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

FEB 7 1994

Docket: 030-19288
License: 25-19824-01
EA 94-025

Community Memorial Hospital
ATTN: Donald J. Rush, CEO
P.O. Box 1690
Sidney, Montana 59270-1690

SUBJECT: NRC INSPECTION REPORT 030-19288/93-01

This refers to the routine, unannounced radiation safety inspection conducted by Ms. L. L. Kasner on August 17, 1993, of activities authorized by Byproduct Materials License 25-19824-01. At the conclusion of the inspection, the findings were discussed with members of your staff. The findings were later reviewed during telephone conversations on August 27, 1993, between Ms. Kasner and Dr. Gregory Faul of your staff, and on September 2, 1993, with Mr. Donald Rush. In addition, the findings of the inspection and the consultant evaluation discussed below were reviewed again with Dr. Faul on January 31, 1994. The enclosed NRC Inspection Report 030-19288/93-01 documents this inspection.

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, and observations by the inspector.

The inspector noted that subsequent to our previous inspection in October 1991, Community Memorial Hospital (CMH) had purchased a software program designed to assist the staff in achieving and maintaining compliance with NRC record requirements and in scheduling certain tasks associated with the radiation safety program. In addition, in March 1993, CMH enlisted the services of a consulting health physics group to conduct audits of its radiation safety program to verify compliance with NRC requirements. These efforts appeared to have been effective in correcting some of the violations identified during our previous inspection.

During the current inspection, two apparent violations were identified regarding the administration of certain radiopharmaceuticals to patients. The first apparent violation involved CMH's failure to establish and maintain a Quality Management (QM) program as required under 10 CFR 35.32 (QM Rule). The rule, which became effective on January 27, 1992, requires that each licensee establish and maintain a QM program to provide high confidence that byproduct material in certain quantities and applications will be administered to patients as directed by an authorized user. The QM Rule also requires that

licensees submit the written program to NRC. Although CMH was authorized and did use quantities and types of byproduct material subject to the QM Rule at the time the rule became effective, as well as thereafter, CMH failed to establish and submit a QM program to NRC. NRC subsequently contacted CMH representatives and issued a Confirmatory Action Letter, dated March 16, 1993, documenting a commitment made by CMH to establish a QM program and submit a copy of the written program to the NRC Region IV office. The program was submitted by letter dated April 26, 1993. The inspector's review of sodium iodide I-131 administrations which occurred after this date revealed that CMH had complied with the provisions of its QM program and the QM Rule once the program was established.

The inspection also revealed that although CMH had failed to establish a QM program as required in January 1992, apparently CMH had become aware of regulatory changes regarding the administration of certain radiopharmaceuticals in August 1992. This was determined through interviews of CMH personnel and review of the minutes documenting discussions held during a Radiation Safety Committee (RSC) meeting on August 16, 1992. The minutes of this RSC meeting document policies for patient and procedure verification prior to the administration of therapeutic and diagnostic doses of sodium iodide I-131. Based on the inspector's review of these policies and discussion with your staff, it appeared that after August 1992, dual patient verification had been accomplished prior to the administration of therapeutic dosages of sodium iodide I-131 and diagnostic dosages in excess of 30 microcuries (uCi).

The second apparent violation involved a failure of individuals working under the supervision of an authorized user to follow the written instructions of the supervising authorized user. This issue is also associated with administration of sodium iodide I-131 to patients during 1992 and 1993. In reviewing the controls established for administration of sodium iodide I-131 prior to April 1993, the inspector noted that CMH had established and maintained a "Clinical Procedures" manual which contained, among other items, the authorized user's written instructions regarding radiopharmaceutical dosages to be administered to patients for specific clinical procedures. One of the procedures described in the manual was a diagnostic thyroid uptake and scan. The dosage of sodium iodide I-131 prescribed in the clinical procedures manual was 50-100 uCi. However, based on a review of radiopharmaceutical administration records, the inspector identified six occasions in which the technical staff had administered dosages in excess of 100 uCi. The dosages administered in these cases ranged from 134 to 208 uCi.

The two apparent violations described above are of significant concern because they involved (1) the failure to establish and maintain a program designed to provide high confidence that byproduct material would be administered as directed by an authorized user and (2) several examples of a failure to administer sodium iodide I-131 in accordance with an authorized user's instructions. In addition, it appears that the second problem resulted in six misadministrations in that the dosage administered to six patients differed

from the prescribed dosage (as documented in the clinical procedures manual) by more than 20 percent of the prescribed dosage and the difference between the administered dosage and the prescribed dosage exceeded 30 uCi. Although it appeared that at least two of these patients later received therapeutic dosages of sodium iodide i-131 for hyperthyroidism, this does not mitigate the fact that the misadministrations occurred.

In addition to the issues discussed above, the failure of the authorized user and Radiation Safety Officer (RSO) to have identified the misadministrations prior to this inspection or to have taken corrective action to ensure that the staff administered the appropriate dosage raises concern regarding the level of detail of program reviews and the oversight provided for day-to-day operations. You should be prepared to address this issue during the conference discussed below.

Although CMH was aware of regulatory changes regarding the administration of certain radiopharmaceuticals as early as August 1992, the inspector was unable to determine the specific reason that a QM program was not established as required. However, based on discussion with your staff, it appeared that the policy changes noted above may have been prompted by information and advice provided by a consultant serving your facility at that time rather than through the staff's or RSO's knowledge of NRC regulations.

In addition to the inspector's review of the above noted misadministrations, NRC requested the assistance of a physician consultant to evaluate the misadministrations and provide an assessment of the potential consequences of the misadministrations. The physician consultant also reviewed actions taken by CMH's authorized user/RSO with regard to patient notification following the inspection. The results of the consultant's evaluation are provided in Attachment 3 of the enclosed report.

Based upon information provided by the physician consultant and through discussions held subsequent to the inspection between the inspector and your RSO, we note that CMH did provide notification of the misadministrations to the affected patients. However, as of the date of this letter, CMH had not yet submitted written notification of the misadministrations to NRC as required under 10 CFR 35.33. The failure to submit a written report of each misadministration is considered an apparent violation of 10 CFR 35.33(a)(2). You should be prepared to discuss this issue during the conference discussed below.

In addition to the apparent violations associated with the QM Rule and administration of radiopharmaceuticals to patients, certain other of your activities appeared to be in violation of NRC requirements. The other apparent violations identified during the inspection involved: (1) failure to perform weekly contamination surveys during certain periods in areas where radiopharmaceuticals were routinely prepared and used; (2) failure to have appropriate survey instruments available; (3) failure to note on survey instruments used by licensee personnel the apparent exposure rate from the

licensee's dedicated check source as determined at the time of instrument calibration; (4) failure to maintain some records of contamination surveys in the proper format; (5) failure to conduct a quarterly inventory of sealed sources; and (6) failure to include the date of disposal and the results of surveys conducted prior to disposal in records associated with waste material disposed of by decay-in-storage. As noted in the enclosed report, Items 4 and 5 are repeat violations.

Based on the results of this inspection, the apparent violations noted above are being considered for escalated enforcement action in accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions" (Enforcement Policy), 10 CFR Part 2, Appendix C. Accordingly, no Notice of Violation is presently being issued for these inspection findings. In addition, please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review.

A telephonic enforcement conference to discuss these apparent violations has been scheduled for February 24, 1994, at 1:00 pm (MST). The decision to hold an enforcement conference does not mean that the NRC has determined that violations have occurred or that enforcement action will be taken. The purposes of this conference are to discuss the apparent violations, their cause and safety significance; to provide you the opportunity to point out any errors in our inspection report; and to provide an opportunity for you to present your proposed corrective action. In addition, this is an opportunity for you to provide any information concerning your perspectives on: 1) the severity of the violations, 2) the application of the factors that the NRC considers when it determines the amount of a civil penalty that may be assessed in accordance with Section VI.B.2 of the Enforcement Policy, and 3) any other application of the Enforcement Policy to this case, including the exercise of discretion in accordance with Section VII. You will be advised by separate correspondence of the results of our deliberations on this matter. No response regarding the apparent violations is required at this time.

The inspector also reviewed the corrective actions taken by CMH in response to violations identified during our previous inspection conducted in October 1991. These violations were described in our letter and Notice of Violation dated December 20, 1991. The inspector confirmed that corrective actions had been taken as described in your letters dated January 3 and April 4, 1992. However, it appears that your corrective actions were not fully effective in preventing recurrence of the violations involving (1) failure to conduct a quarterly inventory of sealed sources and (2) failure to maintain records of contamination surveys in the proper format.

These issues were discussed in detail with your staff. Although the failure to conduct a quarterly inventory was later identified by your consultant, the fact that the violation recurred indicates that the corrective actions taken may need to be formalized through department policy or procedure. The violation involving records of contamination surveys appeared to be due, in

part, to the staff's misunderstanding of how the survey results should be evaluated. Based on discussions with your staff, the inspector noted that further instruction and evaluation of department procedures regarding contamination surveys may be warranted.

In addition to the violations discussed above, the inspector also noted that although the RSO was present at the facility on a daily basis, he had relied upon the consultant physicist and technical staff to conduct many of the tasks associated with the radiation safety program and to ensure that specific tasks were completed as required. This issue was noted as a concern because the technical staff stated that the reason for the violation involving a failure to conduct contamination surveys was that there was insufficient time for the single technologist to complete all of his required assignments, including tasks delegated by the RSO. Because this may have contributed to some of the apparent violations, as well as your failure to identify the misadministrations, you should be prepared to discuss this issue during the aforementioned enforcement conference.

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

Should you have any questions concerning this letter, please contact either Charles L. Cain or Linda L. Kasner of my staff at (817) 860-8186 or 860-8213.

Sincerely,

Dwight D. Chamberlain

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

Enclosures:
1. Appendix A - NRC Inspection Report
   030-19288/93-01
2. Appendix B - Proposed Enforcement
   Conference Agenda

cc:
Montana Radiation Control Program Director

bcc:
DMB - Original (IE-07)
LJCallan
DDChamberlain
LWCamper
RAScarano, RV
CLCain
MMessier, OC/LFDCB (4503)
WLFisher
LLKasner
GFSanborn, EO
NMIS
MIS System
RIV Files (2)
JLLieberman, OE (7 H3)
SLMerchant (6 H3)
WLBrown, RC

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| LLKasner | CLCain | LWCamper | DDChamberlain | |
| 02/2/94 | 02/3/94 | 02/4/94 | 02/4/94 | |

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