

Policy will be available at <http://www.nrc.gov/about-nrc/regulatory/enforcement/public-involvement.html>. If you do not have Internet access or if there are problems in accessing the documents located in ADAMS, contact the PDR Reference staff at 1-800-397-4209, 301-415-4737 or by e-mail to pdr.resource@nrc.gov.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

Background

As discussed in the **SUPPLEMENTARY INFORMATION** of the September 15, 2008 document (73 FR 53286), the NRC, in developing the proposed revised Enforcement Policy, in many instances reworded, deleted, or moved (*i.e.*, moved to the NRC Enforcement Manual, an NRC staff guidance document) some of the information in the current Enforcement Policy. (See the table at ML083050133 for a listing of subject matter in the current Enforcement Policy which was not carried over into the proposed revised Enforcement Policy.) For example, Section 6.0, Supplements-Violation Examples, of the proposed revised Enforcement Policy was significantly reorganized, reworded, and contained much less detail than the supplements in the current Enforcement Policy. In addition, the NRC had also planned to add detailed violation examples to the Enforcement Manual to serve as further guidance to NRC inspectors. However, based on public comments received in response to the September and October 2008 publications of the proposed revised Enforcement Policy, the NRC has reconsidered its original plan to have abbreviated violation examples in the revised Enforcement Policy and detailed violation examples in the Enforcement Manual. The NRC now proposes to continue its past practice of providing violation example supplements in the Enforcement Policy. These revised supplements are intended to cover, in more detail than originally planned, a broad range of circumstances in each of the four severity levels in each of 14 activity areas. It should be noted that the supplements in Section 6.0 of the proposed revised Enforcement Policy are not intended to address every possible circumstance and are therefore neither exhaustive nor controlling.

Because the revised violation supplements that are being proposed for the revised Enforcement Policy have, in some instances, been changed

significantly from those previously published, the NRC is providing an opportunity for public comments on the proposed revised supplements.

The NRC maintains the Enforcement Policy on its Web site at <http://www.nrc.gov>; select Public Meetings and Involvement, Enforcement, and then Enforcement Policy.

Procedural Requirements:

Paperwork Reduction Act

This policy statement does not contain new or amended information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing requirements were approved by the Office of Management and Budget (OMB), approval number 3150-0136.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

Congressional Review Act

In accordance with the Congressional Review Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs.

For the Nuclear Regulatory Commission.

Dated at Rockville, MD, this 1st day of June 2009.

Cynthia A. Carpenter,

Director, Office of Enforcement.

[FR Doc. E9-13298 Filed 6-5-09; 8:45 am]

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NUCLEAR REGULATORY COMMISSION

[NRC-2009-0208]

Report to Congress on Abnormal Occurrences; Fiscal Year 2008; Dissemination of Information

Section 208 of the Energy Reorganization Act of 1974 (Pub. L. 93-438) defines an abnormal occurrence (AO) as an unscheduled incident or event which the U.S. Nuclear Regulatory Commission (NRC) determines to be significant from the standpoint of public health or safety. The Federal Reports Elimination and Sunset Act of 1995 (Pub. L. 104-68) requires that AOs be reported to Congress annually. During Fiscal Year 2008, ten events that occurred at facilities licensed or otherwise regulated

by the NRC and/or Agreement States were determined to be AOs. The report describes five events at NRC-licensed facilities. The first NRC-licensee event involved radiation exposure to an embryo/fetus. The other four NRC-licensee events were medical events, as defined in Title 10, Part 35, of the *Code of Federal Regulations* (10 CFR Part 35). All five NRC-licensee events occurred at medical institutions. The report also describes five events at Agreement State-licensed facilities. [Agreement States are those States that have entered into formal agreements with the NRC pursuant to Section 274 of the Atomic Energy Act (AEA) to regulate certain quantities of AEA licensed material at facilities located within their borders.] Currently, there are 35 Agreement States. The first Agreement State-licensed event involved radiation exposure to an embryo/fetus. The other four Agreement State-licensed events were medical events, as defined in 10 CFR Part 35, and occurred at medical institutions. As required by Section 208, the discussion for each event includes the date and place, nature and probable consequences, the cause or causes, and the actions taken to prevent recurrence. Each event is also being described in NUREG-0090, Vol. 31, "Report to Congress on Abnormal Occurrences: Fiscal Year 2008." This report is available electronically at the NRC Web site <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/>.

There are three major categories of events reported in this document: I. For All Licensees, II. For Commercial Nuclear Power Plant Licensees, and III. Events at Facilities Other Than Nuclear Power Plants and all Transportation Events. The full report, available on the NRC Web site, provides the specific criteria for determining when an event is an abnormal occurrence (AO) and discusses "Other Events of Interest" that do not meet the AO criteria but which the Commission has determined should be included in the report. The event identification number begins with "AS" for Agreement State AO events and "NRC" for NRC AO events.

I. For All Licensees

Human Exposure to Radiation From Licensed Material

During this reporting period, one event at an NRC-licensed facility and one event at an Agreement State-licensed facility were significant enough to be reported as abnormal occurrences (AOs).

AS08-01 Human Exposure to Radiation at St. Luke's Hospital in Bethlehem, Pennsylvania

Date and Place—April 11, 2008, Bethlehem, Pennsylvania.

Nature and Probable Consequences—St. Luke's Hospital (the licensee) reported that a therapeutic dose of 4,958 MBq (134 mCi) of iodine-131, for thyroid cancer treatment, resulted in a dose to an embryo/fetus of 350 mSv (35 rem). Prior to administration of iodine-131, the patient was given a pregnancy test and it yielded a negative result. Following the treatment, the patient suspected she was pregnant and returned to the hospital on April 28, 2008. Subsequent testing indicated that the patient became pregnant approximately 4–6 days following her treatment. The patient and the referring physician were informed of this event. The hospital calculated a total dose to the embryo/fetus of 350 mSv (35 rem). The hospital concluded that based on the total dose to the embryo/fetus of 350 mSv (35 rem), no immediate health effects would be experienced. On May 2, 2008, the patient met with a perinatologist and a recommendation was made to consult with a genetic counselor regarding the fetal exposure.

Cause(s)—The causes of this event were the negative pregnancy test and the patient not using a method of contraception, as advised, following the treatment.

Actions Taken To Prevent Recurrence

Licensee—The licensee is providing additional instructions to its staff to strongly emphasize to patients the risks associated with becoming pregnant following the administration of radioiodine treatments.

State—The State conducted a follow-up inspection on June 10, 2008, and did not take any enforcement action regarding this event.

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NRC08-01 Human Exposure to Radiation at Wilford Hall Medical Center on Lackland Air Force Base in San Antonio, Texas

Date and Place—June 4, 2008, San Antonio, Texas.

Nature and Probable Consequences—Wilford Hall Medical Center, a permit holder under the United States Air Force (USAF) Master Material license, reported that a therapeutic dose of 5.55 GB (150 mCi), for post-thyroidectomy therapy to a patient, administered on June 4, 2008, resulted in a dose to an embryo/fetus of 315 mSv (31.5 rem). Two days prior to administration of the radioiodine-131, a pregnancy test was

given to the patient and it yielded a negative result. Later, on June 26, 2008, the patient became aware that she was pregnant. The hospital's radiation safety staff did not become aware of the pregnancy until August 13, 2008, when the patient contacted the radiation safety staff asking about the consequences of the radioiodine ablation therapy on her embryo/fetus.

The hospital's radiation safety staff immediately conducted an investigation, in consultation with experts at the Department of Energy, and concluded that based on the total dose calculated of 315 mSv (31.5 rem) to the embryo/fetus, no immediate health effects would be experienced. The hospital estimated that the pregnancy was approximately seven days post-conception at the time of the administration and that the zygote (fertilized ovum) was in a pre-implantation state. This estimated condition is supported by the negative pregnancy test results prior to the administration. In addition, the hospital also estimated that the likelihood of childhood cancer had been increased by an estimated 1.9 percent. According to the licensee's report dated September 22, 2008, the pregnancy was progressing satisfactorily.

Cause(s)—Wilford Hall Medical Center believes that it followed its policies and standards of care. A pregnancy test does not typically have the capability to detect a pregnancy at such an early stage. The NRC special inspection is complete and the results are being evaluated for significance and potential regulatory action. The final report will be issued at the completion of the evaluation.

Actions Taken To Prevent Recurrence

Wilford Hall Medical Center—Patients will be advised that serum pregnancy tests are not capable of detecting early stage pregnancy and therefore patients will be advised to abstain from intercourse for a period of 14 days prior to treatment or utilize an effective method of contraception for a period of 30 days prior to treatment. In addition, only quantitative serum tests will be used for detecting pregnancy for patients with the physiological capacity for becoming pregnant.

Department of the Air Force—The United States Air Force (USAF) Radioisotope Committee (RIC) is performing a root-cause analysis of this event. As part of its reviews, the USAF RIC is identifying other hospitals, under its Master Materials license, and asking them to review radioiodine procedures for the past two years to determine if patients had become pregnant either

before or after receiving a radioiodine procedure. The USAF RIC will also review the policies and procedures of these hospitals. In addition, the USAF RIC is arranging to send an inspector from the Air Force Inspection Agency to further assess procedures. The USAF Surgeon General issued a Notice to Airmen (NOTAM) on September 22, 2008, that outlined compliance objectives to reduce the likelihood of future occurrences. The USAF RIC is sending information to educate clinicians and support staff on the intent and implementation of the NOTAM.

NRC—NRC first learned of this incident on September 5, 2008, while conducting a routine unannounced inspection at Wilford Hall Medical Center. On September 9, 2008, NRC initiated a special inspection team to review this event and obtained the services of a medical consultant. NRC's medical consultant corroborated the hospital's total dose estimate to the fetus, with an estimated total dose of 325 mSv (32.5 rem). NRC's medical consultant also concurred with the hospital's assessment of the probable health effects to the fetus.

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II. Commercial Nuclear Power Plant Licensees

During this reporting period, no events at commercial nuclear power plants in the United States were significant enough to be reported as AOs.

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III. Events at Facilities Other Than Nuclear Power Plants and All Transportation Events

Medical Licensees

During this reporting period, four events at NRC-licensed or regulated facilities and four events at Agreement State-licensed facilities were significant enough to be reported as AOs.

NRC08-02 Medical Events at the Department of Veterans Affairs in Philadelphia, Pennsylvania

Date and Place—February 2002 to May 2008, Philadelphia, Pennsylvania.

Nature and Probable Consequences—The VA Medical Center—Philadelphia reported that 92 medical events involving prostate brachytherapy occurred between February 2002 and May 2008. Each patient was prescribed 160 Gy (16,000 rad) using permanent iodine-125 seeds. The licensee determined that 57 of the 92 patients received less than 80 percent of the prescribed dose to the prostate. Thirty-

five patients received excessive doses to other organs. Of these 35 patients, 25 patients received a dose in excess of 100 Gy (10,000 rad) to the rectum due to misplaced iodine-125 seeds. Each patient and the referring physicians were notified of these events. The VA Medical Center—Philadelphia is reviewing possible health effects on the patients. The circumstances for each patient are being evaluated to determine if follow-up medical care is needed.

The NRC-contracted medical consultant reviewed a selected number of the cases and agreed with the licensee's dose analysis. However, in one overdose case, the patient experienced rectal bleeding of the colon and laboratory results indicated ulcerative colitis. The NRC-contracted medical consultant and the licensee agreed that the increased dose to the colon could be a contributing factor to the rectal bleeding.

Cause(s)—The VA Medical Center—Philadelphia identified three root causes as a result of these events in its *Report of Administrative Board of Investigation* dated September 5, 2008: (1) No corrective action was taken when post-implant dosimetry was performed and low doses were observed, (2) inadequate supervision by the physician/authorized users and (3) post-treatment plans were not performed on patients due to computer interface problems. In addition, two factors contributed to these events: (1) Internal procedures were not followed and (2) the succession of minor technical errors that stemmed from a misperception that other team members performed safety checks.

Actions Taken To Prevent Recurrence

Licensee—Corrective actions taken by the VA Medical Center—Philadelphia included: (1) The prostate brachytherapy program has been suspended until a standardized brachytherapy program is established and implemented; (2) a physician and medical physics consultant, who are experts in performing prostate implants, were hired to evaluate the prostate implant program; and (3) several key staff directly involved in the prostate brachytherapy procedures are no longer employed by the VA Medical Center—Philadelphia.

NRC—The NRC Region III Office conducted a reactive inspection on July 23–25, 2008. Based on the results of this inspection and the high number of medical events identified, NRC conducted a special inspection on September 9–12, 2008. On October 14, 2008, NRC issued a confirmatory action letter (CAL) to the Department of

Veterans Affairs (DVA) National Health Physics Program due to the multiple medical events involving permanent prostate brachytherapy treatments. The CAL documents the commitments made by the DVA to identify and address the problems that have led to medical errors and to prevent their recurrence. NRC will verify, through inspections, that the items in the CAL have been successfully completed. Enforcement action is pending.

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NRC08–03 Medical Event at Karmanos Cancer Center in Detroit, Michigan

Date and Place—October 24, 2007, Detroit, Michigan.

Nature and Probable Consequences—Karmanos Cancer Center reported that a medical event occurred associated with its gamma stereotactic radiosurgery unit (gamma knife). A patient being treated for a metastatic brain tumor was scheduled to receive 18 Gy (1,800 rad) to the lesion in the right cerebella area of the brain but received 18 Gy (1,800 rad) to an unintended area adjacent to the tumor. An error in the setup of the magnetic resonance imaging (MRI) unit caused the MRI scan to be reversed (i.e., the image of the right side of the head was on the left side and vice versa). The patient and the referring physician were informed of this event.

Prior to the treatment, the medical physicist, authorized user physician, and neurosurgeon reviewed the MRI scan and treatment plan but failed to recognize the reversed MRI images. The reversed MRI images were scanned into the gamma knife treatment planning computer, and a treatment plan was generated based on the reversed MRI images. The authorized user physician and neurosurgeon reviewed and approved the treatment plan generated from the reversed MRI images, and again the reversed MRI images were not recognized.

The NRC staff conducted a reactive onsite inspection on October 29, 2007. The NRC-contracted medical consultant reviewed the case and agreed with the licensee's analysis, stating that no significant adverse health effect to the patient is expected.

Cause(s)—The medical event was caused by the MRI technologist who inadvertently performed the MRI scans in the “caudal” mode (from the jaw to the top of the head) rather than the “cranial” mode (from the top of the head to the jaw). This change in device mode caused the MRI images to be reversed.

Actions Taken To Prevent Recurrence

Licensee—The licensee initiated several corrective actions to reduce the likelihood of recurrence of a similar event. Specifically, those corrective actions included (1) weekly meetings with the physics staff to discuss technical issues, focusing on the importance of good communication and (2) new written procedures and policies for the MRI staff and gamma knife facility staff that require dual verification of the various steps in the process to ensure that the correct treatment plan is generated from the MRI images.

NRC—On January 10, 2008, NRC issued a Notice of Violation related to this event.

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AS08–02 Medical Event at University of Mississippi Medical Center in Jackson, Mississippi

Date and Place—December 12–17, 2007, Jackson, Mississippi.

Nature and Probable Consequences—University of Mississippi Medical Center (the licensee) reported that a medical event occurred during a high dose-rate (HDR) treatment for cervical cancer using an iridium-192 source with an activity of 185 GBq (5.0 Ci). The authorized user physician prescribed five fractionated doses of 600 cGy (600 rad) each to be administered using tandem and ovoid applicators. The licensee calculated that during the first, second, and third fractionated treatments, the patient received a total dose of 470 cGy (470 rad) to the treatment area and 1,300 cGy (1,300 rad) to the vaginal region inferior to the treatment area. The patient and the referring physician were informed of this event. The licensee concluded that no significant adverse health effect to the patient is expected.

Cause(s)—The medical event was caused by human error due to the incorrect catheter length entered into the treatment planning system. The incorrect value of 128 cm was entered as the length instead of 120 cm, resulting in the 86 mm displacement. An HDR service technician identified the error in the treatment planning system on March 25, 2008.

Actions Taken To Prevent Recurrence

Licensee—The licensee committed to taking several corrective actions as a result of the medical event, including (1) Verification of the length of all disposal catheters and checking the integrity of the catheters prior to treatment, (2) placing an order for and use of a single set of reusable catheters

for HDR cervical cancer treatments, (3) the treatment plan and catheter measurement will be independently checked prior to treatment, and (4) review and modification, if necessary, of the quality assurance plan to ensure accuracy.

State—The State cited the licensee with two violations for failing to verify the treatment plan.

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AS08–03 Medical Event at Southwest Volusia Healthcare Corporation in Orange City, Florida

Date and Place—December 28, 2007, Orange City, Florida.

Nature and Probable Consequences—Southwest Volusia Healthcare Corporation (the licensee, doing business as Florida Hospital Fish Memorial) reported that a patient received 81.4 MBq (2.2 mCi) of iodine-131 for a whole body scan, instead of the intended iodine-123 for a thyroid uptake scan. The administration of 81.4 MBq (2.2 mCi) of iodine-131 resulted in the patient receiving a dose of 17.6 Gy (1,760 rad) to the thyroid and a whole body effective dose equivalent of 1.034 cGy (1.034 rad). The authorized user physician ordered an iodine thyroid uptake scan procedure, but did not specify the isotope in the written directive. The licensee uses iodine-123 for thyroid uptake scan procedures and iodine-131 for whole body scan procedures. On December 17, 2007, the patient received an iodine-131 whole body scan. The patient and the referring physician were informed of this event. The licensee concluded that no significant adverse health effect to the patient is expected.

Cause(s)—The licensee identified four causes of the medical event: (1) The incorrect examination was scheduled in their Radiology Information System, (2) the patient had a prescription from the ordering physician, but did not make it available for verification, (3) the isotope for the incorrect exam was ordered without verifying the prescription, and (4) the technologist involved in the administration did not recognize the error when the written directive was presented.

Actions Taken To Prevent Recurrence

Licensee—The licensee implemented corrective actions by providing counseling and re-training to the hospital personnel involved in the medical event and notified hospital personnel that iodine-131 and iodine-123 studies must be verified prior to scheduling patients for these types of procedures. In addition, the technologists have been instructed to

visually verify the authorized user physician's order on the written directive before ordering the radioisotope and the technologist and radiologist will review the written directive prior to patient administration.

State—The State conducted an investigation and reviewed the licensee's corrective actions and found the corrective actions to be adequate.

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AS08–04 Medical Event at Southern Baptist Hospital of Florida in Jacksonville, Florida

Date and Place—January 24, 2008, Jacksonville, Florida.

Nature and Probable Consequences—Southern Baptist Hospital of Florida (the licensee, doing business as Baptist Medical Center) reported that a patient received 173.9 MBq (4.7 mCi) of iodine-131 for an uptake scan, instead of the intended iodine-123 for the same procedure. The administration of 173.9 MBq (4.7 mCi) of iodine-131 resulted in the patient receiving a dose of 61 Gy (6,100 rad) to the thyroid and a whole body effective dose equivalent of 180 cGy (180 rad). An authorized user physician gave a verbal order to a nurse, who wrote the order for an iodine-123 uptake scan. The nurse incorrectly scheduled an iodine-131 uptake scan and the authorized user physician did not review the order. On January 16, 2008, the authorized user physician reviewed the results of the iodine-131 uptake scan and identified that the wrong isotope had been used in the procedure. The patient and the referring physician were informed of this event. The licensee concluded that no significant adverse health effect to the patient is expected.

Cause(s)—The cause of the medical event was the authorized user physician's failure to write a written directive and failure to review the order for the procedure.

Actions Taken To Prevent Recurrence

Licensee—The licensee implemented corrective actions by rewriting its procedures such that all written directives will be completed and reviewed by the authorized user physician prior to the administration to patients.

State—The State conducted an investigation and reviewed the licensee's corrective actions and found the corrective actions to be adequate.

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NRC08–04 Medical Event at Reid Hospital and Health Care Services in Richmond, Indiana

Date and Place—February 27, 2008, Richmond, Indiana.

Nature and Probable Consequences—Reid Hospital and Health Care Services reported that a medical event occurred during a brachytherapy seed implant procedure to treat prostate cancer. The written directive prescribed a total dose of 110 Gy (11,000 rad) to the patient's prostate using 62 iodine-125 seeds as permanent implants. The licensee calculated that the patient received less than 15 Gy (1,500 rad) to the prostate and the region of the patient's perineum, where the seeds were placed, received a dose of 55 Gy (5,500 rad). The patient and the referring physician were informed of this event.

According to the licensee, the base of the prostate was misidentified through ultrasound, causing 37 of the prescribed 62 seeds to be placed approximately 1 cm to 2 cm below the prostate in the perineum. When it was recognized that the seeds were not in the prostate, the procedure was halted. The licensee physicians stated that the patient may develop possible complications, including fibrosis and necrosis of the tissue in the perineum, where the seeds were implanted.

The NRC-contracted medical consultant agreed with the licensee's dose estimate and stated it was unlikely that the patient would experience radiation-induced rectal wall necrosis or soft-tissue necrosis below the prostate in the perineum area, but that it was possible to have delayed fibrosis of some areas of the genital tract. The NRC-contracted medical consultant further stated that because no tissue necrosis had occurred one month after the medical event, tissue necrosis was very unlikely to occur.

Cause(s)—The licensee determined the root cause of the medical event was the misidentification of the base of the prostate. Specifically, the prostate/bladder interface was not identified properly using the ultrasound due to poor image quality. As a result, the needle used to implant the seeds was not located in the prostate during the implantation.

Actions Taken To Prevent Recurrence

Licensee—The licensee's corrective actions to prevent recurrence included revising its procedure for prostate seed implants to require that the needle location in the prostate be verified by x-ray imaging at the beginning of the procedure, prior to any seeds being implanted, and halting the procedure if

the location of the needle in the prostate cannot be verified with certainty.

NRC—On July 11, 2008, NRC issued a Notice of Violation related to this event.

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NRC08-05 Medical Event at Bon Secours Virginia Health Source in Midlothian, Virginia

Date and Place—May 1, 2008, Midlothian, Virginia.

Nature and Probable Consequences—Bon Secours Virginia Health Source reported that a medical event occurred during a high dose-rate (HDR) treatment for breast cancer using an iridium-192 source with an activity of 165.4 GBq (4.47 Ci). The authorized user physician prescribed 10 fractions of 340 cGy (340 rad) each to be administered using a balloon catheter technique. The licensee calculated that a portion of the target volume received a dose in the range of 86 cGy (86 rad). In addition, a small volume of skin, at the catheter entrance into the patient, received a dose in the range of 1,142 cGy (1,142 rad). The patient and the referring physician were informed of this event.

During the check source run for the first fraction, an HDR alarm interrupted the run. Rather than investigate the cause of the alarm, the physicist concluded that a 2 mm error had been made in the measurement of the catheter length and the alarm occurred because the check source hit the end of the catheter. The physicist adjusted the catheter length value at the treatment console from 1300 mm to 1280 mm, believing this to be a change of 2 mm, and the treatment was administered. Immediately following the first treatment, it was determined that the original catheter length measurement of 1300 mm was correct and the length change made at the treatment console was 20 mm rather than 2 mm. As a result, the source dwell positions were 20 mm from the intended locations and were closer than intended to the skin entry point of the HDR catheter.

Subsequent HDR treatment fractions were administered as intended, with adjustments to the final two treatment fractions to assure that all areas of the target volume received an adequate dose over the course of the treatment. An NRC medical consultant concluded that no significant adverse health effect to the patient is expected.

Cause(s)—The cause of the medical event was human error in (1) failing to investigate the cause of the HDR alarm and (2) adjusting the catheter length value at the console by 20 mm instead of the intended 2 mm.

Actions Taken To Prevent Recurrence

Licensee—The licensee's corrective actions taken to prevent recurrence included updating procedures to define steps that will be taken to resolve HDR device alarms.

NRC—NRC performed a reactive inspection at the facility and issued a Notice of Violation for three violations of regulatory requirements on October 10, 2008.

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AS08-05 Medical Event at Lehigh Valley Hospital in Allentown, Pennsylvania

Date and Place—July 17, 2008, Allentown, Pennsylvania.

Nature and Probable Consequences—Lehigh Valley Hospital (the licensee) reported that a patient was prescribed a dose of 740 MBq (20 mCi) of iodine-131, for treatment of a thyroid condition, but instead was administered 2,775 MBq (75 mCi). The licensee discovered the event within an hour of the administration and gave the patient 130 mg of potassium iodide, a blocking agent, to prevent the uptake of iodine-131 in the thyroid. As a result of the administration, next day measurements indicated that the patient had a 74 MBq (2 mCi) uptake to the thyroid and 370 MBq (10 mCi) whole body retention, resulting in an approximate thyroid dose of 26 Gy (2,600 rad) and whole body effective dose equivalent of 8.7 cGy (8.7 rad). The patient and the referring physician were informed of this event. The licensee determined that as a result of giving the patient 130 mg of potassium iodide, no significant adverse health effect to the patient is expected.

Cause(s)—The cause of the medical event was human error because the technologist accidentally switched the doses between two patients.

Actions Taken To Prevent Recurrence

Licensee—The licensee implemented corrective measures by modifying current procedures involving the administration of radiopharmaceuticals.

State—The State conducted a follow-up inspection on August 21, 2008, to ensure that the licensee's actions taken to prevent recurrence had been implemented and issued a Notice of Violation.

Dated at Rockville, Maryland, this 29th day of May 2009.

For the U.S. Nuclear Regulatory Commission.

Annette L. Vietti-Cook,
Secretary of the Commission.

[FR Doc. E9-13300 Filed 6-5-09; 8:45 am]

BILLING CODE 7590-01-P

SMALL BUSINESS ADMINISTRATION

Business Loan Program Temporary Eliminations/Reductions in Fees

AGENCY: U.S. Small Business Administration (SBA).

ACTION: Notice and request for comments.

SUMMARY: This Notice formalizes the implementation of Section 501 of the American Recovery and Reinvestment Act of 2009. Section 501 authorizes SBA to temporarily reduce or eliminate certain SBA business loan program fees in the 7(a) Loan Program and the 504 Certified Development Company Program. These fee changes are intended to promote economic recovery by providing economic relief to America's small businesses and encouraging lenders to make small business loans. While these changes have been implemented and are underway, this Notice contains the key provisions of SBA's implementation of Section 501 in formal guidance and requests public comment.

DATES: *Effective Date:* This Notice is effective June 8, 2009.

Applicability Dates: This Notice applies to 7(a) loans approved by SBA or issued loan numbers for delegated lender loans by SBA, on or after February 17, 2009 and to 504 loans approved by SBA, pending approval at SBA, or issued loan numbers for delegated CDC loans by SBA, on or after February 17, 2009, until funds appropriated for Section 501 are exhausted.

Comment Date: Comments must be received on or before July 8, 2009.

ADDRESSES: You may submit comments, identified by SBA docket number SBA-2009-0001 by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Mail:* Recovery Act Comments—Office of Financial Assistance, U.S. Small Business Administration, Suite 8300, 409 Third Street, SW., Washington, DC 20416.

- *Hand Delivery/Courier:* Grady Hedgespeth, Director, Office of Financial Assistance, U.S. Small Business Administration, 409 Third Street, SW., Washington, DC 20416.

SBA will post all comments on www.regulations.gov. If you wish to submit confidential business information (CBI) as defined in the User Notice at www.regulations.gov, please submit the information to Grady Hedgespeth, Director, Office of Financial Assistance, U.S. Small