



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION IV

611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8064

MAY 3 1994

Docket: 030-02389
License: 25-01051-01
CAL 4-94-03

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

SUBJECT: CONFIRMATORY ACTION LETTER

In response to notification by Deaconess Medical Center (DMC) on March 21, 1994, of errors discovered in several treatment plans developed for brachytherapy treatments which resulted in misadministrations, NRC conducted a special inspection on March 28 through April 1 and April 5-8, 1994. The findings of the inspection were reviewed with members of your staff during a public interim exit briefing on April 1, 1994, as well as during subsequent telephonic discussions. The inspection findings included several issues involving failures to implement a Quality Management (QM) program which meets the objectives of 10 CFR 35.32 (the QM Rule). These findings will be documented in a formal inspection report which will be published at a future date.

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 QM program and its implementation, we deemed it necessary to confirm with you and your staff the specific actions planned for completion by DMC prior to resuming brachytherapy treatments.

Pursuant to a telephone conversation on April 27, 1994, between yourself, Dr. Mark Edwards, and other members of your staff and Ms. Linda Kasner of this office, it is our understanding that you have taken or will take the following actions prior to resuming brachytherapy treatments at DMC:

1. DMC will ensure that erroneous computer data files are corrected in the Theratronics treatment planning system used by one of its consulting physics groups and will verify the accuracy of dose calculation algorithms of all computerized treatment planning systems used by its authorized user physicians. A description of the method used to verify the accuracy of dose calculation algorithms and the results of DMC's evaluation will be submitted to NRC.

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2. DMC will evaluate any deficiencies or recommendations identified through the independent physics audit conducted to review the use of the Theratronics treatment planning system and the misadministrations reported to NRC and implement corrective actions to address those findings or provide an explanation as to why corrective measures should not be taken. DMC will provide a copy of the auditor's report and a summary of DMC's evaluation of the auditor's findings and recommendations to NRC.
3. DMC will conduct an audit of all treatment planning programs and methodologies used by its physics consultants. This audit will include an onsite review of each consultant's program and associated records. Any deficiencies or items of noncompliance relative to DMC's QM program identified through this audit will be identified to the radiation safety committee, and corrective actions will be taken prior to using the respective consultant for treatment planning services. The findings of the audit will be documented with a copy submitted to NRC.
4. DMC will review the findings and recommendations identified through the above noted audits and will modify its QM program as deemed appropriate by the radiation safety officer and radiation safety committee.

In addition to the above, DMC has committed to complete a review of patient cases as described below. However, DMC's completion of the review described below will be considered separate from the actions identified above and is not a condition to be completed prior to DMC resuming brachytherapy treatments.

DMC will perform a review of all brachytherapy treatments performed in accordance with treatment plans completed since January 1992 on computerized treatment planning systems other than the Theratronics system. This review will be focused on ensuring that such treatments were delivered in accordance with the authorized user physician's written directive or prescription and to identify any recordable events or misadministrations. DMC's findings and evaluation of this review will be submitted to the NRC.

Pursuant to Section 182 of the Atomic Energy Act, 42 U.S.C. 2232, and 10 CFR 2.204, you are required to:

1. Notify me immediately if your understanding differs from that set forth above;
2. Notify me if for any reason you cannot complete the actions specified above; and
3. Notify me in writing, including submission of documents as indicated above, when you have completed the actions addressed in this Confirmatory Action Letter.

Issuance of this Confirmatory Action Letter does not preclude issuance of an order formalizing the above commitments or requiring other actions on the part of the licensee. Nor does it preclude the NRC from taking enforcement action for violations of NRC requirements that may have prompted the issuance of this

Deaconess Medical Center


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letter. In addition, failure to take the actions addressed in this Confirmatory Action Letter may result in enforcement action.

The responses directed by this letter are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Action of 1980, Pub. L. No. 96-511.

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

Sincerely,



L. J. Callan
Regional Administrator

cc:
NRC Public Document Room
Montana Radiation Control Program Director

bcc:

DMB- IE-07

- J. L. Lieberman, D/OE (2) (7 H5)
- L. J. Chandler, Asst. GC/OGC (15 B18)
- H. L. Thompson, DEDS (17 G21)
- R. M. Bernero, D/NMSS (6 E6)
- J. E. Glenn, AC/MACUS (6 H3)
- RIV Coordinator, OEDO (17 G21)
- L. J. Callan, RA
- W. L. Brown, RC
- S. J. Collins, D/DRSS
- R. A. Scarano, DD/DRSS
- W. L. Fisher, Branch Chief
- C. L. Cain, Branch Chief
- F. A. Wenslawski, WCFO
- G. F. Sanborn, EO
- J. T. Gilliland, PAO
- J. Carson, ORA
- RIV Files
- NMIB File
- NMIB and NMLB Inspectors (14)

RIV:NMIB <i>llh</i>	C:NMIB <i>llh</i>	DD:DRSS <i>llh</i>	D:DRSS <i>llh</i>	
LLKasner:cd	CLCain	<i>llh</i>	SJCollins <i>llh</i>	
04/29/94	04/29/94	04/29/94	04/29/94	

EO <i>GFS</i>	RC <i>llh</i>	DRA	RA	AI 94-118
GFSanborn	WLBrown	JMMontgomery	LJCallan <i>llh</i>	
04/2/94	04/2/94	04/ /94	04/6/94	

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