Docket No. 30-20282/90-01 License No. 35-23125-01

Memorial Hospital of Texas County ATTN: Douglas K. Weaver Administrator 520 Medical Drive Guymon, Oklahoma 73942

Gentlemen:

This letter acknowledges our receipt of your letters dated September 18, 1990, in response to our letter and attached Notice of Violation both dated July 20, 1990.

We have reviewed your response and find that additional information is needed. Specifically, we note that you have not responded fully to the items identified on pages 2 and 3 of the Notice for each of the violations. Your reply to this letter should be provided to the NRC Region IV office within 10 days of your receipt of this letter and should address the specific items described below.

Violation 1

Although we note that you have determined the reasons for the violation and that some corrective action has been taken, your response does not describe the measures which have been implemented to prevent recurrence of this problem. Your reply should include a description of the measures taken to ensure that the management representative and the radiation safety officer (RSO) continue to attend radiation safety committee (RSC) meetings.

Additionally, your response raises concerns regarding management's and the RSO's involvement in program activities. Your response implies that these activities may have been directed by the department director, an individual participating in licensed activities under the provision of supervision as described in 10 CFR 35.25. This practice does not reflect management of licensed activities by committee direction.

We also emphasize that it is the RSO's responsibility to implement, audit, and enforce radiation safety policies and procedures, and to provide guidance to the RSC in developing such policies. In this respect, his presence during committee meetings is essential.

Violation 2

Although the specific individual who administered the subject radiopharmaceutical dose may no longer be employed at Memorial Hospital, there are several factors associated with this misadministration. Specifically

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Memorial Hospital of Texas County

your reply does not explain why the RSO, also the authorized user, failed to identify the misadministration and bring it to the RSC's attention.

As reviewed with the RSO during the inspection, the department director indicated that patient doses had been changed in the past by the technical staff, based on the recommendation of a nuclear pharmacist, without the specific consultation of the authorized user/RSO. These changes, specifically for thyroid exams, had gone unnoted at the time although they were later approved by the authorized user/RSO. This example has an underlying cause similar to that of the oversighted misadministration in that the authorized user/RSO failed to note an administered dosage other than what he had routinely prescribed.

Consequently, your response to this violation should include a description of: (1) any weakness, as observed by the RSO, in patient dosage documentation which may have resulted in his failure to identify the misadministration; (2) the specific actions taken which will ensure that such errors are given the proper attention; and (3) those measures which have been implemented to prevent future similar oversights.

Violation 3

The findings of the inspection did support the fact that members of management met periodically with the RSO. As noted in your reply to Violation 1, these meetings occasionally involved briefing the RSO on program activities. However, the inspector was informed by both the administrator and RSO that annual briefings as required under 10 CFR 35.21(b)(3) had not been conducted. Your response appears to indicate that these statements were incorrect. Further, you should note that there is no requirement to maintain records of annual briefings, although a licensee may implement such a requirement if they wish.

In your reply you should: (1) provide supportive information if you contend that the violation did not occur, or (2) provide a description of the measures taken to ensure that this violation does not recur.

Violation 5.a

Your supplemental response should provide a description of: (1) the specific corrective actions taken, (2) those measures implemented to prevent recurrence of the violation, and (3) the reason for the delay in correcting this problem.

In your reply, if the violation has been corrected, please indicate so; otherwise, please review this issue and provide information on whether this specific violation has recurred during the period between the date of the inspection and your reply to this letter.

Memorial Hospital of Texas County

Violation 5.b

Your reply does not identify the reason that the violation occurred. It is imparative that you identify the root cause of the violation in order to implement corrective measures which are adequate to ensure that the violation does not recur.

Your reply should include: (1) the reason that the violation occurred and (2) the reason for the delay in correcting the violation.

Should you have any questions regarding this matter, please contact Linda Kasner at (817) 860-8100.

Original Signed By.,
A. B. BEACH

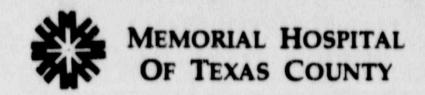
A. Bill Beach, Director Division of Radiation Safety and Safeguards

cc: Oklahoma Radiation Control Program Director

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John Slater



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September 18, 1990

A. Bill Beach, Director Division of Radiation Safety and Safeguards United States Nuclear Regulatory Commission, Region IV 511 Ryan Plaza Drive, Suite 1000 Arlington, Texas 76011

Dear Mr. Beach,

As per my telephone conversation with Ms. Kasner last week, I am enclosing our reply to your letter of July 20, 1990. Please forgive the tardiness; as I told her when we spoke, I truly believed we had responded in early August.

Thanks for your tolerance of our mistake.

Sincerely,

Douglas K. Weaver Administrator

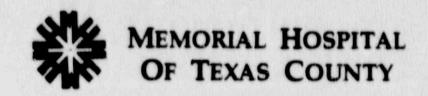
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John Slater



September 18, 1990

A. Bill Beach, Director Division of Radiation Safety and Safeguards United States Nuclear Regulatory Commission, Region IV 611 Ryan Plaza Drive, Suite 1000 Arlington, Texas 76011

Reference:

License:35-23125-01 Docket: 30-20282/90-91

In response to violations cited:

- 1. The Radiology department was short staffed during the time period in question, making it very difficult to allot time for scheduled RSC meetings. As a result, meetings were not held. The RSO was not present during the meetings for two reasons: one being the Department Director misinterpreted 10 CFR 35.22 (a) (2) and (3). She believed only one-half the RSC's members needed be present for meetings, and attandance by the RSO and management was not required, although she did try to have them present. The second reason is the extreme difficulty of scheduling around the RSO's other obligations. Meetings were conducted without him, and he was briefed later.

 Corrective action taken requires all necessary members to attend all RSC meetings, and as of this date this facility is in compliance.
- 2. The April 20, 1988 misadministration incident is clearly a violation of 10 CFR 35.22(b)(5). Due to turnover in personnel since that time, a complete investigation is impossible, but the present staff is aware of the incident and have been inserviced for such misadministration. As of this date Memorial Hospital of Texas County is in compliance.
- 3. The RSO meets with Administration at least once a month, but briefing on byproduct material program was not recorded. This oversight will be reviewed with the RSO and management and documentation will prepared after each briefing. As of November 1, 1990, this facility will come into compliance.

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I believe these measures correct all deficiencies noted by Ms. Kasner in her radiation safety inspection. Thank you for helping us bring this facility in line with federal regulations.

Sincerely.

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Douglas K. Weaver Administrator

DKW: jb

In Reply Refer To: License: 35-23125-01 Docket: 30-20282/90-01

Memorial Hospital ATTN: Douglas Weaver, Administrator 520 East Medical Drive Guymon, Oklahoma 73942

Gentlemen:

This refers to the routine, unannounced radiation safety inspection conducted by Ms. L. L. Kasner of this office on June 12, 1990, of the activities authorized by NRC Byproduct Material License No. 35-23125-01. The findings of this inspection were reviewed with the hospital administrator and radiation safety officer (RSO) 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 the inspection, the inspector also reviewed the organization of the nuclear medicine department and the effectiveness of the radiation safety committee (RSC) and the RSO in managing the various aspects of your radiation safety program.

The inspector observed that you have designated many of the RSO's duties to be performed by the technical staff. Further, she noted that the staff appeared to be unfamiliar with specific requirements of 10 CFR Part 35 and certain procedures described in the license application. This was evidenced in violations related to the failure to: (1) conduct removable contamination surveys, (2) conduct dose calibrator constancy and linearity tests according to license procedures, and (3) properly notify the RSO and subsequently evaluate a diagnostic misadministration.

The performance of tasks normally associated with the position of RSO may be designated to another individual and subsequently reviewed by the RSO; however, it is imperative that the individuals assigned to these tasks fully understand the applicable regulations and license procedures. We wish to emphasize that although the regulations permit the delegation of certain duties, the RSO is responsible for the overall effectiveness and compliance of the radiation safety program with the Commission's rules and regulations and the conditions of the license. Additionally, we are concerned that under circumstances where the RSO (also the authorized user) was not always physically present to observe activities, the RSC failed to conduct quarterly reviews of licensed activities. 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.

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During this inspection, certain of your activities were found not to be conducted in full compliance with NRC recuirements. 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 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 96-7-1.

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

Sincerely,

A. B. BEACH

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

cc: Oklahoma Radiation Control Program Director

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APPENDIX

NOTICE OF VIOLATION

Memorial Hospital Guymon, Okiahoma

Docket: 30-20282 License: 35-23125-01

During an NRC inspection conducted on June 12, 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) (Enforcement Policy), the violations are listed below:

 10 CFR 35.22(a)(2) and (3) require that the radiation safety committee (RSC) meet at least quarterly and that to establish a quorum and to conduct business, at least one-half of the RSC's members must be present, including the radiation safety officer (RSD) and the management's representative.

Contrary to the above, during the period January 1989 through June 12. 1990, the RSC had failed to conduct quarterly meetings having met on only one occasion in June 1989. Also, the RSO had not been present during RSC meetings conducted during July, October, and December 1988.

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

 10 CFR 35.22(b)(5) requires, in part, that the radiation safety committee (RSC) review quarterly, with the assistance of the radiation safety officer (RSO), all incidents involving byproduct material with respect to cause and subsequent actions taken.

Contrary to the above, as of June 12, 1990, the RSC had not reviewed a diagnostic misadministration incident which had occurred on April 20, 1988. The incident involved the administration of a 9.8 millicurie dose of technetium-99m labelled sulfur colloid to a pat to when the prescribed dose was 4 millicuries.

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

 10 CFR 35.21(b)(3) requires that the radiation safety officer (RSO) brief management once each year on the byproduct material program.

Contrary to the above, during calendar years 1987, 1988, and 1989, the RSO had failed to brief management on the byproduct material program.

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

 10 CFR 35.53(c)(2) requires that records of radiopharmaceutical doses must contain the patient's name and identification number if one has been assigned.

Contrary to the above, during the period June 1988 through June 12, 1989, records of radiopharmaceutical doses administered to patients did not

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contain patient identification numbers although one had routinely been assigned for each patient.

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

- License Condition 13 specifies that the license is based on statements and representations contained in the application dated March 25, 1989, and letters dated October 17 and November 8, 1989.
 - A. Item 9.3 of the application specifies that the procedures described in Appendix C of Regulatory Guide 10.8, Revision 2, will be used to calibrate the dose calibrator.

Appendix C requires, in part, that: (1) the licensee establish an action level or tolerance for each recorded daily constancy measurement at which the individual performing the test will automatically notify the appropriate individual of suspected malfunction of the calibrator, and that the action level be written in the log book or posted on the calibrator; and (2) linearity test results be graphed on semilog graph paper and if the measured activity deviates by greater than 5 percent of the predicted value, that a correction table or graph be made to convert the activity indicated by the dose calibrator to "true activity."

Contrary to the above, as of June 12, 1990, the licensee had failed to establish and post an action level or tolerance for daily constancy measurements of the dose calibrator. Also, dose calibrator linearity tests, conducted in May and September 1989 and March and April 1990, revealed several activity measurements which deviated greater than 5 percent from the predicted value, and the licensee had failed to make a correction table or grap; to be used in converting dose calibrator measurements to the "true activity."

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

B. Item 10.12 of the application specifies that the procedures described in Appendix N of Regulatory Guide 10.8, Revision 2, will be used to conduct area radiation surveys. Appendix N requires that removable contamination surveys be conducted weekly in areas of radiopharmaceutical preparation and administration.

Contrary to the above, from January 1983 through June 12, 1990, the licensee had failed to conduct any removable contamination surveys in areas where radiopharmaceuticals had been prepared and administered.

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

Pursuant to the provisions of 10 CFR 2.201, Memorial 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 20th day of July 1990

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License Condition 13 specifie			
representations contained in letters dated October 17 and		rcn 25, 1989	, and
Item 10.12 of the application	specifies that the proc	edures descr	ibed
in Assessed N of Populatory (unda ID. B. Kevision &. W	III DE USEU	
conduct area radiation survey	s. Appendix n requires	CHAL I CHOTAL	
contamination surveys be cond radiopharmaceutical preparati	on and administration.		
		10 1000 +	ha -
Contrary to the above, from conductions	lanuary 1989 through June	ation survey	s in
areas where radiopharmaceutic	als had been prepared an	d administer	ed.
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	PECTOR'S REPORT (Continuation)	03020282 1 9	B COLATON STATES DANS	MELAIL
	spection and Enforcement			7 6 0
· KOLATION OF DE	VIA TION of over up to 2400 chargement or annual			
repre	esertations contained ers dated October 17 a Item 9.3 of the application of Regularity appendix C of Regularity action le. 1 or toler measurement at which automatically notify malfunction of the caling the log book or poresults be graphed on activity deviates by that a correction tablindicated by the dose Contrary to the above to establish and post constancy measurement linearity tests, conditions.	cation specifies that the pro latory Guide 10.8, Revision 2	cedures described , will be used to see establish an constancy test will suspected level be written 2) linearity test the measured predicted value, the activity censee had failed for daily so, dose calibrator 89 and March and	
	failed to make a corr	t from the predicted value, a ection table or graph to be to rements to the "true activity	sed in converting	_

C FORW 200 A	DOCKET NO 18 signs OR LICENSE NO 184 PRODUCTI (13 signs)		MODULE NUMBER	4 200
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(Continuation)		1 1 1 1 1 0 1	12366	HELATE IA CI
fice of Inspection and Enforcement			X	☐ ☐ o
OLATION OR DEVIATION denor up to 2400 characters for ocean me	III. I Pro 1921 Ancidedo Mile Number: E pro do nego		- 20	
10 CFR 35.53(c)(2) requires t	hat records of radiopha	armaceutical dos	es must	
contain the patient's name ar	id identification number	r it one has bee		
- assigned.				
Contrary to the above, during	the period June 1988	through June 12,	1989,	
- records of radiopharmaceutica	il doses administered to	pacients did i		
contain patient identificati	ion numbers although one	e had routinely	been	
assigned for each patient.				_
				Addition 1

INSPECTOR'S REPORT (Continuation) ffice of inspection and Enforcement Outlon on Deviation and Enforcement 10 CFR 35.21(b)(3) requires that the radiation safety officer (RSO) brief management once each year on the byproduct material program. Contrary to the above, during calendar years 1987, 1988, and 1989, the RSO had failed to brief management on the typroduct material program.		
INSPECTOR'S REPORT (Continuation) Iffice of inspection and Enforcement Contract Service decreases and the service of the ser	HAC FORM HE A	DOCKET NO 18 SIGNIS OR LICENSE NE FORT WOODLE NUMBER
(Continuation) flice of inspection and Enforcement Control of Servation and Enforcement Control of Servat		
ffice of inspection and Enforcement Current persons and an analysis of the state o		STATE OF THE PARTY
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10 CFR 35.21(b)(3) requires that the radiation safety officer (RSO) brief management once each year on the byproduct material program. Contrary to the above, during calendar years 1987, 1988, and 1989, the RSO had failed to brief management on the typroduct material program.	0.100.0100.100.1	
management once each year on the byproduct material program. Contrary to the above, during calendar years 1987, 1988, and 1989, the RSO had failed to brief management on the typroduct material program.	The second of th	The state of the s
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management once each year on the byproduct material program. Contrary to the above, during calendar years 1987, 1988, and 1989, the RSO had failed to brief management on the typroduct material program.	10 CFR 35.21(b)(3) reg	wires that the radiation safety officen (DSO) baief
Contrary to the above, during calendar years 1987, 1988, and 1989, the RSO had failed to brief management on the typroduct material program.	management once each ye	ear on the byproduct material program.
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	had failed to brief man	during calendar years 1987, 1988, and 1989, the RSO
		agement on the typrodoct material program.
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OLATION OR DEVIATION Winter up to 2400 characters for each of	AM. I Per ter seconds the number. I yet by access	MAT IN DEPOSITION. LANCE SHOW IN SET OFFICE PROPERTY COME. 1	
10 CFR 35.22(b)(5) requires, ramittee (RSC) review quart safety officer (RSO), all in respect to cause and subsequires. Contrary to the above, as of diagnostic misadministration 1988. The incident involved of technetium-99m labelled subsequires.	erly, with the assistance cidents involving byproduent actions taken. June 12, 1990, the RSC incident which had occur the administration of a	e of the radiation uct material with had not reviewed a rred on April 20, 9.8 millicurie dose	
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NRC FORM	*	DOCKET NO 18 ENGINE OR LICENSE AT MODULE NUMBER	
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	INSPECTOR'S REPORT		RELATED
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mice of inspection and Enforcement		1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
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	10 CFR 35 22(a)(2) and (3) require that the radiation safety	
	committee (DCC) meet at 1	east quarterly and that to establish a quorum and	-
1	to conduct huninger at 1	east one-half of the RSC's members must be diation safety officer (RSO) and the management's	_
	representative.	diacion safety officer (kso) and one management	_
4			
	Contrary to the above, du	ring the period January 1989 through June 12.	
1	1990, the RSC had failed	to conduct quarterly meetings having met on only . Also, the RSO had not been present during RSC	
	meetings conducted during	July, October, and December 1988.	
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