FEB - 6 1991

In Reply Refer To:
License: 35-16717-01
Docket: 30-11681/90-02
EA 90-191

Newman Memorial Hospital
ATTN: Gary Mitchell
Administrator
919 South Main
Shattuck, Oklahoma 73858

Gentlemen:

This is in reference to your letter dated January 17, 1991, in response to our letter and Notice of Violation both dated December 20, 1990. We have reviewed your reply and find it responsive to the concerns raised in our Notice of Violation.

NRC acknowledges that Newman Memorial Hospital (NMH) has taken significant steps to develop policies and procedures which will provide sufficient guidance to staff members and referring physicians when the authorized user is absent from the facility. To ensure that your corrective actions are effective in preventing the recurrence of these and similar violations, it is necessary that the radiation safety officer and supervising authorized users establish adequate authority over program activities and continue routine communication with those staff members participating in licensed activities.

It is our understanding that NMH's nuclear medicine program remains suspended and that you will notify NRC when a decision regarding reinstatement of the service has been reached. Pending this decision, the implementation of your corrective actions will be reviewed during a future inspection to determine whether full compliance has been achieved and will be maintained.

Sincerely,

Original Signed By

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

cc:
Oklahoma Radiation Control Program Director

bcc: (see next page)

*RIV:NMSIS	*C:NMSIS	D:DRSS	*EO
LLKasner:nh	CLCain	ABBeach	GSanborn
/ /91	/ /91	2/5/91	/ /91

*Previously Concurred.

IE07
1/1

bcc:
DMB - Original (IE-07)
RDMartin
GSanborn
ABBeach
LAYandell
MRodriguez, OC/LFDCB (4503)
WLFisher
CLCain
LLKasner
NMSIS
MIS System
RIV Files (2)
RSTS Operator
REHall
JLieberman, OE

NEWMAN MEMORIAL HOSPITAL

905 919 MAIN
SWATTUCK, OK 73858
405 938 2551

January 17, 1991

U. S. Nuclear Regulatory Commission
Attention: Document Control Desk
Washington, D.C. 20555

Re: Response to Notice of Violation

Gentlemen:

Attached is the response of Newman Memorial Hospital to the Notice of Violation dated December 20, 1990. (Docket # 30-11681 and License # 35-16717-01).

With the submission of this material, we have fully complied with the request requirements of the NRC in addressing the problems and concerns at Newman Memorial Hospital regarding of handling radioactive materials within the Nuclear Medicine department. We continue to suspend the operation of that department pending further study by our Medical Staff, Board of Directors, RSO and Radiology department manager.

Respectfully,

Gary W. Mitchell

Gary W. Mitchell, M.S.,
Interim Administrator

GWM/saw

cc: Regional Director, NRC, Region IV
Dan Mitchell, MD, RSO
Brian Dancer, Radiology Manager
J. Mike Stuart, Chairman Board of Directors

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Response to Notice of Violation dated 12/20/90.

(A) Newman Memorial Hospital (NMH) believes that the transfer of 155 millicuries of technetium-99M to a patient for transport to another hospital occurred due to a lack of knowledge of a untrained technician on the date specified. NMH has addressed this problem by reviewing this thoroughly with the technician involved in addition to the department manager responsible for supervision and with the medical staff of the institution. Avoidance of future violations of this particular standard will be accomplished by full implementation and monitoring of a policy to prohibit this activity. Full compliance was achieved as of October 6, 1990 following the incident. (Reference: 10 CFR 30.41 (a), (b) (3), (b) (5); 10 CFR 30.13)

(B) NMH recognizes the stated violation permitting an individual to use biproduct material under the supervision of an unauthorized user without instruction to the individual in the principals of radiation safety appropriate to use. The reason for this violation was the lack of knowledge and expertise by the technician who attempted to be of assistance during this procedure. The resolution and corrective measures are those as stated for item A above. Full compliance was completed on October 6, 1990. (Ref: 10 CFR 35.25 (a) (1) & (2))

(C) (1) NMH recognizes this violation of no finger exposure monitor use during the elution of a generator and during the preparation assay and injection of a radiopharmaceutical. The NRC investigation record has determined that a finger expose device was not issued to the technician in question. Corrective measures to address this matter have been to prohibit this technician from being involved in the preparation of radiopharmaceuticals and suspension of license activities. Further violations are avoided by prohibiting of this individual from the program. Full compliance was achieved as of October 6, 1990. (Ref: 10 CFR 35.21 (a))

(C) (2) NMH recognizes the radiation safety activities were being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee biproduct material program. NMH believes that in the chronology of events from prior violations had not allowed the RSO, during limited opportunities available for review of our activities, to review this specific point of compliance with the Nuclear Medicine staff. Any instruction would have been through the Nuclear Medicine technologist rather than the Radiology technologist

involved in this incident. The RSO also has stated his belief that this incident would have occurred if he had been on premises. Corrective measures include the suspension of activities under the license until such policies and procedures can be reviewed and reapproved to address these issues. Full compliance for this issue was effective November 14, 1990. (Ref: 10CFR 35.21 (b))

(C) (3) NMH recognizes the admission by the Radiation Safety Officer not investigating unauthorized departures from approved radiopharmaceutical preparation procedures, specifically including the departure occurring on October 5, 1990. Again, the Radiation Safety Officer during this period of time had not been able to direct his undivided attention to NMH specifically and the violation occurred during this interim period. The corrective steps taken have been outlined in (C) (3). Full compliance was achieved on November 14, 1990. (Ref: 10 CFR 35.21 (b))

(D) NMH recognizes that the MAA Reagent Kit was reconstituted with 5.2 millicuries of technetium-99m resulting in an excessive exposure of the patient during the injection. Corrective measures are the suspension of activity pending further review, development of policy and procedures for the Nuclear Medicine department and prohibition of all individuals other than the Nuclear Medicine technologist to conduct these activities. Policy statements will include strict guidelines to reconstitution the radiopharmaceutical injection according to manufacturer guidelines and monitoring there by the RSO, the Radiation Physicist and Radiology department manager. Corrective steps to avoid this procedure are full implementation of the procedures with full knowledge of the RSO and department of radiology manager. Full compliance was accomplished as of October 6, 1990. (Ref: 10 CFR 35.200 (b))

(E) NMH recognizes the violations noted in four subdivisions relating to various activities referenced under 10 CFR 71.5 (a), 49 CFR 173.466, 49CFR 173.461, 49 CFR 172.200 (a), 49 CFR 172.403, and 49 CFR 173.443 (a). All of the CFR references deal with transportation of licensed materials outside the confines of the plant and certain Department of Transportation regulations in the 49 CFR sections. NMH believes the cause of the violation(s) deal directly with the lack of knowledge by the department technologist in the nuclear medicine arena and the absence of the Nuclear Medicine technician. NMH has suspended the activities of the license for an indeterminat period of time pending a complete revision of policies and procedures and education of the appropriate individuals. Prevention of this will be prohibition of any transfer of licensed materials from NMH premises under any circumstances.

Full compliance will be completed when activities are reinstuted after notification of NRC of our procedures to comply with these and other requests. (Ref: see list above)

These violations have been discussed and reviewed by the parties involved at NMH. Further information is contained in the transcript of the Enforcement Conference conducted in Arlington, Texas on November 14, 1990.

This response is provided pursuant to the stated provisions of 10 CFR 2.201 requiring a written statement of explanation to the U. S. Nuclear Regulatory Commission with a copy to the Regional Administrator, NRC Region IV.

January 17, 1991
Shattuck Oklahoma