UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8064

OCT 19 1993

Docket: 030-20264
License: 25-23109-01

Holy Rosary Hospital
ATTN: H. Ray Gibbons
Executive Director
2101 Clark Street
Miles City, Montana 59301

SUBJECT: NRC INSPECTION REPORT 030-20264/93-01 (NOTICE OF VIOLATION)

This refers to the routine, unannounced inspection conducted by Ms. Linda Kasner of this office on August 19, 1993. The inspection included a review of activities authorized by Byproduct Materials License 25-23109-01. At the conclusion of the inspection, the findings were reviewed with Messes. Bonnie Cook and Merna Johnson of your staff.

The inspection was an examination of 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 observation by the inspector.

The inspector noted that during this inspection interval, several individuals had either left or been reassigned to positions involved with NRC-licensed activities. Specifically, the senior hospital manager, the authorized user and Radiation Safety Officer (RSO), and the chief technologist had only served in their respective positions for a period of less than 1-year. In addition, two individuals involved with your radiation safety program had terminated their positions at the facility during this inspection interval. The inspector also noted that during this inspection interval, the department was not staffed with a dedicated nuclear medicine technologist and that supervisors had instead assigned responsibility for performing nuclear medicine procedures to several technologists. The impact of these personnel changes is discussed in further detail below.

Based on the results of this inspection, certain of your activities appeared to be in violation of NRC requirements, as specified in the enclosed Notice of Violation (Notice). The violations described in the enclosed Notice involved: (1) failure to perform dose calibrator constancy tests on each day of use; (2) failure to perform quarterly dose calibrator linearity tests; (3) failure to perform a dose calibrator geometric response test which included geometric configurations normally used for measuring patient dosages; (4) failure to use syringe shields routinely when preparing radiopharmaceutical kits and while administering radiopharmaceutical doses to patients; (5) failure to perform weekly contamination surveys during certain periods; (6) failure to perform a

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daily ambient radiation dose rate survey on one occasion; and (7) failure to record the date that waste material disposed of by decay-in-storage was placed in storage in records of waste disposal and on three occasions, to hold contaminated waste material for a period of 10 half-lives prior to disposal.

Several of the violations noted above appeared to be due, in part, to a failure of personnel previously employed by Holy Rosary Hospital to follow radiation safety program requirements. In addition, the inspector noted that some of these problems were identified by your physics consultant; however, it appeared that hospital management and the RSO had either not taken corrective actions in response to the consultant's findings or, alternatively, that the actions taken were not sufficient to prevent recurrence.

In some instances, such as with violations involving failure to perform daily constancy tests for the dose calibrator and weekly contamination surveys, the violations appeared to be due, in part, to oversights by individuals assigned to complete these tasks. Specifically, by review of records, the inspector determined that one individual in particular did not complete daily dose calibrator constancy tests or weekly surveys during periods when the individual was assigned to perform nuclear medicine procedures. Based on discussions with your staff during the inspection, it appeared that the former department supervisor and RSO were either not fully familiar with NRC requirements or had failed to provide sufficient oversight to ensure that the tasks were completed as required.

As noted above, the inspector determined that frequent personnel changes associated with licensed activities were in part responsible for some of the violations. However, the violations also appeared to be due, in part, to a lack of adequate oversight for individuals working under the supervision of authorized users and the RSO. In reviewing the time period(s) in which the violations occurred, the inspector noted that the current RSO and chief technologist were not serving in their present positions at that time. Therefore, the inspector could not determine whether either individual was knowledgeable of the root cause of some of the violations or the specific corrective actions taken by hospital management or the former RSO.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

Based on the results of this inspection, we are concerned about the implementation of your program in the area of management control and with regard to the RSO's oversight of the program. Therefore, in addition to the response referenced above and those specified in the enclosed Notice, you are requested to describe the specific actions planned or taken to improve

oversight of your licensed activities, with particular emphasis on measures being taken to prevent further violations. Your response to this matter should be included with the response specified in the enclosed Notice.

Although normally we would not reinspect your operations for at least two years, because of our concerns regarding the management of your licensed program we intend to conduct a reinspection of your program within one year to confirm that corrective actions have been taken and are effective.

In addition to the violations noted above, the inspector identified several concerns regarding the implementation of program requirements and the specific written guidance provided by your RSO. The first concern involved the misadministration policy developed by your RSO and later approved by the Radiation Safety Committee. The inspector reviewed this policy and noted that the definitions provided therein did not conform to the definitions of a misadministration provided in 10 CFR 35.2. You are encouraged to review the definitions in 10 CFR 35.2 and the provisions of 10 CFR 35.32 and 35.33 and amend your policy as appropriate.

A second concern involved instructions regarding actions to be taken when removable contamination was identified through routine surveys. Specifically, department instructions were in some cases nonspecific and failed to include the level of detail referenced in procedures incorporated by reference in your license. For example, the inspector noted that certain laboratory rules for area surveys recently posted by the RSO specified that "the contaminated area will be considered decontaminated when the [survey] readings are twice background" rather than providing a specific threshold and corresponding actions to be taken. In addition, the inspector noted that results for removable contamination surveys often indicated negative values (as low as -1,952 disintegrations per minute) and that this problem had not been evaluated by the RSO. As discussed with members of your staff during the inspection, this issue needs to be evaluated in order to determine whether background radiation levels are too high in the area where your counting system is located and to ensure that the counting system used for these tests is capable of detecting the minimal detectable activity prescribed by NRC regulations.

A third concern involved an issue for which facts could not be verified during this inspection but which is nonetheless of concern to NRC. Specifically, an individual interviewed during the inspection indicated that on a few occasions several years ago members of your staff may have administered radiopharmaceuticals at a second facility which is located in Miles City, Montana. The inspector was unable to identify the dates on which this may have occurred, and no record of such activity was documented in previous inspection reports, nor was hospital management aware of such activity. However, as discussed with members of your management staff during the inspection, such activity is prohibited under the conditions of your license. You are encouraged to ensure that each individual participating in licensed

activities at your facility fully understands the conditions of your license with regard to areas of use.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

Should you have any questions concerning this letter, please contact Linda L. Kasner of my staff at (817) 860-8213.

Sincerely,

Charles L. Cain

For Dwight D. Chamberlain, Acting Director
Division of Radiation Safety
and Safeguards

Enclosure:
Appendix - Notice of Violation

cc:
Montana Radiation Control Program Director

bcc:
DMB - Original (IE-07)
JLMilhoan
DDChamberlain
CLCain
MMessier, OC/LFDCB (4503)
*WLFisher
*LLKasner
*NMIS
*MIS System
*RIV Files (2)
SLMerchant, NMSS/IMAB (6 H3)

*W/IFS Form

RIV:NMIS	ADD:DRSS	AD:DRSS		
LLKasner	CLCain	DDChamberlain		
10/18/93	10/18/93	10/18/93		

bcc:
DMB - Original (IE-07)
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RIV:NMIS	ADD:DRSS	AD:DRSS		
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