DOCKET FILE

September 18, 1992

United States Nuclear
Regulatory Commission
ATTN: Document Control Desk
Washington, D. C. 20555

Gentlemen:

REPLY TO A NOTICE OF VIOLATION (NRC REPORT NO. 52-01946-07/92-01)

Enclosed please find the response to your notice of violation sent as a result of the inspection carried out at the Medical Sciences Campus on March 12, 1992.

If you need additional information, please let us know.

Sincerely,

José M. Saldaña,
President

Enclosure

c Dr. Steward Ebneter
Regional Administrator
Region II
101 Marietta Street, N.W.
Atlanta, Georgia 30323

[redacted]

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VIOLATIONS AND REPLIES (Report No. 52-01946-07/92-01)

Violation

A. Condition 20 of License No. 52-01946-07 requires, in part, that the licensee conduct its program in accordance with the statements, representations and procedures described in the licensee's application dated August 29, 1988, and licensee's letter dated January 14, 1991.

1. Attachment 11, Subparts 11.1, 11.1.2, and 11.1.6 of the licensee's application states that radioactive waste will be placed in clearly identified receptacles which are appropriately marked with the standard radiation tag or label, and that under no circumstance will radioactive materials be discharged into waste baskets or other containers which would permit the contamination of regular trash.

Contrary to the above, on March 9, 1992, Iodine 125 waste located in Room A-639 of the licensee's research facility was contained in an untagged and unlabeled plastic bag along with non-radioactive waste.

Response

The violation is partially admitted. Although there were radioactive wastes not properly tagged or labeled in Room-A-639; the way this violation is stated shows an apparent contradiction on the side of the NRC Inspector, since he did not have the mechanisms to qualitatively identify the isotope involved, using a GM meter only. As a matter of fact, it took us several days to identify the composition of the radioactive wastes using our sophisticated laboratory instrumentation and techniques.

Corrective Actions Taken

An access control lock was installed in Room A-639. It will prevent the entrance of persons not having access to the lock code.

In addition, the authorized use of the laboratory has been specifically assigned to a prospectus user, who will be responsible for the activities carried out in it.

Violation

2. Attachment 9.1 of the licensee's application designated laboratories A-617A, R-632, R-633, R-643, R-646, R-663, R-688, and R-689, as authorized places of use and as temporary storage locations for licensed material on the sixth floor of the licensee's research facility. Licensee's letter dated January 14, 1991, designated a room located in the basement of the main building for storage of waste associated with research activities.

   Contrary to above:

   a. As of March 9, 1992, the licensee was storing Iodine-125 waste in Room A-639 on the sixth floor of the licensee's research facility, an unauthorized place for use or temporary storage of this licensed material.

   b. As of March 9, 1992, the licensee had been storing Phosphorus-32 waste in Room B-330, an unauthorized waste storage area.

Response

a. This violation is partially admitted due to the same criteria we used to explain the apparent contradiction in violation A-1.

b. This violation is admitted. The LLW was removed almost immediately and was taken to the storage room authorized in the license.

Corrective Action Taken

The persons responsible for the violation were briefed about their responsibilities in our license commitment and the possibility of their permit been canceled in case of violation repetition.

Violation

3. Attachment 10.4, Subparts B.6 and B.7 of the licensee's application states that containers in which radioactive materials are being stored or transported shall be appropriately market with labels or decals identifying the nuclide, the activity within the container, the dated of the activity estimate, and the initials of the responsible custodian.

Contrary to the above, on March 9, 1992, the labels on sealed waste packages containing Carbon 14, Sulphur 35 and Tritium in Room A-643, the labels on sealed waste packages containing Phosphorus 32 in Room B-330, and the labels on a sealed waste plastic bag containing Tritium in Room A-617, did not identify the activities within the containers, the dates of the activity estimates and the initials of the responsible custodian.

Response

This violation is admitted. The authorized users responsible for the activities conducted in laboratories A-643, B-310 and A-617 were briefed once more on these specific license conditions. Corrections were made promptly by adding the missing information to the packages.

Corrective Action Taken

The Radiation Safety Office will offer a short course covering more deeply the details of our license conditions and requirements, so that users could be more aware of their responsibilities pertaining to radiation safety.

Violation

8. 10 CFR 35.70 (a) requires that a licensee survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use of administered.

   Contrary to the above, on October 11 and 17, 1991, the licensee did not survey with a radiation detection instrument at the end of the day the nuclear medicine laboratory, and area where radiopharmaceuticals were routinely prepared for use and administered.

Response

This violation is admitted. There was a misunderstanding between the personnel working in the Hot Room and the Radiation Safety Office Staff in relation to the survey of the laboratory in certain days. The situation gave rise to the violation.

Corrective Actions Taken

The technical personnel from the Nuclear Medicine Department was made aware of the violation. They agreed that the daily surveys were separate from those performed weekly by the RSO. Once the duties of each one were identified, the violation would not be repeated.

Vio'ation

C. 10 CFR 35.70(d) requires that a licensee establish radiation dose trigger levels for the daily and weekly surveys conducted in areas where radiopharmaceuticals are routinely prepared for use or administered and areas where radiopharmaceuticals or radiopharmaceutical waste is stored, and that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds a trigger levels but failed to notify the Radiation Safety Officer if a dose rate exceeds a trigger level.

Contrary to the above, on September 12, October 4 and 24, and November 2, 1991, licensee personnel, while performing surveys of the nuclear medicine laboratory, obtained survey results which exceeded the licensee's established trigger levels but failed to notify the Radiation Safety Officer.

Response

This violation is admitted. The lack of specific instructions for the nuclear medicine technologists regarding this requirement gave rise to this violation. One comment that we could add is that probably the technologists thought that small differences between actual exposure and trigger levels could be ignored without further actions taken.

Corrective Action Taken

Nuclear medicine technologists were instructed in detail on the need to comply with this part of the Regulations. Besides, trigger levels were revised to determine what changes should be made to reflect actual situations in the Hot Room, in agreement with 10 CFR 20.102 (a) and our commitment with ALARA philosophy.

Violation

D. 10 CFR 35.50 (b) (3) requires, in part, that a licensee test each dose calibrator for linearity over the range of its use between the highest dosage that will be administered to a patient and 10 microcuries.

Contrary to above:

1. The licensee's dose calibrator linearity test performed on July 22, 1991 covered only the range between 138 millicuries and 14 microcuries while the highest dosage that the licensee administered to a patient was 146 millicuries.

2. The licensee's calibrator linearity tests performed on October 30, 1991 and January 27, 1992, covered the ranges only down to 12 and 11 microcuries, respectively.

Response

These two (2) violations are admitted. The person responsible for performing dose calibrator linearity test was made aware of the violations.

Corrective Actions Taken

The linearity test due on June 1992 was performed using a maximum of 200 millicuries of Tc-99m and the sample was decayed to less than 10 microcuries to cover the lower portion of the straight line. We do not expect to administer doses higher than 200 mCi.