Good Samaritan Medical Center
Sponsored by the Franciscan Sisters of Christian Charity

March 21, 1994

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

RE: Reply to Notice of Violation in NRC Inspection Report 030-30-954/94001(DRSS)
Good Samaritan Medical Center, License #34-16725-02 EA94-023

Dear Sir:

The following are responses to the above referenced notice of violation. The responses are in the same chronological order as listed in the notice.

A. 10CFR 35.25(a)(1) requires, in part, that a licensee that permits the use of byproduct material by an individual under the supervision of an authorized user shall instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of byproduct material.

Reason for Violation

This violation occurred due to the lack of thorough training of the medical physicist and radiation technologist in Iridium-192 implants.

Corrective Steps

All subsequent implant procedures for brachytherapy will be performed by the authorized user. Ancillary staff such as the radiation therapy technologist or medical physicists will not be involved in the actual medical procedure of implanting or removing the sources. Procedures have been developed that formalize the dosimetrist's "rule of practice" regarding comparison of the brachytherapy ribbon and catheter length prior to source implantation. All individuals involved in the procedure will be trained commensurate with their responsibilities.

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800 Forest Avenue, Zanesville, Ohio 43701-2881 (614) 454-5000

Date of Full Compliance

These policies and procedures were promulgated and placed into effect on November 23, 1993.

B. 10 CFR 35.32(a)(4) requires that a licensee's quality management program (QMP) include written policies and procedures to meet the objective that each administration is in accordance with the written directive.

Reason for Violation

Our policies and procedures did not specifically state who was responsible to present the stat radiograph to the radiation oncologist. This contributed to the delay in reading the radiograph which was an isolated occurrence.

Corrective Steps

The authorized user will promptly review any radiographs taken, record the actual loading sequence of radioactive sources implanted and sign or initial the patient's chart or appropriate record in accordance with the Quality Management Program. These procedures have also been incorporated and policies and procedures reference in part A above.

Date of Full Compliance

These policies and procedures have been implemented subsequent to the notice of misadministration of November 11, 1993.

C. 10 CFR 35.410(a) requires, in part, that a licensee provide radiation safety instruction to all personnel caring for a patient undergoing implant therapy.

Reason for Violation

The violation occurred due to the lack of documentation that appropriate instruction was provided to all personnel caring for patients undergoing brachytherapy.

Corrective Actions

A policy addressing staff education and training involving brachytherapy implants was generated and put into effect in January of 1994. All individuals involved in the care of the brachytherapy patient must receive proper training in radiation safety. Radiation badges will only be issued to those individuals that have received proper radiation safety training. The information presented in bulletin 93-31 will be utilized as a guide in this training. Annual reviews or updates of this radiation safety training will be provided.

The education and training inservice video tape will be redone to improve and

simplify its presentation to the nursing staff. This should be completed by April 30, 1994.

The nursing department is developing a radiation bulletin board for awareness within their unit.

A self study module on radiation therapy is being created and is intended date of completion is March 31, 1994.

A card is placed in all brachytherapy charts notifying the nursing staff that the patient is a radiation therapy patient.

C. 10 CFR 35.410(b) requires, in part, that a licensee retain a record of individuals who have received the instruction required by 10 CFR 35.410(a).

Reason for Violation

This violation occurred due to the misplacement of the nursing log book which recorded individuals inserviced in radiation safety. A new log book has been reinstated and will be kept in a more secure place as well as training records will be in the employees file in staff education.

D. 10 CFR 19.11(a) and (b) require, in part, that a licensee post current copies of Part 19, Part 20, the license, license conditions, documents incorporated into the license, license amendments and operating procedures; or that the licensee post a notice describing these documents and where thy may be examined. 10 CFR 19.11 (c) requires that a licensee post Form NRC-3, "Notice to Employees." 10 CFR 19.11(d) requires that the documents, notices or forms posted must appear in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the document applies.

Reason for Violation

The failure to post a required notification indicated in Part 19-11 was a complete oversight. The postings did occur in radiation therapy and nuclear medicine areas but the nursing unit was the oversight.

Corrective Steps

Upon learning of this deficiency from the NRC inspector, James Cameron, the required posting did occur on the nursing unit the following day. The nursing department is establishing a (radiation awareness) bulletin board containing the required postings and other information to increase awareness and compliance with the NRC regulations.

Date of Full Compliance

The posting of the information occurred immediately after James Cameron's inspection. However, the radiation awareness bulletin board will not be completed until April 1, 1994.

If you have any further questions or comments regarding any of the above, please feel free to contact me at (614)454-5499.

Sincerely,

Daniel L. Sylvester

Daniel L. Sylvester, FACHE
Vice President
Professional Services

DLS:clh

cc: Regional Administrator
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