Went Reporting Handbook

EVENT REPORT COVER PAGE

AGREEMENT STATE

EVENT REPORT NO. M.S- 96 - 05

DATE: July 26, 1996

TO:

Deputy Director Office of State Programs

SUBJECT: Medical mis administration event on May 23, 1996, et U. of Mississippi, Jackson, MS, involving 2 brachy therapy patients. STATE: Mississippi

DLD (SPOH)

PLB2

PHL

PML

Signature and Title: B.J. Smith Health Physicist Administrative 9608120106 960726 PDR STPRG ESGMS PDR 8/6/96 CE: W Leschete, AEOD 03/16/95 8 NRC FILE CLINICR CUPY 34 SP-E-9

JUL-26-96 MON 2:34 PM MSDH RADIOLOGICAL HEALTH FAX NO.

REPORT NO. MS-96-05

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EVENT REPORT

MEDICAL MISADMINISTRATION FORM 566

- (a) LICENSEE: University of Mississippi Medical Center (UMMC) Jackson, Mississippi
- (b) MS-96-05
- (c) Broad Scope (Medical)
- (d) MS-MBL-01
- (e) Item No. 1
- (f) Abnormal Occurrence: YES
- (g) Follow-up Report: YES
- (h) Patient\ Responsible Relative Notified: YES
- (i) 15 day Written Report Provided: YES
- (j) Date of Event: 5-23-96
- (k) Date of this Report: 7-25-96
- (1) Regulatory Reporting Requirement:

Licensee's RSO notified Mississippi State Department of Health on 5-23-96 by telephone

- (m) Abstract:
 - Initial Report:

The RSO notified the Mississippi State Department of Health by telephone at about 4:30 pm on 5-23-96. He stated that they had an incident that occurred in the Radiation Oncology Department where two (2) patients were treated with the wrong source configurations. The medical physicist had prepared three (3) source implants on 5-21-96 and color-coded each applicator straw for each of the three (3) patients. The medical physicist noted that the wrong sources were loaded in Patient A on 5-23-96. He removed all the sources from the patients but only Patient A and Patient B were affected. The medical physicist noted that the color-codes were correct for each patient but the loads must have been switched.

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(m) Abstract (continued)

Isotope:

Cs-137 brachytherapy sources to provide Patient A 4000 cGy (4000 rad) in two fractional doses of 2000 cGy (2000 rad) each and Patient B 2275 cGy (2275 rad) for gynecological treatment.

Exposure: Patient A received 1342 cGy (1342 rad) and Patient B received 2698 cGy (2698 rad) due to the mix-up and were different from the prescribed dose by 33% and 35% respectively.

Treatment Plan: Patient A was prescribed a total treatment dose to a point of 9000 cGy (9000 rad) including the 4000 cGy (4000 rad) from two (2) fractional brachytherapy treatments and 5000 cGy (5000 rad) from accelerator treatment. Patient B was prescribed a total treatment dose 6775 cGy (6775 rad) including the 2275 cGy (2275 rad) from brachytherapy treatment and 4500 cGy (4500 rad) from accelerator treatment.

Referring Physicians notified: YES

This event was caused by human error by the medical physicist. The Radiation Oncology Department performs approximately 80 brachytherapy gynecological treatments per year. In the past, the medical physicist had always prepared the source loads at the same time before loading in the patients. They treat 2 or 3 patients frequently. Source loads were color-coded for each treatment; however, during this event the source loads were switched for 2 of the patients.

No adverse effects should occur to these patients due to the fact that the total treatment dose including brachytherapy and accelerator treatments did not exceed the prescribed dose by more that 10%. Patient A received 3355 cGy (3355 rad) from the two (2) brachytherapy treatments and 5000 cGy (5000 rad) from accelerator treatment for a total treatment dose of 8355 cGy (8355 rad), or 92% of the total prescribed dose. Patient B received 2698 cGy (2698 rad) from the brachytherapy treatment and 4500 cGy (4500 rad) from accelerator treatment for a total treatment for a total treatment dose of 7198 cGy (7198 rad), or 106.2% of the total prescribed dose.

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Corrective actions for the event (1) sources will be loaded immediately after approval of the Radiation Oncologist to prevent the medical physicist from having more than one source loading at a time (2) the copy of the dose summary page will be the only document carried into the Cs-137 safe room and color-coding will be documented on this page (3) color-codes will not be transferred from the dose summery page to the survey sheet. These procedural changes were implemented immediately after the brachytherapy misadministrations.



Division Of Radiological Health

3150 Lawson Street Post Office Box 1700 Jackson, Mississippi 39215-1700

601/354-6657 601/354-6167 FAX MEMORANDUM

R. 1

To: Pat Larkins Richard Woodruff

From: B. J. Smith, Health Physicist Administrative

Date: July 26, 1996

Subject: Abnormal Occurrence

Enclosed for your review are copies of two (2) misadministrations that occurred at one of Mississippi's medical broad scope licensees.

should you have any questions or comments, please call me at (601) 354-6657.

MS-96-05 Medical Brachytherapy Misadministrations at the University of Mississippi Medical Center (UMMC) in Jackson, Mississippi

Appendix A (see Event Type 5 in Table A-1) of the Abnormal Occurrences Report notes that administering a therapeutic dose from a sealed source such that the treatment dose differs from the prescribed dose by more than 10% and the event affects two or more patients at the same facility can be considered an abnormal occurrence.

Date and Place May 21, 1996, through May 23, 1996; University of Mississippi Medical Center (UMMC); Jackson, Mississippi.

Nature and Probable Consequences Two patients were prescribed manual brachytherapy procedures using Cs-137 sealed sources loaded in an intracavitary applicator for gynecological treatment.

During removal of the sources on May 23, 1996, the medical physicist noticed that the wrong sources had been inserted into Patient A. The medical physicist immediately went to Patient B's room and removed the sources prescribed for Patient A. Details of the misadministration are as follows:

- Patient A: The patient was prescribed a manual brachytherapy procedure using Cesium-137 sources loaded in an applicator for a total gynecological dose of 4000 cGy (4000 rad) in two fractional treatments; however, a the second fractional treatment dose of 1342 cGy (1342 rad) was administered, a 33% difference.
- Patient B: The patient was prescribed a manual brachytherapy procedure using Cesium-137 sources loaded in an applicator for a total gynecological dose of 2275 cGy (2275 rad); however, a treatment dose of 2698 cGy (2698 rad) was administered, a 35% difference.

The licensee notified the referring physician and the patient's relatives of the misadministrations. The medical physicist and the RSO concluded that the patients would not experience any adverse health effects as a result of the misadministrations.

<u>Cause or Causes</u> The licensee stated that this event occurred because of human error. The medical physicist prepared three (3) source configurations for three (3) patients at the same time. The loads were color-coded for each patient to prevent mix-ups. On removal of the sources, the medical physicist discovered that Patient A's and Patient B's loads were switched; even though, the color-codes were correct for the patients. Patient C was not affected. The medical physicist stated that he must have switched the loads prior to color-coding the loads for the patients.

Actions Taken To Prevent Recurrence The licensee immediately implemented new procedures for loading brachytherapy sources into patients whereas the medical physicist will only prepare and load sources for one patient at a time.

The Mississippi State Department of Health conducted an investigation on May 24, 1996, and May 28, 1996, to review the circumstances surrounding the misadministrations. The State of Mississippi concurred with the licensee's evaluation of the event and the corrective action implemented by the licensee. No violations were cited.

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