tribal gaming ordinances authorizing class III gaming for the following Indian tribes:

Hopland Band of Pomo Indians
Little River Band of Ottowa Indians
Mooretown Rancheria
Picayune Rancheria of the Chukchansi Indians
Quinault Indian Nation
Round Valley Indian Tribes
Salt River Pima-Maricopa Indian Community
Shingle Springs Rancheria
Tonkawa Tribe of Oklahoma

The following tribe has revoked its class II and class III ordinance:

Ponca Tribe of Nebraska

Ada E. Deer,

Acting Chair.

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NUCLEAR REGULATORY COMMISSION

Report to Congress on Abnormal Occurrences Fiscal-Year 1996; Dissemination of Information

Section 208 of the Energy Reorganization Act of 1974 (PL 93–438) identifies an abnormal occurrence (AO) as an unscheduled incident or event that the 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 (PL 104–66) requires that AOs be reported to Congress on an annual basis. During fiscal-year 1996, eighteen events which occurred at NRC licensed facilities were determined to be AOs. These events are discussed below. 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. 19, ''Report to Congress on Abnormal Occurrences, Fiscal Year 1996.'' This report will be available at NRC's Public document Room, 2120 L Street NW. (Lower Level), Washington, DC, about three weeks after the publication date of this **Federal Register** Notice.

Nuclear Power Plants

96–1 Plant Trip With Multiple Complications at Wolf Creek Nuclear Generating Station

One of the AO reporting criteria notes that major deficiencies in design, construction, use of, or management controls for licensed facilities or material can be considered an AO.

Date and Place

January 30–31, 1996; Wolf Creek Nuclear Generating Station, a Westinghouse-designed pressurized water reactor nuclear power plant, operated by the Wolf Creek Nuclear Operating Corporation and located about 5.63 kilometers (3.5 miles) northeast of Burlington, Kansas.

Nature and Probable Consequences

One train of the essential service water system (ESWS) was inoperable due to frazil [1] ice blockage of the intake trash racks, and the second train was degraded. The ESWS removes heat from plant components which require cooling for safe shutdown of the reactor or following a design basis accident. The ESWS consists of two redundant trains, provides emergency makeup to the spent fuel pool and component cooling water systems, and is the safety related water supply to the auxiliary feedwater system. Freeze protection for the ESWS is a design provision, and is provided by a warming line from each ESWS train which discharges directly in front of the train's trash rack.

At approximately 2:00 a.m. on January 30, 1996, operators at Wolf Creek received alarms indicating that the traveling screens for the circulating water (CW) system were becoming blocked. The site watch reported that the traveling screens for Bays 1 and 3 were frozen and that water levels in these bays were approximately 2.44 meters (8 feet) below normal. The ESWS was started with the intent to separate the ESWS from the service water (SW) system. However, the ESWS was incorrectly aligned, which reduced warming flow to the ESWS suction bays (the lineup was corrected approximately 6 hours later). At approximately 3:30 a.m., operators received a service water low pressure alarm (CW system bays were subsequently determined to be at 3.66 meters (12 feet) below normal) and an electric fire pump started. The shift supervisor then directed a manual reactor/turbine trip. Following the scram, five control rods failed to fully insert (from 12 to 30 steps out). The event was further complicated because the turbine driven auxiliary feedwater pump developed a packing leak and was declared inoperable. The loss of CW system bay level was subsequently determined to be caused by ice blockage of the traveling screens, which was caused by freezing water from the spray wash system.

Train ''A'' ESWS pump was tripped and declared inoperable at 7:47 a.m. due to low discharge pressure and high strainer differential pressure. At about 5:45 p.m. the operators declared Train ''A'' operable based on an engineering evaluation. However, the pump was

[1] Minute ice crystals called frazil were formed when wind and temperature conditions caused water in the ultimate-heat-sink reservoir to become supercooled (cooled to a few hundredths of a degree below the freezing point without solidification). The frazil ice crystals mixed with the supercooled water, and adhered to the objects (i.e., trash racks) with which they collided.

stopped 1½ hours later at approximately 7:30 p.m. when the pump exhibited further oscillations in flow and pressure. At approximately 8:00 p.m., operators noted that ESWS Train ''B'' suction bay level was 4.57 meters (15 feet) below normal and decreasing slowly. Operators placed additional heat loads on Train ''B'' and the suction bay levels subsequently recovered. At 10:14 p.m., the operators again started Train ''A'' ESWS, but later secured it, at 10:27 p.m., due to decreasing flow and pressure. At about 9:00 a.m. on January 31, 1996, divers inspected the suction bay of Train ''A'' and noted complete blockage of the trash racks by frazil ice. The condition of the Train ''B'' trash racks was not determined because the pump was running. The ice blockage was cleared later that day using heating, and air sparging of the trash racks.

Cause or Causes

The root cause of this event was deficiencies in the ESWS warming line design. This problem was exacerbated by the initial incorrect alignment of the ESWS. A 1976 design calculation specified a warming line flow rate of 15,142 liter/minute (4000 gpm) to prevent frazil ice. This calculation assumed a warming line temperature of 2°C (3°F) above freezing. This assumption was never validated: The warming line temperature during the event was only approximately 0.5°C (1°F) above freezing. Additionally, due to the elevations and configuration of the warming line, portions of the line operated with partial pipe flows. Flow through the lines was estimated to have been 9464 liter/minute (2500 gpm) and, with the initial improper lineup, warming flow was estimated to be 6435 liter/minute (1700 gpm), less than half the design specification.

Actions Taken to Prevent Recurrence

Licensee

The hydraulics of the ESWS discharge to the ultimate heat sink, and the warming line to the ESWS pumphouse, have been changed to establish and distribute the proper amount of flow to the ESWS warming line. The licensee has installed back pressure orifices to establish the required flow rates. This work was completed by October 1, 1996.

NRC

NRC entered a monitoring phase following the Notification of an Unusual Event at 9:00 a.m. on January 30, 1996. During February 6 through February 15, 1996, NRC conducted an Augmented Inspection Team inspection at Wolf Creek as a result of this event. NRC issued a civil penalty of $300,000 because of violations as a result of this event.

96–2 Containment-Bypass Leakage via Disconnected Hydrogen-Monitor Lines at Braidwood Units 1 and 2

One of the AO reporting criteria notes that a major reduction in the degree of protection to public health and safety from a major degradation of essential safety-related equipment can be considered an AO.

Date and Place

February 15, 1995; Braidwood Unit 2, a Westinghouse-designed pressurized water nuclear reactor plant, operated by Commonwealth Edison Company and located about 38.6 kilometers (24 miles) south southwest of Joliet, Illinois.

Nature and Probable Consequences

On November 9, 1994, the licensee completed a containment integrated leak rate test (ILRT). For this test, the 6.35-millimeter (0.25-inch) containment penetration hydrogen sensing lines for trains ''A'' and ''B'' were disconnected and a balloon placed on the end to identify any leakage. The procedure did not specify whether to disconnect the sensing line inside the hydrogen monitor cabinet or outside. The operators who lined up the test disconnected the lines inside the cabinet. The licensee's investigation concluded that when other operators restored the system from the test, they observed the exterior sensing lines and assumed that the lines were reconnected. Therefore, the sensing lines remained disconnected inside the cabinet.

On January 31, 1995, the operations department wrote a problem identification report to identify a growing difference in the hydrogen readings on the ''A'' and ''B'' trains which are taken during each shift. On February 15, 1995, during troubleshooting, the ''A'' train lines were found to be disconnected, approximately 3 months after being disconnected. Surveillance tests performed on December 11, 1994, and January 25, 1995, provided opportunities to detect the deficiency with the ''A'' train but were missed. It could not be conclusively determined when the ''B'' train was restored. Two maintenance workers had a recollection of discovering balloons on the sensing lines in a hydrogen monitoring cabinet in late 1994. Maintenance records indicate these individuals worked on the ''B'' train on December 20, 1994. However, computer and operator logs for the ''B'' train appear to have been accurately reading containment hydrogen following the ILRT.

The hydrogen monitors are normally isolated. However, during a loss of coolant accident, the Emergency Operating Procedures direct the operators to put them into service to monitor containment hydrogen concentration. This would create an unfiltered release path from the containment to the auxiliary building. The licensee calculated that, under worst case conditions using guidance from NUREG–1465, ''Accident Source Terms for Light-Water Nuclear Power Plants,'' regulatory dose limits could be exceeded within approximately 3 hours. NRC review found the licensees calculations to be conservative.

There are area radiation monitors near the hydrogen monitors. These area radiation monitors alarm in the control room and the alarm response procedures call for notification of Radiation Protection personnel to survey the area. Additionally, there are radiation monitors in the auxiliary building exhaust that would assist the operators in identifying the leak. The containment bypass flow path could be isolated remotely from the control room and it appears credible that the leak could be isolated prior to exceeding regulatory limits.

Cause or Causes

The cause of this event was a procedural deficiency in that the ILRT procedure did not provide adequate guidance on where the containment penetration hydrogen sensing lines should be disconnected. Additionally, the operator tasked with reconnecting the containment penetration hydrogen sensing lines, after the ILRT was completed, did not display a questioning attitude when he found that the lines appeared to be reconnected.

Actions Taken to Prevent Recurrence

Licensee

Corrective actions included revision of ILRT line up and restoration sheets to provide adequate guidance on where disconnections and connections are to be performed. Additionally, a General Information Notice was issued to all site personnel highlighting the human performance problems identified from this event.

NRC

Escalated enforcement was exercised on this issue and the licensee was assessed a $100,000 civil penalty. Information Notice 96–13, ''Potential Containment Leak Paths Through

Hydrogen Analyzers,'' was issued to alert other licensees to this event.

Other NRC Licensees

(Industrial Radiographers, Medical Institutions, Industrial Users, etc.)

96–3 Medical Brachytherapy Misadministrations by José L. Fernández, M.D., in Mayagüez, Puerto Rico

One of the AO reporting criteria notes that administering therapeutic radiation such that the actual dose is greater than 1.5 times the prescribed dose, or the event (regardless of any health effects) affects two or more patients at the same facility, should be considered an AO.

Date and Place

Between January 14, 1994, and October 10, 1995; José L. Fernández, M.D.; Mayagüez, Puerto Rico.

Nature and Probable Consequences

On January 14, 1994, Dr. Fernández acquired an eye applicator device, which contained a strontium-90 (Sr–90) source of approximately 3219 megabecquerel (87 millicurie) activity, from the estate of a deceased licensee in Mayagüez, Puerto Rico. (Eye applicator devices are used for the supplemental treatment of non-malignant growths on the eye after surgery is performed.) NRC knew that Dr. Fernández acquired the Sr–90 source because the estate was acting under a Confirmatory Action Letter (CAL) to maintain control of the Sr–90 source and to either dispose of it or transfer control of it to an authorized recipient. Since Dr. Fernández was already an NRC licensee for another Sr–90 source in San Juan, Puerto Rico, his license was amended so that he was an authorized recipient when the transfer took place. (After the transfer took place, Dr. Fernández was licensed to have two sources.) NRC did not require Dr. Fernández to receive additional training in the use of the Sr–90 source after he acquired it from the estate because he was already an authorized user for a Sr–90 eye applicator as defined by 10 CFR 35.

When Dr. Fernández took possession of the eye applicator device, it was in the manufacturer's carrying case. A label attached to the carrying case contained the following hand written information: (1) the dose rate for the device, which was calibrated as 24 centigray (cGy) per second (24 rad per second); (2) the instrument used to calibrate the dose rate; (3) the date when the dose rate was calibrated; and (4) the name of the individual who performed the calibration. Dr. Fernández assumed that the hand written information on the label attached to the manufacturer's carrying case was correct and proceeded to treat patients.

On October 18, 1995, during a routine inspection, an NRC inspector questioned the labeled dose rate on the eye applicator device and the resultant administered doses. Dr. Fernández was unable to provide documentation to answer the questions. He then voluntarily ceased the administration of radiation doses and requested a calibration of the device by the manufacturer. The actual dose rate was found by the manufacturer to be 53 cGy per second (53 rad per second); i.e., more than twice the assumed dose rate.

Dr. Fernández and NRC reviewed the computer sorted records of all administrations using the eye applicator device and determined that between October 24, 1994, and October 10, 1995, 87 patients had received radiation doses which were approximately twice the prescribed dose. However, the computer sort was not complete, since Dr. Fernández later discovered an additional 17 cases which occurred between January 1994 and October 1995. Dr. Fernández notified the patients about the misadministrations. NRC contracted a medical consultant to review the medical aspects of the misadministrations.

The NRC medical consultant, who reviewed patient records for the 87 patients initially identified, determined that 25 of the patients were at higher risk for complications. These 25 patients were initially prescribed treatment doses of 1500 to 2880 cGy (1500 to 2880 rad), but received doses of 3312 to 6360 cGy (3312 to 6360 rad) instead. Of these 25 patients, 12 were then prescribed second treatment doses of 1000 to 2160 cGy (1000 to 2160 rad), but received doses of 2208 to 4770 cGy (2208 to 4770 rad) instead. Additionally, two of these 25 patients were prescribed third treatment doses of 1500 to 3000 cGy (1500 to 3000 rad), but received doses of 3313 to 6625 cGy (3313 to 6625 rad) instead. The highest total dose received by a patient was 13,603 cGy (13,603 rad) to the surface of the eye, with an estimated 544 cGy (544 rad) to the lens of the eye.

The NRC medical consultant believes that the long-term consequences of the misadministrations to the 25 highest dose patients could include: (1) increased risk of cataracts; and (2) increased risk of infections, due to severe thinning or ulceration of the sclera, which could cause blindness if not detected early and aggressively treated. No adverse health effects were reported during a reexamination of seven of these 25 patients by Dr. Fernández. However, the NRC medical consultant indicated that the possible adverse consequences to these patients may not appear for a period of up to 10 years after irradiation.

Cause or Causes

Dr. Fernández used an incorrect dose rate for the Sr-90 source, as calibrated by a medical physics consultant employed by the deceased former licensee, to develop treatment plans.

The incorrect dose rate calibration occurred when the former licensee had a medical physics consultant calibrate the Sr-90 source, after the original calibration certificate was lost. The medical physics consultant used an inappropriate measurement instrument for the calibration, which gave an erroneous dose rate calibration of 24 cGy per second (24 rad per second). (The label attached to the carrying case of the eye applicator device indicated that the medical physics consultant calibrated the Sr-90 source in September 1990.)

Also, Dr. Fernández had no Quality Management Program (QMP) as required by 10 CFR 35.32, which could have helped in detecting the calibration error. Medical use licensees, as required under 10 CFR 35.32, must establish a QMP to provide high confidence that radiation will be administered as directed by the authorized user.

Actions Taken to Prevent Recurrence

Licensee

Dr. Fernández initially ceased operations until the eye applicator device was properly calibrated; reliable dosimetric data was available to perform the dose administrations; and a QMP was developed and submitted to NRC for review. Dr. Fernández subsequently decided to cease using the Sr-90 source and to terminate his license. (The QMP was never implemented.)

NRC

A CAL was issued to confirm that Dr. Fernández would submit a QMP for use of the eye applicator device, and that he would cease operations until approval was received from NRC to resume operations. A second CAL was issued confirming that Dr. Fernández would perform an in-depth review of his records to identify the misadministrations and to notify the patients.

After Dr. Fernández requested termination of his license, NRC issued an order, which required him to maintain the Sr-90 sources in locked, safe storage until the sources were transferred to an authorized recipient, to

transfer the Sr-90 source within 90 days, to identify and notify any additional patients who may have received misadministrations, to obtain the services of an independent medical physics consultant with expertise in therapy dosimetry calculations, and to perform several other tasks specified in the order. Dr. Fernández currently has a possession only license until his sources are properly transferred and his request for termination has been granted by the NRC. In addition, NRC is requesting that the Puerto Rico Health Department perform a long-term follow-up of these patients.

NRC also issued Information Notice 96–66, ''Recent Misadministrations Caused by Incorrect Calibrations of Strontium-90 Eye Applicators,'' on December 13, 1996, to alert all medical use licensees authorized to use Sr-90 eye applicators of misadministrations caused by incorrect source strength determinations of Sr-90 eye applicators.

Dr. Fernández purchased the medical practice and the Sr–90 source from the estate of the deceased former licensee, Dr. Luis A. Vázquez of Mayagüez, Puerto Rico. Consequently, Dr. Fernández has the records of all of the administrations that were made using the Sr–90 source while it was licensed to Dr. Vázquez. In a letter to Dr. Fernández dated October 28, 1996, NRC confirmed with Dr. Fernández that he would preserve the patient records of the former licensee and perform a computer search to identify the patients who were treated with the eye applicator. NRC is considering options for the review of these records to determine how many additional misadministrations occurred when the incorrectly calibrated Sr–90 source was in the possession of the former licensee.

96–4 Medical Brachytherapy Misadministrations by Phillip J. W. Lee, M.D., in Honolulu, Hawaii

One of the AO reporting criteria notes that administering a therapeutic dose from a sealed source such that the errors in source calibration and time of exposure result in a calculated total treatment dose differing from the prescribed treatment dose by more than 10 percent, and the event (regardless of any health effects) affects two or more patients at the same facility, can be considered an AO.

Date and Place

May 6, 1995, through November 16, 1995; Phillip J. W. Lee, M.D.; Honolulu, Hawaii.

Nature and Probable Consequences

During an NRC inspection, it was determined that the licensee had incorrectly performed calculations for the decayed activity of a strontium-90 (Sr–90) source in an eye applicator. Consequently, the licensee had the Sr–90 eye applicator calibrated by the National Institute of Standards and Technology (NIST). Based on calibration data provided by NIST, NRC and the licensee determined that 17 misadministrations involving 16 patients had occurred between May 6 and November 16, 1995. (Two of the misadministrations involved one patient who was treated on both eyes.) The delivered doses were from 21.1 to 22.7 percent greater than the prescribed total dose of 4000 centigray (cGy) (4000 rad). (The total dose was to be delivered in four fractions of 1000 cGy [1000 rad] each.)

The licensee and referring physicians did not observe any adverse consequences to the patients. The licensee noted that the misadministered doses were within the ranges recommended for this type of treatment. NRC contracted a medical consultant to review the cases and make an independent assessment of the potential health effects to the patients. As of the date of this report, the reviews of the NRC and its consultant were ongoing.

The licensee notified the patients of the misadministration.

Cause or Causes

The licensee did not know how to calculate the decay of the Sr–90 source, and used a linear function rather than a logarithmic function. In addition, the licensee used an incorrect half-life for Sr–90; however, this error was less significant.

Actions Taken to Prevent Recurrence

Licensee

The licensee had the Sr–90 eye applicator calibrated at NIST and learned how to calculate the decay of the Sr–90 source.

NRC

NRC requested that the licensee have the Sr–90 eye applicator calibrated at NIST and taught the licensee how to calculate the decay of the Sr–90 source. NRC is conducting an inspection, which will remain open until the NRC medical consultant finishes reviewing the cases and provides an assessment of the potential health effects to the patients. Enforcement action may be taken in the future if necessary.

96–5 Medical Brachytherapy Misadministration at Harper Hospital in Detroit, Michigan

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

Date and Place

November 24, 1995; Harper Hospital; Detroit, Michigan.

Nature and Probable Consequences

A patient was being treated with a strontium-90 eye applicator for pterygium (a growth over the eye which causes gradual blindness). The patient was prescribed three 800-centigray (800 rad) treatments lasting 30 seconds each. Each of the treatments was to be administered to the medial side of the left eye. However, the second treatment was mistakenly administered to the lateral side of the left eye. The physician realized the error and immediately treated the correct side with the prescribed dose.

The patient was notified of the misadministration and given a written report. The patient's referring physician was notified. An NRC medical consultant evaluated the effects of the misadministration and concurred with the licensee that the patient was not expected to suffer any adverse health effects.

Cause or Causes

The patient's chart was upside down and the treating physician incorrectly interpreted the sketch of the left eye on the diagram that specified the treatment site. (The diagram was part of the written directive for treatment using the strontium-90 eye applicator; however, it did not show the nose, top of the page, or bottom of the page.) Also, the second treatment was administered by a different physician and physicist than the first treatment.

Actions Taken To Prevent Recurrence

Licensee

The licensee revised the diagram so that it shows the nose, thereby making it obvious which is the left eye and which is the right eye.

NRC

NRC conducted a special safety inspection. A Notice of Violation was issued for failing to ensure that the administration was in accordance with the written directive. Since the inspection showed that actions had been taken to correct the violation and to prevent recurrence, no reply to the violation was required.

96–6 Medical Brachytherapy Misadministration at New England Medical Center in Boston, Massachusetts

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

Date and Place

November 10, 1993; New England Medical Center; Boston, Massachusetts.

Nature and Probable Consequences

A patient with carcinoma of the cervix metastatic to the brain was being treated with an intercavity implant using cesium-137 sources in a gynecological applicator. During treatment a source became dislodged and delivered radiation to the patient's thigh, which was an unprescribed treatment site.

The licensee subsequently calculated that the consequent dose to the patient's thigh was 71 centigray (cGy) (71 rad), as compared to 65 cGy (65 rad) which would have been delivered to the thigh at 20 centimeters (7.87 inches) distance from the applicator during the total procedure if performed as prescribed.

During a routine NRC inspection conducted on April 10–12, 1995, the NRC inspector noted the incident report and brought it to the attention of NRC management. NRC subsequently determined that the event was a misadministration and notified the licensee. The licensee consequently submitted the required notifications to NRC, and notified the patient in writing of the misadministration.

Cause or Causes

A malfunction of the aging gynecological applicator and a possible lack of attention to details by the personnel involved in loading the applicator caused the misadministration.

Actions Taken to Prevent Recurrence

Licensee

The licensee replaced the malfunctioning gynecological applicator. In addition, the licensee now requires that two persons perform loading of the gynecological applicator to insure that the sources are in and that the ovoids are taped to insure that the sources do not come out inadvertently.

NRC

The NRC again reviewed the information provided by the licensee and determined that a violation of the licensee's Quality Management Plan had occurred. An NRC medical consultant reviewed the circumstances of the misadministration, determined that the licensee had used an inaccurate source-to-thigh distance in its dose calculation, and determined that the patient received a dose of 864 cGy (864 rad) to the thigh instead of 71 cGy (71 rad) as calculated by the licensee. The medical consultant stated that the patient experienced no ill effects.

96–7 Medical Brachytherapy Misadministration at William Beaumont Hospital in Royal Oak, Michigan

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

Date and Place

March 19, 1996; William Beaumont Hospital; Royal Oak, Michigan.

Nature and Probable Consequences

A patient with cancer of the vagina was prescribed treatment with a high dose rate (HDR) remote afterloader brachytherapy unit having an iridium-192 source. The treatment plan specified a step size of 2.5 millimeters (mm) (0.098 inches). A wrong step size of 5.0 mm (0.197 inches) was entered into the HDR unit's computer control program. Therefore, a part of the body not scheduled to receive radiation was exposed.

The licensee calculated that the skin of the patient's thighs, which was the wrong treatment site, received a maximum unintended dose of 500 centigray (500 rad) because of the misadministration. An NRC medical consultant determined that the patient should have no side effects as a consequence of the misadministration. The patient and the referring physician were notified of the misadministration.

Cause or Causes

The wrong step size was entered into the HDR remote afterloader brachytherapy unit's computer control program.

Actions Taken To Prevent Recurrence

Licensee

The licensee revised its ''physics worksheet'' to include the step length as an additional entry; developed a checklist for the physicist/dosimetrist to verify the treatment plan parameters, and posted it on the treatment console; and instituted a policy that all treatment plan parameters must be verified, and the verification recorded, prior to each treatment.

NRC

NRC conducted a special safety inspection, where one apparent violation was noted. This was the failure of the licensee's Quality Management Program to provide assurance of correct administration of the prescribed dose in compliance with the physician's written directive.

96–8 Medical Brachytherapy Misadministration at Community Hospitals of Indiana in Indianapolis, Indiana

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

Date and Place

August 16, 1996; Community Hospitals of Indiana; Indianapolis, Indiana.

Nature and Probable Consequences

A patient was prescribed a 500 centigray (cGy) (500 rad) treatment for an esophageal tumor using a high dose rate remote afterloader unit having an iridium-192 source. Because of a treatment planning error, a non-prescribed treatment area approximately 27 millimeters (mm) (1.06 inches [in]) below the tumor volume received a maximum dose of 465 cGy (465 rad) instead of the estimated dose of 50 to 100 cGy (50 to 100 rad).

The patient was notified of the misadministration. The licensee expects no adverse health effects to the patient. A NRC medical consultant was retained to review the case.

Cause or Causes

Because of a treatment planning error, the source was placed approximately 27 mm (1.05 in) below the tumor volume.

Actions Taken To Prevent Recurrence

Licensee

A table of offset distances for the various sources and catheter lengths used by the licensee was placed in the licensee's quality control manual.

NRC

NRC conducted a special safety inspection.

96–9 Medical Brachytherapy Misadministrations at EquiMed, Inc., in Lehighton, Pennsylvania

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

Date and Place

December 31, 1995; EquiMed, Inc.; Lehighton, Pennsylvania.

Nature and Probable Consequences

Two patients were prescribed vaginal treatment with a high dose rate (HDR) remote afterloader brachytherapy unit having an iridium-192 source. The prescribed total dose for each patient was between 2000 and 2200 centigray (cGy) (2000 and 2200 rad), and was to be delivered in five fractional doses over a period of several weeks. Each fractional dose was to be between 400 and 500 cGy (400 and 500 rad).

For one of the treatment fractions, 500 cGy (500 rad) was to be delivered to each patient over a treatment length of 5 centimeters (cm) (1.97 inches [in]) using a step size of 5 millimeters (mm) (0.197 in). However, a wrong step size of 10 mm (0.394 in) was entered into the HDR unit's control console, and a length of 10 cm (3.94 in) was treated instead of the prescribed length of 5 cm (1.97 in). Therefore, radiation was delivered to the wrong treatment site for each patient.

The licensee concluded that each patient received 312 cGy (312 rad) instead of the prescribed dose of 500 cGy (500 rad) (an underdose of 37.6 percent), and an additional length of 5 cm (1.97 in) received an unintended dose of 312 cGy (312 rad).

The licensee did inform the patients of the misadministrations, and does not expect the patients to have any adverse effects from the misadministrations.

Cause or Causes

A wrong step size was entered into the HDR unit's control console because the licensee did not follow its Quality Management Procedures (QMP). The QMP requires that treatment planning information be checked by the person entering the data in the control console, and then verified by the authorized user.

Actions Taken to Prevent Recurrence

Licensee

The licensee's authorized user and the HDR physicist will extract the pre-treatment printout of the input parameters from the HDR treatment console, review the input data for accuracy, and compare it with the written directive. Both the authorized user and the HDR physicist will then initial the printout before the HDR treatment is initiated.

NRC

NRC determined that the incidents occurred because the licensee did not follow its QMP. NRC contracted a medical consultant to evaluate the health effects on the patients from the misadministrations. Subsequently, the consultant determined no probable deterministic effects of the radiation exposure to the unintended site were expected.

96–10 Medical Brachytherapy Misadministration at the University of Wisconsin in Madison, Wisconsin

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

Date and Place

October 19, 1995; University of Wisconsin; Madison, Wisconsin.

Nature and Probable Consequences

A patient had two separate lung tumors, one in the lower section of the right lung and one in the middle section of the left lung. The patient was prescribed a total treatment dose of 1600 centigray (cGy) (1600 rad), with each tumor to receive a total dose of 800 cGy (800 rad). The total treatment dose was to be administered in four fractions of 400 cGy (400 rad) each over 2 days using a high dose rate (HDR) remote afterloader unit having an iridium-192 source. Each fraction was to be administered in two parts; a 200 cGy (200 rad) dose to the lower section of the right lung followed by a 200 cGy (200 rad) dose to the middle section of the left lung. Catheters of appropriate length were inserted into each lung to guide the source during treatment; i.e., a long catheter was inserted into the right lung and a short catheter was inserted into the left lung.

While the HDR controller was inserting the source into the left lung during the first treatment fraction, the source stopped moving when it touched the bottom of the short catheter in the left lung even though the HDR controller was attempting to move it further into the left lung. Because the intended treatment sites had been reversed during treatment planning and were subsequently programmed into the HDR controller, the controller had positioned the source in the middle of the right lung during the first part of the first treatment fraction and was attempting to position the source in the lower part of the left lung during the second part of the first treatment fraction. Consequently, the middle of the right lung had received an unintended dose of 200 cGy (200 rad) during the first part of the first treatment fraction.

After the error was discovered, the correct treatments were delivered. The patient was notified of the misadministration both verbally and in writing. The referring physician was also notified.

An NRC medical consultant evaluated the misadministration and concluded that the patient would not have organ damage or long term biological effects.

Cause or Causes

When planning the treatment, the treating physicist deviated from standard protocol and used different dummy sources to obtain clearer opaque x-ray markers for source location. Upon recording the data, the planned source locations for each treatment fraction were reversed. An independent verification of the treatment plan by a second physicist did not include a review of the x-rays for proper source location, so the error was not immediately discovered.

Actions Taken To Prevent Recurrence

Licensee

The licensee revised its Quality Management Program to include an independent review of the x-rays for source location by a second physicist. Also, when there is a deviation from the protocol, the results must be documented and reviewed by a second physicist.

NRC

NRC conducted a special safety inspection in conjunction with a routine inspection. A Notice of Violation was issued for failing to establish adequate procedures to ensure that final treatment plans were in accordance with the written directive. The licensee responded in writing and no additional actions were required.

96–11 Medical Brachytherapy Misadministration at Thomas Jefferson University Hospital in Philadelphia, Pennsylvania

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

Date and Place

August 14, 1995; Thomas Jefferson University Hospital; Philadelphia, Pennsylvania.

Nature and Probable Consequences

A patient was undergoing brachytherapy treatment of the palate; i.e., the roof of the mouth. A total of 64 iridium-192 seeds, having a total activity of 1102.6 megabecquerel (29.8 millicurie), were inserted into six

catheters. Four of the catheters were sutured inside the mouth, and two were placed in the nostrils.

While making a routine visit to the patient, the prescribing physician noticed that two catheters were outside of the patient's mouth and had been taped to the patient's right cheek. Also, one of the two catheters remaining in the mouth was loose and its sutures were removed. Because the catheters were not properly positioned, the physician terminated the treatment.

The radioactive seeds were subsequently removed. The patient was informed both verbally and in writing that the sources had become dislodged and had consequently delivered radiation to the wrong treatment site. It was determined that the patient's cheek received a dose of 70 centigray (70 rad).

Cause or Causes

While responding to a call from the patient, a nurse noticed that two of the catheters were loose and subsequently taped them to the patient's cheek. The nurse had not been trained to recognize that the radioactive seeds were moved from their intended positions.

Actions Taken to Prevent Recurrence

Licensee

Refresher in-service training was given to the nurses who care for brachytherapy patients. Emphasis was placed on identifying radioactive sources and handling them properly under normal and emergency conditions. Also, the nurses will be briefed on the details of a planned treatment at the time the sources are implanted with emphasis on radiation safety issues. Finally, physicians will visit implant patients at least twice daily during treatment.

NRC

After conducting an investigation, NRC determined that the event was a misadministration. An NRC medical consultant concluded that no significant injury would be expected. A Notice of Violation was issued with one Severity Level IV violation.

96–12 Medical Brachytherapy Misadministration at Macombe Hospital Center in Warren, Michigan

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

Date and Place

March 11, 1996; Macombe Hospital Center; Warren, Michigan.

Nature and Probable Consequences

A patient was undergoing a cervical boost brachytherapy treatment with a manually afterloaded standard gynecological applicator using cesium-137 sources. Approximately 100 minutes after the treatment was started, a nurse found one of the sources from the applicator lying on the sheet between the patient's legs. The dislodged source contained 1.29 gigabecquerel (34.8 millicurie) of cesium-137 and was intended for the right ovoid of the applicator. The nurse placed the source into the portable shielding that was available in the room and notified the radiation safety officer. The radiation safety officer immediately returned to the patient's room with the physician, who inserted the source into the right ovoid for the remainder of the prescribed 48 hours of treatment.

The licensee calculated that the unintended skin dose to the patient's upper inner thighs was 5 centigray (cGy) (5 rad). NRC concurred with the licensee's calculation and did not obtain a medical consultant. The dose of 5 cGy (5 rad) is within the occupational exposure limit and is not expected to result in deleterious effects to the patient. The patient and physician were notified of the misadministration.

Cause or Causes

When the radiation oncologist manually afterloaded the sources from the right and left carriers into the ovoids, difficulty was encountered in identifying the correct carrier for the right ovoid. Also, the hinge on the correct carrier for the right ovoid was tight. The radiation oncologist believed that the sealed source dislodged from the carrier bucket when the problem with the hinge was encountered.

Actions Taken To Prevent Recurrence

Licensee

To prevent recurrence, the licensee will: (1) ensure that the carrier bucket hinges are working properly prior to loading the source into the bucket; (2) inscribe the handles of the ovoid carriers, with ''R'' for right ovoid and ''L'' for left ovoid, so that they can be readily identified without difficulty; (3) require the physicist to observe the radiation oncologist during the afterloading procedure in order to detect a dislodged source; and (4) require that the radiation oncologist complete a visual check of the bed sheets and immediate area before leaving the room.

NRC

NRC conducted a special safety inspection. NRC issued a Notice of Violation for failing to meet the objective that each administration is in accordance with a written directive. The inspection showed that actions had been taken to correct the violation and to prevent recurrence.

96–13 Medical Brachytherapy Misadministration at Unity Hospital in Fridley, Minnesota

One of the AO reporting criteria notes that administering a therapeutic dose such that the actual dose is less than 0.5 times the prescribed dose should be considered an AO.

Date and Place

August 19–20, 1996; Unity Hospital; Fridley, Minnesota.

Nature and Probable Consequences

A patient was prescribed a dose of 2500 centigray (cGy) (2500 rad) for a gynecological brachytherapy procedure, using a gynecological applicator containing cesium-137 sources in two ovoids. Because 3-centimeter (cm) diameter caps had been used on the ovoids of the gynecological applicator, instead of the intended 2-cm diameter caps, the patient received a dose of 1186 cGy (1186 rad) to the vaginal surface.

With the addition of the external beam therapy that the patient had received prior to this treatment, the total administered dose was 5680 cGy (5680 rad). The treating physician determined that the total administered dose was within the medically accepted range of treatment, and that no negative effects to the patient were expected. The treating physician did not plan to administer any further radiation treatments to the patient to compensate for the underdose.

The patient was notified of the misadministration both verbally and in writing. The referring physician was also notified.

Cause or Causes

There was poor communication between the treating physician and the dosimetrist who prepared the treatment plan regarding the size of the ovoid caps to be used for the treatment. (The treating physician may select 2-cm diameter caps, 3-cm diameter caps, or no caps at all from an applicator kit, depending on the anatomy of the patient.) In addition, licensee personnel may have become desensitized to the possibility that an ovoid cap size different than 2-cm in diameter could be used; the treating physician failed to follow-up on earlier instructions to the dosimetrist to verify the correct cap size used; and the applicator kit was not returned immediately to the radiation

oncology department following the implant of the applicator device.

Actions Taken To Prevent Recurrence

Licensee

The licensee revised its written-directive form to require the treating physician to enter the cap size when ovoids are used, and for a second person to verify that the information was entered. If the entry on the form is not made, the person confirming the information must independently verify which size ovoid caps were used.

NRC

NRC conducted a special safety inspection on September 9, 1996. No violations of NRC requirements were identified during the course of this inspection.

96–14 Radiopharmaceutical Misadministration at Universal Imaging in Taylor, Michigan

One of the AO reporting criteria notes that administering a radiopharmaceutical other than the one intended, where the actual dose is greater than five times the prescribed dose, can be considered an AO.

Date and Place

March 18, 1996; Universal Imaging, Inc.; Taylor, Michigan.

Nature and Probable Consequences

A patient was prescribed a 7.4 megabecquerel (MBq) (200 microcurie [μCi]) dosage of iodide-123 (I–123) for a thyroid scan, but was administered 7.4 MBq (200 μCi) of iodide-131 (I–131) instead.

The referring physician's directive stated that I–123 was to be used. (This is the only isotope of iodine used at the facility.) A technologist then accidently ordered the I–131 from the nuclear pharmacy. A second technologist recognized that the I–131 was different from the I–123 routinely used, but assumed that it was prescribed and administered it anyway.

The licensee estimated that the dose to the patient's thyroid was 104 centigray (104 rad).

The referring physician was notified of the misadministration. The referring physician decided not to notify the patient because the information would be harmful to the patient.

An NRC medical consultant reviewed the event and determined that the impact of the misadministration on the status of the patient's health was very low, and that no specific medical follow-up care was necessary.

Cause or Causes

The misadministration was apparently caused by a lack of sufficient oversight of licensed activities, inadequate training, and failure to establish a written protocol for ordering and verifying radiopharmaceuticals.

Actions Taken To Prevent Recurrence

Licensee

The licensee implemented the following corrective actions: (1) All technologists were informed not to use any radiopharmaceutical that was not listed in the licensee's ''Prescribed Dosage List''; (2) orders must be sent to the nuclear pharmacy via facsimile, rather than over the telephone; (3) the nuclear pharmacy was instructed not to deliver I–131, I–125, or any other therapeutic radiopharmaceutical to the licensee; (4) all technologists were informed in writing not to proceed if they were unsure of any procedure; and (5) copies of radiopharmaceutical orders and their activities were to be checked against receipts.

The licensee is not required to have written directives to follow. This is because it does not perform therapy of any kind, does not use I–125 or I–131 in quantities greater than 1.11 MBq (30 μCi), and has no Quality Management Program.

NRC

NRC conducted an inspection. Based on the results of the inspection, eight apparent violations were identified and are being considered for escalated enforcement action. A predecisional enforcement conference was held to discuss the apparent violations and any potential enforcement action is pending.

96–15 Radiopharmaceutical Misadministration at Miami Valley Hospital in Dayton, Ohio

One of the AO reporting criteria notes that if an actual diagnostic dose of a radiopharmaceutical is greater than five times the prescribed dose it can be considered an AO.

Date and Place

September 21, 1995; Miami Valley Hospital; Dayton, Ohio.

Nature and Probable Consequences

A patient was administered a 2.8 megabecquerel (MBq) (77 microcurie [μCi]) dosage of iodine-131 (I–131) for a thyroid uptake study, rather than the prescribed dosage range of 0.19 to 0.37 MBq (5 to 10 μCi) of I–131. The licensee determined that the dose to the patient's thyroid was 80.85 centigray (80.85 rad).

The patient was informed of the misadministration in writing. The patient's referring physician was also notified.

An NRC medical consultant determined that no adverse health effects are expected from the additional dosage.

Cause or Causes

A nuclear medicine technologist inadvertently picked-up the wrong capsule, and in accordance with the licensee's practice did not calibrate the dosage in the dose calibrator prior to administration. The licensee's staff did not believe there was a requirement to assay dosages below 1.11 MBq (30 μCi).

Actions Taken To Prevent Recurrence

Licensee

The licensee implemented procedures to require that all dosages must be assayed regardless of their activity, and to review the assay of dosages on a quarterly basis.

NRC

NRC conducted a special safety inspection. NRC issued a Notice of Violation for failing to measure dosages containing less than 1.11 MBq (30 μCi) before they were administered to patients for medical use. The licensee responded in writing and no additional actions are required.

96–16 Radiopharmaceutical Misadministration at St. Joseph Mercy Hospital in Ann Arbor, Michigan

One of the AO reporting criteria notes that if an actual diagnostic dose of a radiopharmaceutical is greater than five times the prescribed dose it can be considered an AO.

Date and Place

April 9, 1996; St. Joseph Mercy Hospital; Ann Arbor, Michigan.

Nature and Probable Consequences

A patient was administered a 596 megabecquerel (MBq) (16.1 millicurie [mCi]) dosage of iodine-131 rather than the prescribed 122 MBq (3.3 mCi) dosage of I–131 for a diagnostic study of the neck and chest.

The misadministration was discovered after a vial, intended for another patient, was assayed and found to contain 122 MBq (3.3 mCi) instead of the expected 633 MBq (17.1 mCi). The patient was notified of the misadministration. The patient's referring physician was also notified.

The patient's thyroid gland had been removed previously and therefore the licensee anticipated minimal medical consequences. NRC contracted with the Oak Ridge Institute for Science and Education to conduct an assessment of

the I–131 dose to the patient. The assessment concluded that since the patient had no thyroid, the maximum dose was misadministered to the patient's bladder wall and was equal to 48.3 centigray (48.3 rad).

Cause or Causes

The technologist, when administering the dosage, mistakenly picked up a wrong radiopharmaceutical vial.

Actions Taken To Prevent Recurrence

Licensee

Licensee personnel failed to completely follow the written Quality Management Program.

NRC

NRC conducted a special safety inspection. NRC issued a Notice of Violation for failure of the supervised user (technologist) to follow instructions in accordance with the written directive.

96–17 Radiopharmaceutical Misadministration at the Veteran Affairs Medical Center in Charleston, South Carolina

One of the AO reporting criteria notes that administering a therapeutic dose such that the actual dose is less than 0.5 times the prescribed dose should be considered an AO.

Date and Place

January 9, 1996; Veteran Affairs Medical Center; Charleston, South Carolina.

Nature and Probable Consequences

An outpatient was administered 277.5 megabecquerel (MBq) (7.5 millicurie [mCi]) of a prescribed 573.5 MBq (15.5 mCi) dosage of iodine-131 (I–131) in liquid form. The error was discovered when the licensee rechecked the prescription vial with a dose calibrator after the administration to verify that the patient had received all of the prescribed dose. The licensee discovered that approximately 296 MBq (8 mCi) of the prescribed dosage had been retained in the vial cap, and consequently was not administered to the patient. The patient was informed of the event and was subsequently administered an additional 296 MBq (8 mCi) to make up for the underdosage. The licensee also notified the referring physician of the misadministration. The licensee expects no adverse effects to the patient from the misadministration.

Cause or Causes

The root cause for the misadministration was a pronounced reaction of the I–131 with the vial cap, thereby allowing a significant portion of the radioactive material to bind itself to the cap.

Actions Taken to Prevent Recurrence

Licensee

The licensee's Radiation Safety Officer investigated the incident. Bioassays were conducted on the individuals who handled and administered the I–131 dose, and all were found to be negative. The licensee also revised its policy and procedures to require that only I–131 in capsule form be used in the future.

NRC

NRC conducted a special inspection to review the circumstances surrounding the misadministration, and identified no violations of NRC requirements.

The State Agency is working with the nuclear pharmacy that filled the prescription and the intermediate processor of the I–131, both South Carolina state licensees, to determine the cause of event. The nuclear pharmacy informed its customers of the event.

96–18 Radiopharmaceutical Misadministration at Queen's Medical Center in Honolulu, Hawaii

One of the AO reporting criteria notes that administering a therapeutic dose of a radiopharmaceutical differing from the prescribed dose by more than 10 percent, and the actual dose is less than 0.5 times the prescribed dose, can be considered an AO.

Date and Place

December 8, 1995; Queen's Medical Center; Honolulu, Hawaii.

Nature and Probable Consequences

A patient was prescribed a dosage of 18.5 megabecquerel (MBq) (0.5 millicurie [mCi]) of phosphorus-32 (P–32) to be administered to the wrist for treatment of symptoms related to rheumatoid arthritis, but was administered 6.179 MBq (0.167 mCi) instead. The dosage was administered via a saline solution.

Prior to treatment, the volume of the patient's wrist-joint space was to be determined using fluoroscopy so that the proper volume of liquid would be injected. Also, two syringes were to be prepared. One was to contain 18.5 MBq (0.5 mCi) of P–32 in a 0.25 milliliter (ml) volume, and the other was to contain 18.5 MBq (0.5 mCi) of P–32 in a 0.5 ml volume. The appropriate syringe was to be chosen based upon the results of the fluoroscopy.

Because of poor communication, a technologist erroneously prepared one syringe containing 6.179 MBq (0.167 mCi) in a 0.25 ml volume and another syringe containing 12.32 MBq (0.333 mCi) in a 0.5 ml volume. The syringes were not labeled.

Based upon the results of the fluoroscopy, the administering physician chose the syringe with the 0.25 ml volume, believing that it contained 18.5 MBq (0.5 mCi) of P–32. However, the 0.25 ml volume contained only 6.179 MBq (0.167 mCi), which was one-third of the intended dosage. After the administration, the technologist who prepared the dosages asked why both syringes had not been used and explained how they were prepared.

The patient was notified of the misadministration in writing.

The two physicians involved with the misadministration have not observed any adverse health effects to the patient, and do not expect any. NRC determined that a medical consultant would not be required to review the case.

Cause or Causes

The details of the prescribed dosages were not properly communicated to the technologist who prepared the two syringes, the details were not independently confirmed by other licensee personnel, and the written procedure for preparing the dosages did not specify multiple syringe volumes.

Actions Taken to Prevent Recurrence

Licensee

The licensee now requires the prescribing physician to establish a standard activity and volume for each treatment site, and the injecting physician to verbally repeat this information and ask the technologist to verbally confirm it prior to the administration.

NRC

NRC conducted a special inspection and issued a Notice of Violation for deficiencies in the Quality Management Program.

Dated at Rockville, Maryland, this 25th day of April, 1997.

For the Nuclear Regulatory Commission.

John C. Hoyle,

Secretary of the Commission.

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