NOV 16 1989

In Reply Refer To:
License: 25-23109-01
Docket: 30-20264/89-01

Holy Rosary Hospital
ATTN: Anthony D. Pfitzer
Executive Director
2101 Clark Street
Miles City, Montana 59301

Gentlemen:

Thank you for your letter of October 18, 1989, in response to our letter and attached Notice of Violation both dated September 27, 1989. We have reviewed your reply and find it responsive to the concerns raised in our Notice of Violation. We will review the implementation of your corrective actions during a future inspection to determine whether full compliance has been achieved and will be maintained.

Sincerely,

Yandell, for:

A. Bill Beach, Director
Division of Radiation Safety
and Safeguards

cc:
Montana Radiation Control Program Director

bcc w/copy of licensee letter:
DMB - Original (IE-07)
RDMartin
ABBeach
LAYandell
LShea, RM/ALF (AR-2015)
CLCain
RJEverett
WLHolley
NMSB
MIS System
RIV Files (2)
RSTS Operator

RIV:NMIS	C:NMIS	D:DRSS
WLHolley:ch	CLCain	ABBeach by for
11/13/89	11/13/89	11/15/89

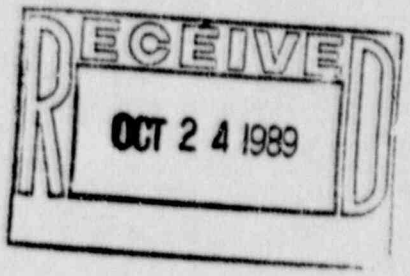
IE07
1/1

Holy Rosary Hospital

(406) 232-2540 1-800-843-3820
2101 Clark Street, Miles City, Montana 59301

October 18, 1989

United States Nuclear Regulatory Commission
611 Ryan Plaza Drive, Suite 1000
Arlington, TX 76011



RE: License No. 25-23109-01
Docket : 30-20264/89-01

Gentlemen:

This letter is in response to an inspection made at Holy Rosary Hospital on August 9, 1989, and a letter based on that inspection dated September 27, 1989.

In response to the number of misadministrations being out of proportion to the number of studies performed at Holy Rosary Hospital, it is the conclusion of Holy Rosary Hospital Administration that this problem has been solved with the departure of the former Chief Technologist. The Chief Technologist was solely responsible for Nuclear Medicine and all its administrative requirements.

We feel that the new Chief Technologist brings with her a fresh, invigorating attitude that assures a positive relationship among all the essential personnel in Nuclear Medicine. The new Technologist brings with her a thorough approach to the drawing of radioactive material and the administration of that material to the patients. Additionally, the Nuclear Medicine Technologist is supervised by the Chief Technologist so there is an administrative structure to detect deficiencies before they occur.

Holy Rosary Hospital offers the following response to the violations noted in the investigator's report of August 9, 1989.

IC-89-Wal 8911010150 891

IE07

Item 1E: Failure to perform accuracy tests:

In response to this violation, our Consulting Physicist, Rod Wimmer, responds:

> "I have visited Holy Rosary Hospital on March 20, 1986, September 12, 1986, November 7, 1986, March 20, 1987, April 27, 1987, May 27, 1988, August 26, 1988, March 3, 1989, and June 20, 1989. Except for the visit on June 20, 1989, I personally performed the accuracy tests on the dose calibrator and reviewed all the records required by the Nuclear Regulatory Commission for operation of the Nuclear Medicine facility. All records were present until March 3, 1989, and all the accuracy tests were current through that date. Additionally, the records for the survey meter calibration were in the notebook used to store such documents.
>
> The disappearance of the critical records clearly demonstrating the performance of the accuracy tests is unexplainable at this time. I would like to personally attest to the performance of these tests and the existence of these records.
>
> It was always the first order of business on my visit to Holy Rosary Hospital to review the records so that previous violations would not be repeated.
>
> Geometric dependence of the dose calibrator: Prior to the former Chief Technologist's departure, I had a conversation with him explaining the procedure for measuring geometric dependency of the dose calibrator for the "loaner" dose calibrator. The Chief Technologist sent me this data and I reviewed it noting that it met Nuclear Regulatory Commission requirements. I advised the Chief Technologist that he should perform this test on the repaired calibrator when it was returned and he assured me he would.
>
> The dose calibrator was returned on March 22, 1989, and a few days later the Chief Technologist was suspended for a week, returned for two weeks and terminated his employment with Holy Rosary Hospital. During his suspension and following his termination, a new staff person assumed his duties. The suspended Technologist did not report the results of the geometry test or advise the new Technologist that it needed to be done. It is felt during this interval that the administrative control of the nuclear medicine facility was inadequate."

The administrative structure that was in place during this episode has been changed hospital-wide. The hospital has a new Administrator, the department has a new Chief Technologist, and a new Nuclear Medicine Technologist. We feel that with these changes better communication exists among the principal parties and the necessary supervision is in place to assure that the events of the past are not repeated.

If there are any additional questions, please do not hesitate to contact me.

Sincerely,

Anthony D. Pfitzer
Executive Director

ADP/pat

cc: Dr. R. E. Sievers
Ms. Kristi Stein
Mr. Paul Bergman

SEP 27 1989

In Reply Refer To:
License: 25-23109-01
Docket: 30-20264/89-01

Holy Rosary Hospital
ATTN: Tony Pfietser
Hospital Administrator
2101 Clark Street
Miles City, Montana 59301

Gentlemen:

This refers to the routine, unannounced radiation safety inspection conducted by Mr. Wesley L. Holley of this office on August 9, 1989, of the activities authorized by NRC Byproduct Material License 25-23109-01, and to the discussion of our findings held by the inspector with members of your staff at the conclusion of the inspection.

The inspection was an examination of the activities conducted under the license as they relate to radiation safety and 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 personnel, independent measurements, and observations by the inspector.

During this inspection, certain of your activities were found not to be conducted in full compliance with NRC requirements. Consequently, you are required to respond to this matter in writing, in accordance with the provisions of Section 2.201 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations. Your response should be based on the specifics contained in the Notice of Violation enclosed with this letter.

The inspector also reviewed the actions you had taken with respect to the violations observed during our previous inspection conducted on March 28, 1985. He verified that the corrective actions for these violations had been implemented as stated in your reply dated April 22, 1985.

The inspector noted that since the previous inspection on March 28, 1985, Holy Rosary Hospital has experienced four diagnostic misadministrations. This number appears unusually high when compared with the number of patients processed by your facility. Therefore, in your response you should identify what management controls you have implemented to aid in the prevention of these incidents.

We also noted that several violations identified during the previous inspection were similar in nature to one identified during the current inspection in that they concerned the calibration and use of your dose calibrator. Therefore, in

*RIV:NMIS	C:NMIS	C:NMSB
WLHolley:jt	CLCain	WLFisher
/ /89	9/27/89	9/27/89

IE07

*Previously Concurred

8910040378 2 IP

your response you should also address what actions have been taken by hospital management to ensure that this instrumentation is properly tested at the required intervals.

The response directed by this letter and the accompanying Notice is not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

Should you have any questions concerning this letter, we will be pleased to discuss them with you.

Sincerely,

Original Signed By:
William L. Fisher

William L. Fisher, Chief
Nuclear Materials Safety Branch

Enclosure:
Appendix - Notice of Violation

cc:
Montana Radiation Control Program Director

bcc:
DMB - Original (IE-07)
RDMartin
ABBeach
LAYandell
JHAustin
WLFisher
LShea, RM/ALF (AR-2015)
*CLCain
*REverett
*Inspector
*NMSB
*MIS System
*RIV Files (2)
*RSTS Operator

*W/766

APPENDIX

NOTICE OF VIOLATION

Holy Rosary Hospital
Miles City, Montana

Docket: 30-20264/89-01
License: 23109-01

During an NRC inspection conducted on August 9, 1989, 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 (1989) (Enforcement Policy), the violations are listed below:

1. 10 CFR 35.50(b) and (c) requires, in part, that each dose calibrator be tested for accuracy annually and for geometry dependency following adjustment or repair.

   Contrary to the above, the licensee did not perform annual accuracy tests on Victoreen CAL/RAD Isotope Calibrator 34-061, Serial No. 23903, for 1987 and 1988. Also, after the dose calibrator had been repaired and received on March 22, 1989, the licensee did not perform the geometric dependence test.

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

2. 10 CFR 35.51(d) requires that a licensee shall retain a record of each survey instrument calibration for 3 years.

   Contrary to the above, the licensee failed to maintain the calibration records for 1986 and 1987 for the survey instrument, Victoreen 498, Serial No. 787M.

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

Pursuant to the provisions of 10 CFR 2.201, Holy Rosary Hospital is hereby required to submit to this office, within 30 days of the date of the letter transmitting this Notice, a written statement or explanation in reply, including for each violation: (1) the reason for the violation if admitted, (2) the corrective steps which have been taken and the results achieved, (3) the corrective steps which will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Where good cause is shown, consideration will be given to extending the response time.

Dated at Arlington, Texas,
this 27th day of September 1989

NRC FORM 790 (1-81) 10 MC 0520

U.S. NUCLEAR REGULATORY COMMISSION

INSPECTOR'S REPORT

Office of Inspection and Enforcement

PRINCIPAL INSPECTOR (Name and Initials): Holley, Wesley L.

REVIEWER: Cain, Chuck L. NRC

INSPECTORS:

LICENSEE/VENDOR	TRANSACTION TYPE	DOCKET NO. (8 digits) OR LICENSE NO. (BY PRODUCT) (13 digits)	REPORT NO	REPORT SEQ.	NEXT INSPEC. DATE MO	NEXT INSPEC. DATE YR
Holy Rosary Hospital 2101 Clark St. Miles City, MT 59301	X I - INSERT M - MODIFY D - DELETE R - REPLACE	03020264	2901	A	0893	

PERIOD OF INVESTIGATION/INSPECTION FROM MO	DAY	YR	TO MO	DAY	YR	INSPECTION PERFORMED BY	ORGANIZATION CODE OF REGION/HQ CONDUCTING ACTIVITY (See IE/NRC 0530 "Manpower Reporting—Weekly Manpower Reporting" for code) REGION	DIVISION	BRANCH
08	09	79	08	09	79	X 1 - REGIONAL OFFICE STAFF 2 - RESIDENT INSPECTOR 3 - PERFORMANCE APPRAISAL TEAM OTHER	4	3	4

REGIONAL ACTION (Check one box only)	TYPE OF ACTIVITY CONDUCTED (Check one box only)			
1 - NRC FORM 591	X 02 - SAFETY	06 - MGMT. VISIT	10 - PLANT SEC.	14 - INQUIRY
X 2 - REGIONAL OFFICE LETTER	03 - INCIDENT	07 - SPECIAL	11 - INVENT. VER.	15 - INVESTIGATION
	04 - ENFORCEMENT	08 - VENDOR	12 - SHIPMENT/EXPORT	
	05 - MGMT. AUDIT	09 - MAT. ACCT.	13 - IMPORT	

INSPECTION/INVESTIGATION FINDINGS (Check one box only)	TOTAL NUMBER OF VIOLATIONS AND DEVIATIONS	ENFORCEMENT CONFERENCE HELD	REPORT CONTAIN 2.790 INFORMATION	LETTER OR REPORT TRANSMITTAL DATE: NRC FORM 591 OR REG. LETTER ISSUED MO	DAY	YR	REPORT SENT TO HQ FOR ACTION MO	DAY	YR
X 2 - VIOLATION	A: 02	1 - YES	1 - YES	09	27	79			
1 - CLEAR 3 - DEVIATION 4 - VIOLATION & DEVIATION	B C D	A B C D	A B C D						

MODULE INFORMATION

REC ORD TYPE	MODULE NUMBER INSP NUMBER	PHASE	MANUAL CHAPTER	PROCEDURE NUMBER	LEVEL	SEQ #	PRIORITY	DIRECT INSPECTION EFFORT IN STAFF HOURS EXPENDED THIS INSPECTION	PERCENTAGE COMPLETED TO DATE	STATUS	MODULE REQ. FOLLOWUP PHASE	MANUAL CHAPTER	PROCEDURE NUMBER	LEVEL
0	1	5	3	0	7	93	A	0100	---					
Management Meeting							B							
							C							
							D							
0	1	5	3	0	8	0	0	A						
Initial							B							
							C							
							D							
0	1	5	8	7	1	0	0	A	0014	100	C			
Program Requirements							B							
							C							
							D							
0	1	5	8	3	8	22	A	0092	100	C				
Radiation Protection							B							
							C							
							D							

● CIRCLE SEQUENCE # VIOLATION OR DEVIATION

MODULE INFORMATION

REC ORD TYPE	MODULE NUMBER INSP NUMBER	PHASE	MANUAL CHAPTER	PROCEDURE NUMBER	LEVEL	SEQ #	PRIORITY	DIRECT INSPECTION EFFORT IN STAFF HOURS EXPENDED THIS INSPECTION	PERCENTAGE COMPLETED TO DATE	STATUS	MODULE REQ. FOLLOWUP PHASE	MANUAL CHAPTER	PROCEDURE NUMBER	LEVEL
0	1	5	8	6	7	40	A							
Transportation							B							
							C							
							D							
							A							
							B							
							C							
							D							
							A							
							B							
							C							
							D							
							A							
							B							
							C							
							D							

NRC FORM 398 A
(7-81)
10 CFR 150

INSPECTOR'S REPORT
(Continuation)
Office of Inspection and Enforcement

DOCKET NO. (5 DIGITS) OR LICENSE NO. (BY PRODUCT) (13 DIGITS)	REPORT NO	REPORT SEQ	MODULE NUMBER
0302026	81	A	
		B	
		C	
		D	

VIOLATION SEVERITY OR DEVIATION							SIG RELATED	SUPL.
1	2	3	4	5	6	D	A C / B D	

VIOLATION OR DEVIATION (Enter up to 2400 characters for each item. If the text exceeds this number, it will be necessary to continue. Limit lines to 80 characters each.)

1 Contrary to 10 CFR 35.5(d), the licensee
2 did not maintain records of survey instrument
3 calibration for the required 3 years.
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NRC FORM 591 A

INSPECTOR'S REPORT
(Continuation)
Office of Inspection and Enforcement

DOCKET NO. (8 digits) OR LICENSE NO. (BY PRODUCT) (13 digits)	REPORT NO	REPORT SEQ	MODULE NUMBER	SUPP.
0302024	89 01	A	5P171010	6

VIOLATION OR DEVIATION (Enter up to 2400 characters for each item. If the text exceeds this number, it will be necessary to paraphrase. Limit lines to 80 characters each.)

Contrary to 10 CFR 35.50(b)(2) & (3), the licensee did not perform the dose calibrator annual accuracy test for 1987 and 1988 and did not perform the geometrical dependence test after the dose calibrator had been repaired on 3/22/89.

U.S. NUCLEAR REGULATORY COMMISSION