JAN 16 1991

In Reply Refer To:
License: 49-23121-01
Docket: 30-20277/90-01

Community Hospital
ATTN: Douglas McMillan
Administrator
2000 Campbell Drive
Torrington, Wyoming 82240

Gentlemen:

Thank you for your letter of December 24, 1990, in response to our letter and attached Notice of Violation both dated December 3, 1990. We have reviewed your reply and find it responsive to the concerns raised in our Notice of Violation. We will review the implementation of your corrective actions during a future inspection to determine whether full compliance has been achieved and will be maintained.

Sincerely,

Original Signed By:
LAWRENCE A. YANDELL for

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

cc:
Wyoming Radiation Control Program Director

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

RIV:NMSIS ADG	C:NMSIS CLC	D:DRSS
ADGaines:nh	CLCain	ABBeach for
1/15/91	1/15/91	1/15/91

9101240060 910116
R.Q4 LIC30
49-23121-01 PDR
23 079

IE-07

Community Hospital
2000 Campbell Drive
Torrington, WY 82240

December 24, 1990

U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington DC 20555

Re: Reply to Notice of Violation

Dear Sirs:

This letter is in response to the NRC communication dated December 3, 1990, concerning the inspection at Community Hospital (Inspection report 30-20277/90-01). Our responses to the items detailed in the Notice of Violation are provided below.

Item 1: This was an oversight. Radiation Safety Meetings are now scheduled with all participants concerned one year in advance during the months of December, March, June, and September. The office of the Hospital Administrator will take responsibility for scheduling meetings. This should eliminate any possibility of meetings being missed in the future. The meeting for the fourth quarter of 1990 was held on December 12, 1990. Full compliance has been achieved as of this date.

Items 2: A & B: Both of these items were an oversight. The quality control procedures for the dose calibrator have been amended as of this date to include:

1) a constancy check on a frequently used setting on each day that the dose calibrator is used

2) a linearity test on the dose calibrator on at least a quarterly basis, (and also upon installation and following service). The reports are to be signed by the Radiation Safety Officer.

Full compliance has been achieved as of this date.

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Items 3.A & B — These items are admitted. During the calibration of the Victoreen CDV-700 survey meter performed during September, 1990, an attempt was made to bring the indicated exposure rate to within 20% of the calculated exposure rate. However, on one range, the unit could not be adjusted to within 20%, presumably, due to the age of the unit. A new survey meter has been purchased and is available for use at the Hospital. (Eberline Model ESP-1, equipped with a model HP-270 probe). This unit is capable of dose rate measurement over the range 1 to 1000 mrem/hr, and will be used for all future surveys. Full compliance has been achieved as of this date.

Item 4 — This item is admitted. A more sensitive instrument for performing area wipe test surveys has been acquired by the Hospital (Eberline Model ESP-1 meter equipped with a HP210L probe and used in the scalar mode). A protocol is being implemented to assure that wipe samples that exceed 2000 dpm of contamination are detected. Full compliance will be achieved by or before January 15, 1991.

Item 5 — This item is admitted. The problem was caused by lack of subtraction of the zero offset reading of the dose calibrator. The protocol for measuring molybdenum breakthrough has been revised to specify that the dose calibrator zero offset reading must be subtracted from each reading used to determine the molybdenum breakthrough concentration. The technologist performing the measurements has been instructed in the revised protocol. Full compliance has been achieved as of this date.

In order to improve the overall effectiveness of management control over licensed activities, the Hospital Administrator will review on a quarterly basis (concurrent with the Radiation Safety Committee meetings) the results of all Quality Control activities. This review will be designed to ensure that all planned Quality Control activities are carried out and that problems, when identified, are promptly resolved.

This response is submitted under oath.

Yours sincerely,

Doug McMillan
Administrator

John Goddard, Ph.D.
Consultant

JG/tg

cc: U.S. Nuclear Regulatory Commission
Regional Administrator
611 Ryan Plaza Drive
Suite 1000
Arlington, TX 76011

Signed before me this 28th day of December, 1990.

Notary Public

DEC 3 [redacted]

Docket No. 30-20277/90-01
License No. 49-23121-01

Community Hospital
ATTN: Douglas McMillan
Administrator
2000 Campbell Drive
Torrington, Wyoming 82240

Gentlemen:

SUBJECT: NOTICE OF VIOLATION (NRC INSPECTION REPORT NO. 30-20277/90-01)

This refers to the routine, unannounced radiation safety inspection conducted by Messrs. Anthony D. Gaines and Gilbert Guerra of this office on October 11, 1990, of the activities authorized by NRC Byproduct Material License 49-23121-01, and to the telephonic discussion of our findings held by the inspectors and Mr. Charles L. Cain with members of your staff on October 17, 1990. The enclosed NRC Inspection Report 30-20277/90-01 documents this inspection. This also acknowledges the records we received from your consultant on October 24, 1990, to finish our review of your program.

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 with 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.

The inspectors also reviewed the actions you had taken with respect to the two violations observed during our previous inspection conducted on June 15, 1987. They verified that the corrective actions for one of these violations had been implemented. However, we noted that one violation has recurred since the previous inspection. This item is identified as Violation No. 1 in the attached Notice.

It was noted by our inspectors that the oversight of the radiation safety program was primarily performed by your consultant, and that the individual named as radiation safety officer on your license acted in a secondary role. The NRC holds the licensee and, in particular, the radiation safety officer accountable for ensuring that the program is performing as it should and in

*RIV:NMSIS	*NMSIS	*C:NMSIS	*D:DRSS
ADGaines:nh	GGuerra	CLCain	ABBeach
/ /90	/ /90	/ /90	12/01/90

*Previously concurred

9012100369

IE-07

compliance with all NRC regulations. In particular, there are certain duties spelled out in the regulations that are to be accomplished by the radiation safety officer. The day-to-day oversight that should have been provided by the radiation safety officer, or even the oversight provided by your consultant, should have been sufficient to detect the violations identified by our inspectors.

Therefore, we are concerned about the implementation of your program in the area of management control that permitted these violations to occur. 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 actions planned or taken to prevent further violations.

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

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 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

Enclosures:
1. Appendix A - Notice of Violation
2. Appendix B - NRC Inspection Report
   30-20277/90-01

cc:
Wyoming Radiation Control Program Director

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

*W/766

APPENDIX A

NOTICE OF VIOLATION

Community Hospital
Torrington, Wyoming

Docket No. 30-20277/90-01
License No. 49-23121-01

During an NRC inspection conducted on October 11-24, 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:

1. 10 CFR 35.22(a)(2) requires that the licensee's Radiation Safety Committee (RSC) meet at least quarterly.

   Contrary to the above, although the RSC met in August 1989 upon opening the nuclear medicine department after its shutdown from March 1988 to August 1989, the RSC did not meet during the fourth quarter of 1989.

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

   This is a repeat violation.

2. A. 10 CFR 35.50(b)(1) requires, in part, that the licensee check each dose calibrator for constancy daily with a dedicated check source on a frequently used setting.

   Contrary to the above, from June 1987 to October 1990, the technetium-99m setting on the dose calibrator was not checked even though this was the only setting used.

   B. 10 CFR 35.50(b)(3) requires, in part, that the licensee test each dose calibrator for linearity upon installation and at least quarterly thereafter. 10 CFR 35.50(e)(3) requires, in part, that records of linearity tests include the signature of the radiation safety officer.

   Contrary to the above, the licensee failed to test the dose calibrator for linearity during the fourth quarter of 1989, and the record of the linearity test performed in September 1990 did not include the signature of the radiation safety officer.

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

3. A. 10 CFR 35.51(b) requires, in part, that when calibrating a survey instrument, the licensee consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent.

Contrary to the above, the record of the September 1990 calibration of the lowest reading scale of the licensee's only survey meter, a Victoreen Model CDV-700, affirmed that the indicated exposure rate differed from the calculated exposure rate by more than 20 percent.

B. 10 CFR 35.220 requires, in part, that a licensee authorized to use byproduct material for imaging and localization studies have in its possession a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.

Contrary to the above, as of October 11, 1990, the licensee did not have in its possession a survey instrument capable of measuring dose rates in excess of 50 millirem per hour.

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

A. 10 CFR 35.70(f) requires that the licensee conduct the surveys required by 10 CFR 35.70(e) so as to be able to detect contamination on each wipe sample of 2000 disintegrations per minute.

Contrary to the above, as of October 11, 1990, the licensee had not performed any calculations or determinations to demonstrate that surveys of wipe samples could detect 2000 disintegrations per minute of contamination. The licensee has used the dose calibrator to perform such surveys. This device would not reasonably be expected to detect this level of contamination.

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

5. 10 CFR 35.204(b) requires that a licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical measure the molybdenum-99 concentration in each eluate or extract.

Contrary to the above, from August 1989 through October 1990, the molybdenum-99 concentration was not measured in that an improper method was used to determine the amount of molybdenum-99 in the eluate.

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

Pursuant to the provisions of 10 CFR 2.201, Community 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 3rd day of December 1990

APPENDIX B

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

NRC Inspection Report: 30-20277/90-01 License: 03-23121-01

Docket: 30-20277

Licensee: Community Hospital
2000 Campbell Drive
Torrington, Wyoming 82240

Inspection At: Community Hospital
Torrington, Wyoming

Inspection Conducted: October 10-24, 1990

Inspectors: Anthony D. Gaines 11/13/90
Anthony D. Gaines, Radiation Specialist Date
Nuclear Materials and Safeguards Inspection
Section

Gilbert Guerra 11/13/90
Gilbert Guerra, Radiation Specialist Trainee Date
Nuclear Materials and Safeguards Inspection
Section

Approved: Charles L. Cain 11/14/90
Charles L. Cain, Chief, Nuclear Materials and Date
Safeguards Inspection Section

Inspection Summary

Inspection Conducted October 11-24, 1990 (Report 30-20277/90-01)

Areas Inspected: This was a routine, unannounced radiation safety inspection of a byproduct material program authorizing the medical use of radiopharmaceuticals for clinical diagnostic procedures. The inspection included the review of organization and management, dose calibrator use, survey instrument use, and radiation surveys.

Results: This inspection identified various violations of NRC requirements. Collectively, the violations identified are indicative of a lack of management oversight of the radiation safety program.

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Within this inspection, the following violations were identified:

Organization and Management

- Failure of the radiation safety committee to meet at least quarterly. (Section 4)

Dose Calibrator Use

- Failure to check frequently used isotope settings during dose calibrator constancy checks. (Section 5)
- Failure to test the linearity of the dose calibrator quarterly. (Section 5)
- Failure to properly measure the molybdenum-99 concentration in generator eluates. (Section 5)

Survey Instrument Use

- Failure to calibrate the lowest scale on the survey meter. (Section 6)
- Failure to possess a survey instrument that measures dose rates from 1 millirem per hour to 1000 millirem per hour. (Section 6)

Radiation Surveys

- Failure to ascertain that wipe samples surveys were able to detect contamination levels as low as 2000 disintegrations per minute. (Section 7)

DETAILS

1. Individuals Contacted

*Douglas McMillan, Administrator
*William T. Ward, M.D., Radiation Safety Officer and Authorized User
*John Goddard, Consultant
Kathy Schwartzkopf, X-Ray Technologist

*Indicates those present during exit interview.

2. Followup on Previous Inspection Findings (June 15, 1987)

(Open) Violation of 10 CFR 35.22(a)(2) (30-20277/87-01): Failure of the radiation safety committee (RSC) to meet quarterly. The inspectors determined during the current inspection that the RSC did not meet quarterly. This item is considered open.

(Closed) Violation of 10 CFR 35.22(a)(4) (30-20277/87-01): Failure of the licensee to include in RSC meeting minutes an ALARA review. The inspectors determined by reviewing the RSC meeting minutes that ALARA reviews were included in the minutes. This item is considered closed.

3. Program Overview

The licensee is authorized to use medical products for diagnostic clinical procedures. The only radioisotope used by the licensee for diagnostic procedures has been technetium-99m. The technetium has been obtained from a molybdenum-99/technetium-99m generator. The licensee has received a generator approximately every 2 weeks.

The licensee has experienced some organizational changes since the last inspection on June 15, 1987. The nuclear medicine technologist (NMT) that was employed during the last inspection left February 22, 1988. The licensee could not find a replacement for the technologist until August 24, 1989. Because of this, the licensee had closed the nuclear medicine department from February 22, 1988, to August 24, 1989. Since reopening the nuclear medicine department, the licensee performed on the average only 5 - 6 diagnostic procedures a month. The license was renewed in June 1990.

4. Organization and Management

The organizational structure was found to be as required, and key personnel have been identified in Section 1 of this report. The radiation safety officer (RSO) and the consultant had been employed by the hospital in their current capacities during previous inspections. The administrator and the NMT were employed after the June 15, 1987, inspection.

The RSO has been the authorized user for the program and also had performed radiology services for other hospitals in the area. Many of the RSO's duties have been, therefore, performed by a consultant.

Quarterly and annual reviews required by 10 CFR 35.22 were performed. The findings of the reviews have been discussed briefly in the RSC meetings, as indicated by RSC minutes.

The RSC, according to 10 CFR 35.22(a)(2), is required to meet at least quarterly. The inspectors, by reviewing records and through discussions during the telephonic exit meeting conducted October 17, 1990, observed that the RSC did not meet during the fourth quarter of 1989. At the exit meeting the consultant stated that the meeting was not held during the fourth quarter of 1989 due to the fact that they believed the meeting held in August 1989, just after reopening the nuclear medicine department, would suffice. The failure of the RSC to meet at least quarterly was identified as a repeat violation of 10 CFR 35.22(a)(2).

One violation was identified.

5. Dose Calibrator Use

The licensee has maintained a Picker dose calibrator, Serial Number 217056-R. The dose calibrator has been used to assay generator elutions, which have ranged from [illegible] to 540 millicuries, and patient doses that generally have ranged from 5 to 20 millicuries.

It was noted by the inspectors that when the dose calibrator constancy checks had been performed, the technetium-99m setting was not checked. The constancy checks were only performed on the cesium-137 and the cobalt-57 settings. The failure to check the dose calibrator for constancy on a frequently used setting was identified as a violation of 10 CFR 35.50(b)(1).

The inspectors could not be provided a dose calibrator linearity record for the fourth quarter of 1989. The consultant stated during the telephonic exit meeting that the dose calibrator had not been tested for linearity during the fourth quarter of 1989. He again stated that this was due to the fact that they performed a linearity test in August 1989 after resuming licensed activities and thought that that would suffice. Also, it was noted by the inspectors that the record of the linearity test performed in September 1990 was not signed by the RSO. The failure to test the dose calibrator quarterly for linearity and to have the RSO sign a linearity test were identified as violations of 10 CFR 35.50(b)(3) and 10 CFR 35.50(e)(3), respectively.

10 CFR 35.204(b) requires that a licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical measure the molybdenum-99 concentration in each eluate or extract. The licensee used the above type of generator and prepared technetium-99m radiopharmaceuticals. A review of molybdenum-99

breakthrough records for August 1989 to October 1990, by the inspectors, indicated that the molybdenum-99 concentrations in the eluates were routinely greater than .15 microcuries of molybdenum-99 per millicurie of technetium-99m. This level is greater than what is allowed to be administered to humans. After discussing this with the consultant at the exit meeting, it was apparent that the NMT used an improper procedure to measure the molybdenum-99 activity, therefore giving inaccurate results for the molybdenum-99 concentrations. The failure to properly measure the molybdenum-99 activity, which in turn gave inaccurate results for the molybdenum-99 concentrations in the eluates was identified as a violation of 10 CFR 35.204(b).

Three violations were identified.

6. Survey Instrument Use

The inspectors observed that the licensee only had one survey instrument, a Victoreen Model CDV-700. This survey instrument was last calibrated in September 1990. From the record of this calibration it was noted that on the lowest scale the calibration factors at two different points were 1.57 and 1.38. This indicated that the lowest scale was not calibrated within plus or minus 20 percent. At the exit meeting the consultant stated that the lowest scale could not be calibrated to within plus or minus 20 percent. The failure to calibrate the lowest scale by no more than 20 percent was identified as a violation of 10 CFR 35.51(b).

The Victoreen Model CDV-700 survey instrument that the licensee possessed had a range of 0 to 50 millirem per hour. Therefore, this survey meter was not capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour. This was identified as a violation of 10 CFR 35.220.

Two violations were identified.

7. Radiation Surveys

The licensee routinely performed area wipe surveys and obtained results of these surveys by reading the wipes in the dose calibrator. The dose calibrator was not evaluated by the licensee to show that it was able to detect contamination on the wipe sample of 2000 disintegrations per minute. This device would not reasonably be expected to detect this level of contamination. Therefore, this was identified as a violation of 10 CFR 35.70(f).

One violation was identified.

8. Exit Interview

The inspectors and the Chief, Nuclear Materials and Safeguards Inspection Section, held a telephonic exit interview with the staff members noted in Section 1 on October 17, 1990. The specific findings as noted in this report were reviewed. The discussion also focused on the need for effective management control and the need for prompt and effective corrective actions for the problems identified.

NRC FORM 766
IE MC 0535

U.S. NUCLEAR REGULATORY COMMISSION

INSPECTOR'S REPORT

Office of Inspection and Enforcement

PRINCIPAL INSPECTOR (Name, last, first and middle initial): Gaines, Anthony D.

REVIEWER: [illegible]

INSPECTORS: Guerra, Gilbert

LICENSEE VENDOR	TRANSACTION TYPE	DOCKET NO (8 digits)	REPORT NO	SEQ	NEXT INSPEC DATE MO	YR
Community Hospital	X I – INSERT; M – MODIFY; D – DELETE; R – REPLACE	03020272	9001		10	92

PERIOD OF INVESTIGATION/INSPECTION FROM (MO DAY YR)	TO (MO DAY YR)	INSPECTION PERFORMED BY	ORGANIZATION CODE OF REGION/HQ CONDUCTING ACTIVITY (REGION / DIVISION / BRANCH)
10 19 90	10 24 90	X 1 – REGIONAL OFFICE STAFF; 2 – RESIDENT INSPECTOR; 3 – PERFORMANCE APPRAISAL TEAM; OTHER	4 / 3 / 4

REGIONAL ACTION (Check one box only): 1 – NRC FORM 591; X 2 – REGIONAL OFFICE LETTER

TYPE OF ACTIVITY CONDUCTED (Check one box only): X 02 – SAFETY (fee); 03 – INCIDENT; 04 – ENFORCEMENT; 05 – MGMT AUDIT; 06 – MGMT 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

INSPECTION/INVESTIGATION FINDINGS (Check one box only): X 1 – CLEAR; 2 – VIOLATION; 3 – DEVIATION; 4 – VIOLATION & DEVIATION

TOTAL NUMBER OF VIOLATIONS AND DEVIATIONS: A: 05

ENFORCEMENT CONFERENCE HELD: 1 – YES

REPORT CONTAINS 2.790 INFORMATION: 1 – YES

LETTER OR REPORT TRANSMITTAL DATE: NRC FORM 591 OR REG LETTER ISSUED: 120390; REPORT SENT TO HQ FOR ACTION:

MODULE INFORMATION

TYPE	MODULE NUMBER INSP	SEQ	DIRECT INSPECTION EFFORT	PERCENTAGE COMPLETED TO DATE	STATUS	Description
	53017.03	A	003	---	–	management meetings
	58710.01	(A)	003	100	C	licensed materials programs
	58382.2	A	002	100	C	radiation protection
	58674.0	A	001	100	C	transportation
	~~58418.5.01~~	A	~~0~~	~~100~~		~~Inspection of Waste Generator Requirements~~
	~~53080.0~~		~~0~~	~~100~~	~~C~~	initial inspection
	59270.2	A	001	---		Followup on violations

® CIRCLE SEQUENCE IF VIOLATION OR DEVIATION

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

NRC FORM 535

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

03020277 9001

SEQ 587100

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.)

10 CFR 35.22(a)(2) requires that the licensee's Radiation Safety Committee (RSC) meet at least quarterly.

Contrary to the above, although the RSC met in August 1989 upon opening the nuclear medicine department after its shutdown from March 1988 to August 1989, the RSC did not meet during the fourth quarter of 1989.

NRC MC 0535

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

SEQ 58710 0
03020277 9001

VIOLATION SEVERITY OR DEVIATION | SITE RELATED | SUPL

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.)

10 CFR 35.50(b)(1) requires, in part, that the licensee check each dose calibrator for constancy daily with a dedicated check source on a frequently used setting.

Contrary to the above, from June 1987 to October 1990, the technetium-99m setting on the dose calibrator was not checked even though this was the only setting used.

10 CFR 35.50(b)(3) requires, in part, that the licensee test each dose calibrator for linearity upon installation and at least quarterly thereafter. 10 CFR 35.50(e)(3) requires, in part, that records of linearity tests include the signature of the radiation safety officer.

Contrary to the above, the licensee failed to test the dose calibrator for linearity during the fourth quarter of 1989, and the record of the linearity test performed in September 1990 did not include the signature of the radiation safety officer.

NRC 0535

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

03020277	90001	SEQ 58701001	VIOLATION SEVERITY OR DEVIATION: 4	SITE RELATED / SUPL: VI

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.)

10 CFR 35.51(b) requires, in part, that when calibrating a survey instrument, the licensee consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent.

Contrary to the above, the record of the September 1990 calibration of the lowest reading scale of the licensee's only survey meter, a Victoreen Model CDV-700, affirmed that the indicated exposure rate differed from the calculated exposure rate by more than 20 percent.

10 CFR 35.220 requires, in part, that a licensee authorized to use byproduct material for imaging and localization studies have in its possession a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.

Contrary to the above, as of October 11, 1990, the licensee did not have in its possession a survey instrument capable of measuring dose rates in excess of 50 millirem per hour.

GPO 987-021

U.S. NUCLEAR REGULATORY COMMISSION

NRC FORM 0525

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

03020277 9001 SEQ 587 99

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.)

10 CFR 35.70(f) requires that the licensee conduct the surveys required by 10 CFR 35.70(e) so as to be able to detect contamination on each wipe sample of 2000 disintegrations per minute.

Contrary to the above, as of October 11, 1990, the licensee had not performed any calculations or determinations to demonstrate that surveys of wipe samples could detect 2000 disintegrations per minute of contamination. The licensee has used the dose calibrator to perform such surveys. This device would not reasonably be expected to detect this level of contamination.

GPO 987-681

U.S. NUCLEAR REGULATORY COMMISSION

NRC FORM 535

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

SEQ 58 71 00 | 03020277 | 9001 | Violation Severity or Deviation: 4 | Supl: VI

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.)

10 CFR 35.204(b) requires that a licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical measure the molybdenum-99 concentration in each eluate or extract.

Contrary to the above, from August 1989 through October 1990, the molybdenum-99 concentration was not measured in that an improper method was used to determine the amount of molybdenum-99 in the eluate.

GPO 907-061

U.S. NUCLEAR REGULATORY COMMISSION