NMSS Licensee Newsletter

U.S. Nuclear Regulatory Commission

Office of Nuclear Material Safety and Safeguards

NUREG/BR-0117
No. 01-3
September-October 2001

NMSS Licensee Newsletter (September - October 2001)

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RISK-INFORMING AND PERFORMANCE-BASING INSPECTION PROCEDURES

The Spent Fuel Project Office (SFPO) is working with the Office of Nuclear Reactor Regulation (NRR) and coordinating with the Risk Task Group of the Office of Nuclear Material Safety and Safeguards (NMSS) to risk-inform and performance-base the inspection procedures used for independent spent fuel storage installations (ISFSIs). The changes to procedures will be accomplished in a short-term phase and a long-term phase.

The short-term approach is to be completed by the end of 2001. The elements of this approach are to:

a. Risk-prioritize the existing inspection procedure subsection, using available risk/ consequence information and an expert panel approach.

b. Apply inspection resources commensurate with risk and the performance history of the inspected entity. (New licensees or fabricators will initially get more in-depth inspections until a performance history is established.)

The long-term approach is conceptualized to more closely align with the NRR risk- informed inspection approach described in the reactor oversight process. The elements of the long-term approach are to:

a. Complete a Probabilistic Risk Assessment (PRA) for ISFSIs. A PRA is currently being prepared by the Office of Nuclear Regulatory Research. An initial product from the PRA is predicted for fiscal year 2002.

b. Using the PRA results, explore the possibility of adopting an oversight program that is based on risk and performance indicators, in a manner similar to the NRR program. Also, evaluate ISFSI inspection resources using the new process. Additionally, evaluate a significance determination process for assessing the significance of inspection findings.

c. Revise inspection procedures appropriately.

The short-term approach uses risk/consequence categories used as ranking factors applied to inspection procedure subsections. The categories were applied to the existing inspection procedure requirements, using an expert-panel approach similar to the approach used by NRR, when risk- informing elements of the reactor oversight process that did not have PRAs associated with the element (e.g., security and emergency preparedness inspections). This approach uses a risk-informed, not risk-based, approach.

Changes in Inspection Report Documentation Methods

U.S. Nuclear Regulatory Commission (NRC) Manual Chapter (MC) 0610, "Inspection Reports," Appendix D, provides guidance on inspection documentation for NMSS inspections. MC 0610 allows for three methods of inspection documentation: narrative, NRC Form 591, and inspector notes. SFPO has traditionally used the narrative format for documenting inspection findings and any related enforcement actions, whereas materials inspections typically use the latter two methods.

SFPO plans to implement a pilot program that will use both the NRC Form 591 and inspector notes, as allowed by MC 0610. NRC Form 591, used for documenting enforcement status, is typically provided to a licensee at the end of an inspection, whereas inspector notes, used to document inspection findings, are prepared in-office after the inspection. Since inspector notes can be handwritten or typed, and only require review, and approval at the section-chief level, SFPO anticipates resource savings through simplification of the report documentation, review, and approval process. This effort will also help NMSS material-inspection documentation to be performed in a more consistent manner. NRC and stakeholder resource savings are expected through use of NRC Form 591, since documentation of, and response to, non-escalated enforcement actions, will be greatly simplified.

Narrative reports will continue to be used in cases of escalated enforcement, reactive or special team inspections, and where serious programmatic issues are identified. The pilot program will start once the SFPO inspection MC has been revised to reflect the alternative documentation methods.

Meeting NRC Strategic Plan Goals

SFPO believes that both efforts described above are consistent with and address several of the performance goals stated in the NRC fiscal year 2000 Strategic Plan in the Nuclear Waste Safety arena. Specific goals addressed through these two efforts are: 1) make NRC activities and decisions more effective, efficient, and realistic; and 2) reduce unnecessary regulatory burden on stakeholders. These efforts will not adversely affect the overall strategic goal of maintaining the protection of the public health and safety and the environment, and the common defense and security.

(Contact: Robert Temps, 301-415-2552; e-mail: rrt@nrc.gov)

PUBLICATION OF NUREG- 1717, "SYSTEMATIC RADIOLOGICAL ASSESSMENT OF EXEMPTIONS FOR SOURCE AND BYPRODUCT MATERIALS"

NUREG–1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials" has been published in final form. The document contains potential radiation doses associated with the current exemptions for byproduct and source material in Title 10, of the *U.S.Code of Federal Regulations* (10 CFR). The study was initiated to assess doses using methods consistent with the current requirements in 10 CFR Part 20 and current information on inventories and uses of the exempt materials. The information contained in this NUREG can be used to review and examine the radiological impact of current exemptions.

Potential radiation doses were estimated for the normal life cycle of a particular product or material,

including distribution and transport, intended or expected routine use, and disposal, over a 1-year time period. Also presented is an assessment of potential radiological impacts, associated with selected products containing byproduct material, which currently may only be used under general licenses and may be candidates for exemptions from licensing requirements.

The NUREG has been sent to all the Agreement States, general licensees, and known facilities using or manufacturing products or materials containing exempt quantities of radioactive material. The NUREG will be available at http://www.nrc.gov/, under "Technical Reports in the NUREG Series" on the "Reference Library" page.

(Contact: Rosemary Hogan, RES, 301-415-7484; e-mail: rth@nrc.gov)

SELECTED *FEDERAL REGISTER* NOTICES

(June 1, 2001 - August 31, 2001)

NOTE: U.S. Nuclear Regulatory Commission (NRC) contacts may be reached by mail at the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

FINAL RULES

"Public Health and Environmental Radiation Protection Standards for Yucca Mountain, NV," 66 FR 32074, June 13, 2001 (Environmental Protection Agency).

Contact: Ray Clark, Office of Radiation and Indoor Air, U.S. Environmental Protection Agency, Washington, DC. 20460-0001; telephone 202-564-9310.

"Revision of Fee Schedules; Fee Recovery for FY 2001," 66 FR 32452, June 14, 2001.

Contact: Glenda Jackson, OFCO, 301-415-6057; e-mail: gcj@nrc.gov.

"List of Approved Spent Fuel Storage Casks: Standardized NUHOMS -24P and -52B Revision" (Direct Final Rule), 66 FR 34523, June 29, 2001.

Contact: Gordon Gundersen, NMSS , 301-415-6195; e-mail: geg1@nrc.gov.

"Revision of Fee Schedules; Fee Recovery for FY 2001; Correction," 66 FR 35529, July 6, 2001.

Contact: Glenda Jackson, OCFO, 301-415-6057; e-mail : gcj@nrc.gov.

"List of Approved Spent Fuel Storage Casks: Westinghouse MC-10 Termination (Direct Final Rule)," 66 FR 43761, August 12, 2001.

Contact: Jayne McCausland, NMSS, 301-415-6219; e-mail: jmm2@nrc.gov.

"List of Approved Spent Fuel Storage Casks: NAC-MPC Revision," 66 FR 45749, August 30, 2001.

Contact: Jayne McCausland, NMSS, 301-415-6219; e-mail: jmm2@nrc.gov.

PROPOSED RULES

"List of Approved Spent Fuel Storage Casks: Standardized NUHOMS -24P and -52B Revision (Companion Proposed Rule)," 66 FR 34588, June 29, 2001.

Contact: Gordon Gundersen, NMSS, 301-415-6195; e-mail: geg1@nrc.gov.

"Revision of the Skin Dose Limit," 66 FR 36502, July 12, 2001.

Contact: Alan K. Roecklein, RES, 301-415-3883; e-mail: akr@nrc.gov.

"List of Approved Spent Fuel Storage Casks: Westinghouse MC-10 Termination," 66 FR 43810, August 12, 2001.

Contact: Jayne McCausland, 301-415-6219; e-mail: jmm2@nrc.gov.

"List of Approved Spent Fuel Storage Casks: NAC-MPC Revision," 66 FR 45788, August 30, 2001.

Contact: Jayne McCausland, NMSS, 301-415-6219; e-mail: jmm2@nrc.gov.

OTHER NOTICES

"Governors' Designees Receiving Advance Notification of Transportation of Nuclear Waste," 66 FR 34724, June 29, 2001.

Contact: Spiros Droggitis, OSTP, 301-415-2367; e-mail: scd@nrc.gov.

"Memorandum of Understanding between the U.S. Nuclear Regulatory Commission and the U.S. Army Corps of Engineers for Coordination of Cleanup and Decommissioning of the Formerly Utilized Sites Remedial Action Program (FUSRAP) Sites with NRC-Licensed Facilities," 66 FR 36606, July 12, 2001.

Contact: Amir Kouhestani, NMSS, 301-415-0023; fax (301) 415-5398; e-mail: aak@nrc.gov.

(General Contact: Paul Goldberg, NMSS, 301-415-7842; e-mail: pfg@nrc.gov)

GENERIC COMMUNICATIONS ISSUED (MAY 1, 2001 - AUGUST 31, 2001)

Note that these are only summaries of U.S. Nuclear Regulatory Commission (NRC) generic communications. If one of these documents appears relevant to your needs and you have not received it, please call one of the technical contacts listed below. The Internet address for the NRC library of generic communications is -- www.nrc.gov/NRC/GENACT/GC/index.html. Please note that this address is case-sensitive and must be entered exactly as shown.

Information Notices (INs)

IN 2001-08, "Treatment Planning System Errors Result in Deaths of Overseas Radiation Therapy Patients," was issued on June 1, 2001. This notice was issued to all medical licensees to inform them of an international event where several patients were overexposed from external beam therapy treatments, because of human errors. The notice provided preliminary information on the event and stated that an update would be provided once an international investigation team released its findings.

(Contacts: Robert Ayres, NMSS, 301-415-5746, e-mail: rxa1@nrc.gov;

Donna-Beth Howe, NMSS, 301-415-7848, e-mail: dbh@nrc.gov;

Roberto J. Torres, NMSS, 301-415-8112, e-mail: rjt@nrc.gov)

IN 2001-08, Supplement 1, "Update on the Investigation of Patient Deaths in Panama, Following Radiation Therapy Overexposures," was issued on June 6, 2001. This notice was issued to all medical licensees to inform them of the preliminary findings from the International Atomic Energy Agency investigation of patient overdoses received during radiation therapy treatments at the National Oncology Institute in Panama.

(Contacts: Robert Ayres, NMSS, 301-415-5746, e-mail: rxa1@nrc.gov;

Donna-Beth Howe, NMSS, 301-415-7848, e-mail: dbh@nrc.gov;

Roberto J. Torres, NMSS, 301-415-8112, e-mail: rjt@nrc.gov)

IN 2001-11, "Thefts of Portable Gauges," was issued on July 13, 2001. This notice was issued to all portable gauge licensees to inform them of recent incidents of thefts of portable gauges, and to remind them of their responsibilities to prevent loss and damage to portable gauges.

(Contact: Samuel L. Pettijohn, NMSS, 301 415-6822, e-mail: slp@nrc.gov)

Regulatory Issue Summaries (RIS')

RIS 2001-13, "10 CFR Part 40 Exemptions for Uranium Contained in Aircraft Counterweights," was issued on July 20, 2001. This summary

was issued to all holders of licenses authorized to manufacture aircraft counterweights containing uranium, and organizations and end users that may possess such counterweights. The RIS highlights the restrictions, applicable to counterweights and other products containing uranium, that are exempt from licensing requirements. Furthermore, the options for transfer and disposal of such products were discussed.

(Contact: Joseph E. DeCicco, NMSS, 301-415-7833, e-mail: jxd1@nrc.gov)

RIS 2001-18, "Requirements for Oath or Affirmation," was issued on August 22, 2001. This summary was issued to holders of licenses issued under 10 CFR Part 72 and holders of certificates issued under 10 CFR Part 76. The RIS describes an alternate means of complying with the oath or affirmation requirement besides using a notary public. This RIS also clarifies the level of authority for signing documents that require an oath or affirmation.

(Contacts: Dan Martin, NMSS, 301-415-2754, e-mail: dem1@nrc.gov;

Ramin R. Assa, NRR, 301-415-1391, e-mail: rra@nrc.gov)

(General Contact: Mark A. Sitek, NMSS, 301-415-5799, e-mail: mas3@nrc.gov)

SIGNIFICANT ENFORCEMENT ACTIONS

Detailed information about these enforcement actions can be accessed via the U. S. Nuclear Regulatory Commission's (NRC's) homepage [http://www.nrc.gov/OE/]. Click on "Enforcement Actions." Cases are listed alphabetically. To access the complete enforcement action, click on the highlighted text after the name of the case.

Medical

Franklin Hospital Corporation, Franklin, Virginia, EA 01-200

On August 1, 2001, a Notice of Violation was issued for a Severity Level III violation involving the licensee's failure to maintain control and constant surveillance of licensed byproduct material involving radiopharmaceuticals in an unrestricted area. The licensed material involved radiopharmaceuticals that were located in the nuclear medicine hot laboratory. The violation occurred during the inspection, when the NRC inspector observed that the door to the nuclear medicine hot laboratory was open and the area unattended and unsecured by the Nuclear Medicine Technologists.

South Pittsburgh Cancer Center, Pittsburgh, Pennsylvania, EA 01-132

On August 22, 2001, a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $8800 was issued for a Severity Level II violation involving the deliberate possession of depleted uranium (in the form of bricks used for shielding within two linear accelerators) without authorization in a specific license issued by NRC.

Gauges

Martin Marietta Aggregates, Raleigh, North Carolina, EA 01-163

On August 21, 2001, a Notice of Violation was issued for a Severity Level III violation involving the unauthorized transfer of a fixed gauging device containing 1850 mega-becquerels (50 millicuries) of cesium-137 to a metal recycling facility not authorized to receive and possess such licensed material. The transfer occurred before February 16, 2001, the effective date of the change to the Enforcement Policy, which provided that notwithstanding the outcome of the normal civil penalty assessment process, NRC would normally issue a civil penalty in cases involving the loss, abandonment, or improper transfer or disposal of sources. Therefore, NRC did use discretion to issue a civil penalty in this case.

Testwell Laboratories, Inc., Ossining, New York, EA 01-149

On June 14, 2001, a Notice of Violation was issued for a Severity Level III violation, based on Testwell Laboratories, Inc., a licensee of the State of New

York, using portable gauges in New Jersey, a non-Agreement State, without a specific license from NRC and without filing a Form 241, "Report of Proposed Activities in Non-Agreement State," with NRC.

Draper Aden Associates, Richmond, Virginia , EA 01-107

On June 4, 2001, a Notice of Violation was issued for a Severity Level III violation, involving the failure to properly block and brace a portable gauge before and during transport, that resulted in the loss of control of the gauge. The loss occurred before February 16, 2001, the effective date of the change to the Enforcement Policy, which provided that notwithstanding the outcome of the normal civil penalty assessment process, NRC would normally issue a civil penalty in cases involving the loss, abandonment, or improper transfer or disposal of sources. Therefore, NRC did use discretion to issue a civil penalty in this case.

Midwest Testing, Inc., Bridgeton, Missouri, EA 01-119

On July 20, 2001, a Notice of Violation and Proposed Imposition of Civil Penalty was issued for a Severity Level III violation involving the failure to control and maintain constant surveillance of a portable density gauge, which resulted in the loss of the gauge. The loss occurred after February 16, 2001. Therefore, although the normal civil penalty assessment process would have fully mitigated the civil penalty, a penalty was proposed in accordance with Section VII.A.1.g. of the Enforcement Policy, to emphasize the significance of the loss of licensed material, in this case.

Macia Consulting Enterprises, Inc., Poughkeepsie, New York, EA 01-123

On May 31, 2001, a Notice of Violation was issued for a Severity Level III violation involving the failure to maintain required security of two portable nuclear density gauges containing 296 megabecquerels (MBq) 8 millicuries (mCi) of cesium-137, and 1480 MBq (40 mCi) of americium-241 at a temporary job site (Newark International Airport).

Turabo Corporation, Caguas, Puerto Rico, EA 01-126

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $3000 was issued for a Severity Level III violation involving the failure to secure from unauthorized removal, or limit access to, two gauges containing approximately 296 megabecquerels (MBq) [8 millicuries (mCi)] of cesium-137, and 1850 MBq (50 mCi) of americium-241, and failure to control and maintain constant surveillance of this licensed material.

SWVA, Inc. d/b/a Steel of West Virginia, Inc., Huntington, West Virginia, EA 01-128

On June 27, 2001, a Notice of Violation was issued for a Severity Level III violation involving the failure to secure from unauthorized removal, or limit access to, three gauges containing 185 gigabecquerels (500 millicuries) of cesium-137, and failure to control and maintain constant surveillance of this licensed material.

Radiography

Stork MSC, Louisville, Kentucky, EA 01-164

On August 3, 2001, a Notice of Violation was issued for a Severity Level III violation involving the failure to control or maintain constant surveillance of a radiography exposure device containing approximately 1073 gigabecquerels (29 curies) of iridium-192 in an unrestricted area.

Allied Inspection Services, Inc., St. Clair, Michigan, EA 01-099

On June 4, 2001, a Notice of Violation was issued for a Severity Level III violation involving the willful failure to test exposure devices using depleted uranium (DU) shielding and an "S" tube configuration for DU contamination, within the required interval.

Vendors

JL Shepherd & Associates, San Fernando, California, EA 01-164

On July 3, 2001, an immediately effective Order Withdrawing Quality Assurance Approval was issued. The Order was based on the Agency's lack of confidence that the company would implement the NRC-approved Quality Assurance Program, in accordance with NRC regulations, in a manner that would assure the required preparation and use of transportation packages, in full conformance with these NRC regulations.

SMI East Coast Medical Waste, Inc., Morrisville, Pennsylvania, EA 01-064

On August 16, 2001, a Notice of Violation was issued for a Severity Level III violation involving the company's willful actions in receiving byproduct material that it was not authorized to possess, in accordance with a general or specific license, and in providing NRC with incomplete and inaccurate information.

Other

Framatome ANP Richland, Inc., Richland, Washington, EA 99-154

On June 5, 2001, a Notice of Violation was issued for a Severity Level III problem involving willfully: (1) shipping licensed material in unapproved packages; (2) exporting licensed material that did not meet required packaging requirements; (3) certifying, in shipping papers, that an export shipment complied with applicable shipping requirements; and (4) failing to maintain approved operating procedures.

Arthur Brisbane Child Treatment Center, Farmindale, New Jersey EA 99-171

On August 16, 2001, a Notice of Violation was issued for a Severity Level III problem involving deliberate improper disposal of radioactive material generated from the cleanup of a broken exit sign and deliberate submittal of inaccurate information to NRC. Although a base civil penalty would normally be proposed for this case, NRC exercised enforcement discretion in accordance with Section VII.B.6 of the Enforcement Policy and refrained from issuing a civil penalty because the licensee was issued a civil penalty for the event by the State of South Carolina, and the licensee is no longer a licensee.

United States Enrichment Corporation, Paducah, Kentucky, EA 99-256 and EA 00-047

On January 3, 2001, a Notice of Violation was issued for a Severity Level III problem involving: (1) creation of classified information on an unclassified computer system; and (2) deliberate failure to report the infraction to the NRC Regional Administrator per regulation; and a Severity Level III violation involving the deliberate failure to initiate a corrective action report for the security infraction.

Black Warrior Wireline Corporation, Gray, Louisiana, EA 01-095

On May 27, 2001, a Notice of Violation was issued for a Severity Level III violation involving the failure of Black Warrior Wireline Corporation, a licensee of the State of Louisiana, to file NRC Form 241, "Report of Proposed Activities in Non-Agreement State, Areas of Exclusive Federal Jurisdiction, or Offshore Waters," before conducting well-logging operations using americium-241/beryllium sealed sources in offshore waters off the Gulf of Mexico in areas of Federal jurisdiction.

Mallinckrodt, Inc., St. Louis, Missouri, EA 01-108

On July 3, 2001, a Notice of Violation was issued for a Severity Level III violation involving the failure to prepare a package containing licensed material that was transported outside the confines of the licensee's plant, so that under conditions normally incident to transport, the radiation levels would not exceed 2 millisievert (200 millirems) per hour at any point on the external surface of the package.

(Contact: John Lubinski, OE 301 415-2740; e-mail:jul@nrc.gov)

SIGNIFICANT EVENTS

The U.S. Nuclear Regulatory Commission (NRC) is providing summaries of these events to inform licensees of conditions they may encounter and of actions that may be taken to deal with them.

Event 1: Misadministration involving the TheraSphere® (yttrium-90 glass microspheres) device at the University of Maryland, Baltimore, Maryland.

Date and Place: October 17, 2000; University of Maryland; Baltimore, Maryland.

Nature and Probable Consequences: The licensee reported a medical event involving a 31-year-old male patient who received 23.4 percent of the prescribed 150- Gray (15,000 - rad) dose while undergoing brachytherapy treatment for liver cancer. The dose was administered using the TheraSphere® device, a brachytherapy system manufactured by MDS Nordion. The TheraSphere® device is comprised of a unit dose of yttrium-90 glass microspheres and a prepackaged administration kit. The administration assembly is used to infuse the yttrium-90 microsphere dose into the hepatic artery to treat liver cancer. The licensee had performed this procedure successfully 10 times before this event. The licensee's preliminary evaluation indicated a problem with the delivery system, resulting from an air leak in the rubber cap of the source vial at the site of the needle insertions. The licensee suspected that the inlet needle and the outlet needle may have been inserted too closely to each other, causing the rubber cap to lose its self-seal capability.

Subsequent to the licensee's evaluation of this misadministration, MDS Nordion performed a follow-up investigation on the involved TheraSphere® source vial, and an analysis of the cause of the event. It provided its findings and corrective actions in a report issued to the State of Maryland on February 20, 2001. MDS Nordion reported that the misadministration at the University of Maryland on October 17, 2000, occurred because the dose vial septum integrity was compromised during the placement of the inlet and outlet needles closely adjacent to each other, causing leakage from the source vial. Additional investigative studies with unused source vials showed that leaking at the dose vial septum through the needle punctures occurred when vial pressures were above atmospheric pressure.

Actions Taken To Prevent Recurrence

Licensee: The licensee temporarily suspended treatments using TheraSphere® (yttrium-90 glass microspheres) and resumed with assistance from the manufacturer.

MDS Nordion, TheraSphere® manufacturer: MDS Nordion now supplies sterile lucite needle guides, with all administration sets, for users to insert into the source vials before the needles are inserted. The needle guides provide accurate needle alignments through the source vial septum and also prevent needle-induced stress on the vial septums. MDS Nordion reported that the needle guides were used in 15 administrations at the University of Maryland between October 17, 2000, and February, 2001, without a repeat misadministration. No other TheraSphere® misadministrations have been reported to NRC since the event at the University of Maryland on October 17, 2000.

Event 2: Overexposure of an assistant radiographer working for Quality Inspection Services, in Jacksonville, Florida.

Date and Place: February 16, 2001; Jacksonville Electric Authority's Northside Repowering Station; Jacksonville, Florida.

Nature and Probable Consequences: The licensee reported a possible overexposure, to an assistant radiographer, of 39.2 centisievert (cSv) (rem) while performing industrial radiography. The radiographers were using an AEA Technology camera (model 660-B) with an iridium-192 source containing an activity of 2.15 tetrabecquerels (58 curies). After a radiography shot, the source was reeled into what was thought to be a locked, shielded, and fully retracted position. The radiographers failed to perform an adequate survey of the camera. The two radiographers involved

proceeded in front of the camera to set up the next shot, taking less than 5 minutes. When they went to unlock the source, they realized that it was not locked and noticed the survey meter was off-scale. They left the area and fully retracted the source. Both pocket dosimeters were off- scale. One radiographer's alarming ratemeter was turned off and the other radiographer's alarming ratemeter had a low battery and did not give an audible alarm. Film badges for the two radiographers showed exposures of 2.9 and 39.2 Centigray (rad). The assistant radiographer whose badge showed the highest exposure had blood drawn for analysis. In addition, the licensee conducted a re-enactment of the event. Landauer was asked to recheck the film badge results and the results were the same as initially reported. The licensee chose not to perform cytogenetic blood testing, but chose to perform a white blood cell count only. The Florida Bureau of Radiation Control would not expect to see a white blood cell deviation at that level of exposure. There have been no signs of erythema in the individual. During the Bureau's investigation it was determined that the assistant radiographer was exposed to 39.2 cSv (rem) (total effective dose equivalent), based on the measurement of the personnel monitoring badge worn by the individual.

Actions Taken To Prevent Recurrence

Licensee: Corrective actions taken include the designation of a new Radiation Safety Officer (RSO) who had completed the required RSO training, and development of quality assurance methods for instrument functionality, calibration due dates, battery replacement dates, and tracking of film badges. In addition, the licensee will develop a radiographer's awareness synopsis of the company's operating and emergency procedure manual.

State Agency: The Florida Bureau of Radiation Control cited the licensee for allowing the assistant radiographer to exceed the annual exposure limit, for not performing adequate surveys of the camera after each radiographic exposure, and for allowing the radiographers to perform work without operating ratemeters.

Event 3: High-Dose-Rate Remote Afterloader Medical Event at Saint Joseph's Regional Health Center in Hot Springs, Arkansas.

Date and Place: March 6, 2001; Saint Joseph's Regional Health Center; Hot Springs, Arkansas.

Nature and Probable Consequences: The licensee reported, on April 12, 2001, to the Arkansas Department of Health (ADH), a medical event involving the superficial treatment of skin cancer using iridium-192 (Ir-192) in a Varian VariSource High-Dose- Rate Remote Afterloader unit. ADH conducted an investigation of the event and determined that the radiation oncologist had prescribed a total dose of 6000 centigray (cGy) (rad) to the hand webbing between the index and middle fingers of the patient's left hand, to be delivered during 30 fractions of 200 cGy (rad) each. The patient had received 24 of the 30 fractions, beginning March 6, 2001, through April 11, 2001, for a total of 4800 cGy (rad) before the misadministration was identified. The treatment was administered using a custom-made applicator with imbedded FlexiGuide needles. The treatments were provided without performing an autoradiograph to confirm the treatment positions. On April 11, 2001, the radiation oncologist requested that the physicist verify the treatment site. Positioning of the treatment delivery system was confirmed by autoradiograph, and the length of the FlexiGuide needles was confirmed to be 25-centimeters (cm) [10-inches (in.)] long. The physicist had assumed that the needles were 20-cm (8-in.) long , instead of the actual 25-cm (10-in.) long, and therefore the remote afterloader unit was programmed incorrectly. This resulted in the Ir-192 source being incorrectly positioned approximately 5 cm (2 in.) from the intended treatment site. Therefore, the back of the patient's hand rather than the hand webbing was treated. The patient was notified of the medical event on April 11, 2001, and a revised treatment plan was developed. The licensee completed an evaluation of the possible health effects on the patient. The patient developed an area of erythema on the back of the left hand. No severe long-term effects are anticipated. However, it is likely the patient will have dry skin in that area. There is a very small risk (less than 5 percent) that the patient may develop scar tissue on the first and/or second dorsal interosseus muscles of the left hand or the extensor tendon and related connective tissues of the second digit of the left hand.

Actions Taken to Prevent Recurrence

Licensee: Corrective actions taken included documenting that the catheter lengths were verified, and confirmation of the catheter lengths (source location) by an autoradiograph, if possible. Also the licensee made changes to the checklist, on the Quality Management Program, for verification of proper procedures.

State Agency: The ADH, conducted an investigation of this medical event on April 13, 2001. Based on the results of the investigation, a notice of violation letter was issued on April 17, 2001. A Management Conference with the medical center administration was held to identify and discuss possible root causes and corrective actions. ADH approved the licensee's corrective actions, and the incident was closed on June 1, 2001.

Event 4: Sodium Iodide Radiopharmaceutical Medical Event at Parkview Memorial Hospital in Fort Wayne, Indiana.

Date and Place: March 26, 2001; Parkview Memorial Hospital; Fort Wayne, Indiana.

Nature and Probable Consequences: The licensee reported a medical event involving the administration of a thyroid ablation dose of iodine-131 (I-131) that was 28 percent higher than what was prescribed. A 65-year-old female patient was prescribed a dose of 4.63 gigabecquerels (GBq) 125 millicuries (mCi) of I-131. The technician inadvertently administered 5.92 GBq (160 mCi) of I-131. The error is attributed to the past practice of physicians ordering 5.55-GBq (150- mCi) doses (+/- 10 percent), which is what the technician ordered from the nuclear pharmacy without receipt of the written directive. The 5.55- GBq (150- mCi) dose was such a standard that when the therapy was scheduled, the computer automatically included "150-mCi" on the schedule. The licensee's Quality Management Program (QMP) form also listed "I-131 150- mCi scan" as a type of procedure to be conducted. The presribing doctor informed the patient and the referring physician informed of the event. The prescribing physician concluded that this event resulted in no change in the clinical outcome and that the increased dosage did not pose a high risk for the patient.

Actions Taken to Prevent Recurrence

Licensee: Corrective actions include requiring separate verification of the prescribed dosage, requiring written directives at the time doses are ordered, and deleting the reference to "150-mCi" on the QMP forms, procedure lists, and patient schedule.

NRC: An NRC medical consultant conducted an assessment and determined that the administered dose was not outside the standard of care.

Event 5: Sodium Iodide Radiopharmaceutical Medical Event at Kaiser Permanente, in Denver, Colorado.

Date and Place: June 29, 2001; Kaiser Permanente; Denver, Colorado.

Nature and Probable Consequences: The licensee reported a medical event involving two patients who received 59 and 60 percent more iodine-131 (I-131) than what was prescribed. A spokesman from the radiopharmaceutical company that delivered the I-131, Syncor International Corporation, stated that it had miscalculated the activity in three I-131 doses that were delivered to two clients. The doses were assayed using incorrect settings on Syncor's dose calibrator. One client identified the error during its assay of the dose before administration to a patient. However, the other client, Kaiser Permanente's (a licensee from the State of Colorado) administered the doses to two patients after measuring the activity on its dose calibrator. Kaiser Permanente's staff mistakenly accepted Syncor's assay instead of the activity measured by its dose calibrator. The licensee's authorized user had prescribed a 0.19-gigabecquerel (GBq) (5-mCi) dose for a whole body scan and a 0.56-GBq (15-mCi) dose for the treatment of hyperthyroidism. The doses dispensed by Syncor contained 0.30 GBq (7.97 mCi) and 0.89 GBq (24 mCi), respectively.

Actions Taken to Prevent Recurrence

Licensee: Syncor took the corrective actions of posting a sign stating "Check the dose calibrator to ensure the setting is at I-131"; refresher training on procedures for all pharmacists; modification of the procedures for the daily constancy test; and

acquisition of a new dose calibrator to be used for I-131.

Kaiser Permanente took the corrective actions of documenting doses administered to the patients; retraining nuclear medicine staff on the use of the dose calibrator; and training on whom to contact in case of problems.

State Agency: The Colorado Department of Public Health and Environment issued a Notice of Violation to Kaiser Permanente for having an I-131 misadministration and for lack of training.

(Contact: Roberto Torres, NMSS, 301-415-8112; e-mail: rjt@nrc.gov)

Comments, and suggestions you may have for information not currently included, that might be helpful to licensees, should be sent to:
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