NOV 26 1990

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

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LLKasner:lm	CLCain	ABBeach
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*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

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