

UNITED STATES NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

April 15, 2011

SECRETARY

COMMISSION VOTING RECORD

DECISION ITEM: SECY-11-0027

TITLE: REPORT TO CONGRESS ON ABNORMAL OCCURRENCES FISCAL YEAR 2010

The Commission (with all Commissioners agreeing) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of April 15, 2011.

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 Jaczko Commissioner Svinicki Commissioner Apostolakis Commissioner Magwood Commissioner Ostendorff OGC EDO PDR

VOTING SUMMARY - SECY-11-0027

RECORDED VOTES

	APRVD DISAPRVD ABSTAIN	NOT PARTICIP COMMENTS	DATE
CHRM. JACZKO	x	Х	3/30/11
COMR. SVINICKI	x	Х	4/4/11
COMR. APOSTOLAKIS	x	X	3/24/11
COMR. MAGWOOD	Х	X	3/28/11
COMR. OSTENDORFF	X	Х	3/30/11

COMMENT RESOLUTION

In their vote sheets, all Commissioners approved the staff's recommendation and provided some additional comments. Subsequently, the comments of the Commission were incorporated into the guidance to staff as reflected in the SRM issued on April 15, 2011.

RESPONSE SHEET

TO:	Annette	Vietti-Cook,	Secretary
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Chairman Gregory B. Jaczko FROM:

SECY-11-0027 - REPORT TO CONGRESS ON SUBJECT: **ABNORMAL OCCURRENCES FISCAL YEAR 2010**

Approved X Disapproved Abstain

Not Participating _____

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COMMENTS: Below ____ Attached X__ None ____

SIGNATURE

3/32/1

DATE

Entered on "STARS" Yes <u>x</u> No ____

Chairman Jaczko's Comments on SECY-11-0027, "Report to Congress on Abnormal Occurrences Fiscal Year 2010."

I approve the publication of the report to Congress on abnormal occurrences for fiscal year 2010, along with including the H.B. Robinson event in Appendix C, and with the following edits:

- 1. For event AS10-02, the second paragraph under "Nature and Probable Consequences" should be updated because it indicates that the pregnancy is "progressing normally" even though it has now been more than nine months since the estimated conception date of March 13, 2010.
- 2. For event AS10-03, the text should indicate why the event, which occurred in 2005, was not reported by the licensee until 2010. For example, AS10-05 (which is similar in the delay) states that events from 2005-2007 were identified in FY 2010 due to a licensee review of all prostate brachytherapy cases over the last 7 years.
- 3. The pictures should be deleted from pages 7 and 13.
- 4. For event NRC10-06, under "Nature and Probable Consequences," correct the second sentence of the second paragraph so that it is a complete sentence.
- 5. In Appendix C, fifth paragraph, delete the text from "To put these levels in perspective, the average American..." through "...or more than twice the exposure received by any worker during this event."
- 6. In Appendix D, confirm that all of the terms in this Glossary are used in the report and reorder the terms that are not in proper alphabetical order.

RESPONSE SHEET

TO:	Annette Vietti-Cook, Secretary
FROM:	COMMISSIONER SVINICKI
SUBJECT:	SECY-11-0027 – REPORT TO CONGRESS ON ABNORMAL OCCURRENCES FISCAL YEAR 2010
Approved <u>XX</u>	Disapproved Abstain
Not Participatin	g
COMMENTS:	Below XX Attached XX None

I approve publication and transmittal of the Abnormal Occurrence Report with inclusion of the H.B. Robinson event in Appendix C, but with the narrative as revised by the staff on March 17, 2011 and further edited by Commissioner Magwood in his vote. I approve the remainder the AO Report subject to the edits of Commissioner Apostolakis and my further edits, attached.

SIGNATURE

DATE

Entered on "STARS" Yes 📈 No ____

following notification by the licensee of their analysis of the event. The licensee's analysis revealed that, based on the specific type of material processed in the event, the nitrogen compound gases generated could have resulted in high occupational consequences.

The preliminary results of the augmented inspection and an interim review of the licensee's overall safety performance identified a number of concerns regarding the licensee's ability to provide reasonable assurance of its ability to safely operate the facility. These concerns involved the adequacy of the licensee's management oversight of facility process changes, perceived production pressures, lack of questioning attitude by workers and management, and poor communications. In addition, NRC identified concerns with the decisions made by the licensee's management in both October and November 2009 to restart the uranium aluminum process lines without fully understanding the causes of the events and without correcting the underlying problems.

On January 7, 2010, NRC issued a Confirmatory Action Letter regarding commitments made by the licensee in a letter dated December 30, 2009. The actions included (1) suspending operation of several processing lines, (2) completing specific actions before restart of operations, and (3) providing NRC with sufficient time to inspect completion of the actions. After extensive team inspections, NRC authorized the restart of four processing lines in March 2010, May 2010, July 2010, and October 2010 respectively. Portions of one process line remain shutdown pending equipment modifications and restart inspections.

On September 2, 2010, NRC imposed a civil penalty of \$140,000 based on a Severity Level III problem involving three violations associated with the event. The penalty was paid in October 2010. The three violations involved (1) failure to have adequate engineered or administrative controls for operations in violation of 10 CFR 70.61(b), (2) failure to comply with multiple facility operating procedures regarding the facility system change process, and (3) failure to maintain records necessary to support the licensee's determination that specific facility changes did not require prior NRC approval in violation of 10 CFR 70.72. Under different circumstances, a more significant event could have resulted in a high consequence occupational exposure.

[SPECULATIVE; NOT FACT-BASED.]

RESPONSE SHEET

TO:	Annette Vietti-Cook, Secretary
FROM:	Commissioner Apostolakis
SUBJECT:	SECY-11-0027 – REPORT TO CONGRESS ON ABNORMAL OCCURRENCES FISCAL YEAR 2010
Approved X	Disapproved Abstain
Not Participatin	g
COMMENTS:	Below X Attached None

I approve staff's recommendation to include H.B. Robinson in Appendix C to the AO report with the standard transmittal letter and the following edits.

Page 7 of the draft report, replace the diagram with a short text explanation of trigeminal neuralgia such as trigeminal neuralgia is a nerve disorder that causes a stabbing or electric-shock-like pain in the skin of the face.

Page 13 of the draft report; delete the picture, because as labeled it would appear the medical event was caused by a malfunction of Nordion equipment. It is not clear that is the case.

In future reports, staff should normalize the discussion of actions taken by NRC or the State by either including dates of actions in all cases or none and either describing the severity level of all notice of violations or noting only that a notice of violation was issued.

Page C-3, update the first few sentences to reflect that the Groundwater Task Force has completed its review and forwarded its report and recommendations to the Commission.

Entered on "STARS" Yes 📐 No ___

RESPONSE SHEET

TO:	Annette	Vietti-Cook,	Secretary
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FROM: Commissioner Magwood

SUBJECT: SECY-11-0027 – REPORT TO CONGRESS ON ABNORMAL OCCURRENCES FISCAL YEAR 2010

Approved X Disapproved Abstain _____

Not Participating _____

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COMMENTS: Below X Attached X None ____

Approve the staff's recommendation to include the H.B. Robinson event in Appendix C, "Other Events of Interest," to the AO report with the standard transmittal letter to Congress consistent with the attached edits.

I also support the edits proposed by Commissioner Apostolakis.

SIGN

2P March 2011 DATE

Entered on "STARS" Yes X No ____

enhance performance, and personnel and management changes. Additionally, the NRC has performed inspections to verify that important operational safety aspects have been addressed.

This event does not currently meet the AO reporting criteria; however, recent information identified during NRC supplemental inspection activities could potentially cause the NRC to determine that this event is of high safety significance (Criterion II.C). Criterion II.C includes events or conditional core damage probability or increase in core damage probability greater than or equal to 1×10⁻³. The NRC staff analyzed this event under the NRC's ASP Program based on new information that was identified and assessed by NRC inspectors in late December 2010. At this time, the preliminary ASP analysis indicates that this event may meet the core damage probability criteria for a significant precursor. This analysis is currently under review by NRC staff and will be publicly transmitted to the licensee for their review and comment. At this time staff is evaluating the event under the NRC's Accident Sequence Precursor (ASP) program

The ASP Program provides an integrated risk analysis of all deficiencies, equipment failures, and degraded conditions that were observed during the event. The inspection program separately assesses the risk associated with each performance deficiency. Therefore, for events involving multiple licensee performance deficiencies and equipment failures, as in the H.B. Robinson event, it is not unexpected that the ASP and inspection programs would assign different risk significance levels. As such, the integrated approach used by the ASP Program complements the inspection program. In the case of the H.B. Robinson event, the staff has concluded that the preliminary results from the integrated ASP analysis are consistent with the risk significance of the two white inspection findings.

If the final ASP analysis of this event results in its identification as a significant precursor, the NRC will report this event in Section II, "Commercial Nuclear Power Plant Licensees," of next fiscal year's AO Report and in the FY 2011 Performance and Accountability Report to Congress.

FACILITIES OTHER THAN NUCLEAR POWER PLANTS

EOI-04 Nuclear Fuel Services Inc.: Adverse Chemical Reaction Event

This event is the result of an adverse chemical reaction that did not result in a release of radioactivity but is included in this report because it caused NRC to increase its attention and oversight to this program area.

On October 13, 2009, Nuclear Fuels Services (NFS) (the licensee) experienced an unexpected exothermic chemical reaction within the Blended Low Enriched Uranium Preparation Facility. The elevated temperatures from the reaction created nitrogen compound gases within the associated process off-gas piping. An instrument located near the ceiling of the facility detected these gases and generated an alarm that resulted in the evacuation of employees from the affected area. In addition, the elevated temperature of these gases caused portions of the plastic off-gas piping system to deform and sag. NFS personnel took action to shut down the system and as a result, no personnel were injured and offsite environmental releases during the event were within regulatory limits.

In response to the event, NRC formed a Special Inspection Team that arrived at the licensee's

RESPONSE SHEET

то:	Annette Vietti-Cook, Secretary
FROM:	COMMISSIONER OSTENDORFF
SUBJECT:	SECY-11-0027 – REPORT TO CONGRESS ON ABNORMAL OCCURRENCES FISCAL YEAR 2010
Approved <u>XX</u>	Disapproved Abstain
Not Participating	9
COMMENTS:	Below Attached <u>XX</u> None

Subject to the attached comments and edits attached.

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SIGNATURE

3/30/n DATE

DATE

Entered on "STARS" Yes XX No ____

Commissioner Ostendorff's comment on SECY 11-0027, "Report to Congress on Abnormal Occurrences Fiscal Year 2010"

I approve of the staff's proposal to publish and transmit to Congress the fiscal year 2010 abnormal occurrence (AO) report with the inclusion of the March 28, 2010 H.B Robinson event in the "other events of interest" section, subject to the attached edits. In addition to the attached edits, I offer the changes below to improve this report and the accuracy and timeliness of future AO reports. Specifically, preliminary conclusions regarding the March 28, 2010 H.B. Robinson event should be removed, explicit time goals for the Accident Sequence Precursor (ASP) Program for assessments of potentially significant reactor events should be established, and additional context around the timeline for the regulatory response to several of the events should be provided.

Since the AO report is the agency's only opportunity to provide Congress and the public a comprehensive overview of the events that have occurred nationwide, it is important that the report be accurate and timely. Because the staff's analysis of the significance of the H.B Robinson event is not yet complete, the event description in the report contained preliminary conclusions. Although there are important nuclear safety insights from the event, I am concerned that providing such preliminary information may undermine the agency's credibility and cause confusion among our stakeholders. Therefore, I support Commissioner Magwood's proposed revisions to the section of the report describing this event. Given that inclusion of this event in the AO report is somewhat unusual, the staff should discuss inclusion of the event in the report with the licensee before the report is issued.

I am also concerned that the final risk assessment of the H.B Robinson event will not be available for potential inclusion in the AO report to Congress until next year's report, approximately two years after the actual event occurred. The staff should continue to provide the AO report to the Commission in February of each year. However, to ensure that in the future the Commission has the timely information needed to clearly communicate the significance of events in the report, the staff should align, to the extent practical and commensurate with the significance of events, the timelines for completing the ASP program's assessment of potentially significant precursor events, the AO report, and other NRC activities such as the industry trends programs and the Agency Action Review Meeting.

As the staff appropriately points out, the fiscal year 2010 report contains 6 events which occurred before 2010 but were evaluated in the 2010 report. Without additional context, it may appear that the NRC or State did not follow up on the events in a timely manner. The staff should supplement the timeline information in the report for these events to clarify when the events were reported.

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

C. Medical Licensees

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

AS10-03 Medical Event at Mercy St. Vincent Medical Center in Toledo, Ohio

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Criterion III.C.1.b, III.C.2.a and III.C.2.b.(iii), "For Medical Licensees," of Appendix A to this report provides, in part, that a medical event shall be considered for reporting as an AO if it results in a dose 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); sepresents either a dose or dosage that is at least 50 percent greater than that prescribed; and is a prescribed dose delivered to the wrong treatment site.

Date and Place - November 8, 2005 (reported on March 3, 2010), Toledo, Ohio

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<u>Nature and Probable Consequences</u> – Mercy St. Vincent Medical Center (the licensee) reported that a medical event occurred associated with a brachytherapy seed implant procedure to treat prostate cancer. The patient was prescribed to receive a total dose of 160 Gy (16,000 rad) to the prostate using 67 iodine-125 seeds. Instead, the patient's sigmoid colon received at least the full prescription dose of 160 Gy (16,000 rad) and a significant portion of the bladder base including the region of the urethral orifices received at least 108 Gy (10,800 rad) (wrong treatment sites). The patient and referring physician were informed of this event.

On March 3, 2010, the Ohio Department of Health (ODH) received information of this previously unreported medical event from the licensee. ODH performed an onsite investigation and confirmed the unreported medical event. The licensee confirmed that 13 of the permanent iodine-125 seeds were improperly positioned in the bladder and subsequently removed from the patient's bladder immediately after the procedure. A post-implant dose calculation showed that the prostate received a dose of 15.43 Gy (1,543 rad), or 9.6 percent of the prescribed dose. The patient chose to then receive an external beam treatment with a linear accelerator to treat the tumor. About 13 months after the brachytherapy procedure, the patient developed rectosigmoid bleeding that required hospitalization and argon laser coagulopathy. In August 2010, ODH ordered an independent medical expert evaluation of the event. The independent medical expert concluded that the subsequent delivery of external beam radiotherapy may have contributed to the rectosigmoid damage, but the high dose from the brachytherapy procedure almost certainly was the primary cause of the damage.

<u>Cause(s)</u> – The cause of the medical event was the failure of the licensee to adequately visualize the prostate prior to the implant procedure.

Actions Taken To Prevent Recurrence

<u>Licensee</u> – Corrective actions taken by the licensee included training of the RSO, medical physicist, clinical director, and radiation oncologists on ODH regulations concerning medical events. New procedures were also developed for brachytherapy seed implant procedures.

NRC10-06 Medical Event at Valley Hospital in Paramus, New Jersey

Criterion III.C.1.b and III.C.2.b.(iii), "For Medical Licensees," of Appendix A to this report provide, in part, that a medical event shall be considered for reporting as an AO if it results in a dose 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.

Date and Place – July 29, 2009, Paramus, New Jersey

<u>Nature and Probable Consequences</u> – Valley Hospital (the licensee) reported that a medical event occurred associated with a brachytherapy seed implant procedure to treat prostate cancer. The patient was prescribed a total dose of 65 Gy (6,500 rad) to the prostate using 46 cesium-131 seeds. Instead, the licensee determined that an unintended volume (30.1 ml) of soft tissue received 100 percent of the prescribed prostate dose. The patient and referring physician were informed of this event.

On August 6, 2009, the patient returned to the hospital for a post-implant CT scan. The images revealed that the seeds were implanted in soft tissue 4 to 5 cm from to the prostate. Post-implant dosimetry calculations indicated that none of the prostate received the prescribed dose of 6,500 cGy (6,500 rad). NRC contracted with a medical consultant who concluded that the additional dose can increase the risk of soft tissue fibrosis or increase the risk of impotency.

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<u>Cause(s)</u> – The cause of the medical event was the licensee's failure to hydentify the position of the prostate due to the patient's unusual anatomy and obesity.

Actions Taken To Prevent Recurrence

<u>Licensee</u> – The licensee revised their prostate implant procedures to include steps to ensure that the prostate and surrounding anatomy is adequately visualized prior to implant.

<u>NRC</u> – The NRC staff conducted an inspection on October 29, 2009, and determined that no violations of NRC requirements occurred.

This event is closed for the purpose of this report.

On September 2, 2010, NRC imposed a civil penalty of \$140,000 based on a Severity Level III problem involving three violations associated with the event. The penalty was paid in October 2010. The three violations involved (1) failure to have adequate engineered or administrative controls for operations in violation of 10 CFR 70.61(b), (2) failure to comply with multiple facility operating procedures regarding the facility system change process, and (3) failure to maintain records necessary to support the licensee's determination that specific facility changes did not require prior NRC approval in violation of 10 CFR 70.72. Under different circumstances, a more significant event could have resulted in a high consequence occupational exposure.