UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

March 30, 2009

SECRETARY

COMMISSION VOTING RECORD

DECISION ITEM: SECY-09-0029

TITLE: REPORT TO CONGRESS ON ABNORMAL OCCURRENCES: FISCAL YEAR 2008

The Commission (with all Commissioners agreeing) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of March 30, 2009.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.

Annette L. Vietti-Cook
Secretary of the Commission

Attachments:
1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Klein
Commissioner Jaczko
Commissioner Lyons
Commissioner Svinicki
OGC
EDO
PDR

SECY Note: To be made publicly available 5 days after dispatch of the report to Congress

VOTING SUMMARY - SECY-09-0029

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. KLEIN	X				X	3/7/09
COMR. JACZKO	X					3/24/09
COMR. LYONS	X				X	3/9/09
COMR. SVINICKI	X				X	3/18/09

COMMENT RESOLUTION

In their vote sheets, all Commissioners approved the staff's recommendation and some provided additional comments. Subsequently, the comments of the Commission were incorporated into the guidance to staff as reflected in the SRM issued on March 30, 2009.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: CHAIRMAN KLEIN

SUBJECT: SECY-09-0029 – REPORT TO CONGRESS ON ABNORMAL OCCURRENCES: FISCAL YEAR 2008

Approved _XX_ Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached _XX_ None ___

SIGNATURE

3/7/09

DATE

Entered on "STARS" Yes _XX_ No ___

Chairman Klein's Comments
SECY-09-0029

I approve the proposed Fiscal Year 2008 Abnormal Occurrence Report to Congress, and the proposed forwarding letters, with editorial corrections and comments.

1. Page 2, "Cause(s)" Paragraph. Rewrite last sentence to read "The NRC special inspection is complete, and the results are being evaluated for significance and potential regulatory action. The final report will be issued when the evaluation is complete."
2. Update Appendix D, page 26, based on final Commission decision on Indian Point Siren enforcement (enforcement actions complete)
3. Enclosure 2, letter to Joseph Biden, the salutation should read, "Dear Mr. President:" The first sentence of the second paragraph should read: "The NRC initially promulgated the AO criteria in a Commission policy statement published in the ..."
4. Enclosure 3, letter to Nancy Pelosi, first sentence of the second paragraph – see comment 6 above.
5. See other editorial comments (pages 24, 25, and 26) attached.

Dale E. Klein 3/7/09 Date

APPENDIX D
UPDATES OF PREVIOUSLY REPORTED OTHER EVENTS OF INTEREST

This appendix discusses "Updates of Previously Reported Other Events of Interest" that the NRC previously reported in the "Report to Congress on Abnormal Occurrences: Fiscal Year (FY) 2007" at two U.S. commercial nuclear power plants. During this reporting period, updated information became available regarding inattentive security officers and the installation of a new siren system.

NUCLEAR POWER PLANTS

Peach Bottom Atomic Power Station: Security Officers Inattentive to Duty (previously reported as EOI-01 in NUREG-0090, Volume 30)

Background – The issue of security officer inattentiveness at the Peach Bottom Atomic Power Station (PBAPS) came to NRC's attention on March 27, 2007, when it received an allegation that some security officers at PBAPS were sleeping on duty while in security watch towers and other areas. After receiving the allegation, NRC convened an Allegation Review Board, which determined that Exelon needed to investigate the allegation and provide the results of its investigation to NRC for review. NRC did not contact the person who made the allegation for additional information because the individual clearly stated in the allegation letter that he did not want to be contacted by NRC. Although not directly related to the allegation, the NRC Region I Office conducted a scheduled baseline security inspection at PBAPS from April 30, 2007, to May 4, 2007. During that inspection, four regional inspectors made unannounced tours of the security posts, including several watch towers, and did not find any security officers to be inattentive.

In June 2007, Exelon reported that its investigation did not uncover instances of inattentive security personnel. Based on Exelon's report, NRC could not substantiate the allegation regarding sleeping security officers in security watch towers and other areas.

In September 2007, NRC was made aware of the existence of, and later provided with, video evidence of inattentive security officers at PBAPS. NRC staff immediately contacted Exelon to confirm that short-term compensatory actions were taken. Shortly afterwards, NRC dispatched an augmented inspection team (AIT) and a follow-up team to investigate. An AIT is an infrequent reactive inspection conducted for the purpose of event assessment and follow-up actions. The ~~events that led to this inspection began when a~~ Peach Bottom security officer had videotaped multiple instances of several security officers inattentive to duty at the station's former power block "ready rooms." The ready rooms are locations within the protected area where officers are staged for response functions while not conducting security patrols.

The AIT conducted a public exit meeting on October 9, 2007, and concluded that Exelon's prompt compensatory measures and immediate actions were appropriate to ensure PBAPS' continued ability to properly implement the Security Plan. NRC determined that the inattentive security officers and deficiencies in Exelon's behavioral observation program, which could have identified and corrected the problem, represent a White finding. In accordance with

Following addition inspection,

NRC's reactor oversight program, a White finding is an NRC-identified or self-revealing issue of concern that is associated with a licensee performance deficiency of low-to-moderate safety significance.

Update on Actions Taken To Prevent Recurrence

~~NRC received 100 percent of licensee responses to~~ NRC Bulletin 2007-01, "Security Officer Attentiveness." ~~The NRC staff performed an initial review of the industry responses and concluded that all licensees provided answers to all questions as requested by the Bulletin.~~ After reviewing all licensee responses to ~~the security Bulletin~~, the NRC staff identified the need for additional information. To gather that information, NRC issued Requests for Additional Information (RAIs) to all licensees in July 2008. ~~NRC has received 100 percent of licensee responses to the RAIs and has assessed, in total, all of the licensee responses to the security Bulletin and subsequent RAIs.~~ The NRC staff is evaluating the licensee's responses to the security Bulletin and associated RAIs. If this evaluation indicates that additional regulatory action is warranted, the NRC staff will make that recommendation to the Commission.

On July 25, 2008, the NRC Office of Investigations (OI) issued its report regarding the inattentive security officers. NRC has taken extensive actions to confirm that the PBAPS security force remains attentive to its duties, including augmented team inspections, enhanced inspection oversight, and issuance of a confirmatory action letter (CAL) to Exelon to confirm NRC expectations regarding the licensee's root cause determinations and effective implementation of corrective actions. Upon completion of commitments by Exelon, NRC closed the CAL on August 28, 2008.

completed the evaluation of the OI report and related inspections, and

On January 6, 2009, NRC took enforcement action against Exelon by issuing a Severity Level III violation with a $65,000 civil penalty for multiple instances of willful security officer inattentiveness.

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Indian Point Nuclear Station: New Sirens (previously reported as EOI-02 in NUREG-0090, Volume 29)

Background – On January 31, 2006, NRC issued a Confirmatory Order modifying the Indian Point license based on congressional action directed by the Energy Policy Act of 2005. This order required that the sirens used to alert the public in the 10-mile emergency planning zone around sites with a specified high population density (for which the Indian Point nuclear station, located 24 miles north of New York City on the Hudson River, was the only affected site) be provided with backup power. Entergy (the Indian Point licensee) decided to install a new siren system rather than retrofit the existing sirens.

operating

electrical

The backup power supply was to be operable by January 30, 2007. However, Entergy requested, and NRC granted, a relaxation of the Order until April 15, 2007. On April 13, 2007, NRC received an additional extension request from Entergy; however, NRC denied the additional extension request because Entergy did not demonstrate good cause.

NRC issued a violation of the siren Order on April 23, 2007, and imposed a significant civil penalty of $130,000 for failing to have the new siren system fully operable in the timeframes directed by the Order and the granted extension. On May 23, 2007, Entergy acknowledged the

violation, paid the civil penalty, and committed to having the siren system fully operable by August 24, 2007. NRC issued a second Order on July 30, 2007, requiring Entergy to meet the August 24, 2007 commitment.

Entergy also failed to fully meet the terms of the second Order since the Federal Emergency Management Agency (FEMA) had not performed its acceptance review by August 24, 2007. NRC issued a violation of the second Order to Entergy on August 30, 2007. On September 12, 2007, FEMA concluded that the new siren system was not adequate in that it did not meet several performance criteria set forth in FEMA guidance. On January 24, 2008, the NRC issued another notice of violation with a proposed civil penalty of $650,000. On February 22, 2008, Entergy responded to the notice of violation and paid the civil penalty. Entergy's response is publicly available through ADAMS, under Accession No. ML080560260.

FEMA communicated to NRC that "the old siren system still in place had been performing above the required thresholds for reliability during routine siren tests, and was acknowledged to be more than adequate in terms of audibility and coverage of the 10-mile emergency planning zone." This provided reasonable assurance that the existing system was adequate to protect the health and safety of the public while issues with the new system were being resolved. The licensee's failure to have the new siren system in operation and approved by FEMA within the timeframe directed by the Order was resolved by NRC, but the delay did not endanger the public's health and safety.

Update on Actions Taken To Prevent Recurrence

FEMA approved the new siren system for service on August 22, 2008, and Entergy placed the new siren system in service on August 27, 2008. The NRC Order required the system to pass three consecutive monthly actuation tests with an actuation rate of at least 97 percent. Those tests were performed in September, October, and November 2008 and were successful, with siren actuation rates of 99.4 percent, 98.3 percent, and 99.4 percent, respectively. System reliability testing required by the NRC Order demonstrated that the new siren system was reliable. NRC notified stakeholders that the new siren system was operational on August 27, 2008. NRC's press release is publicly available through ADAMS, under Accession No. ML082350676.

On December 5, 2008, FEMA issued its final technical review of the preliminary siren design report. The final design report will be submitted to FEMA after approximately one year of reliability testing has been completed. The NRC Order also requires that Entergy receive FEMA approval prior to dismantling the old siren system. FEMA indicated its plans to grant permission to dismantle the old siren system after completion of the review of the final design report. Throughout installation of the new siren system, the existing siren system remained available and operated in a reliable manner. Final NRC closeout, including additional enforcement action (if any), regarding this issue are pending.

update based on latest info.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER JACZKO

SUBJECT: SECY-09-0029 – REPORT TO CONGRESS ON ABNORMAL OCCURRENCES: FISCAL YEAR 2008

Approved __X__ Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below ____ Attached ___ None X

SIGNATURE

03/24/2009

DATE

Entered on "STARS" Yes _X_ No ___

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER LYONS

SUBJECT: SECY-09-0029 – REPORT TO CONGRESS ON ABNORMAL OCCURRENCES: FISCAL YEAR 2008

Approved X **Disapproved** _____ **Abstain** _____

Not Participating _____

COMMENTS: **Below** X **Attached** ___ **None** ___

I note that the medical event that occurred at Geisinger Wyoming Valley Hospital (NRC08-04) was the result of the physician modifying his original written directive without revising or issuing a new written directive. The physician modified the original written directive since he realized that the amount of I-131 prescribed in the original directive was incorrect. The change to the original written directive resulted in the patient receiving the correct dosage.

The intent of the Abnormal Occurrence (AO) report to Congress is to highlight events or incidents that are significant from the standpoint of public health and safety. Although this medical event does meet the criteria for consideration as an AO, the patient did receive the correct dosage as intended by the physician. I believe that this medical event does not meet the threshold for an AO and should not be included in the report to Congress.

I also support the Chairman's editorial comments and comments.

Peter B. Lyons
SIGNATURE

3/9/09
DATE

Entered on "STARS" Yes X No ___

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER SVINICKI

SUBJECT: SECY-09-0029 – REPORT TO CONGRESS ON ABNORMAL OCCURRENCES: FISCAL YEAR 2008

Approved XX Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below XX Attached XX None ___

I concur in the removal of medical event NRC 08-04 for the reasons stated by Commissioner Lyons; support the Chairman's edits and comments; and approve the report as further edited in the attached.

SIGNATURE

03/18/09

DATE

Entered on "STARS" Yes ✓ No ___

through regulations specifying requirements that ensure the safe use of radioactive materials. Those regulations contain design, operation, and quality assurance criteria appropriate for the various activities regulated by NRC. Licensing, inspection, and enforcement programs provide a regulatory framework to ensure compliance with the regulations. In addition, NRC is striving to make the regulatory system more risk-informed and performance-based, where appropriate.

REPORTABLE EVENTS

NRC initially promulgated the AO criteria in a policy statement ~~that the Commission~~ published in the *Federal Register* on February 24, 1977 (42 FR 10950), followed by several revisions in subsequent years. The most recent revision to the AO criteria was published in the *Federal Register* on October 12, 2006 (71 FR 60198) and became effective on that date. That revision established the criteria that NRC used to define AOs for the purpose of this report, as set forth in Appendix A.

Review and response to operating experience are essential to ensure that licensed activities are conducted safely. Toward that end, the regulations require that licensees must report certain incidents or events to NRC. Such reporting helps to identify deficiencies and ensure that corrective actions are taken to prevent recurrence.

NRC and industry review and evaluate operating experience to identify safety concerns. NRC responds to risk significant issues through licensing activities and regulations. In addition, the agency maintains operational data in computer-based data files for more effective collection, storage, retrieval, and evaluation.

NRC also routinely disseminates (to the public, industry, and other interested groups) publicly available information and records regarding reportable events at licensed or regulated facilities. The agency achieves this dissemination through public announcements and special notifications to licensees and other affected or interested groups. To widely disseminate information to the public, NRC also issues a *Federal Register* notice describing AOs at facilities licensed or otherwise regulated by NRC or Agreement States that occurred in the previous fiscal year. In addition, NRC routinely informs Congress of significant events that occur at licensed or regulated facilities.

AGREEMENT STATES

Section 274 of the Atomic Energy Act, as amended, authorizes the Commission to enter into agreements with States whereby the Commission relinquishes, and the States assume, regulatory authority over byproduct, source, and special nuclear materials in quantities not sufficient to form a critical mass. States that enter into such agreements with NRC are known as Agreement States. Agreement States must maintain programs that are adequate to protect public health and safety and are compatible with the Commission's program for such materials. At the end of FY 2008, there were 35 Agreement States.

Agreement States report event information to NRC in accordance with compatibility criteria established by the "Policy Statement on Adequacy and Compatibility of Agreement State Programs," which the agency published in the *Federal Register* on September 2, 1997 (62 FR 46517). NRC has also developed and implemented procedures for evaluating materials events

ABNORMAL OCCURRENCES IN FISCAL YEAR 2008

I. FOR ALL LICENSEES

A. 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), based on the criteria in Appendix A to this report.

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

Criterion I.A.2, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report provides that any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual total effective dose equivalent of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more, shall be considered for reporting as an AO.

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.

This event is closed for the purpose of this report.

Insert the following either as a paragraph right after the title or as a footnote associated with the title:

"The following is a brief explanation of the outline numbering system used in this section of the report. Appendix A provides the specific criteria for determining when an event is an abnormal occurrence (AO) and provides guidelines for reporting other events of interest which may not meet the AO criteria but which the Commission has determined should be in this report. Appendix A contains four major categories: I. For All Licensees, II. For Commercial Nuclear Power Plant Licensees, III. Events at Facilities Other Than Nuclear Power Plants and all Transportation Events, and IV. Other Events of Interest. Category IV events are discussed in Appendix C of the report and Categories I, II, and III are discussed in this section. The first 3 categories each contain significant subelements labeled A, B, C, and one category subelement goes to D. The following information will discuss each of the first 3 categories but will only discuss the specific subelement in each category which has an AO being reported. For example, item I only discusses subelement A. Also, the identification number for all Agreement State AO reports start with the letters "AS". Similarly, the identification number for all NRC AO reports start with the letters "NRC". "

Reason for the insertion: The numbering system can be very confusing to the general reader who has not memorized appendix A and does not instinctively know that AS in an identification number means Agreement State and NRC in an identification number means Nuclear Regulatory Commission. If you read the report in plain language, Item I has an A but no B, Item II has no subelements, and Item III has a C but no A or B. If you read the whole report and put Appendix A next to this section, you could figure out the numbering system, but I would not expect the general public or Congressional staff would have the time analyze the report in that detail.

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

Criterion I.A.2, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report provides that any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual total effective dose equivalent of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more, shall be considered for reporting as an AO.

What date was the dose administered? It is significant compared to the other dates listed.

Date and Place – June 4, 2008, San Antonio, Texas

United States air Force

Nature and Probable Consequences – Wilford Hall Medical Center, a permit holder under the USAF Master Material license, reported that a therapeutic dose of 5.55 GB (150 mCi), for post-thyroidectomy therapy to a patient, 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 still being conducted and the review of this incident is ongoing.

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

III. EVENTS AT FACILITIES OTHER THAN NUCLEAR POWER PLANTS AND ALL TRANSPORTATION EVENTS

C. Medical Licensees

During this reporting period, five events at NRC-licensed or regulated facilities and four events at Agreement State-licensed facilities were significant enough to be reported as AOs, based on the criteria in Appendix A to this report.

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

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provides in part that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site shall be considered for reporting as an AO.

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.

This event is closed for the purpose of this report.

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

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provides in part that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site shall be considered for reporting as an AO.

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.

This event is closed for the purpose of this report.

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

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provides in part that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site shall be considered for reporting as an AO.

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.

This event is closed for the purpose of this report.

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

Criteria III.C.1.b and III.C.2.b(i), "For Medical Licensees," of Appendix A to this report provides in part that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or lens of the eye, or the gonads) and represents a prescribed dose or dosage that uses the wrong radiopharmaceutical shall be considered for reporting as an AO.

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.

This event is closed for the purpose of this report.

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

Criteria III.C.1.b and III.C.2.b(i), "For Medical Licensees," of Appendix A to this report provides in part that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or lens of the eye, or the gonads) and represents a prescribed dose or dosage that uses the wrong radiopharmaceutical shall be considered for reporting as an AO.

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.

This event is closed for the purpose of this report.

NRC08-04 **Medical Event at Geisinger Wyoming Valley Hospital in Wilkes-Barre, Pennsylvania**

Criteria III.C.1.b and III.C.2.a, "For Medical Licensees," of Appendix A to this report provides in part that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or lens of the eye, or the gonads) and represents a dose or dosage that is at least 50 percent greater than that prescribed shall be considered for reporting as an AO.

Date and Place – February 7, 2008, Wilkes-Barre, Pennsylvania

Nature and Probable Consequences – Geisinger Wyoming Valley Hospital reported that a patient was administered 0.37 GBq (10 mCi) of iodine-131 for treatment of a hyperactive thyroid, instead of the prescribed 0.37 MBq (10 µCi). The incident was discovered on April 25, 2008, during a review of the hospital's written directives. Geisinger stated that the authorized user physician prepared a written directive that erroneously prescribed 0.37 MBq (10 µCi). The authorized user physician realized his error and telephoned the nuclear medicine technician to request a change in the activity to the correct dosage of 0.37 GBq (10 mCi). However, the authorized user physician did not revise or issue a new written directive for the administration. The referring physician was informed of this event. The patient was not informed of this event because the correct dosage of 0.37 GBq (10 mCi) was administered for treatment.

Causes – The cause of the medical event was human error in failing to prepare and issue a corrected written directive for the iodine-131 administration.

Actions Taken to Prevent Recurrence

Licensee – The licensee's corrective actions taken to prevent recurrence included counseling the nuclear medicine technician on following procedures, revising the written directive form to exclude a choice of activity units, and enforcing that telephone requests from authorized user physicians, on changing the activity of an administration, will not be accepted until a new or revised written directive is issued for the administration.

NRC – This event was reported to NRC in April 2008 after the license transfer to Pennsylvania, which became a new Agreement State on March 31, 2008. The NRC Region I Office contacted the State about follow-up inspection actions.

State – The State did not conduct a follow-up inspection because the patient received the correct administration for treatment. However, the State noted that had the dosage prescribed in the written directive, 0.37 MBq (10 µCi), been administered to the patient, the patient would have received 288 Gy (28,000 rad) to the thyroid.

This event is closed for the purpose of this report.

NRC08-05 **Medical Event at Reid Hospital and Health Care Services in Richmond, Indiana**

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provides in part that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site shall be considered for reporting as an AO.

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.

This event is closed for the purpose of this report.

NRC08-06 **Medical Event at Bon Secours Virginia Health Source in Richmond, Virginia**

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provides in part that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site shall be considered for reporting as an AO.

Date and Place – May 1, 2008, Richmond, 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.

This event is closed for the purpose of this report.

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

Criteria III.C.1.b and III.C.2.a, "For Medical Licensees," of Appendix A to this report provides in part that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or lens of the eye, or the gonads) and represents a dose or dosage that is at least 50 percent greater than that prescribed shall be considered for reporting as an AO.

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.

This event is closed for the purpose of this report.

5. Any significant unauthorized disclosures (loss, theft, and/or deliberate) of classified information that harms national security or safeguards information that harms the public health and safety.

D. Initiation of High-Level NRC Team Inspections.[7]

II. For Commercial Nuclear Power Plant Licensees

A. Malfunction of Facility, Structures, or Equipment

1. Exceeding a safety limit of license technical specification (TS) [10 CFR 50.36(c)].

2. Serious degradation of fuel integrity, primary coolant pressure boundary, or primary containment boundary.

3. Loss of plant capability to perform essential safety functions so that a release of radioactive materials which could result in exceeding the dose limits of 10 CFR Part 100 or 5 times the dose limits of 10 CFR Part 50, Appendix A, General Design Criterion (GDC) 19, could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system).

B. Design or Safety Analysis Deficiency, Personnel Error, or Procedural or Administrative Inadequacy

1. Discovery of a major condition not specifically considered in the safety analysis report (SAR) or TS that requires immediate remedial action.

2. Personnel error or procedural deficiencies that result in loss of plant capability to perform essential safety functions so that a release of radioactive materials which could result in exceeding the dose limits of 10 CFR Part 100 or 5 times the dose limits of 10 CFR Part 50, Appendix A, GDC 19, could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod drive mechanism).

C. Any reactor events or conditions that are determined to be of high safety significance.[8]

This section addresses

7 Initiation of any Incident Investigation Teams, as described in NRC Management Directive (MD) 8.3, "NRC Incident Investigation Program," or initiation of any Accident Review Groups, as described in MD 8.9, "Accident Investigation."

8 The NRC ROP uses four colors to describe the safety significance of licensee performance. As defined in NRC Management Directive 8.13, "Reactor Oversight Process," green is used for very low safety significance, white is used for low to moderate safety significance, yellow is used for substantial safety significance, and red is used for high safety significance. Reactor conditions or performance indicators evaluated to be red are considered Abnormal Occurrences. Additionally, Criterion II.C also includes any events or conditions evaluated by the NRC ASP program to have a conditional core damage probability (CCDP) or change in core damage probability (ΔCDP) of greater than 1×10^{-3}.

7 - is not a sentence... delete the footnotes are better.

D. Any operating reactor plants that are determined to have overall unacceptable performance or that are in a shutdown condition as a result of significant performance problems and/or operational event(s).[9]

III. Events at Facilities Other than Nuclear Power Plants and all Transportation Events

A. Events Involving Design, Analysis, Construction, Testing, Operation, Transport, Use, or Disposal of Licensed Facilities or Regulated Materials

1. An accidental criticality [10 CFR 70.52(a)].

2. A major deficiency in design, construction, control, or operation having significant safety implications that require immediate remedial action.

3. A serious safety-significant deficiency in management or procedural controls.

4. A series of events (in which the individual events are not of major importance), recurring incidents, or incidents with implications for similar facilities (generic incidents) that raise a major safety concern.

B. For Fuel Cycle Facilities

1. Absence or failure of all safety-related or security-related controls (engineered and human) for a NRC-regulated lethal hazard (radiological or chemical) while the lethal hazard is present.

2. An NRC-ordered safety-related or security-related immediate remedial action.

C. For Medical Licensees

A medical event that:

1. Results in a dose that is
   a. Equal to or greater than 1 Gy (100 rad) to a major portion of the bone marrow or to the lens of the eye; or equal or greater than 2.5 Gy (250 rad) to the gonads; or

   b. Equal to or greater than 10 Gy (1,000 rad) to any other organ or tissue; and

2. Represents either
   a. A dose or dosage that is at least 50 percent greater than that prescribed, or

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9 Any plants assessed by the ROP to be in the unacceptable performance column, as described in NRC Inspection Manual Chapter 0305, "Operating Reactor Assessment Program." This assessment of safety performance is based on the number and significance of NRC inspection findings and licensee performance indicators.

violation, paid the civil penalty, and committed to having the siren system fully operable by August 24, 2007. NRC issued a second Order on July 30, 2007, requiring Entergy to meet the August 24, 2007 commitment.

Entergy also failed to fully meet the terms of the second Order since the Federal Emergency Management Agency (FEMA) had not performed its acceptance review by August 24, 2007. NRC issued a violation of the second Order to Entergy on August 30, 2007. On September 12, 2007, FEMA concluded that the new siren system was not adequate in that it did not meet several performance criteria set forth in FEMA guidance. On January 24, 2008, the NRC issued another notice of violation with a proposed civil penalty of $650,000. On February 22, 2008, Entergy responded to the notice of violation and paid the civil penalty. Entergy's response is publicly available through ADAMS, under Accession No. ML080560260.

FEMA communicated to NRC that "the old siren system still in place had been performing above the required thresholds for reliability during routine siren tests, and was acknowledged to be more than adequate in terms of audibility and coverage of the 10-mile emergency planning zone." This provided reasonable assurance that the existing system was adequate to protect the health and safety of the public while issues with the new system were being resolved. The licensee's failure to have the new siren system in operation and approved by FEMA within the timeframe directed by the Order was resolved by NRC, but the delay did not endanger the public's health and safety.

Update on Actions Taken To Prevent Recurrence

FEMA approved the new siren system for service on August 22, 2008, and Entergy placed the new siren system in service on August 27, 2008. The NRC Order required the system to pass three consecutive monthly actuation tests with an actuation rate of at least 97 percent. Those tests were performed in September, October, and November 2008 and were successful, with siren actuation rates of 99.4 percent, 98.3 percent, and 99.4 percent, respectively. System reliability testing required by the NRC Order demonstrated that the new siren system was reliable. NRC notified stakeholders that the new siren system was operational on August 27, 2008. NRC's press release is publicly available through ADAMS, under Accession No. ML082350676.

On December 5, 2008, FEMA issued its final technical review of the preliminary siren design report. The final design report will be submitted to FEMA after approximately one year of reliability testing has been completed. The NRC Order also requires that Entergy receive FEMA approval prior to dismantling the old siren system. FEMA indicated its plans to grant permission to dismantle the old siren system after completion of the review of the final design report. Throughout installation of the new siren system, the existing siren system remained available and operated in a reliable manner. Final NRC closeout, including additional enforcement action (if any), regarding this issue are pending.

Update this paragraph to reflect the most recent Commission decision.

APPENDIX E
GLOSSARY

Absorbed Dose – as defined in 10 CFR 20.1003, means the energy imparted by ionizing radiation per unit mass of irradiated material; the units of absorbed dose are the rad and the gray (Gy)

Act – as defined in 10 CFR 40.4, means the Atomic Energy Act of 1954 (68 Stat. 919), including any amendments thereto

Augmented Inspection Team (AIT) – as defined in Management Directive 8.3, "NRC Incident Investigation Program," is a group consisting of technical experts from the region in which an incident took place, augmented by personnel from headquarters, other regions, or contractors. The team performs an inspection of a significant operating event and reports directly to the appropriate regional administrator. The objectives of an AIT are to conduct a timely, thorough, and systematic inspection related to significant operational events at facilities licensed by the NRC; assess the health and safety significance of the event and communicate to regional and headquarters management the facts and safety concerns related to the event so that appropriate follow-up actions can be taken (e.g., study a generic concern, issue an information notice or bulletin); collect, analyze, and document factual information and evidence sufficient to determine the cause(s), conditions, and circumstances pertaining to the event

Authorized Medical Physicist – as defined in 10 CFR 35.2, is an individual who (1) meets the requirements in §§35.51(a) and 35.59; or (2) is identified as an authorized medical physicist or teletherapy physicist on (i) a specific medical use license issued by the Commission or Agreement State; (ii) a medical use permit issued by a Commission master material licensee; (iii) a permit issued by a Commission or Agreement State broad scope medical use licensee; or (iv) a permit issued by a Commission master material license broad scope medical use permittee

Authorized User (AU) – as defined in 10 CFR 35.2, is a physician who (1) meets the requirements in §§35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), or 35.690(a); or (2) is identified as an authorized user on (i) a Commission or Agreement State license that authorizes the medical use of byproduct material; (ii) a permit issued by a Commission master material licensee that is authorized to permit the medical use of byproduct material; (iii) a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of byproduct material; or (iv) a permit issued by a Commission master material license broad scope permittee that is authorized to permit the medical use of byproduct material

[1]**Balloon Catheter** – a catheter with an inflatable balloon tip which is used during a procedure to enlarge a narrow opening or passage within the body. The deflated balloon catheter is positioned, then inflated to perform the necessary procedure, and then deflated again to be removed

[1] These terms are not defined in 10 CFR, a management directive, an inspection procedure, or in a NRC policy statement. Rather, these terms are defined based upon definitions in the online *Wikipedia: The Free Encyclopedia* (http://wikipedia.org).

Is this the most authoritative source available to us?

Use more official reference such as medline or webMD or CDC but do not use 'wikipedia' for medical terms.