JAN 8 1991

In Reply Refer To:
License: 40-12378-01
Docket: 030-03249/90-01

Sioux Valley Hospital Association
ATTN: Richard L. Bohy
Vice President, Professional Services
1100 South Euclid Avenue
Sioux Falls, South Dakota 57117-5039

Gentlemen:

This refers to your letter of December 5, 1990, in response to our letter and attached Notice of Violation both dated November 26, 1990. We have reviewed your reply and find that you have not fully responded to each of the four items identified in the Notice.

We are pleased to note that you have taken prompt corrective actions to address our immediate concerns and have instructed personnel in the new procedures which have been implemented in response to the inspection findings; however, we note that your response did not identify the reasons for the violations. To develop measures which will prevent the recurrence of these and similar violations, it is necessary that the underlying cause for each of the violations be identified. Therefore, in accordance with the instructions provided in the Notice, you are requested to describe the reason for the violations and to supplement your response regarding the measures taken to prevent future recurrence if you determine that instruction of personnel will not adequately address this concern.

Your reply should be provided to the NRC Region IV office within 10 days of the receipt of this letter. Should you have any questions regarding this matter, please contact Ms. Linda Kasner at (817) 860-8100.

Sincerely,
Original Signed By:
A. R. BEACH
A. Bill Beach, Director
Division of Radiation Safety
and Safeguards

cc:
South Dakota 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

*Previously Concurred

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REG4 LIC30
40-12378-01 PDR

IE-07

11/26

SIOUX VALLEY HOSPITAL
1100 South Euclid Avenue
P.O. Box 5039
Sioux Falls, South Dakota 57117-5039
(605) 333-1000

DEC 17 1990

December 5, 1990

Refer To:
License: 40-123[illegible] 01
Docket: 30-0324[illegible]

Gentlemen:

This letter is in response to the NRC inspection conducted October 23-26, 1990, during which two violations were identified.

Violation #1) 10 CFR 35.70 (e)

Effective October 27, 1990, the department procedure and area survey map were expanded to include camera rooms and treadmill rooms in the weekly wipe test for removable contamination. All results are recorded on the area survey map.

Violation #2) 10 CFR 35.

"Technetium waste products are returned to W.A. Boade, M.D., Ltd. for decay and disposal in compliance with NRC License 40-12378-01, amendment #37 request dated, January 16, 1989.

Effective October 26, 1990, department procedure for waste disposal was amended to state that all other by product material waste will be held in storage for a minimum of ten (10) half-lives of the product plus the activity levels at surface will be equivalent to background as determined by survey instrument before disposal in ordinary trash.

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IE-07

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These violations and the resulting procedure changes have been reviewed with the entire Nuclear Medicine Technical Staff during the monthly department meeting held November 1, 1990, and were again reviewed along with the NRC inspection review letter dated November 26, 1990, during the December 6, 1990 monthly department meeting.

Since the implementation of these procedural changes October 26, 1990 and October 27, 1990, no further violations have been identified.

Sincerely,

Richard L. Bohy

Richard L. Bohy
Vice President, Professional Services
1100 South Euclid Ave.
Sioux Falls, South Dakota 57117-5039

NOV 26 1990

NMSIS

CORRECTED COPY

In Reply Refer To:
License: 40-12378-01
Docket: 30-03249/90-01

Sioux Valley Hospital Association
ATTN: Richard L. Bohy
Vice President, Professional
Services
1100 South Euclid Avenue
Sioux Falls, South Dakota 57117-5039

Gentlemen:

This refers to the routine, unannounced radiation safety inspection conducted by Ms. L. L. Kasner of this office on October 23-26, 1990, of the activities authorized by NRC Byproduct Material License No. 40-12378-01. The findings of the inspection were reviewed with members of the administrative and technical staffs 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 provided in the enclosed Notice.

The inspector observed that the program audits conducted by your physics consultants had been successful in identifying and resolving two additional violations of NRC requirements during this inspection period. These violations involved: (1) the failure to conduct dose calibrator linearity checks over the full range of activities prescribed under 10 CFR 35.50(b)(3), and (2) the failure to provide and use a dedicated check source for survey instrument operability checks as required under 10 CFR 35.51(a)(3) and (c). A third additional violation, involving the failure to include radiopharmaceutical expiration dates in patient dosage records as required under 10 CFR 35.53(c)(1), was identified by the inspector. This violation was reviewed with Sioux Valley Hospital (SVH) staff as well as with the nuclear pharmacy supplying these

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

*Previously Concurred

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radiopharmaceuticals to ensure that this record omission was properly addressed during the inspection.

These three violations would normally be cited as Severity Level IV and V violations. However, in accordance with 10 CFR Part 2, Appendix C, Sections V.A and V.G.1 (NRC's Enforcement Policy), these issues have not been cited in the enclosed Notice. The inspector verified that: (1) corrective measures had been implemented prior to or during the inspection, (2) corrective measures were properly documented and had been incorporated into department procedure manuals and instructions provided to individuals participating in licensed activities, and (3) those corrective measures implemented had been successful in preventing further recurrence of the violations. Your corrective actions will be reviewed during future inspections to ensure that they remain effective.

While these and other violations observed during the inspection are associated with distinct, unrelated procedures, the inspector noted that the reasons for several of the violations were similar in nature. Specifically, the staff attributed the violations to a lack of familiarity with recently implemented revisions of 10 CFR Part 35 or misinterpretation of specific regulatory requirements. As reviewed with staff members and the RSO during the inspection, we encourage that these individuals routinely review the regulations and NRC information notices to ensure that revisions in NRC requirements do not go unnoted and that procedure revisions are implemented promptly when appropriate.

During the inspection, the inspector observed that many elements of the radiation safety program were characteristic of systematic program reviews and procedure development. Specifically, she noted that procedures were well documented and clearly communicated to SVH staff members involved in licensed activities. Also notable was the level of involvement by both the RSO and radiation safety committee members in daily operations.

The inspector identified one area of weakness in the radiation safety program which is worthy of further management review. This issue was discussed in detail with hospital administration, authorized user physicians, and the RSO during the inspection. This issue involved the failure to maintain adequate patient dosage records for brachytherapy implants using cesium-137 or iridium-192 sources. Although NRC requirements for bracytherapy records are not prescriptive with regard to content, the inspector observed that patient dosage records maintained by SVH were insufficient for the RSO to determine whether the administered radiation dosage varied from the intended dosage prescribed by user physicians. This was primarily due to the fact that complete patient therapy records had not been maintained by SVH, but had instead been maintained at an independent clinic operated by the user physicians authorized for brachytherapy procedures under the SVH NRC license.

The inspector reviewed several brachytherapy cases during the inspection segment conducted at the physicians' clinic. While no misadministration was identified, the inspector noted that several treatment cases lacked sufficient

documentation to determine the authorized users' intended treatment dosage. The failure to maintain adequate records of brachytherapy treatment plans and dosages for subsequent review and audit by the RSO is of concern due to the significant radiation dose received by patients during these procedures. You are reminded that as an NRC licensee, it is SVH's responsibility to maintain records of radiation therapy administered as a licensed activity and are encouraged to review and amend your documentation requirements as appropriate.

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

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

*W/766

APPENDIX

NOTICE OF VIOLATION

Sioux Valley Hospital Association
Sioux Falls, South Dakota

Docket No. 30-03249/90-01
License No. 40-12378-01

During an NRC inspection conducted on October 23-26, 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 35.70(e) requires, in part, that a licensee survey for removable contamination once each week all areas where radiopharmaceuticals are routinely administered.

   Contrary to the above, during the period September 1987 through October 26, 1990, the licensee had failed to conduct weekly surveys for removable contamination in certain imaging and patient injection rooms, areas where radiopharmaceuticals were routinely administered.

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

2. 10 CFR 35.92(a) specifies, in part, that a licensee may hold byproduct material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash if it holds the byproduct material for decay a minimum of 10 half-lives.

   Contrary to the above, during the period September 1987 through October 26, 1990, the licensee had failed to hold iodine-131 and technetium-99m waste products for decay for a minimum of 10 half-lives prior to disposal in ordinary trash. (Radiation surveys of these materials prior to disposal revealed surface dose rates equivalent to background levels as determined using the licensee's survey instrument.)

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

Pursuant to the provisions of 10 CFR 2.201, Sioux Valley Hospital Association is hereby required to submit to this office, within 30 days of the date of the letter transmitting this Notice of Violation (Notice), a written statment or explanation in reply, including 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. 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 26 day of Nov. 1990

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NRC FORM 788
(11-81)
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 L

REVIEWER: C. Cain

INSPECTORS

LICENSEE VENDOR	TRANSACTION TYPE	DOCKET NO (8 digits)	REPORT NO	REPORT SEQ	NEXT INSPEC DATE MO	NEXT INSPEC DATE YR
Sioux Valley Hospital Association	X I - INSERT; M - MODIFY; D - DELETE; R - REPLACE	03003249	9001	A	10	93

PERIOD OF INVESTIGATION/INSPECTION FROM MO	DAY	YR	TO MO	DAY	YR	INSPECTION PERFORMED BY	ORGANIZATION CODE OF REGION/HQ CONDUCTING ACTIVITY (See IE MC 0530 Manpower Reporting — Weekly Manpower Reporting for code) REGION	DIVISION	BRANCH
10	23	90	10	26	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)
- 1 - CLEAR
- X 2 - VIOLATION
- 3 - DEVIATION
- 4 - VIOLATION & DEVIATION

TOTAL NUMBER OF VIOLATIONS AND DEVIATIONS	ENFORCEMENT CONFERENCE HELD	REPORT CONTAIN 2.790 INFORMATION	LETTER OR REPORT TRANSMITTAL DATE: NRC FORM 591 OR REG LETTER ISSUED MO	DAY	YR	REPORT SENT TO HQ FOR ACTION MO	DAY	YR
A B C D: 02	A B C D	A B C D	11	23	93			
	1 - YES	1 - YES						

MODULE INFORMATION

REC ORD	MODULE NUMBER INSP: TYPE	NUMBER	PHASE	MANUAL CHAPTER	PROCEDURE NUMBER	LEVEL	SEQ #	PRIORITY	DIRECT INSPECTION EFFORT IN STAFF HOURS EXPENDED THIS INSPECTION	PERCENTAGE COMPLETED TO DATE	STATUS	MODULE REQ. FOLLOWUP: PHASE	MANUAL CHAPTER	PROCEDURE NUMBER	LEVEL
0	1	5	3	0	7	0 3	A		0 0 1	- - -	1				
management meetings							B								
							C								
							D								
0	1	5	8	7	1	0 0	A		0 1 4	1 0 0	C				
licensed materials programs							B								
							C								
							D								
0	1	5	8	3	8	2 2	A		0 0 2	1 0 0	C				
radiation protection							B								
							C								
							D								
0	1	5	8	6	7	4 0	A		0 0 1	1 0 0	C				
transportation							B								
							C								
0 CIRCLE SEQUENCE IF VIOLATION OR DEVIATION							D								

MODULE INFORMATION

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

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

NRC FORM 195 A

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

DOCKET NO. OR LICENSE NO. (BY PRODUCT)	REPORT NO.	SEQ.	MODULE NUMBER
03003249	9001	A	58710 0 Supp VI

VIOLATION OR DEVIATION

10 CFR 35.70(e) requires, in part, that a licensee survey for removable contamination once each week all areas where radiopharmaceuticals are routinely administered.

Contrary to the above, during the period September 1987 through October 26, 1990, the licensee had failed to conduct weekly surveys for removable contamination in certain imaging and patient injection rooms, areas where radiopharmaceuticals were routinely administered.

NRC FORM 468A

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

DOCKET NO. OR LICENSE NO. (BY PRODUCT)	REPORT NO.	SEQ.	MODULE NUMBER	
03003249	9001		58710 0	Supp VI

10 CFR 35.92(a)(1) specifies, in part, that a licensee may hold byproduct material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash if it holds the byproduct material for decay a minimum of 10 half-lives.

Contrary to the above, during the period September 1987 through October 26, 1990, the licensee had failed to hold iodine-131 and technetium-99m waste products for decay for a minimum of 10 half-lives prior to disposal in ordinary trash. (Radiation surveys of these materials prior to disposal revealed surface dose rates equivalent to background levels as determined using the licensee's survey instrument.)