

# community

memorial hospital

June 1, 1994

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

Director, Office of Enforcement  
US Nuclear Regulatory Commission  
ATTN: Document Control Desk  
Washington, D.C. 20555

RE: Reply To A Notice Of Violation

Enclosed are responses to violations A, B, (violations assessed a Civil penalty) and responses to violations A, B, C, D, E, F, and G (violations not assessed a Civil penalty).

## I. VIOLATIONS ASSESSED A CIVIL PENALTY

### A) Violation A - 10 - CFR 35.32 (a) Failure to establish and maintain a quality management program by January 27th 1992.

1. Admission or denial of the alleged violation - CMH admits to this violation.
2. The reasons for the violations, if admitted - Failure to establish and maintain a quality management program at CMH was an oversight. Because the Nuclear Medicine Supervisor is deceased, there is no way to know why the QM program was not established or brought to the attention to the Radiation Safety Officer or Hospital Administration.
3. The corrective steps that have been taken and the results achieved - The Quality Management Program was established by CMH on March 16, 1993. CMH has been in compliance since the Quality Management program was established. Review mechanisms, including the use of a tickler file, are in place. The Quality Management written directives are reviewed quarterly. The review mechanisms will be monitored by the Hospital Quality Assurance Committee which includes both management personnel and Medical Staff. The inspection on August 17, 1993 confirmed that in the period between implementation of the Quality Management program and the inspection, CMH had complied with the Quality Management Program and further incidence of the type that caused the misadministrations did not occur.

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

9406070185 940601  
PDR ADOCK 03019288  
C PDR

♥ We care for our neighbors

4. The corrective steps that will be taken to avoid future violations - As mentioned above, the Quality Management written directives are reviewed quarterly. The review mechanisms will be monitored by the Hospital Quality Assurance Committee which includes both management personnel and Medical Staff. In addition, a tickler file has been established that will alert the Radiation Safety Officer. New software programs have also been purchased that give auditory and visual warnings if dosages exceed the dosage range established by the authorized user.
5. The date when full compliance will be achieved - Full compliance was achieved on March 16, 1993, prior to the August 17, 1993 routine inspection.

**B) Violation B - 10 CFR 35.25(a) (2) Failure of individuals working under the supervision of an authorized user to follow the written instructions of the supervising authorized user.**

1. Admission or denial of the alleged violation - CMH admits to this violation.
2. The reasons for the violations, if admitted - The investigation by the Radiation Safety Committee is incomplete regarding this issue because the Nuclear Tech who dispensed the radiopharmaceuticals in doses of I-131 which represented misadministrations is deceased. The reasons for the misadministrations would only be speculation on our part.
3. The corrective steps that have been taken and the results achieved - Corrective actions include the elimination of I-131 for diagnostic thyroid scans and uptake measurements with complete conversion to iodine 123 by mid-May 1993. In addition, the Quality Management program was established by CMH on March 16, 1993. No incidence have occurred following instructions of the QMP.
4. The corrective steps that will be taken to avoid future violations - In addition to the Quality Management program, the RSO has established a tickler file to aid in the overseeing of the Nuclear Medicine Department. The tickler file is inspected by the Hospital Quality Assurance Team on a quarterly basis to assure RSO compliance. The RSO also inspects the Nuclear Medicine Department on a daily basis. Maximal permissible doses for all radiopharmaceuticals have been posted and computer software warnings both visual and auditory instituted should a dose administration higher than the protocol be attempted.
5. The date when full compliance can be achieved - The Quality Management program was established by CMH on March 16, 1993. CMH has been in compliance since that date.

**II. VIOLATIONS NOT ASSESSED A CIVIL PENALTY**

**A. Violation A - 10 CFR 35.33(a) (2) and (3) - Failure to submit a written report of six misadministrations to the NRC within fifteen days of discovery of the misadministrations as required.**

1. Admission or denial of the alleged violation - CMH admits to this violation.
2. The reasons for the violations, if admitted - Due to the untimely death of the Radiology Department Manager, the written response was inadvertently not done.

3. The corrective steps that have been taken and the results achieved - A written report of the six misadministrations was submitted to the NRC. In addition, the Hospital notified the six patients of the misadministrations and their physicians.
4. The corrective steps that will be taken to avoid future violations - The Radiation Safety Committee, the Radiation Safety Officer, and the Nuclear Medicine Technician are aware of the regulation to submit a written report to the appropriate NRC Regional Office within fifteen days after the discovery of a misadministration. In addition, CMH is also aware of the requirement to notify the referring physician and patients no later than twenty four hours after its discovery. Because of the corrective steps identified above, the Radiation Safety Officer would become aware of the misadministrations soon after an occurrence and notify the appropriate parties.
5. The date when full compliance will be achieved - A written report of the six misadministrations was submitted to the NRC Region IV Office on February 16, 1994. The six patients were notified by letter dated October 13, 1993.

**B. Violation B 10 CFR 35.70(e) - Failure to survey for removable contamination once each week in all areas where radiopharmaceuticals were routinely prepared and administered and stored.**

1. Admission or denial of the alleged violation - CMH admits to this violation.
2. The reasons for the violations, if admitted - Again, this violation is difficult to address, as the Nuclear Medicine Tech responsible for the completion of these surveys is deceased.
3. The corrective steps that have been taken and the results achieved - No failures or further violations have occurred since May 10, 1992 the date the violation was identified during the August 17, 1993 inspection. CMH does a wipe test for removable contamination on a weekly basis. With the aid of the RSO tickler file and RSO daily inspections, CMH is confident that corrective steps have been taken and no further violations will occur.
4. The corrective steps that will be taken to avoid future violations - Again, future violations should not occur. CMH will continue to do area whip tests on a weekly basis and this will be monitored closely by the RSO with the assistance of the tickler file. The Nuclear Medicine Department is adequately staffed and personnel will continue to be made available should the Nuclear Tech feel insufficient time or resources are available for both the completion of patient care and radiation safety requirements.
5. The date when full compliance will be achieved - CMH has been in full compliance since May 10, 1992.

**C. Violation C - 10 CFR 35.220 - 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.**

1. Admission or denial of the alleged violation - CMH admits to this violation.
2. The reasons for the violations if admitted - When the NRC inspected CMH on August 17, 1993, the cutie pie survey meter capable of reading 1,000 millirem per

hour was being calibrated. With the cutie pie being calibrated, we did not have a meter on hand that could read 1,000 millirem per hour.

3. The corrective steps that have been taken and the results achieved - CMH had corrected the deficiency by purchasing a Ludlem Survey Meter capable of reading 1,000 millirem per hour. CMH now has two survey meters capable of reading 1,000 millirem per hour.
4. The corrective steps that will be taken steps that will be taken to avoid future violations - Because CMH now has two survey meters capable of reading 1,000 millirems per hour, future violations should not occur.
5. The date that full compliance will be achieved - On April 4, 1994 the second survey meter was purchased.

**D. Violation D - 10 CFR 35.59(g) Failure to Conduct Physical Inventories of Sealed Sources in the Licensee's Possession as Required.**

1. Admission or denial of the alleged violation - CMH admits to this violation.
2. The reasons for the violation if admitted - Again, this item is difficult to address as the Nuclear Medicine Tech responsible for the completion of these surveys is deceased.
3. The corrective steps that have been taken and results achieved - This violation was self-identified during a quarterly audit and internally corrected. The new corrective action has proven effective in preventing a reoccurrence. The inspector during the August 17, 1993 inspection acknowledged the resolution of the failure to conduct physical inventories of sealed sources with the use of a software data base used daily to maintain records associated with the Radiation Safety Program. In addition, the tickler file for the Radiation Safety Officer will insure timely survey review. Software data base will provide timely notification to the technician for specific surveys. No errors have occurred since the inception of the nuclear medicine tickler file.
4. The corrective steps that will be taken to avoid future violations - As indicated by the initiation of the tickler file and a software data base was instituted successfully. No further violations are expected.
5. The date when full compliance will be achieved - CMH has been in full compliance since March of 1993.

**E. Violation E - 10 CFR 35.51 (a)(3) - 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.**

1. Admission or denial of the alleged violation - CMH admits to this violation.
2. The reasons for the violations, if admitted - During the inspection it was noted that although an exposure rate was noted on the licensee's survey instruments, the exposure rate was for a source other than a dedicated source used by licensee personnel. The cesium check source was apparently used for instrumentation of daily quality control and was subsequently not sent with the meter for calibration.
3. The corrective steps that have been taken and the results achieved - We have corrected this violation by purchasing a Ludlem instrument which has an on board dedicated check source. We also have a dedicated check source for the cutie pie instrument.

4. The corrective steps that will be taken to avoid future violations - Future violations should not occur because of the corrective actions described above.
5. The date when full compliance will be achieved - Full compliance was achieved April 1994.

**F. Violation F - 10 CFR 35.70(h) Failure to retain records of removable contamination survey with contamination levels expressed in units of desintegrations per minute per 100 square cm as required.**

1. Admission or denial of the alleged violation - CMH admits to this violation.
2. The reasons for the violations, if admitted - The technician had utilized unassigned units. This was self identified and corrected in March 1993 allowing units to be correctly identified as disintegration per minute.
3. The corrective steps that have been taken and results achieved - Currently, the Nuclear Medicine Department utilizes a computer which converts CPMS to DPMS. There have been no failures to record surveys in the correct term since March 1993.
4. The corrective steps that will be taken to avoid future violations - As mentioned above the Nuclear Medicine Department utilizes a computer which converts CPMS to DPMS so the violation should not occur again.
5. The date when full compliance will be achieved - CMH has been in full compliance since March 1993.

**G. Violation G - 10 CFR 35.92(b) Failure to maintain all required information in records of disposal of byproduct material by decay -in-storage as required.**

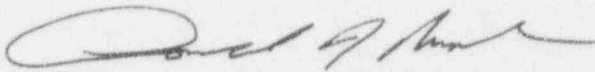
1. Admission or denial of the alleged violation - CMH admits to this violation.
2. The reasons for the violation, if admitted - The computer software utilized did not allow sufficient room for recording the additional data required.
3. The corrective steps that have been taken and results achieved - The apparent cumbersome software was replaced in October 1993. At present, a manual system is utilized which does comply with disposal documentations requirements.
4. The corrective steps that will be taken to avoid future violations - The corrective steps identified above should avoid future violations.
5. The date when full compliance will be achieved - September 1993.

Community Memorial Hospital has taken specific actions to improve daily oversight of licensed operations by hospital management and the Radiation Safety Officer; and to ensure that hospital management and the Radiation Safety Officer become familiar with and remain abreast of NRC regulations and the conditions of the license. Specifically, the following actions have been taken:

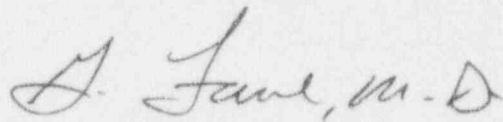
1. All correspondence from the NRC is now addressed to the Administrator of the Hospital. Correspondence had been going directly to the Nuclear Medicine Technician. The Administrator will review the correspondence and subsequently forward it on to the Radiation Safety Officer for review. The correspondence will be subsequently forwarded on to the Nuclear Medicine Technicians. This way, all correspondence from the NRC concerning new regulations or changes in regulations will be brought to the attention of the Hospital management and RSO.

2. Utilization of radiation consultant to help provide knowledge and to help ensure compliance with present and any future NRC regulations.
3. Radiation Safety planning calendar which lists all RSO requirements on a weekly basis.
4. Quality Assurance Committee which includes administrative personnel and Medical Staff outside the department of Nuclear Medicine to ensure compliance by the RSO.
5. Dedicated effort by Radiation Safety Committee, RSO, and Administration to provide management of the Nuclear Medicine Department which will prevent any reoccurrence of the recent violations, prevent new violations and ensure adequate involvement and knowledge by all personnel involved in Nuclear Medicine.

Sincerely,



Donald J. Rush, CEO  
Chairman, Radiation Safety Committee  
COMMUNITY MEMORIAL HOSPITAL



Gregory R. Faul, MD  
Radiation Safety Officer  
COMMUNITY MEMORIAL HOSPITAL

cc: US Nuclear Regulatory Commission - Region IV