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December 4, 1985

Mr. Thomas T. Martin, Director
Division of Radiation Safety
and Safeguards
US Nuclear Regulatory Commission
Region I
631 Park Avenue
King of Prussia, PA 19406

Reference: Inspection No. 85-01, License Nos. 20-17131-01,03,04

Dear Mr. Martin,

In this letter I wish to respond on behalf of this institution to your inspection summary dated 5 November, 1985.

We appreciate the detailed inspection, the flexibility of the Commission, and the opportunity this has given us to improve our radiation safety program.

We confirm the understandings previously rendered to you verbally that: (1) Lead vial shields with screw-on shield tops are now provided in the Radiopharmacy and in Nuclear Medicine in order to reduce fingertip exposures while drawing doses; (2) The log book for the Shepherd irradiator in the Tissue Typing Laboratory will be keyed to last names; and (3) Radioiodine therapy patients will have placed on their terminal survey record a comment indicating that at discharge they contained less than 30 mCi or that the measured exposure rate at 1 meter was less than 6 mR/hr.

In the following paragraphs, we respond on an item by item basis to the detailed Notice of Violations, Appendix A, of your letter.

A. Security in an unrestricted area. The Thyroid laboratory in the E-F 2nd area has been moved to the 10th floor of our Biosciences Research Building, hence there is no longer any need to store low-level radwaste in the hall of the F-2nd area observed by the inspector. An adjacent lab is expanding to use the area, and keyed locks will be placed on the doors in order to avoid entry by the general public. We do wish to note that this laboratory is in an area not normally in the paths of any persons not associated with the laboratory, and that both doors had posted an easily visible radiation caution sign.

The critical necessity for maintaining a locked door to the thyroid uptake probe room at all times when not occupied or supervised by badged radiation workers has been reviewed with all users of the room. We will also make monthly unannounced checks of the door and record the results thereof in an effort to ensure that this directive of the Radiation Safety Office is complied with at all times.

B. Proper testing for molybdenum-99 activity in a generator eluant. The inspectors accurately depicted a nuclear medicine technologist who did not know to use the correction factor for breakthrough activity. However, we believe no hazard to patients existed because the numbers recorded by him in the logbook matched those for acceptably negligible breakthrough activity when properly tested. In other words, he has been incorporating the correction factor without knowing that he was. This is an educational deficiency which must be corrected. We propose to do this by requiring: (1) All nuclear medicine and radiopharmaceutical technologists will have a quarterly didactic session vis-a-vis use of their instruments, particularly the dose calibrators, and that attendance be mandatory and recorded; (2) The chief technologist and chief radiopharmacist have been directed to maintain a log by name of all authorized and instructed users, the instruction to be verified by signature, so that there should be an additional constraint preventing future such violations; and (3) No person may use the dose calibrators without completing a written examination on operating theory and practice.

C. We have reviewed with the chief of Security our previous two written understandings that Security personnel do not handle radioactive packages except in circumstances of life-saving emergencies. Their procedures explicitly state that Security guards will direct or accompany the vendor/carrier delivery man to the Radiopharmacy but not carry the packages themselves. See also (B).

D. 1. Long-term calibration check of dose calibrators. The Radiopharmacy personnel had indeed failed to log observed calibration counts during three weeks for the Cesium-137 source and for two weeks for the Cobalt-57 source; similarly, there was a three week gap in Cobalt-57 source plotting in Nuclear Medicine. Punctual recording of such observations is most difficult to assess on the basis of a quarterly audit. It would seem full compliance is totally dependent upon repetitive training and closer supervision of the individuals doing the logging. We anticipate the measures described in B above will suffice to correct these record keeping deficiencies. In addition, the Radiation Safety Office will require each unit supervisor to submit a monthly statement saying that the proper calibrations have been done and logged.

It is our interpretation of Regulatory Guide 10.8, Appendix D, that radium may be used as a long-lived standard. Our professional and technical nuclear medicine personnel do use radium as such a standard, and maintain a log thereof. Finding that they were not using Cesium-137 would appear not to be a violation of license conditions; it is not clear why the radium log tables were not shown to the inspector.

D. 2. We will henceforth ensure that detailed audits include reviews of the type conducted by the NRC inspectors. We anticipate that violations should be minimized with modifications of our audit procedures, procedural reporting changes noted in the previous paragraph, and our pursuit of an amendment to discontinue uniquely numbered package seals. Nevertheless, we acknowledge the limitations of quarterly audits to detect sporadic deviations occurring on a daily basis.

Our earlier decision to include uniquely numbered package seals for shipments via common carrier was initiated specifically for packages shipped several miles to the Mt. Auburn and Faulkner Hospital. These shipments have since been terminated. At present we use common carriers to deliver packages to the New England Deaconess and Beth Israel Hospitals, each less than one quarter mile distance. We believe that the uniquely numbered package seals do not now afford significant extra protection for the package or the public, and under separate cover we apply for an amendment to our license to permit discontinuance of their use.

D. 3. Henceforth we will include in the Radiopharmacy package receipt log a note of exposure rates made at 3 feet and at package surface for received packages.

D. 4. Daily surveys for contamination in the Radiopharmacy will continue to be conducted and documented in writing. The performance of these will also be verified by a monthly report from the director of the Radiopharmacy.

We anticipate that these efforts should correct the observed violations and deviation. Should there be questions in this regard, please call or write my office.

Sincerely yours,

David E. Drum

David E. Drum, M.D., Chairman
Radiation Safety Committee

DED:JBM