NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTIES

Deaconess Medical Center
Billings, Montana

Docket: 030-02389
License: 25-01051-01
EA 94-077

During an NRC inspection conducted on March 28-April 1, and April 5-29, 1994, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose civil penalties pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalties are set forth below:

I. Violation Associated with Misadministrations

A. 10 CFR 35.32(a) requires, in part, that the licensee establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user.

1. Pursuant to 10 CFR 35.32(a)(3), the quality management program must include, in part, written policies and procedures to meet the specific objective that final plans of treatment and related calculations for brachytherapy are in accordance with the applicable written directive.

Contrary to the above, as of March 28, 1994, the licensee failed to establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material is administered as directed by the authorized user, as evidenced by the following examples:

(a) the licensee's quality management program (QMP) for brachytherapy stated, as an objective, "Final plans of treatment and related calculations for brachytherapy are in accordance with the written directive", but the QMP did not include any written policies or procedures to meet this objective;

(b) the licensee's checks of the computer-generated dose calculations from the Theraplan computer system were inadequate to determine the accuracy of algorithms used by that system to calculate the radiation dose rate from the licensee's cesium-137 brachytherapy sources, which resulted in two situations where the radiation administered in accordance with the final treatment plan differed from the written directive by approximately 21% and 24% respectively; and

(c) for seven brachytherapy treatments performed between February 1992 and March 1994, the treatment plan maintained by the licensee did not match the written directive, either because the source strengths specified in the treatment plan did not match the source strength specified in the written directive or because related calculations did not match the exposure time or total dose documented in the written directive. (01013)

This is a Severity Level III violation (Supplement VI).
Civil Penalty $2,500

II. Other Violations of Quality Management Program Requirements

A. 10 CFR 35.32(a), effective January 27, 1992, requires, in part, that the licensee establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user.

Contrary to the above, between January 27 and May 1, 1992, the licensee administered sodium iodide I-131 to patients on six occasions in dosages ranging from 2.93 to 148.2 millicuries, and radiation from cesium-137 brachytherapy sources on two occasions during this period, and the licensee had not implemented a written quality management program. (02013)

B. 10 CFR 35.32(a) requires, in part, that the licensee establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user.

1. Pursuant to 10 CFR 35.32(a)(4), the quality management program must include, in part, written policies and procedures to meet the specific objective that each administration is in accordance with the written directive.

Contrary to the above, as of March 28, 1994, the licensee's quality management program (QMP) for brachytherapy stated, as an objective, "Each administration is in accordance with the written directive", but the QMP did not include any written policies or procedures to meet this objective. (02023)

2. Pursuant to 10 CFR 35.32(a)(4), the quality management program must include, in part, written policies and procedures to meet the specific objective that any unintended deviation from the written directive is

identified and evaluated, and that appropriate action is taken.

Contrary to the above, as of March 28, 1994, the licensee's quality management program (QMP) for brachytherapy stated, as an objective, "Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken", but the QMP did not include any written policies or procedures to meet this objective. (02033)

C. 10 CFR 35.32(a) requires, in part, that the licensee establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user.

Pursuant to 10 CFR 35.32(a)(1), the quality management program must include written policies and procedures to meet the objective that, prior to administration, a written directive is prepared for any brachytherapy radiation dose.

The licensee's quality management program, dated April 24, 1992, requires, under "Elements for Brachytherapy", that prior to administration, a written directive be prepared for any brachytherapy radiation dose and that, with regard to brachytherapy, a written directive means an order in writing for a specific patient dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, and containing, for brachytherapy other than high dose rate remote afterloading brachytherapy: (a) prior to administration, the radioisotope, number of sources, and source strengths; and (b) after implantation but prior to completion of the procedure, the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

Contrary to the above, between February 1992 and September 1993:

(1) a written directive was not prepared for two brachytherapy treatments,

(2) the authorized users failed to sign written directives for nine brachytherapy treatments,

(3) the total dose or total source strength and exposure time was not specified in written directives for six brachytherapy treatments, and

(4) the treatment site was not specified in written directives for two brachytherapy treatments. (02043)

D. 10 CFR 35.32(b) requires, in part, that the licensee develop procedures for and conduct a review to verify compliance with all aspects of the quality management program at intervals no greater than 12 months.

Contrary to the above, the licensee did not conduct a review to verify compliance with the quality management program between May 1, 1992, and March 28, 1994, an interval greater than 12 months. (02053)

E. 10 CFR 35.32(a) requires, in part, that the licensee establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user.

10 CFR 35.25(a)(1) requires, in part, that a licensee that permits the use of byproduct material under the supervision of an authorized user instruct the supervised individual in the licensee's written quality management program.

Contrary to the above, as of March 28, 1994, the licensee had not instructed three medical physicists, individuals using byproduct material under the supervision of an authorized user, in the licensee's written quality management program. The medical physicists were responsible for developing treatment plans for brachytherapy and for assisting authorized users in handling brachytherapy sources. (02063)

These violations represent a Severity Level III problem (Supplement VI).
Civil Penalty - $5,000

III. Violations not Assessed a Civil Penalty

A. 10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's procedures are described in letters dated May 23 and December 8, 1988.

Item 3 in Appendix S, "Radiation Safety During Implant Therapy," of the letter dated December 8, 1988, states that nurses are to be briefed on radiation safety precautions and that a sample form titled "Nursing Instructions for Patients Treated with Temporary Implant Sources" is to be used.

Contrary to the above, as of March 28, 1994, the licensee failed to ensure that radiation safety activities were being performed in accordance with the above procedure. Specifically, in several instances from January 1992 to March 1994, nurses were not briefed

on radiation safety precautions prior to caring for patients undergoing brachytherapy treatment. (03014)

This is a Severity Level IV violation (Supplement VI).

B. 10 CFR 35.406(b) requires that a licensee make a record of brachytherapy source use, including: (1) the name of the individuals permitted to handle the sources, (2) the number and activity of sources removed from storage, the number and activity of the sources in storage after the removal, and the initials of the individual who removed the sources from storage; (3) the number and activity of sources returned to storage, the patient's name and room number, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

Contrary to the above, as of March 28, 1994, the licensee's records of brachytherapy source usage did not include the number of sources removed from storage and the number and activity of the sources in storage after the removal. In addition, the records did not include the number of sources returned to storage and the number and activity of sources in storage after the return. (04014)

This is a Severity Level IV violation (Supplement VI).

C. 10 CFR 35.415(a)(4) requires that the licensee retain for three years a record of each survey of dose rates in restricted and unrestricted areas contiguous to rooms of patients implanted with brachytherapy sources. The record shall include the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in millirem per hour, the instrument used to make the survey, and the initials of the individual who made the survey.

Contrary to the above, as of March 28, 1994, the licensee's survey records of dose rates in restricted and unrestricted areas contiguous to rooms of patients implanted with brachytherapy sources did not include the instrument used to make the survey. (05015)

This is a Severity Level V violation (Supplement VI).

D. 10 CFR 35.404(b) requires, in part, that records of patient surveys conducted in accordance with § 35.404(a) be retained for a period of three years and that each record include the date of the survey, the name of the patient, the dose rate from the patient expressed as millirem per hour and measured at one meter

from the patient, the survey instrument used, and the initials of the individual who made the survey.

Contrary to the above, as of March 28, 1994, the licensee's records of patient surveys conducted pursuant to §35.404(a) did not include the instrument used and the licensee failed to retain a record of two brachytherapy patient surveys treatments performed between January 1992 and March 1994, a period less than three years. (06015)

This is a Severity Level V violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Deaconess Medical Center (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalties (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved.

If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalties by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the cumulative amount of the civil penalties proposed above, or may protest imposition of the civil penalties, in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalties will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalties, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalties should not be imposed. In addition to protesting the civil penalties, in whole or in part, such answer may request remission or mitigation of the penalties.

In requesting mitigation of the proposed penalties, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalties due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalties, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above (Reply to Notice of Violation, letter with payment of civil penalties, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011.

Dated at Arlington, Texas,
this 23rd day of August 1994

ENFORCEMENT CONFERENCE PARTICIPANTS

LICENSEE: Deaconess Medical Center, Billings, Montana

TIME/DATE: 8:15 a.m. CDT, June 28, 1994

LOCATION: NRC Region IV, Arlington, Texas

EA NUMBER: 94-077

Deaconess Medical Center representatives

Patrick Garrett, Vice President
Marc Edwards, Ph.D., Radiation Safety Officer
Jerry D. Wolf, M.D., Radiologist
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