JAN 7 1991

In Reply Refer To:
License: 03-01082-01
Docket: 030-01212/90-01

Veterans Administration Medical Center
John L. McClellan Memorial Hospital
ATTN: Robert Patton
Hospital Director
4300 West 7th Street
Little Rock, Arkansas 72205

Gentlemen:

Thank you for your letter of December 6, 1990, in response to our letter and attached Notice of Violation both dated November 8, 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:
A. B. BEACH
A. Bill Beach, Director
Division of Radiation Safety
and Safeguards

cc:
James W. Fletcher, M.D.
Director, Nuclear Medicine Service (115)
Veterans Administration
Washington, D.C. 20420

Arkansas Radiation Control Program Director

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

RIV:NMSIS	C:NMSIS	D:DRSS
LLKasner:ch	CLCain	ABBeach
1/7/91	1/7/91	1/7/91

1/1

IE07

John L. McClellan
Memorial Veterans' Hospital
4300 West 7th Street
Little Rock AR 72205

Veterans Administration

DEC 06 1990

In Reply Refer To: 115/LR

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

Subject: NRC Inspection Letter dated 11/8/90

1. This is in response to the NRC inspection letter dated November 8, 1990, Docket No. 30-01212/90-01.

2. Please refer to the attachment which addresses the points contained in the Notice of Violation as an appendix to that letter.

ROBERT T. PATTON
Medical Center Director

cc: USNRC
Region IV

~~9012120183~~

IE-442

REPLY TO A NOTICE OF VIOLATION

Veterans Administration Medical Center
Little Rock, Arkansas

Docket No. 30-01212/90-01
License No. 03-01082-01

Item A.1.

1) Reason for violation: Although researchers had previously been notified of this requirement, including the distribution to them of Information Notice 89-35, it appears that all of them were not fully aware of the requirement. Additionally, some of the labs remained unlocked at time when housekeeping personnel were in the area.

2) Corrective steps taken : A memo has been distributed to all affected personnel reemphasizing the important nature of this issue. Additionally, all housekeeping is now done during the day shift (0730-1600).

3) Corrective steps taken to avoid future violations: Increased surveillance by VA staff and emphasis of this point at orientations and annual refresher training.

4) Date when full compliance will be achieved: 31 December 1990.

Item A.2.

1) Reason for violation: Lack of awareness of affected staff members to document verbal training instructions and reliance on proximity of experienced individuals to monitor activities.

2) Corrective steps taken: All keys and access to the irradiator will be limited to only a few trained experienced individuals. Infrequent users will not be allowed to operate irradiator. A sign and instructions to this effect have been posted on the irradiator.

3) Corrective steps taken to avoid future violations: Monthly followup will be made by the radiation safety staff.

4) Date when full compliance will be achieved: Immediate.

Item B.1.

1) Reason for violation: Human error - oversight. Please note that this incident had been fully documented, investigated and corrective action taken prior to the inspection. A report was given to the inspector during her visit.

2) Corrective steps taken: Noted above.

3) Corrective steps taken to avoid future violations: A reminder note is posted in the misadministration file regarding the requirements.

4) Date when full compliance will be achieved: Immediate.

NOV 8 1990

License No.: 03-01082-01
Docket No.: 30-01212/90-01

Veterans Administration Medical Center
John L. McClellan Memorial Hospital
ATTN: Robert Patton
Hospital Director
4300 West 7th Street
Little Rock, Arkansas 72205

Gentlemen:

This refers to the routine, unannounced radiation safety inspection conducted by Ms. L. L. Kasner of this office on September 25-28, 1990, of the activities authorized by NRC Byproduct Material License No. 03-01082-01, and to the discussion of our findings held by the inspector with members of the administrative staff and the 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 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. In preparing your response, please refer to the instructions contained in the enclosed Notice.

The inspector observed that many aspects of the program were associated with well developed procedures and corresponding documentation and that generally, the program incorporated an adequate number of internal audits to ensure that activities were conducted in accordance with license conditions and NRC requirements. Also notable was the RSO's involvement in directing program activities. The inspector noted that the RSO had been granted, and exercised, a level of authority characterized by the stringent management controls observed in many aspects of the radiation safety program.

During the inspection, the inspector also reviewed several procedural revisions which will be implemented with renewal of the license in January 1991. These changes are primarily related to requirements which were implemented with the

RIV:NMSIS	C:NMSIS	D:DRSS
LLKasner:lm	CLCain	ABBeach
11/7/90	11/7/90	11/7/90

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revision of 10 CFR Part 35 and from which you were previously exempt under the provisions described in § 35.999.

The inspector noted that one individual had been designated the responsibility for conducting radiation surveys and instrument calibrations. While this individual had met the current qualification requirements regarding these specific activities, both the size of the program and the increased frequency at which these tasks must be performed under the current version of 10 CFR Part 35 and future revisions of the license may require that you involve a greater number of your staff in conducting these activities. This and similar resource issues should be given further consideration by the RSO and management to ensure that you will be able to meet future program requirements.

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

The response directed by this letter and the accompanying Notice is not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

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

Sincerely,

Original Signed By:
A. B. BEACH

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

Enclosure:
Appendix - Notice of Violation

cc:
James W. Fletcher, M.D.
Director, Nuclear Medicine Service (115)
Veterans Administration
Washington, D.C. 20420

Arkansas Radiation Control Program Director

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

*W/766

APPENDIX

NOTICE OF VIOLATION

Veterans Administration Medical Center
Little Rock, Arkansas

Docket No. 30-01212/90-01
License No. 03-01082-01

During an NRC inspection conducted on September 25-28, 1990, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1990), the violations are listed below:

A. License Condition 26 requires, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the letter and application dated July 6, 1984.

1. Item 11.7 of the application specifies that rooms or other controlled areas (containing radioactive materials) must be locked after hours or during lengthy periods of absence to prevent unauthorized entry and that radioactive materials must be secured against unauthorized removals.

Contrary to the above, on September 25, 1990, the inspector observed that several rooms within the research area had been left unlocked with millicurie quantities of radioactive material stored in fume hoods or in unsecured refrigerators. This observation was made after normal working hours when licensee staff was not available to provide direct surveillance of the subject material.

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

2. Section 20 of the application describes the radiation safety procedures for the licensee's J. L. Sheppard Mark I irradiator. Item 20.2 specifies that all individuals desiring to use the irradiator must receive permission from the chief of the nuclear medicine service and radiation safety committee (RSC) and must demonstrate familiarity with the operating procedures of the unit, as recommended by the manufacturer.

Contrary to the above, during the period June 1989 through September 1990, several individuals from another research facility had used the irradiator without having received permission from the chief of the nuclear medicine service and RSC or demonstrating their familiarity with the operating procedures of the unit prior to such use.

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

B. 10 CFR 35.33(c) requires, in part, that when a misadministration involves a diagnostic procedure, that the licensee notify the appropriate NRC Regional Office in writing within 15 days if the misadministration

involved administration of a byproduct material such that the patient is likely to receive an organ dose greater than 2 rem.

Contrary to the above, as of September 28, 1990, the licensee failed to notify the NRC Region IV Office of a diagnostic misadministration which involved administration of a byproduct material such that the patient likely received a bladder dose greater than 2 rem. (A 20 millicurie technetium-99m labeled MDP dose was administered rather than the intended 20 millicurie technetium-99m labeled RBC dose.)

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

Pursuant to the provisions of 10 CFR 2.201, Veterans Administration Medical Center 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 7th day of October 1990

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): Kasner, Linda K
REVIEWER: C. Cain

INSPECTORS:

LICENSEE VENDOR	TRANSACTION TYPE	DOCKET NO (8 digits)	REPORT NO	REPORT SEQ	NEXT INSPEC DATE MO	NEXT INSPEC DATE YR
VETERANS ADMINISTRATION MEDICAL CENTER	X I - INSERT; M - MODIFY; D - DELETE; R - REPLACE	0 3 0 0 2 1 2	0 0 0 1	A	0 5	8 1

PERIOD OF INVESTIGATION/INSPECTION FROM MO	FROM DAY	FROM YR	TO MO	TO DAY	TO YR	INSPECTION PERFORMED BY	ORGANIZATION CODE OF REGION/HQ CONDUCTING ACTIVITY (See IE MC 0530 Manpower Reporting for code) REGION	DIVISION	BRANCH
0 5	1 0	8 1	0 5	1 4	8 1	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 - INVNT VER
- 12 - SHIPMENT/EXPORT
- 13 - IMPORT
- 14 - INQUIRY (no fee)
- 15 - INVESTIGATION

INSPECTION/INVESTIGATION FINDINGS (Check one box only)

A	B	C	D	
				1 - CLEAR
X				2 - VIOLATION
				3 - DEVIATION
				4 - VIOLATION & DEVIATION

TOTAL NUMBER OF VIOLATIONS AND DEVIATIONS A	B	C	D	ENFORCEMENT CONFERENCE HELD A	B	C	D	REPORT CONTAIN 2.790 INFORMATION A	B	C	D	LETTER OR REPORT TRANSMITTAL DATE: NRC FORM 591 OR REG LETTER ISSUED MO	DAY	YR	REPORT SENT TO HQ FOR ACTION MO	DAY	YR
0	3											1 - YES	1 - YES	0 8	1 7		

MODULE INFORMATION

SEQ #	PRIORITY	DIRECT INSPEC TION EFFORT IN STAFF HOURS EXPENDED THIS INSPECTION	PERCENTAGE COMPLETED TO DATE	STATUS	MODULE REQ FOLLOWUP PHASE	MANUAL CHAPTER	PROCEDURE NUMBER	LEVEL	MODULE NUMBER INSP ORD TYPE	NUMBER	PHASE	MANUAL CHAPTER	PROCEDURE NUMBER	LEVEL	Description
A		0 0 4	- - -	I					0	5 3 0 7 0 3					management meetings
B															
C															
D															
A		0 1 2	1 0 0	C					0	5 8 7 1 0 0					licensed materials programs
B															
C															
D															
A		0 0 1	1 0 0	C					0	5 8 3 8 2 2					radiation protection
B															
C															
D															
A		0 0 0	1 0 0	C					0	5 8 6 7 4 0					transportation
B															
C															
D															

MODULE INFORMATION

SEQ #	PRIORITY	DIRECT INSPEC TION EFFORT IN STAFF HOURS EXPENDED THIS INSPECTION	PERCENTAGE COMPLETED TO DATE	STATUS	MODULE REQ FOLLOWUP PHASE	MANUAL CHAPTER	PROCEDURE NUMBER	LEVEL	MODULE NUMBER INSP ORD TYPE	NUMBER	PHASE	MANUAL CHAPTER	PROCEDURE NUMBER	LEVEL	Description
A		0 1 6	1 0 0	C					0	5 8 4 8 5 0					Inspection of Waste Generator Requirements
B															
C															
D															
A		0	1 0 0	C					0	~~5 3 0 8 0 0~~					~~initial inspection~~
B															
C															
D															
A		0 0 0	- - -	-					0	5 9 2 7 0 2					Followup on violations
B															
C															
D															
A															
B															
C															
D															

* CIRCLE SEQUENCE IF VIOLATION OR DEVIATION

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

NRC FORM 591A

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

DOCKET NO. (LICENSE OR CERTIFICATE NO. OR PROPOSED NO.)	REPORT NO	SEQ	MODULE NUMBER	VIOLATION SEVERITY	DEVIATION
03002232	9001	A	87100	3 4 5	
		B			
		C			
		D			

VIOLATION OR DEVIATION (ENTER NO. TO 400 CHARACTERS PER LINE. IF YOU NEED MORE SPACE, USE ADDITIONAL SHEETS.)

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Item 11.7 of the application specifies that rooms or other controlled areas (containing radioactive materials) must be locked after hours or during lengthy periods of absence to prevent unauthorized entry and that radioactive materials must be secured against unauthorized removals.

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NRC FORM 658 A

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

DOCKET NO. (8 digits) OR LICENSE NO. (BY PRODUCT) (7 digits)	REPORT NO.	SEQ.	MODULE NUMBER	VIOLATION SEVERITY OR DEVIATION
03861212	4861	A	87100	
		B		
		C		
		D		

VIOLATION OR DEVIATION (Enter up to 2,400 characters for each item. If you need additional space, continue on a blank page. Identify each item as appropriate.)

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DOCKET NO. (IF APPLICABLE) OR LICENSE NO. (IF BY PRODUCT) (1)	REPORT NO.	SEQ.	MODULE NUMBER 58710 344 II
03 212	9001	A	VIOLATION SEVERITY OR DEVIATION
		B	
		C	
		D	

VIOLATION OR DEVIATION (Enter up to 2,400 characters for each item. If the text exceeds this number, it will be necessary to continue. Label items as appropriate.)

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