NOV 24 1989

In Reply Refer To:
License: 25-26847-01/CAL 89-24
Docket: 030-29504

Kalispell O.B. Gyn. Associates
ATTN: John L. Heine, M.D.
210 Sunny View Lane
Kalispell, Montana 59901

Gentlemen:

SUBJECT: CONFIRMATION OF ACTION LETTER

The purpose of this letter is to confirm the commitments made during the telephone discussion between Dr. John L. Heine and members of my staff including Mr. Jack E. Whitten and Ms. Vivian Campbell on November 22, 1989.

During this discussion, Dr. Heine explained that the Lunar Radiation Corporation Model DP3 spine scanner had malfunctioned on September 21, 1989. He indicated that a similar malfunction had occurred previously, but was unable to specify the date. On both occasions, the malfunction occurred while the technician was retrieving and printing patient scan data from memory while simultaneously performing another scan. The malfunction resulted in the shutter remaining in the open position and the rectilinear drive mechanism containing the gadolinium-153 sealed source not moving, thereby exposing the patient to unnecessary radiation. Radiation measurements previously reported by the manufacturer indicate that the normal dose to a patient during a spine scan using a 1-curie gadolinium-153 sealed source is about 15 millirem.

Based on the conversation with Dr. Heine, we understand you will do the following:

1. No longer retrieve from scanner memory and print previous patient data while coincidently performing scans,

2. Instruct all technicians in the procedure described in No. 1 above,

3. Instruct all technicians not to leave a patient unattended while scans are being conducted and to immediately remove the patient from the scanner table in the case of malfunction,

4. Provide detailed information of the events related to the spine scanner malfunction, including a complete description of how the technician manually overrode and physically closed the shutter mechanism,

*RIV:NMLS	*NMLS	*C:NMLS	*C:NMIS	AI 89-319
JEWhitten	VHCampbell	RJEverett	CLCain	
/ /89	/ /89	/ /89	/ /89	
EO (w)for	D:DRSS	RA (w)		
GFSanborn	ABBeach (w)for	RDMartin		
11/24/89	11/24/89	11/24/89		

*Previously Concurred

IE-07

5. Provide a summary of the information provided to Kalispell O.B. Gyn. Associates by Lunar Radiation Corporation relative to the scanner malfunction. This summary should include the information provided by the manufacturer's representative, Mr. Thomas Demke, on the estimated radiation doses received by patients as a result of equipment failure. Also, describe any actions to be taken by Lunar Radiation Corporation to repair the device,

6. Notify the NRC of any further operational problems with the unit, and

7. Outline the specific safety actions you have implemented or will take to provide additional assurance that a patient will not be unnecessarily exposed on the scanner in the event it malfunctions.

Issuance of this Confirmation of Action Letter does not preclude the issuance of an order formalizing the above commitments or requiring other actions on the part of Kalispell O.B. Gyn. Associates; nor does it preclude NRC from taking other actions in regards to this problem. If your understanding differs from that set forth above, please call Mr. Whitten at (817) 860-8197 immediately.

Sincerely,

Original Signed By

Robert D. Martin
Regional Administrator

cc:
Montana Department of Health
and Environmental Sciences

bcc:
DMB - IE-07
J. L. Lieberman, D/OE
H. L. Thompson, DEDS
J. E. Glenn, C/MACUS
R. D. Martin, RA
L. A. Yandell
C. L. Cain
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B. Summers, OE
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NMIS Inspectors (5)
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RIV Files