

DEC - 6 1990

In Reply Refer To:
License: 35-16298-01
Docket: 030-10758/90-01

Claremore Regional Hospital
ATTN: Ken Seidel, Executive Director
1202 North Muskogee Street
Claremore, Oklahoma 74017

Gentlemen:

Thank you for your letter of October 31, 1990, in response to our letter and attached Notice of Violation both dated October 15, 1990. We have reviewed your reply and have found that additional information is needed as specified below.

Violation B related to the failure of the radiation safety officer (RSO) to fulfill the responsibilities specified in 10 CFR 35.21. As indicated in our Notice of Violation, this failure was evident by the number and the nature of the violations cited. In your response to Violation B you stated that this item was not discussed with you by the inspection team and that your radiologist, who we presume is the RSO, is knowledgeable of regulatory requirements.

Although this violation was not discussed with you by the inspectors on the day the inspection was completed at your facility, this matter was discussed with Mr. Seidel and other members of your staff during the telephonic conference on September 27, 1990. We do not deny that your radiologist has adequate knowledge to fulfill the role of RSO. In fact, such knowledge and capability are prerequisites for NRC having approved this individual to serve in this capacity. The violation focuses solely on his failure to fulfill his designated responsibilities.

As a result of our review of your response, we have determined that you have not provided information which would indicate that the violation did not occur as previously stated. Therefore, we request that you provide further response to this violation including (1) the reason for the violation, or if further contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further similar violations, and (4) the date when full compliance will be achieved.

RIV:NMSIS *pa*
RLeonardi:ch
12/5/90

C:NMSIS *ch*
CLCain
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AB
D:DASS
ABBeach
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IE-07
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Your response should be provided within 10 days of your receipt of this letter so that we can continue our review. Should you have further questions, please contact Charles Cain of my staff at (817) 860-8186.

Sincerely,
Original Signed By:

A. B. BEACH

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

cc:
Oklahoma Radiation Control Program Director

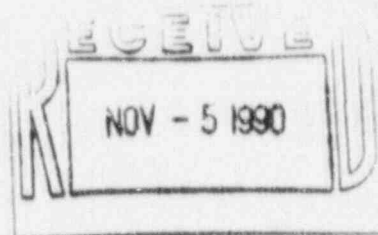
bcc w/copy of licensee letter:
DMB - Original (IE-07)
RDMartin
ABBeach
LAYandell
MRodriguez, OC/LFDCB (MS 4503)
CLCain
WLFisher
RLeonardi
NMSIS
MIS System
RIV Files (2)
RSTS Operator

CLAREMORE REGIONAL HOSPITAL
RADIOLOGY DEPARTMENT

October 31, 1990

A. BILL BEACH, DIRECTOR
DIVISION OF RADIATION SAFETY
AND SAFEGUARDS

KENNETH D. SKIDMORE, R.T.
RADIOLOGY MANAGER
CLAREMORE REGIONAL HOSPITAL
1202 N. MUSKOGEE
CLAREMORE, OK 74017



Gentlemen;

This refers to your letter dated October 15, 1990. It contains our response to violations discovered by an unannounced radiation safety inspection of our facility by Richard A. Leonardi and Anthony D. Gaines on September 19, 1990. Our license number is: 35-16298-01 and the docket number is: 030-10758/90-01.

We have examined our operation with our physicist consultant, Dr. David Gooden, and feel that we have instituted proper corrective actions that will be addressed specifically later in this letter pertaining to actions taken to improve the effectiveness of the management controls of our license. We also feel that we have addressed the future prevention of violations.

VIOLATION A: CFR 30.34 (b)

1. The hospital name changed but the location, operation, personnel, and all other aspects of our license remained the same as our license stated. We also had initiated a letter of change on September 21, 1989 when we discovered that this had not occurred. However, there seems to be no record of you receiving such letter.
2. We have initiated a letter dated 10-19-90 requesting said changes along with a check for \$340.00. (We are inclosing copies of both letters for your records.)
3. We will be more aware of the regulation that requires this in the future, but have no plans for any more changes at this time.
4. Full compliance will be achieved by the end of November 1990.

VIOLATION B: CFR 35.21

1. This item was not discussed with us by the inspection team and we feel that our radiologist has adequate knowledge of NRC regulations and requirements, or has access to such knowledge through association with his colleagues at Saint Johns Hospital in Tulsa, Oklahoma and with our contracted physicist consultant, Dr. David Gooden.

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EPIC HEALTHCARE GROUP
An Employee-Owned Company

IE-07

CLAREMORE REGIONAL HOSPITAL
RADIOLOGY DEPARTMENT

VIOLATION C: CFR 35.22 (a)(3)

1. The stated lack of a quorum for a meeting of the Radiation Safety Committee on March 23, 1990 was investigated and we feel that Dr. Gooden is referring to what needed to be discussed at the upcoming RSC meeting in April, 1990 which we have documented. Also, the Radiology Manager is the designated management representative and I was present at that discussion.
The 12-24-88 meeting was attended by Dr. Richard Barbee, who is on our license along with Dr. Brian Cosmann and should be recognized as capable of RSO responsibility. He also has consulted with Dr. Cosmann on any operational changes. also, there was no actual business conducted and Dr. Cosmann was advised upon his return to our hospital.
2. Future adherence to established criteria will correct this deviance.
3. No Radiation Safety Committee meetings will occur without the specific Radiation Safety Officer in attendance. The Radiology Manager is the designated management representative.
4. Full compliance is in affect now.

VIOLATION D: CFR 35.27 (a)(1)

1. the radiologists that work at our facility when Dr. Cosmann or Dr. Barbee are elsewhere are on the NRC license at Saint Johns Hospital and were considered to be authorized users.
2. The RSC officially granted up to 60 days per year to authorized members of Tulsa Radiology Associates, Inc. to perform nuclear medicine procedures in our October 1990 meeting.
3. The Radiation Safety Officer will review all nuclear medicine procedures that occur during his absence. This will be accomplished via a QA form that will provide documentation necessary for JCAHO standards.
4. Full compliance is in affect now.

VIOLATION E: CFR 35.50 (b)(3)

1. Only recently have we been doing linearity testing below 1. microcuries. Inspectors haven't checked this in the past, so we had not identified that we were in deviation in this area.
2. All linearity tests will be tested down to 10 microcuries at all times.
3. Documentation will be checked by our consultant and the RSO on every test performed.
4. Full compliance is in affect now.

CLAREMORE REGIONAL HOSPITAL
RADIOLOGY DEPARTMENT

VIOLATION F: CFR 35.50 (e)

1. the documentation of constancy checks conducted between November 1987 to February 1988 and September 1989 to February 1990 were not completed, or cannot be found. However, this was being done prior to and following these times and the techs who were here at these times are no longer employed at our facility. We did have a high degree of turnover in this position and feel that the lack of documentation occurred mostly due to this fact.
2. In February 1990, we established a much more thorough logging system that corrects these deficiencies.
3. Strict adherence to documentation in the future will avoid the possibility of reoccurrence.
4. Full compliance is in affect now.

VIOLATION G: CFR 35.50 (e)(2), (3), and (4)

1. Our consultant physicist was providing three copies of dose calibrator checks in the past, one copy for administration, one copy for the radiologist, and one copy for the Nuclear Medicine documentation file and all of these documents were addressed to the Radiology Manager. All of these documents have been initialed by the department manager and placed in the Nuclear Medicine file. Administration and the radiologist reviewed all the documentation at all times.
2. We will receive one document that will be signed off by the RSO, administration, and the department manager before it is placed in the Nuclear Medicine file.
3. Review for all signatures before filing in the Nuclear Medicine file.
4. Full compliance is in affect now.

If we can be of further service or provide any additional information, please notify us so that we can be in total compliance to NRC regulations which is our goal.

Sincerely,


Kenneth D. Skidmore, R.T.

Incl: 7

cc: Dr. Brian Cosmann
Ken Seidel, E.D.
Jeff Meigs, CFO/COO
Dr. David Gooden
Nuclear Medicine, CRH

(3)



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION IV
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TEXAS 76011

OCT 15 1990

In Reply Refer To:
License: 35-16298-01
Docket: 030-10758/90-01

10/18/90

Ken,
Please prepare a
response to
letter by 1/31
Ther...
[Signature]

Claremore Regional Hospital
ATTN: Ken Seidel, Executive Director
1202 North Muskogee Street
Claremore, Oklahoma 74017

Gentlemen:

This refers to the routine, unannounced radiation safety inspection conducted by Messrs. Richard A. Leonardi and Anthony D. Gaines of this office on September 19, 1990, of the activities authorized by NRC Byproduct Material License No. 35-16298-01, and to the discussion of our findings held by the inspectors with members of your staff at the conclusion of the inspection. The results of this inspection were also discussed by telephone on September 27, 1990, between Mr. Seidel and other members of your staff, and Charles L. Cain, Chief, Nuclear Materials and Safeguards Inspection Section, and the inspectors.

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 inspectors.

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.

We are concerned about the implementation of your program in the area of management control that permitted these violations to occur. The nature and the number of violations identified indicate an apparent lack of management oversight of the radiation safety program. The turnover in nuclear medicine technologist personnel apparently contributed to this lack of effectiveness of



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the radiation safety program. Consequently, in your reply to this letter, you should describe those specific actions planned or taken to improve the effectiveness of the management control of your licensed operations, with particular emphasis on measures currently being taken to prevent further violations.

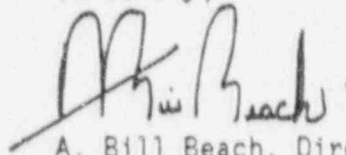
The inspectors also reviewed the actions you had taken with respect to the violations observed during our previous inspection conducted on December 29, 1987. They verified that the corrective actions for these violations had been implemented.

In accordance with 10 CFR 2.790 of the Commission's regulations, a copy of this letter, the enclosure, and your response to this letter will be placed in the NRC Public Document Room.

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,



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

Enclosure:
Appendix - Notice of Violation

cc:
Oklahoma Radiation Control Program Director

APPENDIX

NOTICE OF VIOLATION

Claremore Regional Hospital
Claremore, Oklahoma

Docket No. 10758/90-01
License No. 16298-01

During an NRC inspection conducted on September 19, 1990, 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 (1990), the violations are listed below:

- A. CFR 30.34(b) requires that no license issued or granted pursuant to the regulations in this part and Parts 31 through 35, and 39 of Title 10, nor any right under a license be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing.

Contrary to the above, in October 1988 Claremore Regional Medical Center was sold to Epic Healthcare Group and the name was changed to Claremore Regional Hospital. This transfer was accomplished without the written consent of the Commission.

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

- B. 10 CFR 35.21 requires, in part, that the Radiation Safety Officer (RSO) ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program. In addition, specific duties are prescribed in paragraph (b) of that section.

Contrary to the above, as of September 19, 1990, the RSO was not ensuring that the radiation safety activities were being performed in accordance with approved procedures and regulatory requirements, as evidenced by the violations cited in this Notice and the RSO's lack of knowledge of NRC regulations and requirements on the day of the inspection.

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

- C. 10 CFR 35.22(a)(3) requires, in part, that to establish a quorum and to conduct business, at least one-half of the Radiation Safety Committee's (RSC) membership must be present, including the Radiation Safety Officer and the management's representative.

Contrary to the above, a quorum was not established during a business meeting of the RSC on March 23, 1990, for which the management's representative was not present and, on December 24, 1988, because the Radiation Safety Officer was not present.

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

- D. 10 CFR 35.27(a)(1) and (2) requires, in part, that a licensee may permit any visiting authorized user to use licensed material for medical use under the terms of the licensee's license for 60 days each year if the visiting authorized user has the prior written permission of the institution's Radiation Safety Committee and the licensee has a copy of a license issued by the Commission or an Agreement State that identifies the visiting authorized user by name as an authorized user for medical use.

Contrary to the above, the licensee's Radiation Safety Committee had not given prior written permission to or obtained a copy of the license identifying visiting authorized users who served at the hospital from December 1987 to September 1990.

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

- E. 10 CFR 35.50(b)(3) requires, in part, that the licensee test the dose calibrator for linearity over the range of its use between the highest dosage that will be administered to a patient and 10 microcuries.

Contrary to the above, checks for linearity of the dose calibrator from January 1988 to September 1990, were not tested down to 10 microcuries.

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

- F. 10 CFR 35.50(e) requires, in part, that the licensee retain a record of each dose calibrator check and test required by §35.50 for 3 years.

Contrary to the above, records of dose calibrator constancy checks, a daily check required by 10 CFR 35.50(b)(1), were not retained for checks conducted from November 1987 to February 1988, and from September 1989 to February 1990.

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

- G. 10 CFR 35.50(e)(2), (3), and (4) require, in part, that the record of each dose calibrator check required by 10 CFR 35.50(b)(2) through (b)(4) (for dose calibrator accuracy, linearity, and geometry) include the signature of the Radiation Safety Officer.

Contrary to the above, records of these checks required by 10 CFR 35.50(b)(2) through (b)(4) performed from December 1987 to September 1990 did not include the signature of the Radiation Safety Officer.

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

Pursuant to the provisions of 10 CFR 2.201, Claremore Regional Hospital is hereby required to submit a written statement or explanation to the U.S.

Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region IV, and if applicable, a copy to the NRC Resident Inspector, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order may be issued to show cause why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Dated at Arlington, Texas
this 15th day of October 1990

CLAREMORE REGIONAL HOSPITAL
1202 North Muskogee Street
Claremore, Oklahoma 74107

September 21, 1989

Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive
Arlington, Texas 76011

Dear Sirs:

Please amend our License No. 35-16298-01 to reflect a change of ownership and a name change of the institution. Ownership of the facility conducting nuclear medicine activities under this license has been transferred from AMI, Incorporated to Epic Healthcare Group, Incorporated. As a result of this change of ownership, there has also been a name change from Claremore Regional Medical Center to Claremore Regional Hospital. These changes represent primarily internal structural changes.

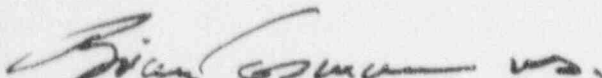
No substantive changes of our nuclear medicine program and related personnel occurred as a result of the change of ownership and name change.

Thank you for your attention in this matter.

Sincerely,

Betty Walker
Administrator

Approval:



Dr. Brian Cosmann
Radiation Safety Officer

BW/trh

~~901130035~~ K.



CLAREMORE REGIONAL HOSPITAL

October 19, 1990

Mr. Maurice Messier
License Fee & Debt Collection
U.S. Nuclear Regulatory Commission
Branch, OC/DAF
Mail Stop MNBB 4503
Washington, D.C. 20555

Re: Control No. 463305
NOTAMI Hospitals of Oklahoma, Inc.
d/b/a Claremore Regional Hospital

This refers to your letter dated October 11, 1990 pertaining to our request for amendment to Materials License 35-16298-01.

Enclosed you will find a check # _____ in the amount of \$340.00 to cover the amendment fee made out to the U.S. Regulatory Commission.

It is our understanding that you will notify the Region IV Licensing Staff located at 611 Ryan Plaza Drive, Suite 1000, Arlington, Texas 76011 that you have received this fee.

We would like for you to acknowledge receipt of the fee since there is a 30 day calendar time limit in your letter. If we can be of further help in this matter please do not hesitate to contact us.

Sincerely,

Ken Seidel,
Executive Director

KS:o
Enc: (1)
cc: Region IV

1202 N. Muskogee Street
Claremore, Oklahoma 74017
918-344-2756
FAX 918-342-3330

CLAREMORE REGIONAL HOSPITAL

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