UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8064

JUN 10 1994

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

Deaconess Medical Center
ATTN: Mr. Lane Basso
Chief Executive Officer
P.O. Box 37000
Billings, Montana 59107

SUBJECT: NRC INSPECTION REPORT 030-02389/94-01 (NOTICE OF VIOLATION)

This refers to the special, announced inspection conducted by Ms. Linda Kasner of this office on March 28 through April 1, and April 5-29, 1994. The inspection included a review of activities authorized by Byproduct Materials License 25-01501-01, with particular focus on Deaconess Medical Center's (DMC) brachytherapy program. On April 1, 1994, a public, interim exit briefing was conducted to review the findings of the initial segment of the inspection. DMC was represented by Dr. Mark Edwards, Mr. Robert Doolan, and other members of the management and radiology staffs during that briefing. On April 29, 1994, Ms. Kasner reviewed the findings of the full inspection during a telephonic exit briefing with Dr. Edwards. The enclosed NRC Inspection Report 030-02389/94-01 documents this inspection.

The inspection was an examination of activities conducted under the license as they relate to compliance with the Commission's rules and regulations and the conditions of the license. The inspection consisted of selective examinations of procedures and representative records, interviews of DMC personnel and DMC's consultants, and observation of activities in progress. Within the scope of the inspection, the inspector's review was limited to the two misadministrations reported to NRC and an assessment of the adequacy of DMC's Quality Management Program (QMP) and its implementation relative to brachytherapy procedures. The specific areas reviewed during the inspection are discussed in detail in the enclosed report.

The inspection was conducted in response to a telephonic notification of two misadministrations made by DMC representatives to the NRC Operations Center and the NRC Region IV office. The misadministrations involved brachytherapy treatments (gynecological treatments using cesium-137 sources) performed at DMC in September and November 1993. DMC representatives reported that the misadministrations were discovered during a comprehensive review of treatments administered in accordance with treatment plans developed using a Theratronics (Theraplan) computerized treatment planning system. The review was performed in response to your radiation safety officer's (RSO) and consulting physicist's identification of errors in computer-generated dose tables prepared for a brachytherapy treatment on March 16, 1994.

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Through their review, the RSO and consulting physicist determined that at some time between July and October 1992, data in a software file used to compute dose tables for cesium-137 sources was deleted and was later replaced with data which did not properly characterize the cesium-137 sources used by DMC. Errors in the data file included, in part, the use of a default set of values for the source capsule attenuation coefficient. It was later determined that the treatment planning system users had inadvertently entered a default set of values which corresponded to attenuation of a spectrum of gamma energies characteristic of radium-226, as filtered by platinum, rather than a single value corresponding to attenuation of a monoenergetic cesium-137 source as filtered by stainless steel.

Several factors involving clarity of instructions provided in the Theraplan users' manual and in prompts and data presented to users in printed format and at the treatment planning console were identified as contributing factors to the inadvertent entry of and failure to detect the erroneous data entered in program software for linear cesium-137 sources. These issues are discussed in detail in the enclosed report.

Based upon a detailed review of the misadministrations conducted by the consulting physicists and an independent radiation oncologist, the authorized users involved in these two cases have determined that no long-term adverse health effects beyond those normally expected for this form of treatment are anticipated for the patients. Given the findings of reviews conducted during the inspection and through discussions with the authorized users, the NRC has not identified any information contrary to the authorized users' initial determination regarding the potential medical consequences of the misadministrations. However, as you were informed during the inspection, an NRC medical consultant has been requested to review information relating to the misadministrations and to provide an assessment of the potential medical consequences of the radiation doses received by the affected patients to the NRC. The findings of the medical consultant's review will be forwarded to you upon completion of her review.

The inspection also disclosed significant weaknesses in DMC's implementation of its QMP for brachytherapy procedures. Among other problems identified during the inspection, the root cause of the misadministrations was determined to be a failure to conduct independent (manual) verification checks of treatment plans that were adequate to determine the accuracy of computer-generated dose tables. This problem was not limited to treatment plans developed using the Theratronics treatment planning system. However, based upon verification checks performed during the inspection, the dose tables generated by a second treatment planning system used by some of DMC's authorized users appeared to be correct for linear cesium-137 sources. At the conclusion of the inspection, a third treatment planning system used by one of DMC's authorized users had not yet been checked to determine the accuracy of dose tables used to develop patient treatment plans.

Based on the results of this inspection, apparent violations were identified and are being considered for escalated enforcement action in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), 10 CFR Part 2, Appendix C (1994). One of the apparent

violations involved a failure to establish a QMP in January 1992 as required by 10 CFR 35.32; however, the inspector determined that a QMP was later established in April or May 1992. In addition, the QMP established by DMC failed to meet the objectives that: (1) written directives were signed by authorized users and completed in accordance with NRC regulations, (2) final plans of treatment were in accordance with the respective written directive, and (3) each administration of radiation was in accordance with the applicable written directive. Other apparent violations included failures to: (1) conduct an annual review of the QMP during the calendar years 1992 and 1993, (2) train all individuals working under the supervision of DMC's authorized users in the provisions of its QMP, (3) train nursing personnel who cared for patients undergoing brachytherapy treatment in accordance with the conditions of the license, (4) maintain records of brachytherapy source usage and inventory in accordance with NRC requirements, and (5) include all required information in records of radiation surveys performed following implantation and explanation of brachytherapy sources. Accordingly, no Notice of Violation is presently being issued for these inspection findings. In addition, please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review.

In addition to the apparent violations noted above, several concerns were identified regarding: (1) communications between the RSO, the authorized users, and other members of your staff; and (2) the level of oversight of brachytherapy activities provided by management and your former RSO. The latter issue was of particular concern because the former RSO admitted to the inspector that he had relied upon the technical staff to monitor the brachytherapy program and the technical staff lacked the authority to provide direction to authorized users regarding compliance with NRC regulations and your QMP.

At the conclusion of the inspection, DMC voluntarily suspended further brachytherapy treatments until certain corrective measures could be implemented. However, because the findings of the inspection indicate significant, programmatic weaknesses in your QMP and its implementation, the NRC sought to confirm with DMC staff the specific actions planned for completion prior to resuming brachytherapy treatments. These actions were documented in a Confirmatory Action Letter issued by NRC on May 3, 1994.

An enforcement conference to discuss these apparent violations has been scheduled for June 28, 1994, at 8:15 a.m. (CDT). The decision to hold an enforcement conference does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. The purposes of this conference are to discuss the apparent violations, their causes and safety significance; to provide you the opportunity to point out any errors in our inspection report; and to provide an opportunity for you to present your proposed corrective actions. In addition, this is an opportunity for you to provide any information concerning your perspective on 1) the severity of the issues, 2) the factors that the NRC considers when it determines the amount of a civil penalty that may be assessed in accordance with Section VI.B.2 of the Enforcement Policy, and 3) the possible basis for exercising discretion in accordance with Section VII of the Enforcement Policy. You will be advised by

separate correspondence of the results of our deliberations on this matter. No response regarding these apparent violations is required at this time.

This enforcement conference will be open to public observation in accordance with the Commission's trial program as discussed in the enclosed Federal Register notice. Although not required, we encourage you to provide your comments on how you believe holding this conference open to public observation affected your presentation and your communications with the NRC.

In addition to the apparent violations discussed above, two violations which were not related to your QM program were identified during the inspection. One of the violations involved a failure to amend your license when a new RSO was appointed. However, the inspector noted that the new RSO had been named in a license renewal application submitted to the NRC in October 1993 and that he had only assumed his duties as the RSO in March 1994 (the license renewal had not yet been reviewed by NRC at the time of the inspection). This violation was promptly corrected after it was brought to management's attention, and a license amendment was issued by the NRC Region IV office during the inspection. The second violation involved a failure to perform surveys of all areas adjacent to rooms housing patients who were undergoing brachytherapy procedures. This issue involved the staff's frequent failure to perform surveys in a stairwell that was adjacent to the room routinely used for such patients. Based upon information provided by your staff, it appeared that this area is frequented by members of the general public. However, the inspector reviewed data for surveys conducted within the patient's room and determined that given the radiation levels recorded for these surveys, it did not appear that radiation levels in the stairwell area would have exceeded regulatory limits.

The above noted violations are described in the enclosed Notice of Violation (Notice). You are required to respond to this letter in regard to these violations and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC Public Document Room.

The response directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96.511.

Should you have any questions concerning this letter, please contact Ms. Kasner at (817) 860-8213.

Sincerely,

for John M. Montgomery

Samuel J. Collins, Director
Division of Radiation Safety
and Safeguards

Enclosures:
1. Appendix A - Notice of Violation
2. Appendix B - NRC Inspection Report 030-02396/94-01
3. Appendix C - Proposed Enforcement Conference Agenda
4. Appendix D - Federal Register, Vol. 57, No. 133, July 10, 1992

cc:
Montana Radiation Control Program Director

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Chairman, Board of Directors
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bcc:
DMB - Original (1E-07)
LJCallan
SJCollins
RAScarano, DRSS/RIV
DWeiss, OC/LFDCB (T-9E10)
*WLFisher
*CLCain
*FAWenslawski
*LLKasner
*NMIB
*MIS System
*RIV Files (2)
RWise, AC
GSanborn, EO
WLBrown, RC
JLieberman, OE (7 H5)
DSerig, NMSS (8-F-5)
SLMerchant, NMSS (8-F-5) w/field notes
JTGilliland, PAO

*W/IFS Form

RIV:NMIB	AC:NMIB	DD:DRSS	D:DRSS	
LLKasner	CLCain	RAScarano	SJCollins	
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