

Davis Memorial Hospital

P.O. Box 1484 Elkins, West Virginia 26241

ROBERT L. HAMMER
Chief Executive Officer

304-636-3300

August 10, 1990

Director, Office of Enforcement
U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, DC 20555

RE: Reply to Notice of Violation

Gentlemen:

The following is in response to the notice of violation dated July 24, 1990.

A. 1) Failure to hold quarterly RSC meetings:

Response:

- 1) Violation is valid.
- 2) Violation occurred due to lack of management and RSC oversight.
- 3) Since the initial inspection, quarterly RSC meetings have been initiated at this facility.
- 4) We have planned to hold RSC meetings to coincide with our consultant's quarterly visits to ensure that meetings are held in a timely manner.
- 5) March, 1990.

2, 3, 4) Failure of management, radiation safety officer and the radiation safety committee to perform a formal annual review of the radiation safety program.

Response:

- 1) Violation is valid.
- 2) Violation occurred due to oversight of management, RSC and RSO.
- 3) The review of the radiation safety program has been scheduled for the next radiation safety committee meeting to be performed by management, RSO and RSO.

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- 4) In the future, the formal review will be performed at one of the radiation safety committee meetings with the assistance of our consultant.
 - 5) September, 1990.
- 5) Failure of RSC to review training and experience of individuals who handle radioactive material.

Response:

- 1) Violation is valid.
 - 2) Violation occurred due to oversight by the RSC.
 - 3) The RSC will review training and experience records of all individuals who handle radioactive material.
 - 4) The RSC will review credentials of all radioactive material users.
 - 5) July, 1990.
- 6) Violation of package opening procedures.

Response:

- 1) Violation is valid.
 - 2) Violations occurred due to oversight of nuclear medicine technologist and RSO.
 - 3) The technologist has been instructed as to the proper procedures to follow when action levels are exceeded.
 - 4) Survey records will be periodically reviewed to ensure that decontamination procedures are initiated if action levels are exceeded.
 - 5) March, 1990.
- 7) Failure to initiate decontamination procedures.

Response:

- 1) Violation is valid.
- 2) Violation occurred due to oversight of Radiation Safety Officer and nuclear medicine technologist.
- 3) The technologist has been instructed as to the proper procedure to follow when contamination levels are exceeded.
- 4) Area survey records will be reviewed to ensure that decontamination procedures are initiated if action levels are exceeded.
- 5) March, 1990.

- 8) Failure to correctly document molybdenum breakthrough ratios.

Response:

- 1) Violation is valid.
- 2) Violation occurred due to oversight of the nuclear medicine technologist and RSO.
- 3) The technologist has been instructed as to the proper procedure for documenting molybdenum breakthrough concentrations.
- 4) Molybdenum breakthrough records will be periodically reviewed to ensure compliance with regulations.
- 5) March, 1990.

- 9) Failure to perform quarterly linearity evaluations.

Response:

- 1) Violation is valid.
- 2) Violation occurred due to oversight of the nuclear medicine technologist and RSO.
- 3) The technologist has been instructed in the proper procedure for performing linearity evaluations.
- 4) Linearity evaluations will be periodically reviewed to ensure compliance with regulations.
- 5) March, 1990.

- 10) Failure to perform dose calibrator accuracy testing according to license application procedures.

Response:

- 1) Violation is valid.
- 2) Violation occurred due to oversight of the previous consulting firm.
- 3) The license application has been renewed in order to eliminate the restrictive statements which caused this violation.
- 4) Dose calibrator accuracy testing procedures have been reviewed. Future accuracy evaluations will be reviewed to ensure compliance with regulations.
- 5) March, 1990.

- 11) Failure to perform daily gamma camera quality control.

Response:

- 1) Violation is valid.

- 2) Violation occurred due to oversight of the nuclear medicine technologist.
 - 3) The nuclear medicine technologist has been instructed to perform daily floods on the gamma camera. Gamma camera floods are now being performed on a daily basis.
 - 4) Gamma camera quality control records will be reviewed periodically to ensure compliance with regulations.
 - 5) March, 1990.
- 12) Failure to mathematically calculate radiopharmaceutical doses before administration.

Response:

- 1) Violation is valid.
 - 2) Violation occurred due to oversight of the nuclear medicine technologist.
 - 3) The license application has been renewed, eliminating this restrictive obligation.
 - 4) Patient dose records will be reviewed periodically to ensure compliance with regulations.
 - 5) July, 1990.
- 13) Failure to assay patient doses in the dose calibrator prior to administration.

Response:

- 1) Violation is valid.
 - 2) Violation occurred due to oversight of the nuclear medicine technologist and RSO.
 - 3) The nuclear medicine technologist has been instructed to assay all patient doses in the dose calibrator prior to administration. Prescribed dose ranges have been reviewed by the technologist in order that these ranges are not exceeded.
 - 4) Patient dose records will be reviewed periodically to ensure compliance with regulations.
 - 5) March, 1990.
- 14) Failure to document administered radioactive material doses in the patient dose log.

Response:

- 1) Violation is valid.
- 2) Violation occurred due to oversight of the nuclear medicine technologist and RSO.

- 3) The nuclear medicine technologist has been instructed to record administered doses in the patient dose log.
 - 4) Patient dose records will be periodically reviewed to ensure compliance with regulations.
 - 5) April 2, 1990.
- 15) Failure to employ adequate radiation safety devices.

Response:

- 1) Violation is valid.
- 2) Violation occurred due to oversight of the nuclear medicine technologist and RSO.
- 3) Adequate radiation safety equipment has been purchased and installed in the nuclear medicine department.
- 4) The RSO and radiation safety committee shall review equipment and procedures with respect to keeping radiation exposures as low as reasonably achievable.

- B. Failure to provide nursing and housekeeping personnel with radiation safety training.

Response:

- 1) Violation is valid.
- 2) Violation occurred due to oversight of the nuclear medicine technologist and RSO.
- 3) Since the inspection, housekeeping and nursing personnel have been given radiation safety training.
- 4) Nursing and housekeeping personnel will be provided radiation safety training on an annual basis.

- C. Failure to properly calibrate survey instruments.

Response:

- 1) Violation is valid.
- 2) Violation occurred due to oversight of our previous consulting firm.
- 3) All survey instruments have been properly calibrated according to NRC regulations.
- 4) Survey instrument calibration records will be periodically reviewed to ensure compliance with regulations.
- 5) June 1, 1990.

- D. Failure to document survey instrument correction factors deduced from calibration data.

Response:

- 1) Violation is valid.
- 2) Violation occurred due to oversight of our previous consulting firm.
- 3) Survey instruments have been properly calibrated. Any correction factors have been documented.
- 4) Survey instrument calibration data will be periodically reviewed to ensure compliance with regulations.
- 5) June 2, 1990.

- E. Failure to possess proper survey instruments.

Response:

- 1) Violation is valid.
- 2) Violation occurred due to oversight of the nuclear medicine technologist and RSO.
- 3) The nuclear medicine department now possesses a survey instrument capable of measuring dose rates over the range of 1 millirem per hour to 1000 millirem per hour.
- 4) Survey instruments will be periodically reviewed to ensure compliance with regulations.
- 5) June 2, 1990.

- F. Failure of radiation safety officer to sign quality control records.

Response:

- 1) Violation is valid.
- 2) Violation occurred due to oversight of the RSO.
- 3) Recordkeeping as described in 10 CFR 35.50(e) and 10 CFR 35.59 have been signed by the RSO.
- 4) These records will be reviewed by our consultant to ensure that the RSO has signed off on them.
- 5) June 2, 1990.

- G. Failure to properly post radiation areas.

Response:

- 1) Violation is valid.
- 2) Violation occurred due to oversight of the nuclear medicine technologist and RSO.
- 3) The door which accesses the nuclear medicine hot lab and imaging area has been posted with a radiation area sign.

- 4) Caution signs will be reviewed for compliance with current regulations.
- 5) February 8, 1990.

H. Violation of 10 CFR 20.105 (b)(2)-exceeding unrestricted area dose rates.

Response:

- 1) Violation is valid.
- 2) Violation occurred due to oversight of the nuclear medicine technologist and RSO.
- 3) Used generators were moved so that radiation levels were within regulatory limits.
- 4) The storage room is now being surveyed on a weekly basis to ensure that radiation levels do not exceed those levels listed in 20.105.
- 5) February 8, 1990.

I. Failure of the radiation safety officer to ensure that radiation safety activities are being performed in a safe manner.

Response:

- 1) Violation is valid.
- 2) Violation occurred due to oversight of the RSO.
- 3) The radiation safety officer has been performing daily reviews of the nuclear medicine department operations. Daily RSO review of nuclear medicine operations will be conducted until it is assured that records and recordkeeping in the nuclear medicine department are being performed and recorded in a proper manner.
- 5) February 16, 1990.

J. Failure to survey weekly all areas where radiopharmaceuticals are stored.

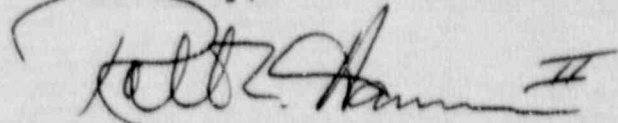
Response:

- 1) Violation is valid.
- 2) Violation occurred due to oversight of the nuclear medicine technologist and the RSO.
- 3) Radiopharmaceutical storage in waste areas are being surveyed on a weekly basis. Radiation dose rate trigger levels have been established for the waste storage area.
- 4) Surveys of the storage area will be reviewed periodically for compliance with regulations.
- 5) February 16, 1990.

We believe that the actions that we have listed above will meet all requirements for compliance with our NRC license.

If any additional information is required, please feel free to contact me at your convenience.

Sincerely,

A handwritten signature in dark ink, appearing to read "Robert L. Hammer, II". The signature is fluid and cursive, with a large initial "R" and a distinct "II" at the end.

Robert L. Hammer, II
Chief Executive Officer

RLH/sm

cc: Regional Administrator
U.S. Nuclear Regulatory Commission
Region II
101 Marietta Street, N.W.
Atlanta, GA 30323

Enclosure: Check #080020