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APR 05 1988

Docket No. 030-11155
License No. 52-16033-01

Hospital Metropolitano
ATTN: Ms. R. Esteras
Administrator
P.O. Box EH - Caparra Heights Station
San Juan, PR 00922

Gentlemen:

SUBJECT: ENFORCEMENT CONFERENCE SUMMARY
(NRC INSPECTION REPORT NO. 52-16033-01/88-01)

This letter refers to the Enforcement Conference held at our request on March 4, 1988. This meeting concerned activities authorized for your Hospital Metropolitano facility.

The issues discussed at this conference related to violations concerning the use and storage of radioiodine solutions, quality assurance testing of the dose calibrator, survey meter calibrations, laboratory surveys and monitoring, management and Radiation Safety Committee oversight, and training.

A list of attendees, a summary, and Regulatory Guide 8.20 are enclosed. We are continuing our review of these issues to determine the appropriate enforcement action.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and its enclosures will be placed in the NRC Public Document Room.

Should you have any questions concerning this matter, please contact us.

Sincerely,

J. Nelson Grace
Regional Administrator

Enclosures:
1. List of Attendees
2. Enforcement Conference Summary
3. NRC Reg Guide 8.20, 9/79

bcc w/encl: 1 and 2: (See page 2)

1/1

IE07

bcc w/encls 1 and 2:
J. Lieberman, DCE
G. R. Jenkins, EICS
Document Control Desk
Commonwealth of PR
G. Sjoblom, IMNS
W. E. Cline, DRSS
J. P. Stohr, DRSS

RII	RII	RII	RII	RII	RII
EKline:	JPotter	WCline	JPStohr	GJenkins	MErnst
3/23/88	3/23/88	3/29/87	3/31/88	3/30/88	3/ /88

4/5

ENCLOSURE 1

List of Attendees

NRC Attendees: W. E. Cline, Chief, NMSS Branch, DRSS, RII
E. B. Kline, Radiation Specialist, DRSS, RII
N. L. McElroy, Chief, Medical and Academic Section, INMS, HQ

Licensee Attendees: R. E. Marcias, MHA, Administrator
S. Sostre, M.D., Nuclear Medicine Physician
J. M. Diaz, M.D., Nuclear Medicine Physician
P. J. Montes, M.S., Radiation Safety Officer

ENCLOSURE 2

Enforcement Conference Summary

The violations identified during the January 13, 1988, NRC Inspection under License No. 52-16033-01 were individually reviewed and discussed in-depth. Based on new information submitted by the licensee, three of the violations are under re-evaluation by NRC management. A subsequent follow-up inspection on March 3, 1988, of certain unresolved items regarding activities in the Nuclear Medicine Department revealed four (4) additional apparent violations. These four violations were acknowledged by the licensee at the Enforcement Conference on March 4, 1988.

The following is a brief synopsis of violations currently under re-evaluation by NRC management:

The licensee failed to post access doors with radiation signs. The licensee contends that the appropriate radiation signs were posted when the area in question became a radiation area during the clinical usage of radioactive materials. Also the licensee, since the inspection, has permanently posted the Hot Lab access door. Based on this new information and licensee action, the violation is being re-evaluated.

The licensee failed to conduct initial and annual radiation safety training for security personnel. The licensee contends that security personnel have no involvement in the receipt of radioactive materials at the hospital. Radioactive material is delivered directly to the Nuclear Medicine Department by the dispatching radiopharmaceutical company. Based on this new information, the violation is being re-evaluated.

The licensee failed to mathematically correct dosage readings for dose calibrator linearity errors, and failed to repair/replace the dose calibrator. The licensee contends that the errors were due to the failure of the nuclear medicine technologist to push the correct dose calibrator buttons during the linearity test. In January 1988, the licensee tested the dose calibrator for linearity and found the errors to be within acceptable limits. Further discussions revealed a failure of the licensee to initially calibrate the linearity of the dose calibrator correctly. Based on this new information, the violation is being re-evaluated.

Based on follow-up inspection activities on March 3, 1988, the following additional apparent violations were identified:

The licensee failed to initially determine the efficiency of a survey instrument and check the efficiency every three months. Also the licensee failed to record the surveys in appropriate units.

The licensee failed to properly calculate thyroid uptakes (bioassays) for individuals who prepared and handled therapeutic quantities of radioiodine solutions.

The licensee failed to monitor, upon receipt, packages of radioactive material for contamination.

The licensee failed to properly store therapeutic quantities of radioiodine in a proper container and under a fume hood.

The licensee felt that the majority of violations were due to a failure of the licensee to devote appropriate time and effort to the discipline.

The NRC attendees discussed the two critical areas of radiation safety and concern in the hospital's Nuclear Medicine Department: (1) the use of therapeutic quantities of iodine-131, and (2) the proper checking and testing of the dose calibrator. In particular, the majority of the violations encompassed these two areas. The additional violations (3 out of 4 violations) also concerned the use of therapeutic radioiodine. Therefore, the overall safety significance of all of the violations increased due to new findings concerning therapeutic radioiodine and dose calibrator violations.

The licensee has implemented certain corrective actions as discussed during the Enforcement Conference. The licensee has ordered an area radiation monitor (Primalert) to be installed in the Hot Lab. The device will alert the radiation worker(s) of elevated radiation levels. The licensee also ordered a survey meter (Victoreen) which will allow radiation surveys capable of detecting radiation levels ranging between 0.01 mR/hr and 1,000 mR/hr. This will alleviate the licensee's need to use their current Victoreen Model 740F survey meter which is not calibrated and is currently inoperable. The licensee plans to order a survey meter with a pancake probe for measuring laboratory swipes for contamination. Currently the licensee has been utilizing a device at another facility for measuring contamination. This will allow such measurements to be conducted in-house.

J. M. Diaz, M.D., Nuclear Medicine Physician, stated and emphasized at the Enforcement Conference that he will take a personal interest in all regulated Nuclear Medicine activities and actively pursue involvement in these activities on a daily basis. In particular, Dr. Dias assured the NRC that bioassays for all individuals who handle therapy doses of iodine-131 would be performed and calculated correctly, and according to the I-131 bioassay guide given to the licensee (an additional copy is provided, Enclosure 3) by the NRC attendees during the Enforcement Conference. Also, Dr. Diaz stated that the licensee will amend the hospital's license to reflect a new trigger level for bioassay testing at 30 mCi usage rather than 1 mCi. The licensee also committed to improved training of the current nuclear medicine technologist (individual A.C.) in the areas of general radiation safety and quality assurance of the dose calibrator. P. J. Montes, M.S., Radiation Safety Officer, committed to purchasing the required barium-133 and cobalt-57 sources for accuracy tests on the dose calibrator.

In summary, the licensee stated that more involvement and time will be spent by the Nuclear Medicine Physicians and Radiation Safety Officer in correcting the identified violations and preventing their recurrence.