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

SECRETARY

April 7, 2006

# COMMISSION VOTING RECORD

DECISION ITEM: SECY-06-0055

TITLE: REPORT TO CONGRESS ON ABNORMAL OCCURRENCES: FISCAL YEAR 2005

The Commission (with all Commissioners agreeing) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of April 7, 2006.

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 Diaz
Commissioner McGaffigan
Commissioner Merrifield
Commissioner Jaczko
Commissioner Lyons
OGC
EDO
PDR

SECY NOTE: THIS VOTING RECORD WILL BE RELEASED TO THE PUBLIC 5 DAYS AFTER DISPATCH OF THE REPORT TO CONGRESS.

## VOTING SUMMARY - SECY-06-0055

## RECORDED VOTES

| | APRVD | DISAPRVD | ABSTAIN | NOT PARTICIP | COMMENTS | DATE |
|---|---|---|---|---|---|---|
| CHRM. DIAZ | X | | | | X | 3/21/06 |
| COMR. McGAFFIGAN | X | | | | X | 3/22/06 |
| COMR. MERRIFIELD | X | | | | X | 3/27/06 |
| COMR. JACZKO | X | | | | | 3/31/06 |
| COMR. LYONS | X | | | | | 3/20/06 |

## 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 April 7, 2006.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: CHAIRMAN DIAZ

SUBJECT: **SECY-06-0055 - REPORT TO CONGRESS ON ABNORMAL OCCURRENCES: FISCAL YEAR 2005**

Approved X Disapproved ____ Abstain ____

Not Participating ____

COMMENTS:

Approved with one minor edit as attached.

SIGNATURE

3.21.06

DATE

Entered on "STARS" Yes ✓ No ___

## AGREEMENT STATE LICENSEES

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

AS 05-01 Iridium-192 Brachytherapy Seed Medical Event at LDS Hospital in Salt Lake City, Utah

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that is (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or the gonads, or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ; and represents a prescribed dose or dosage that is delivered to the wrong treatment site, will be considered for reporting as an AO.

Date and Place — October 26, 2004; LDS Hospital; Salt Lake City, Utah

Nature and Probable Consequences — A patient received 27.56 Gy (2,756 rads) instead of the prescribed 5 Gy (500 rads) during a high dose-rate (HDR) treatment for larynx cancer. The event involved an iridium-192 (Ir-192) source with an activity of 244.2 GBq (6.6 Ci). The error was caused by the use of the diameter instead of the radius of a circular tool to mark the treatment site in a computer software program. As a result, the area treated was 2 centimeters (cm) away from the intended treatment site. The error was discovered before ~~to~~ the third fraction. The prescribing physician stopped the treatment until dosimetry information was completed. The licensee notified the patient and the patient's referring physician of the event. The licensee determined that the impact of the additional dose is probable acute radiation effects and possible late or chronic toxicities.

Cause(s) — This event was caused by human error. The incorrect size button corresponding to the circle tool was used, which caused the diameter instead of the radius to be used in the dosing plan. This caused the incorrect dose to be administered to the incorrect location.

Actions Taken to Prevent Recurrence

Licensee — The licensee suggested that the software manufacturer print the word "RADIUS" on the "size" button located adjacent to the circle tool. To date, the manufacturer has not responded to this issue. The licensee will measure the distance on the brachytherapy device's hard copy output with a ruler to confirm that the distance is entered correctly. The licensee also modified the HDR dose check program so that, in addition to confirming the doses to coordinates entered into the device's input, user specified point coordinates may be manually entered into the check program and compared to what is calculated.

State Agency — The Utah Division of Radiation Control investigated the event on November 3, 2004 and approved the corrective actions that the licensee implemented to prevent the recurrence.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MCGAFFIGAN

SUBJECT: **SECY-06-0055 - REPORT TO CONGRESS ON ABNORMAL OCCURRENCES: FISCAL YEAR 2005**

Approved X Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Minor edits are attached.

Edward McGaffigan Jr.
SIGNATURE

March 22, 2006
DATE

Entered on "STARS" Yes X No ___

# ABSTRACT

Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438) defines an "abnormal occurrence" (AO) as an unscheduled incident or event that 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 (Public Law 104-66) requires that the NRC must report AOs to Congress annually. This report describes those events that the NRC or an Agreement State identified as AOs during fiscal year (FY) 2005.

The report describes three events at NRC-licensed facilities that meet the criteria to be classified as AOs, as defined in Appendix A to the report. All three events occurred at medical institutions. The first event involved a patient who received the incorrect dose distribution while undergoing therapeutic brachytherapy[1] treatment. The second event involved an infant who was administered the incorrect diagnostic dosage of technetium-99m. The third event involved three patients who received unintended radiation doses to the skin of their thighs while undergoing therapeutic treatment.

Reports from Agreement States are also included. 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 material at facilities located within their borders. Currently, there are 34 Agreement States (Minnesota became the 34th Agreement State on March 31, 2006). During Fiscal Year 2005, Agreement States reported six events that occurred at Agreement State-licensed facilities, including five therapeutic medical events and one diagnostic medical event. All six events met the criteria for AO categorization.

Appendix A to this report presents the NRC's criteria for selecting AOs, as well as the guidelines for selecting "Other Events of Interest." Appendix B, "Updates of Previously Reported Abnormal Occurrences," does not contain any updated information on AO events reported in the FY 2004 Report to Congress on Abnormal Occurrences because no new significant information became available. Appendix C, "Other Events of Interest," contains one new event of interest on safe-shutdown safety-related systems at the Kewaunee Power Station and updated information on a spent fuel record accountability discrepancy at the Humboldt Bay Power Plant.

< add footnote

1 Brachytherapy means a method of radiation therapy in which sources are used to deliver a radiation dose at a distance of up to a few centimeters by placement of sources on the body surface, in natural body cavities, or by placement directly in tissues.

## ACRONYMS and ABBREVIATIONS

| | |
|---|---|
| AEA | Atomic Energy Act |
| AO | abnormal occurrence |
| Bq | becquerel |
| CFR | *Code of Federal Regulations* |
| Ci | curie |
| cGy | centigray |
| cm | centimeter |
| Cs-137 | cesium-137 |
| FR | *Federal Register* |
| FY | Fiscal Year |
| GBq | gigabecquerel |
| Gy | gray |
| HDR | high dose-rate |
| I-123 | iodine-123 |
| I-125 | iodine-125 |
| I-131 | iodine-131 |
| Ir-192 | iridium-192 |
| in | inch |
| MBq | megabecquerel |
| μCi | microcurie |
| mCi | millicurie |
| NRC | U.S. Nuclear Regulatory Commission |
| SNM | special nuclear material |
| Sr-90 | strontium-90 |
| Sv | sievert |
| Tc-99m | technetium-99 metastable |
| TEDE | total effective dose equivalent |
| Y-90 | yttrium-90 |

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that is (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or to the gonads or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ; and represents a prescribed dose or dosage that is delivered to the wrong treatment site will be considered for reporting as an AO.

Date and Place —Between January 26 and March 22, 2004 (reported March 25, 2005 due to a misinterpretation of reporting requirements by the licensee), South Bend, Indiana

Nature and Probable Consequences — The licensee reported in March and April 2005, that between January 26 and March 22, 2004, three patients received unintended radiation doses to the skin of their thighs from cesium-137 brachytherapy sources. The vaginal applicator used for the treatments was loaded with incorrectly sized cesium-137 sources, which ~~had the ability to migrate~~ migrated from the intended treatment position through the placement spring when the patient moved to a more up-right position. As a result of the sources moving, the patient's inner thighs received unintended doses of radiation. Approximately two weeks after treatment, the patients developed skin lesions on their inner thighs. The licensee determined that these patients received unintended doses to a small area of the skin on the upper thigh of approximately 2000, 1500, and 2000 cGy (rad), respectively. Based on clinical observations, the licensee determined that all patients received the respective prescribed doses to the intended treatment areas. The referring physician and patients were notified of the event. The licensee referred the patients to other institutions and care providers for specialized followup wound care to treat the recurring skin ulcerations. The NRC retained a medical consultant during the inspection associated with the event. The long-term health effects on the patients, as a result of the unintended doses, is unknown.

Cause(s) — The causes of these events were improper source selection, inadequate manufacturer instructions, inadequate management oversight, and inadequate procedures.

Actions Taken to Prevent Recurrence — Corrective actions taken by the licensee involved modifying the applicator by using different hardware to hold the sources in place, revising their procedures, and retraining the staff on the new procedures.

This event is closed for the purpose of this report.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MERRIFIELD

SUBJECT: **SECY-06-0055 - REPORT TO CONGRESS ON ABNORMAL OCCURRENCES: FISCAL YEAR 2005**

Approved ✓ Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

See attached edits.

SIGNATURE

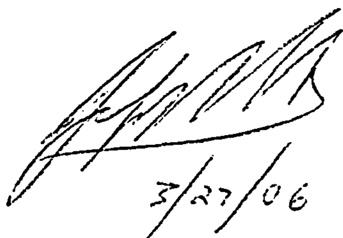
3/27/06

DATE

Entered on "STARS" Yes X No ___

Comments from Commissioner Merrifield on SECY-06-0055:

I approve the staff recommendation to submit the abnormal occurrences report to Congress. I compliment the staff for their efforts in preparing this report. This is an annual report submitted to Congress. In past years, I provided significant comments on previous versions of this report because I did not believe the staff effort properly presented a Commission level report to Congress. This year, it is obvious that staff made a considerable effort to properly integrate past Commission guidance on previous reports. Keep up the good work.



NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: **COMMISSIONER JACZKO**

SUBJECT: **SECY-06-0055 - REPORT TO CONGRESS ON ABNORMAL OCCURRENCES: FISCAL YEAR 2005**

Approved __X__ Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

SIGNATURE

3/31/06

DATE

Entered on "STARS" Yes _X_ No ___

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

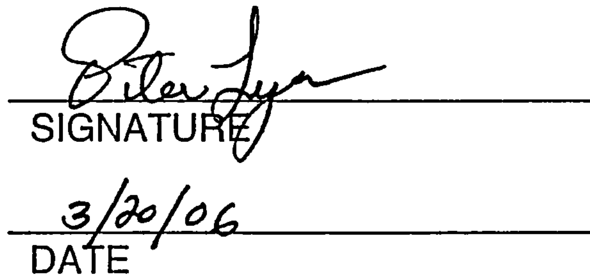
FROM: COMMISSIONER LYONS

SUBJECT: **SECY-06-0055 - REPORT TO CONGRESS ON ABNORMAL OCCURRENCES: FISCAL YEAR 2005**

Approved __X__ Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:



SIGNATURE

3/20/06

DATE

Entered on "STARS" Yes _X_ No ___