



Veterans  
Administration

June 9, 1981

License No. 02-12726-01



US Nuclear Regulatory Commission  
Region V  
1990 N. California Boulevard  
Suite 202, Walnut Creek Plaza  
Walnut Creek, California 94596

Attention: G. S. Spencer, Director  
Division of Technical Inspection

Gentlemen:

Subject: Response to Enforcement Conference and NRC Inspection

The following corrective actions have been taken to bring into compliance those items of non-compliance presented in the Notice of Violation and discussed in the Enforcement Conference:

A. 10 CFR 20.101(a) An individual in a restricted area received whole body exposure of 1.50 rems during the period of June 24, 1980 to September 29, 1980 and no Form NRC-4 (or an equivalent record) was submitted.

CORRECTIVE ACTION: We did not file a Form NRC-4 (or equivalent record) because it is our desire to keep the exposure of any individual working in the restricted area in any one calendar quarter to less than 1.25 rems of whole body exposure. We plan to operate within the limits of 1.25 rems of whole body exposure per one calendar quarter and do not plan at this time to submit Form NRC-4 (or an equivalent record) to raise the level to 3 rems per calendar quarter.

PREVENTIVE STEP: Monitoring of radiation exposure by Radiation Safety Officer and Radiation Safety/Radionuclide Committee.

FULL COMPLIANCE: Achieved.

B. 10 CFR 20.405(a) No thirty-day report was filed concerning the 1.5 rem exposure of one individual during the period of June 24, 1980 to September 29, 1980.

In Reply Refer To: 649/115

8107150334 810702  
NMS LIC30  
02-12726-01 PDR

CORRECTIVE ACTION: See copy of attached report to USNRC Office of Inspection and Enforcement. Appendix A.

PREVENTIVE STEP: Monitoring of radiation exposure by Radiation Safety Officer and Radiation Safety/Radionuclide Committee.

FULL COMPLIANCE: Achieved.

C. In accordance with 10 CFR 19.13, the individual receiving an exposure of 1.5 rems during the period of June 24, 1980 to September 29, 1980 was not notified by the licensee.

CORRECTIVE ACTION: See attached copy of letter of notification. Appendix B.

PREVENTIVE STEP: Monitoring of radiation exposure by Radiation Safety Officer and Radiation Safety/Radionuclide Committee.

FULL COMPLIANCE: Achieved.

D. License Condition 14. A visiting physician not named on the NRC License and not having written permission from the hospital administrator and Medical Isotope Committee authorized the administration of licensed materials.

CORRECTIVE ACTION: At its meeting on April 1, 1981, the Medical Isotope Committee recommended that no radionuclides be administered to patients while Dr. Gere is absent from the hospital. This policy will remain in effect until License Condition 14 can be met. Hospital administration has stipulated that this recommendation be instituted. See Appendix C.

PREVENTIVE STEP: Radionuclide Committee will oversee policy concerning authorized users.

FULL COMPLIANCE: Achieved.

E. License Condition 15.

E.1. Administration of technetium-99m containing more than one microcurie of molybdenum-99 per millicurie of technetium-99m to patients.

CORRECTIVE ACTION AND PREVENTIVE STEPS: (a) No eluted technetium-99m will be prepared for administration to patients until the results of the assay for molybdenum-99 contamination has been approved by the responsible users.

(b) These assay results will be reviewed by the Radiation Safety Officer and reported to the Radiation Safety/Radionuclide Committee.

FULL COMPLIANCE: Achieved.

E.2. Training of personnel performing tests to detect and quantitate molybdenum-99 breakthrough contamination not performed.

CORRECTIVE ACTION: The Radiation Safety/Radionuclide Committee, at its April 1, 1981 meeting, directed that retraining of the technicians in the detection of molybdenum-99 breakthrough be carried out promptly and documented. See attached documentation of that retraining, Appendix D.

PREVENTIVE STEP: Annual training and monitoring by Radiation Safety Officer and annual review by Radiation Safety Committee.

FULL COMPLIANCE: Achieved.

E.3. Documentation of training of personnel performing molybdenum breakthrough tests was not available.

CORRECTIVE ACTION: See Appendix D.

PREVENTIVE STEP: Annual training and monitoring by Radiation Safety Officer and annual review by Radiation Safety Committee.

FULL COMPLIANCE: Achieved.

F. License Condition 16. Licensee did not use licensed materials in accordance with statements, representations and procedures contained in application dated February 22, 1978 and May 16, 1978, and letter dated April 13, 1979.

F.1. Item 10 of Application. Quarterly linearity tests of dose calibrator not performed.

CORRECTIVE ACTION: See attached copies of linearity tests carried out since the inspection on March 28, 1981. Appendix E.

PREVENTIVE STEP: The Radiation Safety/Radionuclide Committee will review the Radiation Safety Officer's report on this activity.

FULL COMPLIANCE: Achieved (4/27/81).

F.2. Item 17 of Application. Wipe tests not performed.

CORRECTIVE ACTION: Wipe tests are now being performed as required.

PREVENTIVE STEP: Results documented for review by the Radiation Safety Officer.

FULL COMPLIANCE: Achieved.

F.3. Item 7 of Application. Responsibilities of the Radiation Safety/Radionuclide Committee not carried out.

CORRECTIVE ACTION: (a) A copy of the draft notice of violation has been circulated to each member of the committee along with a copy of the license and copy of the duties and responsibilities as described in Item No. 7 of the application dated February 22, 1979. See copy of minutes of committee meeting held May 26, 1981. Appendix F.

(b) A Nuclear Physicist has been appointed to the committee to provide technical assistance.

PREVENTIVE STEP: The minutes of committee meetings will document the necessary monitoring and review to reflect the discharging of responsibility.

FULL COMPLIANCE: Achieved and ongoing.

G. Records of surveys required by 10 CFR 20.201(6) and discharges of radioactive materials into a sanitary sewer system pursuant to 10 CFR 20.303 were not complete.

1. Molybdenum-99/technetium-99m generators and solid waste disposal records were not adequately maintained.

CORRECTIVE ACTION: Records of exposure rates of molybdenum-99/technetium-99m generators packaged to return to the manufacturer and exposure rates of the solid wastes packaged for disposal will be added to our present disposal records.

PREVENTIVE STEP: Disposal records will be reviewed by the Radiation Safety/Radionuclide Committee.

FULL COMPLIANCE: Achieved.

2. Disposal records of periodic releases to sanitary sewer system of microcurie amounts of chromium-51 were not maintained.

CORRECTIVE ACTION: The microcurie amounts of chromium-51 disposed of into the sanitary sewer system are now part of our disposal record.

PREVENTIVE STEP: These disposal records will be reviewed by the Radiation Safety/Radionuclide Committee.

FULL COMPLIANCE: Achieved.

H. Leak wipe tests on sealed sources used as dose calibrator reference sources were not conducted every six months.

CORRECTIVE ACTION: The required leak wipe tests on sealed sources will be conducted every six months by our consultant in nuclear physics. The test was last performed on 3/26/81 and will be repeated as required within each six months.

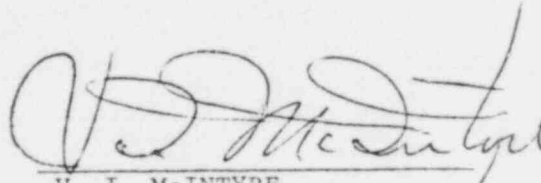
PREVENTIVE STEP: The Radiation Safety/Radionuclide Committee will monitor this procedure for compliance.

FULL COMPLIANCE: Achieved (3/26/81).

As a result of the inspection and the Enforcement Conference, I am certain that the authorized users and members of the Radiation Safety/Radionuclide Committee have a greatly increased awareness of their duties and responsibilities to oversee the use of licensed byproduct material under the conditions of the License.

"I certify that all information contained in this letter, including any supplements attached thereto, is true and correct to the best of my knowledge and belief."

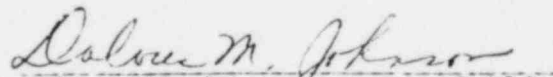
June 9, 1981  
(Date)

  
V. I. McINTYRE  
Medical Center Director

Enclosures  
6 Appendices (A through F)

State of Arizona  
County of Yavapai

The foregoing instrument was acknowledged before me this the 9th day of June, 1981 by V. I. McINTYRE.

  
Dolores H. Johnson, Notary Public  
My Commission Expires June 15, 1982

June 9, 1981

License No. 02-12726-01

US Nuclear Regulatory Commission  
Region V  
1990 N. California Boulevard  
Suite 202, Walnut Creek Plaza  
Walnut Creek, California 94596

Attention: G. S. Spencer, Director  
Division of Technical Inspection

Gentlemen:

Subject: Response to Enforcement Conference and NRC Inspection

The following corrective actions have been taken to bring into compliance those items of non-compliance presented in the Notice of Violation and discussed in the Enforcement Conference:

A. 10 CFR 20.101(a) An individual in a restricted area received whole body exposure of 1.50 rems during the period of June 24, 1980 to September 29, 1980 and no Form NRC-4 (or an equivalent record) was submitted.

CORRECTIVE ACTION: We did not file a Form NRC-4 (or equivalent record) because it is our desire to keep the exposure of any individual working in the restricted area in any one calendar quarter to less than 1.25 rems of whole body exposure. We plan to operate within the limits of 1.25 rems of whole body exposure per one calendar quarter and do not plan at this time to submit Form NRC-4 (or an equivalent record) to raise the level to 3 rems per calendar quarter.

PREVENTIVE STEP: Monitoring of radiation exposure by Radiation Safety Officer and Radiation Safety/Radionuclide Committee.

FULL COMPLIANCE: Achieved.

B. 10 CFR 20.405(a) No thirty-day report was filed concerning the 1.5 rem exposure of one individual during the period of June 24, 1980 to September 29, 1980.

CORRECTIVE ACTION: See copy of attached report to USNRC Office of Inspection and Enforcement. Appendix A.

PREVENTIVE STEP: Monitoring of radiation exposure by Radiation Safety Officer and Radiation Safety/Radionuclide Committee.

FULL COMPLIANCE: Achieved.

C. In accordance with 10 CFR 19.13, the individual receiving an exposure of 1.5 rems during the period of June 24, 1980 to September 29, 1980 was not notified by the licensee.

CORRECTIVE ACTION: See attached copy of letter of notification. Appendix B.

PREVENTIVE STEP: Monitoring of radiation exposure by Radiation Safety Officer and Radiation Safety/Radionuclide Committee.

FULL COMPLIANCE: Achieved.

D. License Condition 14. A visiting physician not named on the NRC License and not having written permission from the hospital administrator and Medical Isotope Committee authorized the administration of licensed materials.

CORRECTIVE ACTION: At its meeting on April 1, 1981, the Medical Isotope Committee recommended that no radionuclides be administered to patients while Dr. Gere is absent from the hospital. This policy will remain in effect until License Condition 14 can be met. Hospital administration has stipulated that this recommendation be instituted. See Appendix C.

PREVENTIVE STEP: Radionuclide Committee will oversee policy concerning authorized users.

FULL COMPLIANCE: Achieved.

E. License Condition 15.

E.1. Administration of technetium-99m containing more than one microcurie of molybdenum-99 per millicurie of technetium-99m to patients.

CORRECTIVE ACTION AND PREVENTIVE STEPS: (a) No eluted technetium-99m will be prepared for administration to patients until the results of the assay for molybdenum-99 contamination has been approved by the responsible users.

(b) These assay results will be reviewed by the Radiation Safety Officer and reported to the Radiation Safety/Radionuclide Committee.

FULL COMPLIANCE: Achieved.

E.2. Training of personnel performing tests to detect and quantitate molybdenum-99 breakthrough contamination not performed.

CORRECTIVE ACTION: The Radiation Safety/Radionuclide Committee, at its April 1, 1981 meeting, directed that retraining of the technicians in the detection of molybdenum-99 breakthrough be carried out promptly and documented. See attached documentation of that retraining, Appendix D.

PREVENTIVE STEP: Annual training and monitoring by Radiation Safety Officer and annual review by Radiation Safety Committee.

FULL COMPLIANCE: Achieved.

E.3. Documentation of training of personnel performing molybdenum breakthrough tests was not available.

CORRECTIVE ACTION: See Appendix D.

PREVENTIVE STEP: Annual training and monitoring by Radiation Safety Officer and annual review by Radiation Safety Committee.

FULL COMPLIANCE: Achieved.

F. License Condition 16. Licensee did not use licensed materials in accordance with statements, representations and procedures contained in application dated February 22, 1978 and May 16, 1978, and letter dated April 13, 1979.

F.1. Item 10 of Application. Quarterly linearity tests of dose calibrator not performed.

CORRECTIVE ACTION: See attached copies of linearity tests carried out since the inspection on March 28, 1981. Appendix E.

PREVENTIVE STEP: The Radiation Safety/Radionuclide Committee will review the Radiation Safety Officer's report on this activity.

FULL COMPLIANCE: Achieved (4/27/81).

F.2. Item 17 of Application. Wipe tests not performed.

CORRECTIVE ACTION: Wipe tests are now being performed as required.

PREVENTIVE STEP: Results documented for review by the Radiation Safety Officer.

FULL COMPLIANCE: Achieved.



F.3. Item 7 of Application. Responsibilities of the Radiation Safety/Radionuclide Committee not carried out.

CORRECTIVE ACTION: (a) A copy of the draft notice of violation has been circulated to each member of the committee along with a copy of the license and copy of the duties and responsibilities as described in Item No. 7 of the application dated February 22, 1979. See copy of minutes of committee meeting held May 26, 1981. Appendix F.

(b) A Nuclear Physicist has been appointed to the committee to provide technical assistance.

PREVENTIVE STEP: The minutes of committee meetings will document the necessary monitoring and review to reflect the discharging of responsibility.

FULL COMPLIANCE: Achieved and ongoing.

G. Records of surveys required by 10 CFR 20.201(6) and discharges of radioactive materials into a sanitary sewer system pursuant to 10 CFR 20.303 were not complete.

1. Molybdenum-99/technetium-99m generators and solid waste disposal records were not adequately maintained.

CORRECTIVE ACTION: Records of exposure rates of molybdenum-99/technetium-99m generators packaged to return to the manufacturer and exposure rates of the solid wastes packaged for disposal will be added to our present disposal records.

PREVENTIVE STEP: Disposal records will be reviewed by the Radiation Safety/Radionuclide Committee.

FULL COMPLIANCE: Achieved.

2. Disposal records of periodic releases to sanitary sewer system of microcurie amounts of chromium-51 were not maintained.

CORRECTIVE ACTION: The microcurie amounts of chromium-51 disposed of into the sanitary sewer system are now part of our disposal record.

PREVENTIVE STEP: These disposal records will be reviewed by the Radiation Safety/Radionuclide Committee.

FULL COMPLIANCE: Achieved.

H. Leak wipe tests on sealed sources used as dose calibrator reference sources were not conducted every six months.

CORRECTIVE ACTION: The required leak wipe tests on sealed sources will be conducted every six months by our consultant in nuclear physics. The test was last performed on 3/26/81 and will be repeated as required within each six months.


PREVENTIVE STEP: The Radiation Safety/Radionuclide Committee will monitor this procedure for compliance.

FULL COMPLIANCE: Achieved (3/26/81).

As a result of the inspection and the Enforcement Conference, I am certain that the authorized users and members of the Radiation Safety/Radionuclide Committee have a greatly increased awareness of their duties and responsibilities to oversee the use of licensed byproduct material under the conditions of the License.

"I certify that all information contained in this letter, including any supplements attached thereto, is true and correct to the best of my knowledge and belief."

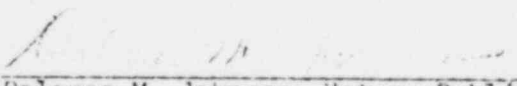
\_\_\_\_\_  
(Date)

  
\_\_\_\_\_  
V. I. McINTYRE  
Medical Center Director

Enclosures  
6 Appendices (A through F)

State of Arizona  
County of Yavapai

The foregoing instrument was acknowledged before me this the 9th day of June, 1981 by V. I. McINTYRE.

  
\_\_\_\_\_  
Dolores H. Johnson, Notary Public

My Commission Expires June 23, 1982  
\_\_\_\_\_