IE07

PUBLIC

APR 21 1994

Good Samaritan Hospital
ATTN: Sister Myra James Bradley
President and CEO
375 Dixmyth Avenue
Cincinnati, OH 45220

License No. 34-00991-02
Docket No. 030-02665

Dear Sister Myra James Bradley:

This refers to the special safety inspection conducted by Mr. J. L. Cameron of this office on March 8-9, 1994, of activities authorized by NRC Byproduct Material License No. 34-00991-02, and to the discussion of our findings with Mr. F. Kolb and other members of your staff at the conclusion of the inspection. The inspection was prompted by your January 13, 1994 report of a radiopharmaceutical misadministration.

The inspection was an examination of activities conducted under your license as they relate to radiation safety and to compliance with the Commission's rules and regulations and with the conditions of your license. The inspection consisted of a selective examination of procedures and representative records, observations, independent measurements, and interviews with personnel.

During this inspection, certain of your activities were found to be in violation of NRC requirements, as specified in the enclosed Notice. A written response is required.

The violations are indicative of a continued weakness in the implementation and management of your radiation safety program, which we originally identified to you in our May 13, 1993 letter transmitting a Notice of Violation. We noted, during our March 31, 1993 and March 8-9, 1994 inspections, that neither your Radiation Safety Officer nor your Radiation Safety Committee appeared to be adequately informed of regulatory requirements or sufficiently involved in the radiation safety program to effectively oversee the use of licensed material. We further note that you have employed an outside consultant to perform routine audits of your radiation safety program; however, none of those audits noted any of the violations identified during this inspection and described in the enclosed Notice of Violation. The NRC expects that effective program reviews, whether performed by or for the licensee, to be able to identify most, if not all, radiation safety problems. Furthermore, effective reviews should initiate, recommend, or provide corrective actions and should verify the effective and timely implementation of corrective actions. The NRC expects a medical institution licensee through its Radiation Safety Officer and Radiation Safety Committee to assure that all requirements of the NRC license are met and that potential violations are identified and expeditiously corrected. Furthermore, we expect a medical institution licensee, through its Radiation Safety Officer and Radiation Safety Committee, to review incidents involving the use of licensed material with respect to the cause(s) and subsequent actions taken to prevent reoccurrence.

260023

As a result of the inspection, we concluded that it is unlikely that the incident reported to us in your January 13, 1994 correspondence resulted in a misadministration as defined in 10 CFR 35.2. This conclusion is based on the information supplied by your chief nuclear medicine technologist during the inspection regarding anomalies in the operation of your dose calibrator and its associated printer. Your chief technologist demonstrated to our inspector that if sufficient time is not allowed for your dose calibrator to stabilize prior to activating the print command, the measurement and resulting documented dosage will be erroneous. This information was confirmed by the manufacturer of the dose calibrator. Notwithstanding that finding, had the incident actually resulted in a misadministration, several additional violations would have been included in the enclosed Notice of Violation regarding your failure to: (1) notify the NRC by telephone within 24 hours after discovery of a misadministration; (2) provide a written report to the NRC within 15 days after discovery of a misadministration; and (3) notify the referring physician and the patient within 24 hours after discovery of a misadministration. We are concerned that your Radiation Safety Officer was not sufficiently knowledgeable of the misadministration reporting requirements to make timely and appropriate notifications regarding the incident. We are further concerned that at the time of the inspection, this incident had not been discussed with or evaluated by your Radiation Safety Committee.

In addition to the above, we are concerned that the current staffing in your nuclear medicine department may not be adequate to support your radiation safety needs. We noted during the inspection that you planned to extend your normal workweek in the nuclear medicine department from five days to six days. Inspection findings indicate that Good Samaritan Hospital is in the process of hiring an additional 0.5 FTE nuclear medicine technologist, however, we also note that you plan to eliminate the 0.75 FTE available to the department via your use of nuclear medicine technologists supplied by temporary staff. Such workloads, current and planned, with the lack of available personnel, could increase the potential for reportable events and may hinder your ability to comply with Commission requirements.

Based upon the results of our inspection, we requested a management conference between members of the NRC Region III management and staff and members of your organization. The conference was conducted on March 31, 1994 and included a discussion of the identified violations and concerns, their causes and safety significance, and your proposed corrective actions. Of particular interest to NRC staff was the discussion of your plans for strengthening the oversight and control of licensed activities provided by your Radiation Safety Officer and Radiation Safety Committee. We request that you submit your plans in writing to us, along with your response to the Notice of Violation. Include in that submittal a discussion of the actions you have taken to insure that your RSO is knowledgeable of misadministration notification requirements and all other pertinent NRC requirements, and your plans for addressing our concern regarding the adequacy of your current and proposed staffing level.

After reviewing your response, including your proposed corrective actions and the results of future NRC inspections, the NRC will determine whether further NRC action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the Commission's regulations, a copy of this letter, the enclosure, 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 are 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.

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

Original Signed by Roy J. Caniano

Roy J. Caniano, Chief
Nuclear Materials Safety Branch

Enclosure: Notice
of Violation

bcc w/enclosure:
PUBLIC

RIII	RIII	RIII	RIII
Cameron/jaw	Holt	DeFayette	Caniano
4/19/94	4/14/94	4/15/94	4/21/94