APPENDIX A

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Inspection Report: 030-19288/93-01

License No: 25-19824-01 EA 94-025

Licensee: Community Memorial Hospital
P.O. Box 1690
Sidney, Montana 59270-1690

Facility Name: Community Memorial Hospital

Inspection At: Sidney, Montana

Inspection Conducted: August 17, 1993

Inspector: Linda L. Kasner, Senior Radiation Specialist

Approved: Charles L. Cain 2/3/94
Charles L. Cain, Chief, Nuclear Materials Inspection Section — Date

Inspection Summary

Areas Inspected: Routine, unannounced radiation safety inspection of licensed activities involving the use of byproduct material for diagnostic and therapeutic nuclear medicine procedures.

The inspection included a review of organization and management oversight; surveys and instrumentation; material use, storage, and disposal; and the licensee's implementation of a Quality Management (QM) program. In addition, the licensee's corrective actions regarding violations identified during a previous inspection were also reviewed to determine their effectiveness in preventing further similar violations.

With regard to the licensee's implementation of a QM program, the inspection focused on controls established for administration of radiopharmaceuticals during the period from January 1992 to April 1993, when the licensee had not established a QM program, as well as the licensee's compliance with the program once it was established in April 1993. The inspection also included a review of six misadministrations which were identified during the inspection and had gone unrecognized by the licensee.

In addition to the inspector's review, 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 the licensee's authorized user/Radiation Safety Officer subsequent to the inspection with regard to

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providing notification of the misadministrations to the affected patients. The results of the consultant's evaluation is provided in Attachment 3 of this report.

Results:

- Weaknesses were identified in the detail of program reviews conducted by the Radiation Safety Officer, also the sole authorized user, and in the oversight provided for day-to-day activities. In addition, it appeared that the RSO had relied upon the technical staff and a consultant to perform the majority of tasks associated with the radiation safety program (Section 1).

- Several apparent violations were identified involving radiation survey and instrument calibration requirements, material inventory requirements and record maintenance for waste disposal (Sections 2 and 3).

- Although the licensee failed to submit a QM program as required in January 1992, the licensee was aware that changes had occurred with respect to regulations governing the administration of byproduct material in certain quantities and for certain applications. However, it was not determined that the licensee's staff was aware of the QM Rule or that it became effective on January 27, 1992. The licensee had established policies and procedures regarding patient identification and procedure verification in August 1992 (Section 4).

- In addition to the policies noted above, the licensee had established a "Clinical Procedures" manual which included, among other items, the authorized user's written instructions for diagnostic radiopharmaceutical dosages. However, the staff failed to follow the authorized user's written instructions regarding diagnostic dosages of sodium iodide I-131 (Section 4).

- Six misadministrations were identified by the inspector involving diagnostic administrations of sodium iodide I-131 in quantities that (1) exceeded the authorized user's prescribed dosage by greater than 20 percent and (2) differed from the prescribed dosage by more than 30 microcuries. The dosages administered in these cases ranged from 134 to 208 microcuries and occurred before the licensee submitted a QM program (Section 4).

- The licensee submitted a QM program in April 1993, in response to a Confirmatory Action Letter issued by NRC on March 16, 1993. The licensee had complied with the provisions of the program once it was established (Section 4).

Summary of Inspection Findings:

- Apparent violation 030-19288/9301-01 was opened: Failure to possess either a portable radiation detection survey instrument or a portable radiation measurement survey instrument capable of detecting or measuring dose rates over the range(s) prescribed under 10 CFR 35.220 (Section 2.1).

- Apparent violation 030-19288/9301-02 was opened: Failure to note the exposure rate from a dedicated check source as determined at the time of calibration on a survey instrument used to demonstrate compliance with 10 CFR Part 35 as required by 10 CFR 35.51 (Section 2.1).

- Inspection Followup Item 30-19288/9301-01 was opened because the licensee had not yet determined the counting efficiency of an instrument used to analyze removable contamination samples taken during routine, weekly surveys (Section 2.1).

- Apparent violation 030-19288/9301-03 was opened: Failure to survey for removable contamination once each week in all areas where radiopharmaceuticals were routinely prepared, administered, and stored as required by 10 CFR 35.70 (Section 2.2).

- Apparent violation 030-19288/9301-04 was opened: Failure to retain records of removable contamination surveys with contamination levels expressed in units of disintegrations per minute per 100 square centimeters as required by 10 CFR 35.70 (Section 2.2).

- Apparent violation 030-19288/9301-05 was opened: Failure to conduct physical inventories of sealed sources in the licensee's possession as required by 10 CFR 35.59 (Section 3).

- Apparent violation 030-19288/9301-06 was opened: Failure to maintain all required information in records of disposal of byproduct material by decay-in-storage as required under 10 CFR 35.92 (Section 3).

- Apparent violation 030-19288/9301-07 was opened: Failure to establish and maintain a QM program that met each of the objectives identified in 10 CFR 35.32 (Section 4.1).

- Apparent violation 030-19288/9301-08 was opened: Failure of individuals working under the supervision of an authorized user to follow the written instructions of the authorized user as required under 10 CFR 35.25 (Section 4.2).

- Apparent violation 030-19288/9301-09 was opened: Failure to submit a written report of six misadministrations to NRC within 15 days of discovery of the misadministrations as required under 10 CFR 35.33 (Section 4.2).

Attachments:

- Attachment 1 - Persons Contacted and Exit Meeting
- Attachment 2 - Quality Management Program
- Attachment 3 - Letter dated December 6, 1993, from Barry Siegel, M.D., to Linda Kasner, U.S. Nuclear Regulatory Commission

DETAILS

1 ORGANIZATION AND MANAGEMENT OVERSIGHT (87100)

1.1 Program Overview

The licensee operates a nuclear medicine department which performs approximately 35-40 clinical procedures per month. The majority of the procedures involve the use of technetium-99m labeled radiopharmaceuticals. However, the licensee had performed several diagnostic and therapeutic thyroid procedures per month during 1992 and 1993. The license authorizes diagnostic use of byproduct materials described in 10 CFR 35.100 and 35.200 plus the use of sodium iodide I-131 for treatment of hyperthyroidism and cardiac dysfunction. The possession limit for I-131 is 30 millicuries.

Due to the geographical location of the facility and the attendant difficulties in receiving radiopharmaceuticals, the licensee had relied upon the use of molybdenum-99/technetium-99m generators as a source of technetium-99m for reconstituting radiopharmaceuticals. In addition, the licensee had relied upon the use of sodium iodide I-131 rather than sodium iodide I-123 for thyroid imaging because of frequent delays in performing patient examinations due to travel difficulties experienced by patients who lived some distance from the licensee's facility.

NRC last inspected the licensee's radiation safety program in October 1991. During the 1991 inspection, 10 violations of NRC requirements were identified. Of the 10 violations identified in 1991, 2 violations were identified as apparent repeat violations during the current inspection (see Sections 2.2 and 3).

1.2 Management Organization

NRC License 25-19824-01 identifies a single physician as an authorized user of byproduct material and as the Radiation Safety Officer (RSO). This physician has practiced at CMH for some period of time and had worked closely with the chief technologist of the radiology department for several years. The chief technologist, with periodic assistance from a second technologist, was largely responsible for performing many of the tasks associated with the radiation safety program as well as patient procedures. With regard to human use of byproduct material, the technologists worked under the supervision of the licensee's sole authorized user. With regard to the administrative aspects of the licensee's program, the chief technologist reported to the chief executive officer as well as the authorized user/RSO.

Because the license authorizes only a single physician user, the licensee had relied upon visiting authorized users to oversee licensed activities during periods when the permanent physician authorized user was unavailable. In fact, during the inspection conducted at the licensee's facility in August 1993, a visiting authorized user was present. Based upon interviews of

the staff and review of selected records, it appeared that the licensee had complied with the provisions of 10 CFR 35.27 regarding visiting authorized users.

The licensee's Radiation Safety Committee (RSC) was comprised of the chief executive officer, an administrative nursing representative, the RSO, the chief technologist, and the licensee's consulting physicist. The physicist had only recently begun service at CMH and had joined the RSC in March 1993. Based upon a review of committee minutes for meetings conducted during 1992 and 1993, it appeared that an appropriate range of issues were discussed by the RSC, that meetings had been conducted quarterly as required, and that all required individuals were present at each meeting.

In addition to radiation safety tasks completed by CMH's technical personnel, the licensee had relied upon the services of a consulting physicist. According to the authorized user and the chief technologist, throughout 1992 the authorized user/RSO had relied upon the chief technologist to perform dose calibrator quality control testing; routine and nonroutine surveys; and tasks associated with material inventory, transfer, receipt, and disposal. The consulting physicist serving the facility at that time conducted an annual audit of the program and had performed annual survey instrument calibrations.

According to the staff, the former consultant's involvement with the licensee's program was primarily limited to an annual review, the above noted calibrations, and conducting limited annual training for CMH staff members. In addition, the technical staff noted that the consultant was not very familiar with NRC regulations since he resided in an Agreement State and the majority of his clients were also located in Agreement States. The issues raised by the technical staff regarding the consultant's lack of familiarity with NRC regulations appeared consistent with some of the consultant's correspondence reviewed during the inspection.

During March 1993, the licensee enlisted the services of a new consulting physicist to assist in performing quarterly audits of the radiation safety program, quarterly quality control testing of the dose calibrator and other counting equipment, and in completing an application for renewal of CMH's NRC License. According to the technical staff, the assistance provided by the current consultant was valuable in helping to identify potential problems and in providing the technical staff with a better understanding of NRC requirements. Apparently, the majority of correspondence received by CMH regarding NRC regulations and requirements had been received by the authorized user/RSO. According to the chief technologist, this information had not routinely been shared with the individual(s) responsible for conducting radiation safety tasks except during annual refresher training. As a result, the technologists felt that they were not as familiar with NRC requirements as they should have been. This issue was discussed with management and was noted as an item warranting further review, particularly since the authorized user/RSO relied heavily upon the technical staff to complete various tasks associated with the radiation safety program.

In reviewing the effectiveness of management oversight of the program and the program organization, the inspector identified one concern. This issue involved the level of participation and oversight of licensed activities provided by the authorized user/RSO. As noted above, the technical staff was largely responsible for performing many of the tasks normally associated with the position of RSO. In addition, tasks which were not completed by the technical staff were completed by the consulting physicist. Although the RSO was present at the facility on a daily basis (according to the staff) and had reviewed the results of quality control testing and records associated with the radiation safety program, he had not routinely monitored how certain tasks were performed in order to ensure that they were done in accordance with NRC requirements. In addition, the RSO had failed to notice some of the apparent violations identified during this inspection despite the fact that they had occurred over some period of time. Specifically, the authorized user/RSO failed to note, among other items, that: (1) the staff had not adhered to his written instructions regarding certain radiopharmaceutical dosages (Section 4.2), (2) weekly removable contamination surveys had not been conducted over a period of time (Section 2.2), and (3) removable contamination surveys were not properly recorded and evaluated (Section 2.2).

It also appeared that the RSO, as well as licensee management, was not fully familiar with NRC regulations. This was evidenced by the fact that as of March 1993, the authorized user/RSO was apparently unaware of the requirement to establish and maintain a Quality Management (QM) program. In fact, the licensee had only become aware of this requirement, which became effective in January 1992, when informed by its consultant during the process of completing an application for renewal of CMH's NRC License.

In addition to the level of attention to licensed activities provided by the RSO, the inspector also noted a second factor which may have contributed to some of the violations. This issue involved personnel resources and the work load assigned to individuals associated with the radiation safety program. During interviews with the staff, the chief technologist, who was responsible for performing radiation safety tasks as well as patient examinations in several imaging modalities, stated that he often was left with little time to complete radiation safety tasks because of limited personnel resources and the fact that patient examinations were assigned a high priority. In particular, the technologist cited this as a reason that removable contamination surveys had not been conducted during a two-month period in 1992 (Section 2.2).

In evaluating the significance of the RSO's reliance upon the chief technologist and instances where the RSO's reviews of radiation safety tasks may have been lacking in detail, the inspector reviewed the licensee's past performance overall as well as performance in those program areas in which violations were identified during the previous inspection. The inspector noted that while the issues discussed above may have contributed to apparent violations identified during the current inspection, based upon interviews of CMH staff and the findings of the previous and current inspections, it appeared that the RSO and licensee management had devoted some additional time and resources to the radiation safety program. In addition, rather than a

failure of the RSO to execute his incumbent responsibilities, it appeared that there were some specific aspects of the radiation safety program that required additional attention from the RSO.

In summary, it appeared that CMH's management organization was in accordance with statements provided in the license application. However, it appeared that the RSO had not reviewed or monitored program activities with the level of detail required to identify items of noncompliance. In addition, the RSO had relied upon the chief technologist to complete many of the tasks associated with the radiation safety program despite the fact that the chief technologist had conflicting responsibilities involving the need to perform patient examinations and to provide supervision to the remainder of the technical staff. These issues appeared to have contributed to the apparent violations discussed elsewhere in this report and were identified to licensee management as issues warranting management attention.

2 SURVEYS AND INSTRUMENTATION (87100, 83822)

2.1 Survey and Counting Instruments

The licensee had maintained two portable survey instruments, an Atomic Products Model 69-700 survey instrument (SN 8365) and a Victoreen Model 740F survey instrument (SN 2961). The Atomic Products survey instrument is capable of detecting dose rates over a range of 0-50 millirem per hour and the Victoreen survey instrument is capable of detecting dose rates over a range of 1-1000 millirem per hour. The licensee had typically sent one instrument at a time for calibration so that a survey instrument would always be available to the staff.

During the portion of the inspection conducted at the licensee's facility, the inspector noted that the only survey instrument in the licensee's possession was the Atomic Products survey instrument. Apparently, after the Victoreen survey instrument was calibrated on July 1, 1993, and returned to the facility, it was noted that the instrument was not working properly. The staff returned the instrument for repair but failed to request that a "loaner" instrument be provided for their use. As a result, during the period from July 1 to August 17, 1993, the licensee did not have a portable radiation measurement survey instrument which met the criteria prescribed in 10 CFR 35.220. Specifically, 10 CFR 35.220 requires, in part, that a licensee authorized to use byproduct material for imaging and localization possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 to 100 millirem per hour and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 1 to 1000 millirem per hour. The fact that from July 1 to August 17, 1993, the licensee did not possess a radiation measurement survey instrument capable of detecting/measuring the aforementioned dose rates and instead possessed a survey instrument that was only capable of detecting dose rates over the range of 0-50 millirem per hour was identified as an apparent violation of 10 CFR 35.220.

As noted in Section 1.1, the licensee had used the services of consulting physicists for survey instrument calibrations. The licensee had recently changed consultants during 1993 and as a result, had found it necessary to send its survey instruments to the consultant's lab for calibration. In reviewing records of survey instrument calibrations, the inspector determined that each instrument had been calibrated in accordance with NRC requirements and the conditions of the license. However, one problem was identified regarding the consultant's and licensee's arrangement for determining the apparent exposure rate from a dedicated check source during instrument calibration as described below.

10 CFR 35.51(a)(3) requires, in part, that licensees conspicuously note the apparent exposure rate from a dedicated check source, as determined at the time of calibration, on each survey instrument used to demonstrate compliance with 10 CFR Part 35. In examining the survey instruments used by CMH, the inspector discovered that although an exposure rate was noted on the licensee's survey instruments, the exposure rate was for a source other than the dedicated source used by licensee personnel to test operability of each survey instrument. The noted exposure rate instead represented the measured exposure rate from a check source possessed by the licensee's consulting physicist. This problem had apparently occurred during the most recent instrument calibrations conducted on June 27 and July 1, 1993. The failure to note the exposure rate, as determined at the time of calibration, from a dedicated check source on an Atomic Products Model 69-700 survey instrument was identified as an apparent violation of 10 CFR 35.51(a)(3).

In addition to the survey instruments noted above, the licensee had installed and used a Capentec CAPRAC wipe test counting unit (this unit consists of a small well detector unit coupled with a scaler). This unit had been placed in service following the previous NRC inspection when the licensee had used a similar unit manufactured by another company.

Through review of records, the inspector noted that licensee personnel had used two different efficiency factors to evaluate wipe samples and quantify the contamination present on each sample. From December 1991 to August 1992, the staff had used an efficiency factor of 100 percent (or 1.0) for all radionuclides. From September 1992 to August 1993, the staff had used an efficiency factor of 80 percent (or 0.8) for all radionuclides. In response to questions regarding the origin of these factors, the staff noted that they had assumed that the 100 percent value was correct when the unit was purchased. Following some period of use, the chief technologist contacted the manufacturer for guidance and was informed that 80 percent was a "general efficiency" factor that should be used. No objective testing had been performed on the unit to determine the counting efficiency of the unit for technetium-99m or iodine-131 (the radionuclides most commonly used by the licensee). This issue was noted as something requiring followup in order to ensure that removable contamination survey results were properly evaluated. The failure to determine the counting efficiency of the instrument was identified as an Inspection Followup Item and will be reviewed during a future inspection (IFI 30-19288/9301-01).

2.2 Surveys

As noted in Section 1.2, radiation surveys were typically performed by the chief technologist. A review of records for routine and nonroutine surveys revealed that ambient radiation levels in unrestricted areas adjacent to rooms where byproduct material was used and stored had been conducted at monthly intervals and that the detected radiation levels were well within regulatory limits (recorded values ranged from 0.02-0.04 millirem per hour). In addition, daily radiation dose rate surveys were routinely conducted. Through review of survey records cross-referenced with material use records, the inspector was able to verify that surveys had been conducted on each day of use.

In reviewing the licensee's methods for conducting removable contamination surveys and associated records, two problems were identified. The first item is associated with the evaluation and documentation of removable contamination sample counts. As noted above, the licensee had earlier relied upon a counting system which was no longer in its possession for counting wipe test samples. This system basically provided a "pass/no pass" read out for the user and did not display the actual count data (the "pass/no pass" was determined by whether the count exceeded a set threshold). Thus, in the past, the licensee had not recorded actual test data.

The unit described above was replaced with a Capentec CAPRAC wipe test counter in December 1991. The licensee had used an alternative method for counting wipe samples after NRC's inspection in October 1991 until the CAPRAC counter was purchased and installed. In reviewing removable contamination survey records during this period, the inspector noted that from October 1991 to March 20, 1992, the staff had recorded numerical data but was unable to confirm what the numbers meant (no units were shown on survey records). Based upon interviews of the chief technologist, it appeared that the numerical data recorded in the licensee's survey records during this period may have represented units of counts per minute (cpm). The staff did confirm that they had not converted survey data to units of disintegrations per minute (dpm) during this period.

10 CFR 35.70(h) requires, in part, that a licensee retain a record of each removable contamination survey and that the record include, among other items, the removable contamination in each area surveyed expressed in dpm per 100 square centimeters. The failure to include removable contamination expressed in units of dpm per 100 square centimeters in records of surveys conducted during October 1991 through March 20, 1992, was identified as an apparent repeat violation of 10 CFR 35.70(h).

In addition to the issue noted above, the inspector found that the licensee had failed to conduct removable contamination surveys within the nuclear medicine department from March 20 to May 10, 1992, despite the fact that radiopharmaceuticals had routinely been prepared and used during this period. When questioned as to why the surveys had not been conducted, the staff

informed the inspector that they had been "too busy" to conduct the surveys during this period because of the increased patient case load.

10 CFR 35.70(e) requires that a licensee survey for removable contamination once each week in all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored. The failure to survey for removable contamination in the nuclear medicine imaging room and hot lab from March 20 to May 10, 1992, was identified as an apparent violation of 10 CFR 35.70(e).

Based upon a review of daily dose rate surveys and interviews of the staff, it did not appear likely that any contamination incidents had occurred during the period when contamination surveys were not conducted.

3 MATERIAL USE, STORAGE, AND DISPOSAL (87100)

Based upon a review of records associated with receipt of byproduct material, interviews of personnel, and inspection of the licensee's facilities, the inspector determined that the licensee had received, possessed and used licensed materials in accordance with the provisions of CMH's NRC License. As noted in Section 1.1, the majority of materials received and used during this inspection interval consisted of molybdenum-99, technetium-99m, and iodine-131. In addition to the aforementioned radionuclides, the licensee had in its possession several sealed sources which were used for quality control testing. The sources contained cesium-137, barium-133, and cobalt-57, the latter of which is not regulated by the NRC.

Areas of the facility where materials were stored and used were found to be as described in the license application. Areas reserved for storage of licensed materials were found to have adequate security, and the licensee had installed additional locks on the door to the hot lab, an area where radiopharmaceuticals and molybdenum-99/technetium-99m generators were routinely stored. During tours of the licensee's facility, the staff showed the inspector an area which was being prepared for storage of spent generators and other materials being held for decay-in-storage. Following tours of the facility, the inspector discussed with licensee personnel the need to notify NRC and obtain approval for any prospective changes in areas of material use prior to storing or using licensed material in areas not currently identified in the license.

One problem was identified regarding the licensee's efforts to conduct physical inventories of sealed sources. During NRC's inspection in October 1991, a violation was identified involving the failure to conduct quarterly physical inventories of all sealed sources in the licensee's possession over a 2-year interval. During the current inspection, the inspector found that the licensee had failed to conduct a physical inventory of all sealed sources in its possession during the first quarter of 1992. This was identified as an apparent repeat violation of 10 CFR 35.59(g) which requires, in part, that a licensee in possession of a sealed source conduct a quarterly physical inventory of all such sources in its possession.

The inspector also noted that the failure to conduct a physical inventory of sealed sources was identified by the licensee's consultant who recommended that a reminder be established in a software database used daily by the licensee to maintain records associated with the radiation safety program. This was apparently effective in preventing recurrence of this problem throughout the remainder of the inspection interval. However, the failure to conduct a physical inventory was identified as an apparent violation because the corrective steps taken by the staff had not been formalized or communicated to all individuals involved in the program and the actions taken in response to previous inspection findings should have prevented recurrence of this problem.

The licensee had also used the above noted software program to track material receipt and use, as well as the disposal of byproduct material. Although the program appeared effective in helping the staff to maintain adequate records of material receipt and use, the staff had not used the program effectively to maintain records of materials disposed of by decay-in-storage. Specifically, the staff had not adequately annotated waste disposal records associated with five packages and had failed to indicate the date of disposal, the background dose rate as determined at the time of disposal, and the dose rate measured at the surface of each waste container. Based upon a review of records, the packages were determined to contain technetium-99m and iodine-131. The failure to include the above noted information was identified as an apparent violation of 10 CFR 35.92(b) which requires, in part, that records of disposal of byproduct material by decay-in-storage include the date of disposal, the background dose rate, and the dose rate measured at the surface of each waste container.

Through interviews of the licensee's staff, the inspector determined that each package had been held for decay for the required ten half-lives and that surveys had been conducted to verify that dose rates at the surface of the packages were indistinguishable from background dose rates prior to disposal.

In summary, the licensee's use of byproduct material and provisions for storage of material were found to be adequate. However, two apparent violations were identified regarding a failure to conduct a quarterly physical inventory and the failure to include all required information in records of waste disposal.

4 USE OF RADIOPHARMACEUTICALS SUBJECT TO THE QUALITY MANAGEMENT RULE (87100)

NRC License 25-19824-01 authorizes the use of diagnostic quantities of sodium iodide I-131 as well as therapeutic quantities up to 30 millicuries. Because the provisions of 10 CFR 35.32 (QM Rule) became effective subsequent to NRC's last inspection of CMH's program, the licensee's implementation of the program and procedures required by the QM Rule was of particular interest during the inspection. Within this area, the QM program submitted to NRC on April 26, 1993, was reviewed; the policies and procedures regarding administration of radiopharmaceuticals prior to April 1993 were reviewed; selected records associated with administrations of sodium iodide I-131 during 1992 and 1993

were reviewed; and interviews of personnel were conducted to verify the level of training provided to individuals working under the supervision of the licensee's authorized user and their understanding of the authorized user's instructions regarding administration of radiopharmaceuticals to patients.

As discussed in the following sections, two apparent violations were identified involving (1) the licensee's failure to implement a QM program and (2) an individual's failure to comply with the authorized user's written instructions regarding diagnostic administrations of sodium iodide I-131 on several occasions prior to the licensee's establishment of a QM program. In addition, six misadministrations involving diagnostic dosages of sodium iodide I-131 were identified by the inspector. The misadministrations had previously gone unrecognized by the licensee.

4.1 Establishment of a QM Program

The QM Rule requires, in part, that each licensee establish and maintain a QM program to meet specific objectives for all administrations of sodium iodide I-131 in quantities greater than 30 microcuries (uCi). (CMH is not authorized for possession and does not use other types of byproduct material subject to the QM Rule.) The objectives of the QM Rule are described in 10 CFR 35.32(a)(1-5) and include the following: (1) prior to administration a written directive is prepared for any administration of sodium iodide I-131 in quantities greater than 30 uCi; (2) prior to administration, the patient's identity is verified by more than one method as the individual named in the written directive; (3) each administration is in accordance with the written directive; and (4) any deviation from the written directive is identified and evaluated, and appropriate action is taken.

Although CMH's authorized user had promoted the use of sodium iodide I-123 (a radionuclide not regulated by the NRC) for diagnostic thyroid procedures, the technical staff stated that they often had difficulty receiving I-123 capsules in a timely manner and that patients were often unable to meet their scheduled appointment times. Because of the short half-life of I-123, the latter problem often required that the examination be rescheduled and that additional capsules be purchased. As a result, the staff determined that use of I-123 was too expensive and instead relied upon the use of I-131 as a routine alternative for diagnostic thyroid procedures during the latter part of 1992.

Notwithstanding the staff's decision to use sodium iodide I-131 exclusively during the latter part of 1992, CMH had routinely administered sodium iodide I-131 in quantities greater than 30 uCi prior to and throughout 1992 but had failed to establish and submit to NRC a Quality Management (QM) program in January 1992 as required under 10 CFR 35.32 (QM Rule) or, alternatively, to suspend the use of sodium iodide I-131. The failure to establish and submit a QM program was identified as an apparent violation of 10 CFR 35.32(a).

The failure to submit a program subsequently prompted NRC Region IV staff to contact the licensee to determine why a program was not submitted by January 27, 1992, as required. This issue was discussed on March 4, 1993,

during a telephone conversation between an NRC Region IV staff member and the chief technologist of CMH's nuclear medicine department. The Region IV staff member was informed that CMH had not established a QM program but had recently been made aware of the requirement to do so, and that CMH planned to address this issue during the upcoming license renewal process. (An application for renewal of the license was being prepared at that time and was later submitted to NRC on March 16, 1993.)

NRC subsequently issued a Confirmatory Action Letter, dated March 16, 1993, documenting CMH's commitment to promptly establish and submit a QM program within thirty days of the date of the letter. CMH submitted a copy of its QM program by letter dated April 26, 1993. Through review of patient administration records and interviews of personnel, the inspector determined that CMH had trained the staff in the QM program and had complied with the provisions of the program after April 1, 1993. (The licensee had implemented the program on April 1, 1993. The inspector determined that between March 16 and April 1, 1993, no administrations of byproduct material subject to the QM Rule occurred.)

4.2 Radiopharmaceutical Administrations

In reviewing the controls implemented by CMH prior to April 1993 regarding administration of radiopharmaceuticals to patients, the inspector discovered that CMH had been aware of regulatory changes regarding misadministrations as early as August 1992. However, the inspector was unable to determine the exact changes that CMH staff was aware of at that time. Based upon interviews conducted with CMH staff, the inspector was unable to conclude that the staff was aware of the specifics of the QM Rule. Through discussions with CMH personnel and review of minutes of Radiation Safety Committee (RSC) meetings, the inspector determined that policies and procedures for patient identification and procedure verification had been implemented in August 1992. These policies were documented in the minutes of a RSC meeting conducted on August 16, 1992.

The policies and procedures addressed diagnostic and therapeutic procedures involving administration of sodium iodide I-131 and were described under a heading titled "Misadministration/Patient Identification Safeguard Policy/ Procedure Against Possible I-131 Misadministration." The procedure included the following:

> For diagnostic procedures involving administration of sodium iodide I-131:
>
> - A written order from the patient's personal physician was to be presented at the time the patient registered at CMH for a diagnostic thyroid exam.
>
> - Reception personnel were required to check the patient's written name, date of birth, and other identifying data presented with the

patient's hospital records and confirm this information with identification presented by the patient at time of registration. Written and verbal verification were required for the information noted above.

- Prior to administration of a radiopharmaceutical, the technical staff was required to confirm the patient's identity verbally and with written identification presented by the patient prior to the exam. The technical staff was also required to confirm the patient's physician, clinical symptoms, and to make a judgement on whether the symptoms described by the patient were consistent with diagnoses associated with the requested exam.

For therapeutic procedures involving sodium iodide I-131, the staff was required to complete the steps outlined above plus the following:

- A written request for therapy from the patient's physician was required.

- The authorized user was required to determine whether therapy with sodium iodide I-131 was appropriate and to document an order for therapy on the patient's record. (According to the technologist, this did not include the specific dosage to be administered to the patient prior to April 1993.)

- The technologist was responsible for placing the order for a sodium iodide I-131 capsule and documenting the quantity ordered, the date the order was placed, and the date of delivery. (According to the technologist, the physician verbally instructed the staff regarding the dosage to be administered to the patient. The staff then ordered the dose, based on the verbal instruction, and attempted to obtain a capsule with activity matching the verbal instruction.)

- On the day of administration, the radiologist was required to be present and to verbally instruct the patient regarding precautions and potential risks prior to treatment. The patient was also required to sign an "informed consent" document prior to treatment. Prior to treatment, the dosage to be administered to the patient was to be confirmed with the authorized user.

Based on discussions with the technical staff, the inspector determined that subsequent to implementation of the aforementioned policy, CMH had complied with the requirement to obtain dual patient verification prior to administration of sodium iodide I-131 in quantities greater than 30 uCi. However, prior to August 1992, no formal procedure or policy was established regarding patient identification. In reviewing routine practice at the facility prior to August 1992, the inspector determined that although the patient's identity may have been verified by more than one method by

receptionist personnel, the technical staff administering radiopharmaceutical dosages did not routinely verify the patient's identity by more than one method.

As noted above, prior to April 1993, the staff had relied upon verbal communication between the technologist and authorized user regarding the dosage of sodium iodide I-131 to be administered to patients for therapeutic procedures. The technologist interviewed during the inspection (the principal individual responsible for ordering and administering doses of I-131) stated that the authorized user had not included the dosage to be administered in the written order for a therapeutic procedure. However, the technologist did confirm that the authorized user was present during therapeutic procedures and had reviewed the dosage to be administered to the patient prior to administration.

Although CMH had not established a QM program or other controls to ensure that written directives were routinely used, the authorized user and technologist had maintained a "Clinical Procedures" manual which provided specific instructions for each procedure. The manual included, among other items, the dosages to be administered for each diagnostic exam. For a thyroid uptake and scan, the dosage identified in the manual was 50-100 uCi for sodium iodide I-131. (The procedure also prescribed a dosage for sodium iodide I-123.) Both the technologist and authorized user confirmed that the manual was current at the time of the inspection, and the technologist acknowledged that the manual had last been reviewed in January 1993, although the instructions for a thyroid uptake and scan had not changed during 1992 and 1993. The authorized user confirmed that this was his intended dosage for the procedure, and the technologist acknowledged that he had been trained and was familiar with the procedure.

In reviewing radiopharmaceutical administration records, the inspector noted that during early 1992 the staff had used I-123 for diagnostic thyroid procedures. However, as noted above, during the latter part of 1992 the staff had apparently relied upon the use of I-131 for diagnostic thyroid procedures. The technologist explained that this was due to problems associated with ordering and receiving I-123, as well as the fact that patients frequently were unable to make their scheduled appointments and because of the short half-life of I-123. This often required that additional capsules be purchased.

Based on a review of records for all sodium iodide I-131 administrations for 1992 and 1993, the inspector determined that eight diagnostic procedures were performed prior to April 1993, and two diagnostic procedures were performed after April 1993 (after the licensee's QM program was established). Of the diagnostic procedures performed before the licensee implemented a QM program, the inspector identified six administrations of sodium iodide I-131 in quantities that exceeded the authorized user's prescribed dosage (as

documented in the clinical procedures manual). The dosages and dates of administration are shown below:

Date of Administration	Dosage
July 9, 1992	134.2 uCi
November 9, 1992	208 uCi
November 21, 1992	208 uCi
November 24, 1992	188 uCi
January 25, 1993	203 uCi
February 3, 1993	141 uCi

These administrations were identified as examples of an apparent violation of 10 CFR 35.25(a)(2) which requires, in part, that a licensee that permits the use of byproduct material by an individual under the supervision of an authorized user must require the supervised individual to follow the instructions of the supervising authorized user. In the six examples identified above, an individual working under the supervision of an authorized user failed to follow the written instruction of the authorized user with regard to the dosage of sodium iodide I-131 to be administered to patients for a diagnostic thyroid uptake and scan.

The six examples identified above were also determined to be misadministrations in accordance with the definitions specified in 10 CFR 35.2. 10 CFR 35.2, in part, defines a misadministration as a radiopharmaceutical dosage greater than 30 uCi of sodium iodide I-131 when the administered dosage differs from the prescribed dosage by more than 20 percent and the difference between the administered dosage and prescribed dosage exceeds 30 uCi.

The administrations described above were discussed with the technologist and authorized user. The technologist acknowledged that he was aware of the authorized user's prescribed dosage; however, he explained that I-131 capsules were ordered with higher activities because of difficulties encountered in shipping and receiving the radiopharmaceuticals from the manufacturer and because he was told that the manufacturer did not have other capsules of lower activities available at the time that he had placed orders for the subject doses. (The inspector did not investigate this explanation with the manufacturer.) The authorized user stated that he had not specifically noted the discrepancies when he reviewed the cases and was unable to explain why no action had been taken to address the issue at the time the administrations occurred. Both the technologist and authorized user stated that the discrepancy between the dosage prescribed in the procedure manual and the actual dosages administered to the 6 patients had not been discussed prior to the inspection.

The failure to have identified and corrected the practice of administering dosages of sodium iodide I-131 in quantities significantly greater than the authorized user's prescribed dosage was noted as a significant weakness in program oversight and an item warranting review by management and the RSC.

Based on review of radiopharmaceutical administration records, the inspector determined that two of the six patients were subsequently treated for hyperthyroidism using millicurie quantities of sodium iodide I-131. The remaining four patients apparently had no further evaluations or treatment at CMH.

The inspector discussed the administrations with CMH management and the authorized user, noting that the six cases appeared to constitute misadministrations in accordance with 10 CFR 35.2. Licensee personnel were also advised of misadministration reporting requirements as specified in 10 CFR 35.33. However, as of the date of this report, the licensee had not yet submitted a written report of the misadministrations to the NRC Region IV office. This was identified as an apparent violation of 10 CFR 35.33(a)(2) which specifies, in part, that a licensee must submit a written report to the appropriate NRC Regional Office within 15 days after discovery of a misadministration.

4.3 Physician Consultant Review

NRC requested the assistance of a physician consultant to evaluate the misadministrations and provide an assessment of the potential consequences to the affected patients. The consultant gathered information regarding the dosages administered to the patients, the procedures established by the licensee at the time the misadministrations occurred, the medical condition of the patients, and subsequent actions taken by the licensee through interviews of licensee personnel, review of records associated with each administration, and review of subsequent correspondence between the licensee and the patients.

The physician consultant verified the dosages administered to each patient and found them to be as described in Section 3.2. (Because of a duplication in records associated with one administration, it was initially thought that seven misadministrations had occurred rather than six as noted above. This error is referenced in the consultant's report.) In addition, the consultant reviewed the dose calculations completed by the licensee's authorized user following the inspection. Based upon his review and confirmatory calculations, the physician consultant reported that the radiation doses for the patients' thyroid glands were underestimated by the licensee. The consultant estimated the thyroid doses to range from 35 to 626 rem and estimated the effective doses to range from 0.2 to 18.9 rem.

With regard to medical consequences for the affected patients, the physician consultant also noted that two of the six patients were later referred for treatment of hyperthyroidism and that for these two patients the consequences, if any, of the misadministrations would be irrelevant. (The two patients were later administered therapeutic dosages of sodium iodide I-131.) The consultant also noted that no medical consequences were likely for the other four patients and that it would be highly improbable that hypothyroidism, the deterministic effect associated with administration of sodium iodide I-131, would result from dosages in the range noted for these cases. In addition, the physician consultant noted that surveys conducted by other sources

identified no increased risk of thyroid carcinoma for persons exposed to I-131 for diagnostic procedures (with administered doses in the range of those received by the group of patients at CMH).

In summary, the physician consultant concluded that "the impact of these misadministrations on the health of these patients should be negligible" and that "no long-term disability is expected." (The consultant's report, dated December 6, 1993, is included with this report as Attachment 3.)

The physician consultant also reviewed with the authorized user/RSO the actions taken by CMH to provide notification of the misadministrations to the affected patients. The authorized user informed each patient of the misadministration by letter dated October 13, 1993. The physician consultant reviewed each letter and noted that the information provided to the patients constituted an adequate representation of the misadministration and the potential consequences. In addition, the authorized user's letters indicated that the associated referring physicians had been notified and that the report which would subsequently be submitted to the NRC would be made available to both the physicians and the patients. (As noted above, as of the date of this report, CMH had not yet provided written notification of the misadministrations to the NRC Region IV Office.)

4.4 Implementation of a QM Program

The inspector also reviewed the QM program submitted by CMH by letter dated April 26, 1993 (see Attachment 2). The program generally appeared to include policies which met the objectives of 10 CFR 35.32(a)(1-5). However, the inspector noted that the program did not contain policies regarding prompt review of radiopharmaceutical administrations to identify any deviations and instead was focused on an annual review of radiopharmaceutical administrations. In addition, the program did not contain: (1) instructions or guidance in the definitions of a recordable event or the regulatory criteria used to define a misadministration and (2) instruction or guidance in documenting the findings of annual program reviews. These items were discussed with the staff and noted as issues which should be reviewed by the RSC and CMH management with actions taken as appropriate.

5 FOLLOWUP ON PREVIOUS INSPECTION FINDINGS (92702)

During the inspection the inspector reviewed actions taken by CMH to correct violations identified during NRC's previous inspection in October 1991. The violations and the corrective actions taken by CMH, as well as their apparent effectiveness, are briefly described below.

5.1 (Closed) Violation 30-19288/9101-01: Failure to Adequately Secure Licensed Material in Storage

During the previous inspection, inspectors found that the licensee's hot lab, which was routinely used to store radiopharmaceuticals, was not always locked when personnel were not in attendance. Subsequent to that inspection, the

licensee installed a coded lock on the door, and personnel were instructed in the requirement to lock the door when they were not in immediate attendance of the area. Based upon observations and interviews during the current inspection, the licensee's corrective actions appeared effective in ensuring that adequate security was provided for the hot lab.

5.2 (Closed) Violation 30-19288/9101-02: Failure to Develop and Implement an ALARA Program

During the previous inspection, inspectors found that the licensee had not developed and implemented a written radiation protection program that included provisions for keeping occupational radiation doses As Low As Reasonably Achievable (ALARA) and that as a result, the licensee was unaware that some staff members had not worn extremity radiation monitors. Subsequent to that inspection, the licensee developed and implemented a written radiation protection program consistent with Regulatory Guide 10.8, Revision 2. In addition, through interviews with the technical staff, review of exposure records, and direct observation, the inspector confirmed that extremity monitors had been worn by the staff.

5.3 (Closed) Violation 30-19288/9101-03: Failure to Perform Daily Dose Calibrator Constancy Checks

NRC's previous inspection revealed that between April 1 and October 21, 1991, the licensee had failed to check its dose calibrator for constancy prior to using the instrument to measure patient doses. Subsequent to that inspection, the licensee had conducted refresher training for the staff regarding this requirement and had implemented use of a computer software program which required the user to enter dose calibrator constancy test results before any records of daily material use could be initiated. Based upon a review of licensee records and interviews with the staff, these actions were apparently effective throughout this inspection interval.

5.4 (Closed) Violation 30-19288/9101-04: Failure to Calibrate Survey Instruments at Required Annual Intervals

Following NRC's previous inspection, the licensee had implemented the use of a software program to provide notification of when certain calibrations and tests were due. This appeared to have been effective in preventing recurrence of this violation.

5.5 (Open) Violation 30-19288/9101-05: Failure to Perform Quarterly Physical Inventories of Sealed Sources

NRC's previous inspection revealed that the licensee had not conducted a physical inventory of sealed sources in its possession from October 1989 to October 1991. Although the licensee discussed this requirement with its staff, it had not implemented any modifications to department procedures or conducted audits to ensure that this requirement was met. As a result, the staff failed to conduct a physical inventory of sealed sources during the

first quarter of 1992. However, the licensee's consultant identified this failure, and inventories were conducted during all subsequent calendar quarters.

5.6 (Closed) Violation 30-19288/9101-06: Failure to Perform Daily Radiation Dose Rate Surveys

During the previous inspection, inspectors identified one occasion on which the licensee failed to perform a daily dose rate survey in the nuclear medicine department. During the current inspection interval, records indicated that dose rate surveys were performed in the nuclear medicine imaging area and hot lab on each day that byproduct material was used.

5.7 (Closed) Violation 30-19288/9101-07: Failure to Maintain a Copy of an Agreement State or NRC License Identifying a Visiting Authorized User

During the current inspection interval, the licensee had a visiting authorized user working at its facility. The licensee had obtained a copy of the Agreement State license identifying the physician as an authorized user.

5.8 (Closed) Violation 30-19288/9101-08: Failure of the RSO to Sign Dose Calibrator Accuracy, Linearity, and Geometry Test Records

During the current inspection interval, the RSO had reviewed and signed records of dose calibrator quality control test results.

5.9 (Closed) Violation 30-19288/9101-09: Failure of the RSO to Sign Leak Test Records

During the current inspection interval, the RSO had reviewed and signed leak test records.

5.10 (Open) Violation 30-19288/9101-010: Failure to Include All Required Information in Contamination Survey Records

During the previous inspection, inspectors found that the licensee had not expressed contamination survey results in units of dpm per 100 square centimeters. During the current inspection, the inspector found that the licensee had not implemented prompt, effective corrective actions, and as a result, from October 1991 to March 1992, the license had again failed to evaluate and record contamination levels in units of dpm per 100 square centimeters.

APPENDIX B

PROPOSED ENFORCEMENT CONFERENCE AGENDA

COMMUNITY MEMORIAL HOSPITAL
SIDNEY, MONTANA

February 24, 1994
1:00 pm (MST)

I.	INTRODUCTION AND PURPOSE	L. J. CALLAN
II.	EXPLANATION OF ENFORCEMENT POLICY	G. F. SANBORN
III.	NRC DISCUSSION OF APPARENT VIOLATIONS	C. L. CAIN L. L. KASNER
IV.	LICENSEE COMMENTS AND RESPONSE/CORRECTIVE ACTIONS	DON RUSH, CEO G. FAUL, M.D.
V.	CLOSING COMMENTS	D. D. CHAMBERLAIN

ATTACHMENT 1

1 PERSONS CONTACTED

1.1 Licensee Personnel

*•Dr. Gregory Faul
Dennis Damm, CNMT, Chief Technologist
+Donald J. Rush, CEO
Mike Simmons, Pacific Health Physics, Inc.

1.2 NRC Personnel

*+•Linda L. Kasner, Senior Radiation Specialist

*Denotes individuals present during a telephonic exit briefing conducted on January 31, 1994
+Denotes individuals present during telephonic exit briefing conducted on September 2, 1993
•Denotes individuals present during telephonic exit briefing conducted on August 27, 1993

2 EXIT MEETING

An interim exit briefing was conducted at the site on August 17, 1993, with the hospital director and Chief Executive Officer. This exit briefing was supplemented on August 27 and September 2, 1993, after telephonic interviews were conducted with staff members who were not present on site at the time of the inspection. The inspector reviewed the specific findings as presented in the report with particular emphasis on implementation of the licensee's Quality Management Program. In addition, a final, telephonic exit briefing was conducted on January 31, 1994, with individuals as noted above to review the consultant's evaluation of the misadministrations and other findings as presented in this report.

ATTACHMENT 2

RECEIVED
DRSS
MAY - 3

community
memorial hospital

April 26, 1993

James L. Milhoan, Regional Administrator
Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive, Suite 400
Arlington, Texas 76011-8064

Dear Mr. Milhoan:

I am writing in regards to your letter dated March 16, 1993.

The QM program NRC 10 CFR 35.32 has been implemented as of March 16, 1993. It was verified by Radiation Safety Committee and consulting health physicist. Attached is a copy of our minutes. Nuclear license 25-19824-01 license renewal.

This information is public document which means anyone can review our license and/or correspondence.

Sincerely,

Donald J. Rush, CEO
COMMUNITY MEMORIAL HOSPITAL

DJR/jrr

93-1058

216 14th Avenue S.W., Post Office Box 1690, Sidney, Montana 59270-1690, 406-482-2120

license# 25-19574-01

Community Memorial Hospital

Supplementary Quality Management Program

Administration of Therapeutic Dosages of Radiopharmaceuticals in excess of 30 Microcuries of I-131 as Sodium Iodide

I. Purpose

This document establishes policies for a quality management program in Nuclear Medicine in accordance with 10 CFR §35.32 regarding administration of radiopharmaceutical therapy dosages sodium iodide I-131 in amounts greater than 30 microcuries but not to exceed 30 millicuries, (I-125 as sodium iodide will not be administered to pateints). Directives contained herein are appended to the Nuclear Medicine and Radiation Safety procedure manuals to ensure the highest level of patient care service in Nuclear Medicine while minimizing risks to patients, technical personnel, and the general public.

II. Policy

A. A written directive (see Appendix 1) will be issued by an authorized user prior to administration of any therapeutic dosage of sodium iodide I-131 in excess of 30 microcuries. This directive will include identification of the radiopharmaceutical, the dosage to be administered, and the route of administration, and will be signed by the authorized user. No administration of said radiopharmaceutical by any Nuclear Medicine personnel (technologist or authorized user) will be permitted in the absence of a signed written directive with all the specified elements completed, except in cases of emergency as specified in subsection C.

B. Prior to radiopharmaceutical dosage administration the individual responsible for said administration will verify the information contained in the written directive and positively identify the patient by more than one method. Patient identification methods will be indicated by said individual through completion of the QM Program record , (see Appendix 1).

C. Oral directives and revisions to written directives are allowed under the specified conditions as stated in 10 CFR §35.32 (A)(1). Regulations of this part will be consulted and adhered to when deviation from this policy is considered.

III. Annual Review

A. Scope

All instances of radiopharmaceutical therapy dosages of I-131 sodium iodide grater than 30 microcuries will be reviewed annually. This review will involve examination of information recorded on the written directives and will document any discrepancies between the radiopharmaceutical name,

Appendix 1
Community Memorial Hospital
QM Program Written Directive

Date of Administration:

Patient Name:

Patient ID Number:

Radiopharmaceutical: ^{131}I as NaI

Amount Prescribed:

Amount Administered:

Route of Administration:

Administered By:

Authorized User Signature:

Methods of Patient Identification (indicate method used):

[ ] Name on Nuclear Medicine request matches hospital ID wristband.

[ ] Patient recites correct social security number.

[ ] Patient recites correct date of birth.

[ ] Patient recites correct residence address.

[ ] Positive identification by relative or legal guardian.

[ ] Positive drivers license identification.

(others as desired)

Audit Findings:

Radiopharmaceutical is identified by name, amount, route of administration, and written directive has been signed by an authorized user:

[ ] Yes [ ] No

Amount administered is within 10% of amount prescribed:

[ ] Yes [ ] No

Patient was positively identified by two methods:

[ ] Yes [ ] No

Auditor's initials and date:

dose, and route of administration specified by the authorized user and that administered. Presence of all required documentation and verification of patient identification will also be noted. If possible, said review shall be performed by and individual other than the authorized users at this institution.

B. Actions to Address and Resolve Problems

Annual results will be reviewed by the Radiation Safety Committee and subsequently recorded in the minutes. Recommendations regarding the need for new or revised policies, procedures, or increased training or supervision will be assessed, if warranted, in this review.

IV. Maintenance of Records

Copies of all written directives will be retained in the Nuclear Medicine file room and made available for external regulatory agency review.

COMMUNITY MEMORIAL HOSPITAL
Sidney, Montana

RADIATION SAFETY MEETING
March 16, 1993

AGENDA

I. Old Business

a. Health Physicist Inspection/Audit

b. ALARA Assessment/Audit

II. New Business

a. Nursing Service Representative Appointee to Radiation Safety Committee

b. Health Physicist Inspection/Audit

c. ALARA Audit

d. License Renewal

e. Audit Review

COMMUNITY MEMORIAL HOSPITAL
Sidney, Montana

RADIATION SAFETY MEETING
March 16, 1993

Present: Dr. Faul, Dennis Damm, Don Rush, Karen Granger - Nursing Service Rep., and Brian Simmons - Health Physicist/Consultant

The meeting was brought to order by Dr. Faul. A quorum was present.

I. OLD BUSINESS

Procurement of health physicist services for an internal licenses renewal, ALARA and NRC compliance audit.

II. NEW BUSINESS

Motion made by Mr. Rush that a nursing representative (Diane Thiel, Nursing Administrator) be appointed a part of Radiation Safety Committee with voting privileges and the right to appoint a alternate nursing representative in their absence. Motion seconded by Dennis Damm and the Motion was carried, three (3) votes, motion carried.

Health Physicist discussed the employee training and annual ALARA program. Brian Simmons will either conduct the lectures himself or take a video, which can be showen by CMH staff, Nuclear Medicine Department to those employees he recommended and license renewal to be part of the training, Radiation safety and ALARA program June 7, 1993. If lectures/training are given by CMH, Nuclear Medicine staff, Physicist will review and approve content based on current NRC regulations.

Health Physicist gave a report of his complete audit and comments needing addressing, are listed below:

a. QA - accuracy done correctly, logged, and signed.
b. Quarterly source currently completed, logged, and signed.
c. Daily Surveys completed, logged, and signed.
d. Health Physicist created a new users file to keep Dr. Fizzotti's and Dr. Crage's records on file.
e. Radiation Safety meetings were held quarterly but the last two were over the three month quarter time limit wrote in minutes why they were postponed.
f. Meetings should reflect ALARA reviews (film badges findings and action taken if necessary.
g. Physicist recommended that reports of whole body badges be used by techs who do both Nuclear and Radiology.
h. Surveys (ALARA) should be recorded ASNO incidents (no exposures warranting action levels.

ATTACHMENT 3

MIR
MALLINCKRODT
INSTITUTE OF RADIOLOGY
WASHINGTON UNIVERSITY
MEDICAL CENTER

DIVISION OF
NUCLEAR MEDICINE

6 December 1993

Ms. Linda Kasner
U.S. Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive, Suite 400
Arlington, TX 76011-8064

Re: Report of Medical Consultant Regarding I-131 Misadminstrations
(License 25-19824-01; Inspection Report 030-19288/93-01)

Dear Ms. Kasner:

I am responding to the 30 September 1993 letter from James L. Milhoan, Regional Administrator, requesting that I provide medical consultation services with respect to the above-named misadministrations. In preparing this report, I have had access to several different sources of information. Region IV supplied me with a copy of the above-named inspection report (in draft form) describing the inspection conducted in August 1993 at the facilities of the licensee (Community Memorial Hospital, Sidney, Montana). I subsequently made contact by telephone with the authorized-user physician at Community Memorial Hospital, Gregory B. Faul, M.D. Pursuant to my request, Dr. Faul provided me with brief summaries of the misadministrations, along with copies of the I-131 dispensing records, the thyroid scintigraphy and uptake reports, and letters dated 13 October 1993 written to each of the patients involved (notifying them of the misadministration). Dr. Faul also provided me with names, addresses, and phone numbers of these patients' referring physicians. I did not contact these referring physicians, because I did not believe I needed additional information from them to formulate my report. I contacted Dr. Faul after I had received this package of information from him and requested that he send me additional information indicating how he had calculated the radiation doses to the involved patients' thyroid glands. This information was transmitted to me by letter dated 4 November 1993 from Dr. Faul.

Based on the above information, I offer the following observations and conclusions.

The Patients and the Misadministrations: The salient information concerning these patients is summarized in the attached Table. Please note that the draft inspection report indicates that there were 7 misadministrations. According to Dr. Faul, there were only 6 patients and 6 misadministrations. He indicates that the two separate 203-μCi doses reportedly administered on 26 January and 29 January 1993 actually represent "duplication of hospital records rather than a seventh misadministration." The records Dr. Faul provided to me do apparently

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St. Louis, Missouri 63110-1076
(314) 362-2809 FAX (314) 362-2630

show duplicated radiopharmacy records on these two separate dates for patient #34857. There is only one record for thyroid uptake and scintigraphy corresponding to the earlier administration date. Accordingly, the subsequent analysis is based on the presumption that there were 6 misadministrations to 6 distinct patients.

As is shown in the Table, all of the patients were women. They ranged in age from 35 to 78 years. All were referred for thyroid scintigraphy and thyroid uptake measurement. The indications for these studies are not clearly documented in the available record. However, by inference, two of the patients appear to have been under evaluation for hyperthyroidism (and were subsequently treated with larger doses of I-131), two of the patients appear to have been referred for evaluation of nodular thyroid disease, and one of the patients was referred for investigation of suspected substernal goiter.

The Clinical Procedures Manual at Community Memorial Hospital specifies that I-131 thyroid scintigraphy and uptake are to be performed with an administered dose of 50-100 μCi. Reportedly, because of difficulty obtaining I-131 capsules within this range, capsules with higher activity levels were obtained and administered to these 6 patients by the nuclear medicine technologist. As noted in the Table, the administered activity of I-131 ranged from 134-208 μCi. These administrations of I-131, in doses exceeding 30 μCi and differing from the prescribed dosage (specified in the Clinical Procedures Manual) by more than 20% and by more than 30 μCi, thus constitute misadministrations.

Radiation Doses: The 24-hour thyroidal I-131 uptake results for these 6 patients are shown in the Table as also are thyroidal absorbed radiation doses estimated by the licensee and by me. Since it appeared to me, on initial inspection of the information supplied by Dr. Faul, that the radiation doses estimated by the licensee were too low, I asked for specific information concerning how these doses had been calculated. In his 4 November 1993 letter to me, Dr. Faul indicated the following. "The patient dosage of I-131 was multiplied by the uptake measurement. This value was then multiplied by 1.1 rad/μCi." As shown, this method underestimates the radiation dose to the thyroid glands of these patients by approximately a factor of 5. The 1.1 rad/μCi value reflects the radiation dose to a thyroid gland of normal size and with normal uptake per microcurie of I-131 administered to the patient (not per microcurie accumulated and retained in the thyroid gland). My dose estimates are based on the tables provided in *ICRP Publication No. 53. Radiation Doses to Patients from Radiopharmaceuticals* (Oxford: Pergammon Press; 1988: 275-278). The tables in *ICRP Publication No. 53* provide dosimetry summaries for 24-hour thyroid uptake values ranging from 5% to 55%. With use of these tables, the thyroidal absorbed radiation doses (and effective doses) for these patients were determined by interpolation (or extrapolation for patients 38687 and 38765). As noted, the thyroidal absorbed radiation doses range from 35 rem to 626 rem. Note that no information is available concerning the thyroid gland sizes in these patients. The dose estimates in *ICRP Publication No. 53* are based on normal thyroid size. Hence, if any of the patients had thyroid enlargement, the actual absorbed radiation dose would be lower. It is likely that both of the patients with hyperthyroidism (patients 202 and 38765), the patient with substernal goiter (34857) and the patient with multinodular goiter (10261) had thyromegaly. As is shown in the Table, the effective doses ranged from 0.2 to 18.9 rem. Doses to other organs and tissues in these patients are not of concern, as these will all be less than 1% of the thyroidal absorbed radiation doses.

Medical Consequences of the Misadministrations: In two of these patients, the medical consequences of the misadministrations (if there were any) would be irrelevant. Both of these patients had hyperthyroidism and received therapeutic doses of I-131 four and 1.5 weeks, respectively, after the diagnostic studies. No medical consequences are likely in the other four patients. The deterministic effect from I-131 administration of most concern is the induction of hypothyroidism. This is highly improbable with I-131 doses of this size. Usual hypothyroidism-inducing doses are several thousand rads or greater. It is also unlikely that these remaining four patients are at significant risk for stochastic effects. With radiation absorbed doses in this range, the stochastic effect of greatest potential concern is induction of thyroid carcinoma. A large survey based on the Swedish Cancer Registry (Holm LE, Wicklund KE, Lundell GE, et al. Thyroid cancer after diagnostic doses of iodine-131: a retrospective study. J Natl Cancer Inst 1988; 80:1132-1136) indicates no increased risk of thyroid carcinoma in persons exposed to I-131 for diagnostic procedures (with administered doses over a range that includes the doses received by these patients). In the final column of the Table, I have calculated a "lifetime" risk of thyroid carcinoma (assuming survival to age 80) for each of these four patients based on the prediction model recommended in *NCRP Report No. 80. Induction Of Thyroid Carcinoma By Ionizing Radiation* (Bethesda, MD: National Council on Radiation Protection and Measurements; 1985:54-58). These estimates (which probably represent overestimates) show that the risk to age 80 of development of thyroid carcinoma in these patients is quite low (0.05-0.51%).

Thus, in my opinion, the impact of these misadministrations on the health of these patients should be negligible. No long-term disability is expected.

Medical Follow-up and Care Required: No medical care or follow-up is required as a consequence of these misadministration.

Patient Notification: Dr. Faul wrote to each of these 6 patients on 13 October 1993. In my opinion, his description of the misadministration sent to the patient in these letters is a fair representation of the events and the consequences; each patient was told that they had received a dose of I-131 greater than that specified in the protocol established in the Nuclear Medicine Department of Community Memorial Hospital. The patients were informed, based on the Swedish Cancer Registry Study, that they were not at increased risk of developing thyroid cancer. Since Dr. Faul's letters do not include specific radiation doses for each patient, he does not need to revise them to account for the higher doses I calculated. In the case of the two patients who subsequently received therapeutic doses of I-131, his letters stated this to be the case and indicated that they were not at risk for an increased incidence of cancer (based on the Thyrotoxicosis Therapy Follow-up Study). Dr. Faul's letters further indicate that the patients' referring physicians had been notified and that the report subsequently to be submitted to the Nuclear Regulatory Commission will be available to them or the patients.

Department of Energy Office of Epidemiology and Health Surveillance Long-Term Study Program: I did not discuss this follow-up program with any of the licensee's staff and I did not contact the patients or the patients' referring physicians. Accordingly, I was not able to discuss this program with them. In my opinion, the nature and magnitude of the radiation exposures to these patients do not warrant their enrollment in the DOE Long-Term Medical Study Program.

Information Provided to the NRC by the Licensee: No written report of misadministration(s) prepared by the licensee was available for my review. Based on my most recent conversation with you concerning these misadministrations, I understand that the official written report from the licensee has not yet been submitted to the NRC. If you wish, I will be happy to review the licensee's written report when it is received.

Please let me know if you need additional information.

Sincerely yours,

Barry A. Siegel

Barry A. Siegel, M.D.
Professor of Radiology and Medicine
Director, Division of Nuclear Medicine

Enclosure

BAS:mtc

Patient No.	Age (Yr)/ Gender	Administration Date	I-131 Activity (μCi)	24-Hour Uptake (%)	Licensee Thyroid Dose Estimate (rem)	Consultant Thyroid Dose Estimate (rem)	Effective Dose (rem)	Risk of Thyroid Cancer to Age 80 (Comments)
202	78/F	07/09/92	134	53.0	78.0	377	11.4	NA (Underwent I-131 therapy (19.8 mCi) on 08/05/92 for hyperthyroidism)
38687	41/F	11/09/92	208	3.2	6.8	35	0.2	0.08%
32135	54/F	11/21/92	208	32.0	73.0	352	10.6	0.51%
38765	35/F	11/24/92	188	62.4	116.0	626	18.9	NA (Underwent I-131 therapy (9.6 mCi) on 12/03/92 for hyperthyroidism)
34857	66/F	01/25/93	203	21.0	46.8	225	6.9	0.17% (Substernal goiter)
10261	66/F	02/03/93	141	8.4	12.9	62	2.0	0.05% (Multinodular goiter and thyroiditis)