

2:30 p.m. Audience comments and questions
 3:00 p.m. Break
 3:30 p.m. Major recommendations (continued): Participant discussion
 4:45 p.m. Audience questions
 5:15 p.m. Wrap up

Notification of Attendance: It is strongly encouraged that prospective participants contact NRC prior to the meeting to expedite the required security processing for NRC visitors. Contact Kim Karcagi, telephone: (301) 415-6701; e-mail: kxk2@nrc.gov, or Jayne McCausland, telephone: (301) 415-6219; e-mail: jmm2@nrc.gov, or Rose Conn, telephone: (301) 415-7438; e-mail: rmc@nrc.gov and submit participant name, affiliated organization, phone number, address, and citizenship status. Also, it is suggested that invited speakers as well as attendees, limit the amount of personal items and electronic devices brought into the building. If hardware from a participant, like a laptop, must be brought in, it has been suggested by security that a typed letter indicating the laptop's make, model, and owner's contact information be given to security staff upon arrival.

Travel Information: NRC Headquarters, where the public workshop will be held, is very accessible by public transportation. It is recommended that participants commute to the workshop via the Metrorail system (Metro). The White Flint Metro stop, along the red line, is adjacent to the One White Flint Building, along Rockville Pike and Marinelli Road. There are limited spaces available in the public meter parking and Metro parking lot along Marinelli Road. Due to security processing upon entrance into the building, it is recommended that attendees allot additional time to arriving at the workshop.

FOR FURTHER INFORMATION CONTACT:

Questions on the public meeting process should be directed to Chip Cameron; e-mail: fxc@nrc.gov, telephone: (301) 415-1642; Office of the General Counsel, USNRC, Washington, DC 20555-0001. Questions on the rulemaking process should be directed to Frank Cardile, telephone: (301) 415-6185; e-mail: fpc@nrc.gov, Office of Nuclear Material Safety and Safeguards, USNRC, Washington, DC 20555-0001. Questions on the environmental scoping process should be directed to Phyllis Sobel; e-mail: pas@nrc.gov, telephone: (301) 415-6714; Office of Nuclear Material Safety and Safeguards, USNRC, Washington, DC 20555-0001.

Dated at Rockville, Maryland, this 11th day of April, 2003.

For the Nuclear Regulatory Commission.

Charles L. Miller,

Director, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Material Safety and Safeguards.

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NUCLEAR REGULATORY COMMISSION

Report to Congress on Abnormal Occurrences, Fiscal Year 2002; Dissemination of Information

Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438) identifies an abnormal occurrence (AO) as an unscheduled incident or event that the U.S. Nuclear Regulatory Commission (NRC) determines is significant from the standpoint of public health or safety. The Federal Reports Elimination and Sunset Act of 1995 (Public Law 104-66) requires that AOs be reported to Congress annually. During fiscal year 2002, 10 events that occurred at facilities licensed or otherwise regulated by the NRC and/or Agreement States were determined to be AOs. The report describes three AOs at facilities licensed by the NRC. One event involved the degradation of the reactor head at a nuclear power plant, the second event involved a gamma stereotactic radiosurgery misadministration and the third event involved an overexposure of a radiopharmacist at a materials facility. The report also discusses seven events at facilities licensed by Agreement States. 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. 25, "Report to Congress on Abnormal Occurrences, Fiscal Year 2002." This report will be available electronically at the NRC Web site <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/>.

Nuclear Power Plants

02-1 Performance Deficiency Resulting in Reactor Vessel Head Degradation at Davis-Besse Nuclear Power Station in Oak Harbor, Ohio

Date and Place—March 6, 2002; Davis-Besse Nuclear Power Station, a pressurized-water reactor plant designed by Babcock and Wilcox Company, operated by First Energy Nuclear Operating Company and located near Oak Harbor, Ohio.

Nature and Probable Consequences—On February 16, 2002, the Davis-Besse facility began its 13th refueling outage, which included inspections of the control rod drive mechanism (CRDM) nozzles in accordance with NRC Bulletin 2001-01, "Circumferential Cracking of Reactor Pressure Vessel Head Penetration Nozzles," issued on August 3, 2001. These nozzles penetrate through the reactor pressure vessel (RPV) head and are attached by welds. Nozzle cracking was first discovered in the industry in the late 1980s. The concern with cracking is the potential loss of control rod drive function (rod ejection) and the resultant loss of coolant accident (LOCA) should the cracks reach a critical size and orientation. Also of concern is the potential for the reactor coolant to leak through small cracks in CRDM nozzles and cause boric acid corrosion of the RPV head. The RPV head is an integral part of the reactor coolant pressure boundary (Figure 1) and loss of its integrity can likewise result in a LOCA.

On February 27, 2002, the licensee notified the NRC that non-destructive examination of CRDM Nozzles 1, 2 and 3 identified that those nozzles contained small through-wall cracks. The licensee decided to repair these three nozzles plus two other nozzles with identified cracks that did not appear to be through-wall. The repair process included machining away the lower portion of the CRDM nozzle to a point above the cracks in the nozzle material. During this activity, CRDM nozzle 3 loosened in the head and on March 6, 2002, the licensee began an investigation to identify the cause. At the same time, activities were underway to remove boric acid deposits from the top of the RPV head caused by leakage of reactor coolant from the cracks and past leaking CRDM flanges. After removing the boric acid deposits, the licensee identified a large corrosion cavity in the head material adjacent to CRDM Nozzle 3 (Figure 2). The cavity was approximately 6 inches in length and 4 to 5 inches in width. Within this area the 6.63 inch thick low alloy steel head was corroded away leaving only the stainless steel cladding layer on the inside. The remaining cladding layer ranged in thickness from 0.20 to 0.31 inches. Subsequent metallurgical examination of this section of cladding identified a shallow crack approximately 3/8 inch in length. This cladding layer is designed as a corrosion resistant layer and is not specifically designed to retain reactor operating pressure. In addition to the cavity adjacent to Nozzle 3, a comparatively

small cavity was identified adjacent to Nozzle 2. This cavity was approximately 1.75 inches wide, 4 inches long, and 0.25 inches deep. Region III sent an Augmented Inspection Team (AIT) to the site to determine the facts and circumstances of the head degradation, beginning on March 12, 2002, and held a public exit meeting on April 5, 2002. A follow-up inspection identified several apparent violations of Agency regulations. The apparent violations will be processed in accordance with Agency procedure.

On April 8, 2002, prior to discovery of the crack in the cladding, the licensee submitted a safety significance assessment for the degraded RPV head to the NRC. This assessment determined that the as-found stainless steel cladding layer would have remained intact during anticipated operational occurrences and postulated accidents. Further, this assessment determined that had the RPV head failed due to the corrosion: (a) Adequate core cooling could have been established and maintained for the long term, (b) the reactor could have been placed and maintained in a safe shutdown condition, and (c) the integrity of containment would not have been compromised. The NRC staff is performing an independent assessment and reviewing the adequacy of the licensee's assessment. The NRC has not reached a final conclusion on the significance of this condition.

Cause or Causes—On April 18, 2002, the licensee submitted its Root Cause Analysis Report to the NRC. In this report, the licensee concluded that the most probable technical cause of the RPV head degradation was boric acid corrosion resulting from leakage through a crack in the CRDM penetration nozzle attributable to primary water stress corrosion cracking. Further, this corrosion had occurred over a period of several years. Absent more definitive information, the licensee's technical root cause analysis represents a plausible scenario for the degradation.

The licensee has completed a number of activities designed to identify management and human performance issues which contributed to this event. Several management and human performance issues were subsequently identified by both the licensee and NRC. NRC continues to monitor these activities and independently assess the effectiveness of the licensee's efforts in this area.

Actions Taken To Prevent Recurrence

Licensee—The licensee elected to replace the damaged head with one procured from the owners of the

canceled Midland nuclear power plant located in Michigan. The licensee has also completed a number of activities designed to identify the management and human performance deficiencies which contributed to the degradation of the reactor vessel head and implemented a series of inspections and evaluations to identify and correct any other potentially problematic plant issues.

NRC—Region III issued Confirmatory Action Letter (CAL) 3-02-001 on March 13, 2002, and Revised CAL 3-02-001A on May 15, 2002, which detailed specific licensee actions to be taken before NRC would consider restart of Davis-Besse. The NRC issued two Information Notices (IN) and two Bulletins to promptly inform the industry of the event: IN 2002-11, "Recent Experience with Degradation of Reactor Pressure Vessel Head"; IN 2002-13, "Possible Indicators of Ongoing Reactor Pressure Vessel Head Degradation"; Bulletin 2002-01, "Reactor Pressure Vessel Head Degradation and Reactor Coolant Pressure Boundary Integrity"; and Bulletin 2002-02, "Reactor Pressure Vessel Head and Vessel Head Penetration Nozzle Inspection Programs."

The NRC placed Davis-Besse under the Inspection Manual Chapter 0350 "Oversight of Operating Reactor Facilities in a Shutdown Condition With Performance Problems" on April 29, 2002. Further inspections and assessment of Davis-Besse performance will be performed before plant restart is considered. The NRC also chartered a Lessons Learned Task Force (LLTF). The objective of this task force was to independently evaluate the NRC's regulatory processes related to assuring RPV head integrity in order to identify and recommend areas for improvement that may be applicable to either the NRC or the nuclear industry. The LLTF completed its evaluation and its conclusions were reviewed by a Senior Management Review Team to determine appropriate Agency actions. The recommendations of the Senior Management Review Team were issued November 26, 2002. A Commission meeting was held on January 14, 2003, to brief the Commission on the Senior Management Review Team recommendations and the Commission approved proceeding with the recommendations.

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

Fuel Cycle Facilities (Other Than Nuclear Power Plants)

None of the events that occurred at fuel cycle facilities during this period was significant enough to be reported as an AO.

Other NRC Licensees (Industrial Radiographers, Medical Institutions, etc.)

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

02-2 Gamma Stereotactic Radiosurgery (Gamma Knife) Misadministration at St. Luke's Medical Center in Milwaukee, Wisconsin

Date and Place—July 10, 2001; St. Luke's Medical Center; Milwaukee, Wisconsin.

Nature and Probable Consequences—A patient undergoing Gamma Stereotactic Radiosurgery (Gamma Knife) was prescribed treatment of 20 Gy (2,000 rad) to a portion of the brain. During the treatment, the licensee completed three of eight treatment fractions and approximately one-half of the fourth fraction when the medical physicist and radiation therapist realized that the administered treatment utilized the treatment parameters for another patient, resulting in a dose of 12.8 Gy (1,280 rad) to an unintended portion of the brain (*i.e.*, wrong treatment site).

For treatment, the licensee's medical physics staff prepared treatment plans for two patients, to be treated on the same day. The treatment plan for Patient A consisted of a prescribed dose of 18 Gy (1,800 rad). Prior to initiating treatment of Patient A, someone on the licensee's staff handed the plan of treatment for Patient B to the licensee's radiation therapist; later, the therapist could not recall who had handed her the plan. Using Patient B's treatment plan, the treatment team set up and delivered the first three fractions to Patient A and began delivery of the fourth fraction. The error was discovered by the medical physicist during delivery of the fourth fraction. Once notified of the error, the radiation oncologist terminated the treatment.

The medical physicist determined that the treatment delivered a dose of 12.8 Gy (1,280 rad) to an unintended region of the patient's brain. The radiation oncologist determined that the location of the unintended site was far enough away from the intended site to proceed with the intended treatment.

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

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

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

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

Actions Taken To Prevent Recurrence

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

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

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

This event is closed for the purpose of this report.

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

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

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

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

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

Actions Taken To Prevent Recurrence

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

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

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

This event is closed for the purpose of this report.

Agreement State Licensees

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

during this reporting period, were significant enough for reporting as AOs:

AS 02-1 Loss of Package Integrity and Elevated Radiation Levels Measured at Federal Express Facility in Kenner, Louisiana

Date and Place—January 2, 2002, Federal Express facility at New Orleans International Airport, in Kenner, Louisiana.

Nature and Probable Consequences—A package containing iridium-192 (Ir-192) with elevated surface radiation levels was discovered at the Federal Express facility located at the New Orleans airport. The package was identified as a routine shipment for Source Production and Equipment Company (SPEC), located in St. Rose, Louisiana. After being notified by Federal Express authorities, a representative of SPEC picked up the package from the Federal Express facility. While loading the package, known as the SAFKEG, onto his truck, the individual noticed that his survey meter was offscale and his pocket dosimeter showed a reading of 1.6 mSv (160 mrem). The SAFKEG was transported back to SPEC facilities and entombed in high-density concrete bricks in its secured warehouse. The individual's total exposure during these activities was later determined to be 3.45 mSv (345 mrem).

The SAFKEG was shipped from a Swedish Company, Studsvik AB, and contained three vials loaded with a total of 1078 Ir-192 discs. The total activity was 366 terabecquerels (TBq) (9893 curies (Ci)). Shipping papers accompanying the package indicated that the Ir-192 was solid metal, in a Type B(U) package with a yellow radioactive III label, and a transportation index of 2 (radiation levels of 0.02 mSv/hr (2 mrem/hr) at one meter from the surface). Photographs taken by SPEC personnel, in St Rose, Louisiana, prior to the SAFKEG entombment confirmed that the appropriate U. S. Department of Transportation (DOT) labeling was affixed to the package. Surveys conducted at about the same time at 15 feet from the cask revealed measured radiation levels of 10 mSv/hr (1 rem/hr). The package remained entombed until a hot cell capable of remote inspection was constructed. After the SAFKEG's contents were removed, in the hot cell, and before it's shipment from the St. Rose facility, surveys for radiation levels and leak tests conducted for removable contamination showed no removable contamination.

The SAFKEG was originally shipped by Federal Express. A Health Physicist/

Consultant to Federal Express performed dose estimate calculations for personnel exposed to the package during its transit. Personnel monitoring devices were worn by the flight crews for both the flights; specifically, from Sweden to Paris and from Paris to Memphis. The First Officer for the Paris to Memphis flight received 0.05 mSv (5 mrem) for the January-February 2002 monitoring period and 0.39 mSv (39 mrem) for the November-December 2001 period. The consultant concluded that there were no excessive radiation levels from the SAFKEG on either flight. The consultant's calculations estimated the highest dose to any Federal Express employee at 20 mSv (2 rem). The French and Swedish regulatory agencies evaluated the portions of the event that occurred within their jurisdictions.

Cause or Causes—On February 7, 2002, after construction of the hot cell, appropriate SPEC personnel opened the SAFKEG utilizing robotics. The tamper seal was intact; after it was broken, it was sealed in plastic and put aside. The interior shielded pot was removed and placed into a small lead shield. The shielding pot lid is normally secured with six allen head screws; however, one of the six screws was found loose. The plug assembly accessing the cavity containing the three vials of Ir-192 disks was removed, revealing that two of the three vials were open. The screw tops for the vials and a large number of Ir-192 disks were visible along the lip of the inner cavity. It is presumed the screw tops became unscrewed during transportation, resulting in the elevated external radiation levels.

Actions Taken To Prevent Recurrence

Licensee—The licensees involved in this occurrence are the package shipper, Studsvik AB, the package manufacturer, Croft, and the U.S. recipient, SPEC. The shipper and package manufacturer are pursuing corrective actions, but these have not been formalized as of the date of this report.

The inner-shielded pot of the package remained in the hot cell of the SPEC facility at the time of this report. SPEC had no plans to attempt further decontamination of the pot.

DOT—DOT issued a revision to the certificate of compliance (COC) requiring the type of radioactive material transported in the SAFKEG be contained in special form source capsules. This revision prohibits the use of the screw-top type vials that were used during this incident. The revised COC should prevent this type of occurrence in the future. DOT has discussed possible enforcement action as a result of this event.

State Agency—The State of Louisiana had the lead role in the investigation of this event and has concluded its investigation.

This event is closed for the purpose of this report.

AS 02-2 Industrial Radiography Occupational Overexposure at Longview Inspection in Channahon, Illinois

Date and Place—The Illinois Department of Nuclear Safety (the Department) was notified on January 15, 2002, by the licensee's RSO, that in June 2000, a radiographer experienced an overexposure and subsequent injury at a temporary job site near Channahon, Illinois.

Nature and Probable Consequences—On January 15, 2002, the licensee reported a potential overexposure to a radiographer and a subsequent injury that could have resulted from the overexposure. The overexposure occurred in June 2000, and involved a 3.0 TBq (81.2 Ci), Ir-192 source at a temporary job site near Channahon, Illinois. The radiographer, believing that the source was secured following the radiographic exposure, approached the guide tube area and knelt down without looking at his survey meter. The radiographer's alarming rate meter was inoperable because of a low battery. After changing the radiography film for the next shot and unhooking the guide tube, he noticed the source drive cable was still in the guide tube and his survey meter showed an off-scale reading. He immediately cranked the source back into the shielded position. His self-reading pocket dosimeter was off-scale. The radiographer did not inform the licensee of the incident. Approximately 2 weeks after the incident, the radiographer noticed skin redness in a 2-centimeter sized area of his left calf. Over the next year, the wound became ulcerated and would not heal. A physician examined the individual and concluded that it could have resulted from radiation. In January 2002, the licensee's RSO became aware of the condition and reported it to the Department. Prior to commencing an extensive investigation, the Department recommended that the licensee seek immediate assistance from Oak Ridge Radiation Emergency Assistance Center/ Training Site (REAC/TS). The REAC/TS concluded that the injury could have resulted from the overexposure in June 2000. The Department performed interviews and extensive time-motion studies and concluded that the incident could have occurred as described by the radiographer. The estimated dose to the individual was 15,000 mSv (1,500 rem) to the extremity. The licensee's

radiation monitoring program revealed a whole body dose of 9.1 mSv (0.910 rem) assigned to the radiographer for the month of June 2000. The reading was within the normal range for this individual, based on licensee records.

The radiographer underwent skin grafting on February 26, 2002. Based on the results of the medical treatment, no long-term adverse health effects are expected.

Cause or Causes—The cause was identified as a failure to conduct a lockout survey of the camera after the source was retracted, the failure to conduct radiation surveys and the failure to utilize an operable alarming rate meter due to a low battery.

Actions Taken To Prevent Recurrence

Licensee—The licensee terminated the radiographer's employment and incorporated the event into the annual refresher training at all 31 Longview Inspection offices.

State Agency—The Department conducted an investigation and concluded that the subsequent injury could have resulted from the overexposure. The Department imposed a suspension of the radiographer's certification for one year.

This event is closed for the purpose of this report.

AS 02-3 Industrial Radiography Occupational Overexposure at McShane Industries in Baltimore, Maryland

Date and Place—September 25, 2001, McShane Industries, Baltimore, Maryland. The NRC was informed of this event in September 2001; however, this event was not documented as an AO in the "Report to Congress on Abnormal Occurrences, Fiscal Year 2001" because of its investigation at that time.

Nature and Probable Consequences—On September 25, 2001, a radiographer employed by Accurate Technologies Incorporated (ATI) of Tinton Falls, New Jersey, was overexposed while conducting industrial radiography in Baltimore, Maryland. (On December 20, 2001, the licensee changed its name to United Evaluation Services Incorporated.) The radiographer was using an Amersham 660A radiography exposure device (camera) when the sealed source containing 2.16 TBq (58.4 Ci) of Ir-192 failed to retract into the shielded position inside the camera following the previous radiographic exposure. The radiographer thought that the source was completely retracted into the shielded position when he relocated the camera, crank, guide tube and its

extension tube in preparation for next exposure. The radiographer did not use a survey meter and was not wearing a pocket dosimeter, a whole body badge, or an alarming rate meter. The radiographer changed the film and identification, then secured the tip of the guide tube on to a different pipe weld for the next exposure. While attempting to unlock the camera for the next exposure, the radiographer noticed that the self-locking device on the camera was not in the locked position. Using the crank, the radiographer retracted the source into the shielded and secured position inside the camera. On September 29, 2001, the radiographer experienced burning and itching sensations in his fingers. On October 1, 2001, the radiographer notified the RSO and visited a physician. The physician reported that, on October 1, 2001, the radiographer had erythema on his fingers and palms. On October 5, 2001, State Inspectors observed radiation burns and blisters on the radiographer's hands. At the request of the State of Maryland, the United States Department of Defense, Armed Forces Radiobiology Research Institute, analyzed a 30 milliliter blood sample obtained from the radiographer, using cytogenetic biological dosimetry techniques, and reported a mean whole body dose estimation of approximately 2,670 mGy (267 rad). The assistant radiographer on site during this incident was not exposed.

Cause or Causes—The root cause of this radiation injury was identified as a failure by the radiographer to follow licensed radiation safety procedures, to comply with Maryland Regulations regarding radiation safety requirements for industrial radiographic operations, and to properly use required radiation detection and measurement devices. Specifically, the radiographer failed to wear an audible alarming rate meter or any type of dosimetry. He also failed to use a radiation survey meter. He inadvertently entered a very high radiation area caused by the Ir-192 sealed source that did not retract into the shielded position inside the camera. Finally, he failed to ensure that the source was secured in the shielded position prior to relocating the equipment from one location to another.

Actions Taken To Prevent Recurrence

Licensee—On October 4, 2001, the licensee agreed to discontinue all licensed activities until the completion of the Departmental Investigation.

State Agency—The licensee was cited for violations of Maryland Regulations for Control of Radiation. Specifically, the licensee was cited for exceeding

occupational exposure limits; failure to conduct radiation surveys; failure to secure the device after the exposure; failure to wear and properly use a pocket dosimeter, alarming rate meter and film badge; failure to notify the Agency of an overexposure; failure to maintain a utilization log; failure to report a bankruptcy to the Agency; failure to notify the Agency before vacating premises; failure to authorize the RSO on the license; and several other associated violations. On October 25, 2001, the Agency issued a Cease and Desist Order to the licensee, prohibiting all industrial radiography activities in Maryland. ATI's Maryland radioactive materials license expired on December 31, 2001, and was terminated. The incident has been referred for escalated enforcement.

This event is closed for the purpose of this report.

AS 02-4 Intra Vascular Brachytherapy Misadministration (IVB) at Rhode Island Hospital, Providence, Rhode Island

Date and Place—January 28, 2002; Rhode Island Hospital, Providence, Rhode Island.

Nature and Probable Consequences—A patient was prescribed a dose of 8 Gy (800 rad) to the coronary artery during a Cordis Checkmate IVB procedure using 10 Ir-192 seeds, 8991 MBq (243 mCi). On January 31, 2002, during a review of dosimetry and physician records, the licensee discovered that the diameter of the artery was used in the treatment plan calculation instead of the radius. This error resulted because the physicians (authorized users) using the CORDIS device were more familiar with the procedures for a NOVOSTE device also in use at this institution. The Novoste device uses the diameter of the artery in the dosimetry calculations whereas the Cordis device uses the radius. The authorized user provided the wrong dimension (diameter instead of radius) which led to an incorrect dose being calculated. As a result the patient received an actual dose of 14.6 Gy (1,460 rad) to the outer coronary artery site instead of the prescribed 8 Gy (800 rad). The licensee indicated that there will probably be no adverse health effect to the patient.

Cause or Causes—As stated, the misadministration occurred due to human error in the use of the diameter of the artery instead of the radius of the vessel as required when using the Cordis system. The physicians' (authorized users) familiarity with the procedures for a Novoste device was a contributing factor.

Actions Taken To Prevent Recurrence

Licensee—The licensee informed the State of Rhode Island the next day by telephone of the potential misadministration and provided a written report of the incident on February 14, 2002. In-service training has been conducted concerning the misadministration. In addition, the prescription form has been modified to indicate if the radius or the diameter of the vessel is being used for the treatment plan.

State Agency—The Agency has been in contact with the licensee concerning this matter and the effectiveness of the corrective measures implemented. The licensee indicated that there will probably be no adverse health effects to the patient. To date there has been no recurrence of the problem.

This event is closed for the purpose of this report.

AS 02-5 Strontium-90 Eye Applicator Brachytherapy at South Broward Hospital District in Hollywood, Florida

Date and Place—January 4, 2002; South Broward Hospital District, Hollywood, Florida.

Nature and Probable Causes—A patient was prescribed radiation treatment for pterygium in his left eye. The patient was to receive a total dose of 30 Gy (3,000 rad) in three 10 Gy (1,000 rad) fractions spaced approximately a week apart. Due to human error, the third and final fraction, given on January 4, 2002, was 24.84 Gy (2,484 rad) instead of the prescribed 10 Gy (1,000 rad).

The prescribed dose was to be administered via a 3M Company Model 6D1A eye applicator using a 973 MBq (26.3 mCi) strontium-90 (Sr-90) source. The written directive called for each fraction to consist of a treatment duration of 44 seconds to deliver a 10 Gy (1,000 rad) dose. The correct fractionated dose was administered as planned on December 20, 2001, and December 28, 2001. A routine administration of the eye applicator required one person to time the event with a stopwatch while the authorized user administered the dose. The nurse and the authorized user became distracted in conversing with the patient and lost track of the time. The stopwatch used was the old style that simply counted time up and the nurse lost focus in trying to make the patient more comfortable and at ease. The authorized user had to remind the patient to gaze in a certain direction to treat the affected area. As a result, the third fractionated treatment time was 109 seconds instead of the prescribed 44

seconds resulting in a dose of 24.84 Gy (2,484 rad).

The patient was counseled about the slight increase in late effects including cataract formation and scleral scar tissue formation.

Cause or Causes—The State found and the licensee agreed that the misadministration occurred due to human error and the failure of staff to attend to details as required in licensee's procedures.

Actions Taken To Prevent Recurrence

Licensee—The licensee has identified and made changes in their procedures for use of the Sr-90 ophthalmic applicator. The facility purchased a digital stopwatch that has a large display, counts time down and not up, audibilizes the time in the last 10 seconds, and alarms at the end of treatment. In addition, the nurse has been counseled and all personnel have received training in the revised procedures using the new stopwatch.

State Agency—The Florida Bureau of Radiation Control performed an on-site investigation on February 7, 2002, to review the licensee's corrective actions, which were found adequate by the State. The State also determined that while the patient was informed verbally of the misadministration, the licensee did not inform the patient in writing as required. The licensee was cited for failure to notify the patient in writing within 15 days.

This event is closed for the purposes of this report.

AS 02-6 Industrial Radiography Occupational Overexposure at Technical Welding Laboratory, Inc. in Houston, Texas

Date and Place—April 10, 2002, Technical Welding Laboratories Inc., Houston, Texas.

Nature and Probable Consequence—On April 10, 2002, a radiographer received an overexposure calculated at 0.70 Sv (70 rem) due to handling his radiographic equipment with the source in an unshielded condition.

The exposure occurred while conducting radiography using an Amersham 660 radiography exposure device (camera) containing a 1.30 TBq (35 Ci) cobalt-60 (Co-60) radiography source. At the conclusion of a radiograph, the radiographer cranked the source to the shielded position without conducting a survey and then repositioned the source guide tube for the next radiograph. When he attempted to crank out the source for the next radiograph, the radiographer realized the source had not been retracted to its fully shielded position and was

contained at the end of the guide tube. The radiographer notified the Radiation Safety Officer and returned to the office. The licensee then notified the State of Texas. While being interviewed for the event, the radiographer stated that although the camera's automatic locking mechanism was inoperable while performing radiography, he did not stop work and proceeded to complete the job. Subsequently, the licensee hired a consultant to check the equipment's operability and found no problem. The equipment was placed back in service with no repair necessary.

The radiographer was sent to a doctor, underwent blood tests and participated in a chromosome aberration study. Although the blood tests results were negative, the chromosome aberration study indicated a radiation exposure ranging from 0.70 Sv (70 rem) to 1.52 Sv (152 rem) with a 95-percent confidence level. In addition, due to the radiographer's difficulty in performing a good reenactment, a dose calculation of the exposure was difficult, however a consultant determined that an exposure of 0.70 Sv (70 rem) did occur. Although the radiographer stated that he could have possibly touched the end of the guide tube where the source was located, no erythema or blistering of the hand, as expected with an incident of this type was seen. A second consultant conducted calculations for a possible extremity exposure which resulted, in a possible 2.01 Sv (201 rem) exposure to the right hand.

Cause or Causes—It was determined that the cause of the overexposure involved the radiographer's failure to: (1) Wear his alarming rate meter; and (2) wear a personnel monitoring device.

Actions Taken To Prevent Recurrence

Licensee—The licensee terminated the radiographers employment and reviewed the incident with other radiographers employed by the company. A licensee consultant evaluation of the equipment determined that the camera was functioning properly.

State Agency—The licensee and radiographer were cited for not performing a lockout survey after a radiographic exposure, not using an alarming rate meter during radiographic operations; not using a collimator during radiographic operations and not using an individual monitoring device during radiographic operations. The licensee was also cited for allowing an individual to receive an exposure in excess of regulatory limits.

The licensee has since terminated its license and the radiographer no longer

works in the industrial radiography industry.

This event is closed for the purposes of this report.

AS 02-7 Diagnostic Misadministration at Cedars-Sinai Medical Center in Los Angeles, California

Date and Place—May 29, 2002, Cedars-Sinai Medical Center in Los Angeles, California.

Nature and Probable Consequences—A patient was erroneously administered 111 MBq (3 mCi) of iodine-131 (I-131) for a neck scan instead of receiving a diagnostic uptake scan of 7.4 MBq (0.2 mCi) of iodine-123 (I-123). This resulted in a dose of 30.8 Gy (3,087 rad) from the I-131 to the patient's remaining thyroid tissue, rather than 0.07 Gy (7 rad) that would have resulted from the prescribed I-123.

The elderly patient was from another country, had some language difficulties, and had no medical records. The patient had a scar on her neck, and answered affirmatively when the referring physician (who was not an endocrinologist) asked if she had a thyroidectomy. Because there were no medical records, and because she had symptoms indicating a potential thyroid dysfunction, the referring physician ordered a "thyroid scan," and in the referral noted that the patient had a thyroidectomy. A temporary scheduling clerk at the administering hospital noted the thyroidectomy information and, after conferring with a nuclear medicine technologist (NMT), scheduled a dosage of 111 MBq (3 mCi) of I-131 for the patient. When the patient arrived at the licensee's facility, the NMT received confirmation from the patient that a scar on the patient's neck was the result of a thyroidectomy, the NMT proceeded to administer the scheduled neck scan with I-131. Neither the temporary scheduling clerk nor the NMT consulted with the authorized user or the referring physician to confirm their use of 111 MBq (3 mCi) of I-131 instead of 7.4 MBq (0.2 mCi) of I-123. It was determined later that the patient had only a partial thyroidectomy, with approximately 50 percent of her thyroid mass remaining. The dose to the patient's remaining thyroid tissue 30.87 Gy (3,087 rad) from the I-131, instead of 0.07 Gy (7 rad) had I-123 been administered. Because of a possible reduction of thyroid function, the patient's physician will follow her medical needs.

Cause or Causes—The misadministration occurred due to human errors and inadequate procedures. The patient had language barriers that impeded clear communication with medical providers

and licensee staff failed to consult the authorized user to obtain clarification from the referring physician. Finally, training and written instructions were not adequate to have prompted the temporary scheduling clerk or the NMT to seek appropriate assistance to resolve the dosage scheduled and administered.

Actions Taken To Prevent Recurrence

Licensee—Corrective actions taken to prevent recurrence included modifying the Nuclear Medicine Department procedures and ensuring that scheduling for all I-131 administrations, no matter what the activity, are performed by the Thyroid Treatment Coordinator or by the Chief, NMT.

State Agency—The California Department of Health Services has reviewed and approved the licensee's corrective actions. The State is considering enforcement actions.

This event is closed for the purposes of this report.

Dated in Rockville, Maryland, this 14th day of April, 2003.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

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SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549.

Extension: Form F-9; OMB Control No. 3235-0377; SEC File No. 270-333. Form F-10; OMB Control No. 3235-0380; SEC File No. 270-334.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) the Securities and Exchange Commission ("Commission") has submitted to the Office of Management and Budget requests for extension of the previously approved collections of information discussed below.

Form F-9 is a registration statement under the Securities Act of 1933 that is used to register investment grade debt or investment grade preferred securities that are offered for cash or in connection with an exchange offer and either non-convertible or not convertible for a period of at least one year from the date of issuance and, except as noted in paragraph (E), are thereafter only

convertible into a security of another class of the issuer. The purpose of the information collection is to permit verification of compliance with securities law requirements and to assure the public availability and dissemination of such information. The principal function of the Commission's forms and rules under the securities laws' disclosure provisions is to make information available to the investors. Approximately 18 respondents file Form F-9 annually and at 25 hours per response for a total of 450 annual burden hours. It is estimated that 25% of the 450 annual burden hours (113 burden hours) is prepared by the company. Form F-9 is a public document. All information provided is mandatory. Finally, persons who respond to the collection of information contained in Form F-9 are not required to respond unless the form displays a currently valid control number.

Form F-10 is a registration statement under the Securities Act of 1933 that is used by certain Canadian "substantial issuers"—those issuers with at least 36 calendar months of reporting history with a securities commission in Canada and a market value of common stock of at least \$360 million (Canadian) and an aggregate market value of common stock held by non-affiliates of at least \$75 million (Canadian). The purpose of the information collection is to facilitate cross-border offerings by specified Canadian issuers. Approximately 25 respondents file Form F-10 annually and at approximately 25 hours per response for a total of 625 annual burden hours. It is estimated that 25% of the 625 total burden hours (156 burden hours) is prepared by the company. Form F-10 is a public document. All information provided is mandatory. Finally, persons who respond to the collection of information contained in Form F-10 are not required to respond unless the form displays a currently valid control number.

Written comments regarding the above information should be directed to the following persons: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503; and (ii) Kenneth A. Fogash, Acting Associate Executive Director/CIO, Office of Information Technology, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Comments must be submitted to OMB within 30 days of this notice.