

20 York Street, New Haven, CT 06504

November 29, 1990

Ronald R. Bellamy, Chief Nuclear Materials Safety Branch U. S. Nuclear Regulatory Commission Region 1 475 Allendale Road King of Prussia, PA 19406

> Re: License #06-00B19-03 Docket #030-01244

Bentlemen:

Subject: Reply to Notice of Violation, Dated October 3, 1990 Relating to Routine Inspection No. 030-01244/90-001.

Yale-New Haven Hospital has taken the following actions to correct the apparent violations noted in the NRC inspection conducted by Betsy Ullrich and Craig Gordon, on August 1 and 2, 1990. The steps taken in each case identified in Appendix A of your letter dated October 3, 1990 are noted below.

A. Loss of licensed material on April 14, 1990.

In our report of this incident to the NRC, dated May 14, 1990, corrective actions taken to prevent a recurrence were detailed concerning the Xenon-133 and Thallium-201 vials incident. Since that date these corrective measures have prevented a reoccurrence.

B. 1. Daily and weekly surveys

These apparent violations were identified by the Radiation Safety Officer during his monthly review of the Nuclear Medicine Department. The violations were not due to one individual but were spread out among many individuals. At that time, verbal warnings from the RSD and Chief Technologist were issued to the responsible personnel. A weekly survey has not been missed since the RSD identified this problem. We believe that this demonstrates effective correction action on the part of our Radiation Safety Staff.

To further improve compliance, a new policy of written warnings has been initiated. Each violation noted by the RSO's review is written on a form. A copy of the form is given to the employee and a copy is placed in their personnel file. These forms will be reviewed annually during the employee's performance appraisal. The records will be used to help determine the employee's annual merit salary increase.

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Yale-New Haven Hospital is a large institution. There are four separate imaging areas used for Nuclear Medicine studies which are served by a centralized hot lab. These areas contain 22 rooms, some of which require multiple survey points. The number of NRC required daily, weekly, and weekend measurements and the new NRC documentation requirements make this a formidable task under the best of circumstances.

A review of our survey records will demonstrate that greater that 98% of all required surveys are performed. We believe that this is a commendable performance. An occasional missed weekend or weekly imaging room survey does not represent a serious breakdown in procedures nor a significant risk to the health and safety of the public or hospital personnel.

## 2. Patient dose calibration

Yale-New Haven Hospital performs approximately 60 diagnostic studies each weekcay. In order to handle this demand efficiently, diagnostic patient doses are precalibrated each morning in the dose calibrator to deliver the correct dose to the patient at the appointment time. If a patient is more than 30 minutes late for their appointment, the diagnostic dose is adjusted and recalibrated to the correct amount.

If the dose is Technetium-99m, a half hour delay in delivering the dose will mean a 6% difference in the precalibrated dose which is within the 10% commitment in our license application dated December 13, 1984. In the license application it says: "The preparation and assay of patient doses are done in the morning. No dose will be used if the activity is greater than +/- 10% of the standard."

This procedure has the approval of Dr. Hoffer, the Director of Nuclear Medicine. The hospital believes that this is not a violation of our license commitments.

C. Dose measurement and initials on records

Yale-New Haven Hospital will modify our procedures to record and initial the uncorrected morning precalibration measurement on the patient dose label. Compliance with this requirement will be achieved before January 1, 1991.

D. Yale-New Haven Hospital will modify our moly assay recording forms to include the actual Molybdenum-99 and Technetium-99m activities as well as the derived microcurie/millicurie result. Dompliance with this requirement will be achieved before January 1, 1991.

If any further information regarding this reply is necessary, please contact Michael J. Bohan, Radiation Safety Officer, at (203) 785-2950.

Norman /G/. Roth

Asst. Vice President

Michael 3. Bohan Radiation Safety Officer/

Health Physicist

cc: Dr. Robert Schulz, Chairman, Radiation Safety Committee Dr. Paul Hoffer, Director of Nuclear Medicine Virginia Roddy, Director of Medicolegal Affairs