

NOV 19 1990

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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*Previously Concurred

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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

-3-

Violation 5.b

Your reply does not identify the reason that the violation occurred. It is imperative 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.

Sincerely,

Original Signed By,

A. B. BEACH

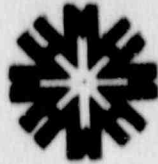
A. Bill Beach, Director
Division of Radiation Safety
and Safeguards

cc:
Oklahoma Radiation Control Program Director

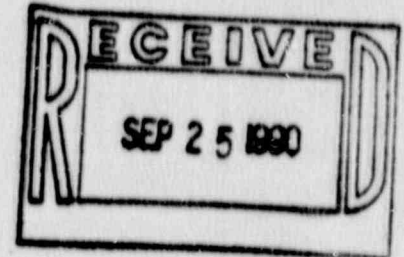
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DME - Original (IE-07)
RDMartin
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MRodriguez, OC/LFDCB (4503)
WLFisher
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LLKasner
NMSIS
MIS System
RIV Files (2)
RSTS Operator
REHall, URFD

ADMINISTRATOR
Douglas K. Weaver

BOARD OF CONTROL
James M. Boring
Fred Freeman
John Garrison
Gail Parsley
John Slater



MEMORIAL HOSPITAL OF TEXAS COUNTY



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

DKW:jb

enclosure

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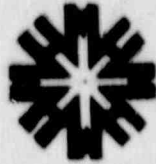
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ADMINISTRATOR
Douglas K. Weaver

BOARD OF CONTROL
James M. Borring
Fred Freeman
John Garrison
Gail Parsley
John Slater



MEMORIAL HOSPITAL OF TEXAS COUNTY

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 attendance 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 be prepared after each briefing. As of November 1, 1990, this facility will come into compliance.

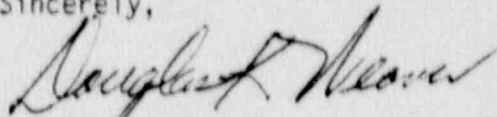
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September 18, 1990

4. Patients have been designated by last name due to misinterpretation of 10 CFR 35.53(c)(2).
The departmental logs now include the patient's complete name and hospital identification number, and compliance is achieved.
- 5a. Failure to incorporate a correction table/graph into daily routine was due to misinterpretation of the requirement for the conversion to "true activity".
The Department Director is waiting for a response from the Radiation Physicist/Consultant regarding the correct form or graph to use, and expects to be in full compliance by November 1, 1990.
- b. Procedures described in Appendix N of Regulatory Guide 10.8, Revision 2 were not performed although the area was surveyed using a meter.
Corrective action is being taken, removable contamination surveys will be conducted weekly, and the facility will be in compliance by November 1, 1990.

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,



Douglas K. Weaver
Administrator

DKW:jb

JUL 20 1990

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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7/17/90

D:DRSS
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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 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:

A. B. BEACH

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

cc:
Oklahoma Radiation Control Program Director

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

*W/766

APPENDIX

NOTICE OF VIOLATION

Memorial Hospital
Guymon, Oklahoma

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:

1. 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 (RSO) 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)

2. 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 patient when the prescribed dose was 4 millicuries.

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

3. 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)

4. 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)

5. 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 graph 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 1989 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

REGIONAL INSPECTOR (NAME, TITLE AND PHONE NUMBER)
 KASNER, Linda L.
 REVIEWER
 C. Cain OMC

INSPECTORS

LICENSEE/VENDOR	TRANSACTION TYPE	DOCKET NO. (8 digits)	REPORT				NEXT INSP. DATE
			NO.	SEC.	MO.	YR.	
Memorial Hospital	X I - INSERT M - MODIFY D - DELETE R - REPLACE	030202812	9001	A	06	93	

PERIOD OF INVESTIGATION/INSPECTION						INSPECTION PERFORMED BY		ORGANIZATION CODE OF REGION/HQ CONDUCTING ACTIVITY (See IEMC 0530 Manpower Reporting - Weekly Manpower Reporting by code)				
FROM			TO			X 1 - REGIONAL OFFICE STAFF 2 - RESIDENT INSPECTOR 3 - PERFORMANCE APPRAISAL TEAM		OTHER		REGION	DIVISION	BRANCH
MO	DAY	YR	MO	DAY	YR					4	3	4
06	13	90	06	13	90							

REGIONAL ACTION (Check one box only)		TYPE OF ACTIVITY CONDUCTED (Check one box only)			
<input checked="" type="checkbox"/> 1 - NRC FORM 801	<input checked="" type="checkbox"/> 2 - REGIONAL OFFICE LETTER	<input checked="" type="checkbox"/> 02 - SAFETY (fee)	<input type="checkbox"/> 03 - INCIDENT	<input type="checkbox"/> 04 - ENFORCEMENT	<input type="checkbox"/> 05 - MGMT. AUDIT
		<input type="checkbox"/> 06 - MGMT VISIT	<input type="checkbox"/> 07 - SPECIAL (fee)	<input type="checkbox"/> 08 - VENDOR	<input type="checkbox"/> 09 - MAT. ACCT.
		<input type="checkbox"/> 10 - PLANT SEC.	<input type="checkbox"/> 11 - INVENT. VER.	<input type="checkbox"/> 12 - SHIPMENT/EXPORT	<input type="checkbox"/> 13 - IMPORT
		<input type="checkbox"/> 14 - INQUIRY (no fee)	<input type="checkbox"/> 15 - INVESTIGATION		

INSPECTION INVESTIGATION FINDINGS (Check one box only)				TOTAL NUMBER OF VIOLATIONS AND DEVIATIONS				ENFORCEMENT CONFERENCE HELD				REPORT CONTAIN 270 INFORMATION				LETTER OR REPORT TRANSMITTAL DATE					
A	B	C	D	A	B	C	D	A	B	C	D	A	B	C	D	MO	DAY	YR	MO	DAY	YR
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1 - CLEAR								1 - YES				1 - YES									
2 - VIOLATION																					
3 - DEVIATION																					
4 - VIOLATION & DEVIATION																					

MODULE INFORMATION												MODULE INFORMATION											
REC. ORD.	MODULE NUMBER INSP.				DIRECT INSP. TIME EFFORT IN SAFE HOURS EXPENDED THIS INSPECTION	PERCENTAGE COMPLETED TO DATE	STATUS	MODULE REG FOLLOWUP				REC. ORD.	MODULE NUMBER INSP.				DIRECT INSP. TIME EFFORT IN SAFE HOURS EXPENDED THIS INSPECTION	PERCENTAGE COMPLETED TO DATE	STATUS	MODULE REG FOLLOWUP			
TYPE NUMBER	PHASE	MANUAL CHAPTER	PROCEDURE NUMBER	LEVEL				PHASE	MANUAL CHAPTER	PROCEDURE NUMBER	LEVEL		TYPE NUMBER	PHASE	MANUAL CHAPTER	PROCEDURE NUMBER				LEVEL	PHASE	MANUAL CHAPTER	PROCEDURE NUMBER
0	53	77	03	A	003	-	-	-	-														
management meetings										Inspection of Waste Generator Requirements													
0	58	71	00	A	008	1	0	0	C		58	08	00	A	0	1	0	C					
licensed materials programs										initial inspection													
0	58	38	22	A	002	1	0	0	C		59	27	02	A	0	-	-	-					
radiation protection										Followup on violations													
0	58	67	40	A	001	1	0	0	C														
transportation																							

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DOCKET NO. (8 digits) OR LICENSE NO. (BY PRODUCT) (13 digits)

PORT

MODULE NUMBER

030202912

9001

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VIOLATION SEVERITY OR DEVIATION

SITE RELATED

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

VIOLATION OR DEVIATION (Enter up to 2400 characters for each item. If the text exceeds this number, if the so necessary to paraphrase. Limit space to 80 characters each.)

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.

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 1989 through June 12, 1990, the licensee had failed to conduct any removable contamination surveys in areas where radiopharmaceuticals had been prepared and administered.

DOCKET NO. (8 digits) OR LICENSE NO. (BY PRODUCT) (11 digits)

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MODULE NUMBER

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INSPECTOR'S REPORT

(Continuation)

Office of Inspection and Enforcement

NO	SEQ	VIOLATION SEVERITY OR DEVIATION						SITE RELATED
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	A							A C
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	C							
	D							

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 50 characters each.)

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.

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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."

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NO. (BY PRODUCT) (13 digits)

PORT

MODULE NUMBER

03020282

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VIOLATION SEVERITY OR DEVIATION

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

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

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.

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

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

DOCKET NO. (8 digits) OR LICENSE NO. (BY PRODUCT) (13 digits)		REPORT NO.		MODULE NUMBER	
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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 60 characters each.)

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.

DOCKET NO (8 digits) OR LICENSE NO (BY PRODUCT) (13 digits)

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MODULE NUMBER

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

NO	SEQ	A	B	C	D	VIOLATION SEVERITY OR DEVIATION						SITE RELATED					
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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.)

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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 patient when the prescribed dose was 4 millicuries.

INSPECTOR'S REPORT
(Continuation)

Office of Inspection and Enforcement

DOCKET NO (8 digits) OR LICENSE NO (8) PRODUCT (13 digits)		ORT		MODULE NUMBER	
030202912		NO	SEC	5871 UC SURVE	
		9001		VIOLATION SEVERITY OR DEVIATION	
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VIOLATION OR DEVIATION (ENTER UP TO 2400 CHARACTERS FOR EACH ITEM. IF THE TEXT EXCEEDS THIS NUMBER, IT MAY BE NECESSARY TO PARAPHRASE. LIMIT WORDS TO 50 CHARACTERS EACH.)

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 (RSO) 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.

nm13

NRC FORM 708
11-81
11 MC 053

U.S. NUCLEAR REGULATORY COMMISSION

REGIONAL INSPECTOR (A)

SI 091 AND MOBILE FIELD

INSPECTOR'S REPORT

Office of Inspection and Enforcement

KASNER Linn E.
REVIEWER
C. Cain OMC

INSPECTORS

LICENSEE/VENDOR <i>MEMORIAL HOSPITAL</i>	TRANSACTION TYPE <input checked="" type="checkbox"/> I - INSERT M - MODIFY D - DELETE R - REPLACE	DOCKET NO. <i>03020292</i>	REPORT NO. <i>9001</i>	REPORT SEC. <i>A</i>	REPORT MO. <i>01</i>	REPORT YR. <i>1993</i>	NEXT INSP. DATE
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PERIOD OF INVESTIGATION/INSPECTION FROM: <i>01/26/93</i> TO: <i>01/26/93</i>	INSPECTION PERFORMED BY: <input checked="" type="checkbox"/> 1 - REGIONAL OFFICE STAFF <input type="checkbox"/> 2 - RESIDENT INSPECTOR <input type="checkbox"/> 3 - PERFORMANCE APPRAISAL TEAM	OTHER	ORGANIZATION CODE OF REGION/HQ CONDUCTING ACTIVITY (See 10 MC 05.30) REGION: <i>4</i> DIVISION: <i>3</i> BRANCH: <i>4</i>
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REGIONAL ACTION <input checked="" type="checkbox"/> 1 - NRC FORM 801 <input checked="" type="checkbox"/> 2 - REGIONAL OFFICE LETTER	TYPE OF ACTIVITY CONDUCTED (Check one box only) <input checked="" type="checkbox"/> 01 - SAFETY (fee) 02 - INCIDENT 03 - ENFORCEMENT 04 - MOBT AUDIT 05 - MOBT VISIT 07 - SPECIAL (fee) 08 - VENDOR 09 - MAT ACCT 10 - PLANT SEC. 11 - INVENT VER. 12 - SHIPMENT/EXPORT 13 - IMPORT 14 - INQUIRY (no fee) 15 - INVESTIGATION
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INSPECTION INVESTIGATION FINDINGS (Check one box only) <input checked="" type="checkbox"/> 1 - CLEAR <input type="checkbox"/> 2 - VIOLATION <input type="checkbox"/> 3 - DEVIATION <input type="checkbox"/> 4 - VIOLATION & DEVIATION	TOTAL NUMBER OF VIOLATIONS AND DEVIATIONS A: <i>0</i> B: <i>0</i> C: <i>0</i> D: <i>0</i>	ENFORCEMENT CONFERENCE HELD A: <i>0</i> B: <i>0</i> C: <i>0</i> D: <i>0</i>	REPORT CONTAINS THE INFORMATION A: <i>0</i> B: <i>0</i> C: <i>0</i> D: <i>0</i>	LETTER OR REPORT TRANSMITTAL DATE MO: <i>01</i> DAY: <i>26</i> YR: <i>1993</i>
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MODULE INFORMATION										MODULE INFORMATION															
REC. ORD.	MODULE NUMBER RSP				PRIORITY	DIRECT INSP. EFFORT IN STAFF HOURS EXPENDED THIS INSPECTION	PERCENTAGE COMPLETED	STATUS	MODULE REQ FOLLOWUP			REC. ORD.	MODULE NUMBER RSP				PRIORITY	DIRECT INSP. EFFORT IN STAFF HOURS EXPENDED THIS INSPECTION	PERCENTAGE COMPLETED	STATUS	MODULE REQ FOLLOWUP				
TYPE	NUMBER	PHASE	MANUAL CHAPTER	PROCEDURE NUMBER	LEVEL	SI	SI	SI	SI	SI	SI	TYPE	NUMBER	PHASE	MANUAL CHAPTER	PROCEDURE NUMBER	LEVEL	SI	SI	SI	SI	SI	SI		
	530703					003	-	-	-			54850						0	100	C					
	management meetings											Inspection of Waste Generator Requirements													
	587100					003	100	C				530800						0	100	C					
	licensed materials programs											initial inspection													
	583822					002	100	C				592702						0	-	-	-				
	radiation protection											Followup on violations													
	586740					001	100	C																	
	transportation																								

Mark through module numbers not reviewed. Fill in leading 0's for hours.

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

DOCKET NO. (8 digits) OR LICENSE NO. (BY PRODUCT) (13 digits)		REPORT NO.		MODULE NUMBER		VIOLATION SEVERITY OR DEVIATION		SITE RELATED	
030202912		9001		597100		S400 VI		A C	
						1 2 3 4 5 6		B D	
						X			

VIOLATION OR DEVIATION IF... (up to 2400 characters for each row. If the last 600 characters are necessary to describe, leave space to do operator's name.)

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.

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 1989 through June 12, 1990, the licensee had failed to conduct any removable contamination surveys in areas where radiopharmaceuticals had been prepared and administered.

INSPECTOR'S REPORT
(Continuation)

Office of Inspection and Enforcement

DOCKET NO (8 digits) OR LICENSE NO (51 PRODUCT) (13 digits)		JRT	MODULE NUMBER		SITE RELATED A CI B DI
03020282		NO	SEQ	58171 D.D. 4000-VI	
			A	VIOLATION SEVERITY OR DEVIATION	
			B	1	2
			C	3	4
			D	5	6

VIOLATION OR DEVIATION (Enter up to 1400 characters for each item. If the text exceeds the number, it may be necessary to abbreviate. Limit shall be 50 characters each.)

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.

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 graph to be used in converting dose calibrator measurements to the "true activity."

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

DOCKET NO. (8 digits) OR LICENSE NO. (BY PRODUCT) (13 digits)		MODULE NUMBER							
030207912	90101	587100	5100VI						
		VIOLATION SEVERITY OR DEVIATION				SITE RELATED			
		A	1	2	3	4	5	6	A C I
		B							B D
		C							
		D							

VIOLATION OR DEVIATION ENTRY UP TO 2400 CHARACTERS PER ROW. IF THE ROW EXCEEDS THE NUMBER, IT WILL BE NECESSARY TO REFORMAT. LINE UP TO 60 CHARACTERS ONLY.

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

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

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

DOCKET NO. (8 digits) OR LICENSE NO. (8 Y PRODUCT) (13 digits)		REPORT NO.		MODULE NUMBER	
03020292		9004		59171001	
				VIOLATION SEVERITY OR DEVIATION	
				1 2 3 4 5 6	
				X -	
				SITE RELATED	
				A C I	
				B D I	

VIOLATION OR DEVIATION (Enter up to 2400 characters for each item. If the text exceeds the number, it may be necessary to paraphrase. Limit space to 20 characters each.)

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.

DOCKET NO. (8 digits) OR LICENSE
NO. (BY PRODUCT) (112 digits)

JRT

MODULE NUMBER

03070252

9001

58710101 Support

INSPECTOR'S REPORT
(Continuation)

Office of Inspection and Enforcement

NO	SEQ	VIOLATION SEVERITY OR DEVIATION						SITE RELATED
		1	2	3	4	5	6	
	A							A C B D
	B							
	C							
	D							

VIOLATION OR DEVIATION NUMBER IS TO 2400 CHARACTERS FOR EACH CASE. IF THE CASE EXCEEDS THIS NUMBER, IT MAY BE NECESSARY TO SUBMIT MORE THAN ONE TO 2400 CHARACTER CASE.

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 patient when the prescribed dose was 4 millicuries.

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

DOCKET NO. (8 digits) OR LICENSE NO. (8Y PRODUCT) (13 digits)	BY	MODULE NUMBER
030202912	60	5871 LIC SUPPL
	SEC	
	A	VIOLATION SEVERITY OR DEVIATION
	B	1 2 3 4 5 6
	C	X -
	D	
		SITE RELATED
		A CI
		B DI

VIOLATION OR DEVIATION: (Enter up to 2400 characters for each item. If the first character is a number, it will be necessary to add a zero. Limit ends to 20 characters each.)

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 (RSO) 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.