

MAR 30 1993

Docket Nos. 030-00571 and 030-19502
License No. 52-13598-01 and 52-13598-03

Hospital Ramón E. Betances
Centro Médico de Mayagüez
ATTN: Mr. Angel Franceschi
Executive Director
410 Road No. 2
Mayagüez, PR 00680-1522

Gentlemen:

SUBJECT: NRC INSPECTION REPORT NOS. 52-13598-01/92-02 and 52-13598-03/92-02

Thank you for your response of March 2, 1993, to our Notice of Violation issued on January 5, 1993, concerning activities conducted under NRC License Nos. 52-13598-01 and 52-13598-03.

We have evaluated your response and found that, for the reasons stated in the Enclosure to this letter, it does not meet the requirements of 10 CFR 2.201. We request that you submit to this office, within 30 days of the date of this letter, a supplemental response providing the information requested in the "Action required by licensee" sections of the Enclosure.

We appreciate your cooperation in this matter.

Sincerely,

dfc Original Signed By
D. M. Collins
J. Philip Stohr, Director
Division of Radiation Safety
and Safeguards

Enclosure:
Evaluation of Licensee
Response

cc w/encl:
Commonwealth of Puerto Rico

bcc w/encl:
Document Control Desk

*See previous concurrence

RII:DRSS	RII:DRSS	RII:DRSS	RII:DRSS	RII:EICS
*	*	*	*	*
HBermúdez	CHosey	DCollins	BMallett	GJenkins
3/ /93	3/ /93	3/ /93	3/ /93	3/ /93

9304130033 930330
PDR ADOCK 03000571
C PDR

IE07

MAR 29 1993

Docket Nos. 030-00571 and 030-19502
License No. 52-13598-01 and 52-13598-03

Hospital Ramón E. Betances
Centro Médico de Mayagüez
ATTN: Mr. Angel Franceschi
Executive Director
410 Road No. 2
Mayagüez, PR 00680-1522

Gentlemen:

SUBJECT: NRC INSPECTION REPORT NOS. 52-13598-01/92-01 and 52-13598-03/92-01

Thank you for your response of March 2, 1993, to our Notice of Violation issued on January 5, 1993, concerning activities conducted under NRC License Nos. 52-13598-01 and 52-13598-03.

We have evaluated your response and found that, for the reasons stated in the Enclosure to this letter, it does not meet the requirements of 10 CFR 2.201. We request that you submit to this office, within 30 days of the date of this letter, a supplemental response providing the information requested in the "Action required by licensee" sections of the Enclosure.

We appreciate your cooperation in this matter.

Sincerely,
ORIGINAL SIGNED BY
J. PHILIP STOHR

J. Philip Stohr, Director
Division of Radiation Safety
and Safeguards

Enclosure:
Evaluation of Licensee
Response

cc w/encl:
Commonwealth of Puerto Rico

bcc w/encl:
Document Control Desk

RII:DRSS	RII:DRSS	RII:DRSS	RII:DRSS	RII:ECIS
HBermúdez	CHasey	DCollins	BMallett	GGenkins
3/24/93	3/24/93	3/26/93	3/29/93	3/29/93

ENCLOSURE

During an NRC inspection conducted on November 30 and December 1, 1992, violations of NRC regulatory requirements were identified. The inspection findings were documented in a Notice of Violation (Notice) issued to the licensee on January 5, 1993. The licensee responded to the Notice in a letter dated March 2, 1993. The NRC's evaluation of the licensee's response is as follows:

Restatement of Violation I.A.2.a:

Condition 15 of License No. 52-13598-03 requires, in part, that licensed material be used and possessed in accordance with the statements, representations and procedures described in the license application dated January 24, 1992, and in the licensee's letters dated February 24, March 18, and March 25, 1992.

Item 9.2 of the license application requires, in part, that the licensee establish and implement the Model Procedure for Calibrating Survey Instruments published in Appendix B to Regulatory Guide 10.8, Revision 2.

Item 7 of Appendix B to Regulatory Guide 10.8, Revision 2, states, in part, that a single point on a survey meter scale may be considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than 10 percent.

Contrary to the above, on December 1, 1992, the licensee's TBM-3 survey instrument which was used to perform required radiation surveys was not successfully calibrated, in that during its November 18, 1992 calibration, the indicated exposure rate differed from the calculated exposure rate by 11 percent at various points on several scales of this instrument, and by 33 percent on the X1 scale. The licensee had assigned an overall correction factor of 11 percent to this instrument.

This is a Severity Level IV violation (Supplement VI).

Summary of licensee's response to Violation I.A.2.a:

The licensee states that there appears to be a mistake in the violation as stated in the Notice. The licensee indicates that the referenced survey instrument calibration resulted in differences between 1.11 and 1.26 percent, and that an overall calibration factor of 0.85 was assigned in order to be within the 20 percent allowed by 10 CFR 35.51.

NRC evaluation of licensee's response to Violation I.A.2.a:

The NRC agrees the overall correction factor for the instrument should have been 15%. The record provided by the licensee shows average differences between the indicated and calculated exposure rates of -14% and -20% on the X100 and X10 scales, respectively.

The NRC concludes that the violation occurred as stated in the Notice, except that the overall correction factor should have been 15%, not 11%.

Action required by licensee:

The licensee should specify the corrective actions planned to prevent recurrence of the violation to include adjustment of the survey instrument readings when readings differ by more than 10% from the actual dose rate.

Restatement of Violation I.A.2.b:

Item 8.a of Appendix B to Regulatory Guide 10.8, Revision 2, states, in part, that meters on which the user selects a linear scale must be calibrated at no less than two points on each scale. The points should be at approximately 1/3 and 2/3 of full scale.

Contrary to the above, the calibrations of the licensee's TBM-3 survey instrument performed on May 1 and November 18, 1992, were not performed at two separated readings on the X1 scale.

This is a Severity Level IV violation (Supplement VI).

Summary of licensee's response to Violation I.A.2.b:

The licensee indicated that calibration of such instrument in the X1 scale is very difficult because even background readings affect the accuracy.

NRC evaluation of licensee's response to Violation I.A.2.b:

The licensee indicated that they do not have suitable equipment to calibrate survey instruments in the near-background range.

Action required by licensee:

The licensee should specify the corrective actions planned to prevent recurrence of the violation. This should include alternate means for survey instrument calibrations which would ensure compliance with regulatory requirements.

Restatement of Violation I.A.2.d:

Item 11 of Appendix B to Regulatory Guide 10.8, Revision 2, states, in part, the necessary information to be included in survey instrument calibration records. Item 11.c specifies that the calibration record will include, for each calibration point, the calculated exposure rate, the indicated exposure rate, the deduced correction factor, and the scale selected on the instrument.

Contrary to the above, the records of the licensee's Xetex Model 305B survey instrument calibrations performed on May 1 and November 18, 1992, did not include the indicated exposure rate and the deduced correction factor.

This is a Severity Level V violation (Supplement VI).

Summary of licensee's response to Violation I.A.2.d:

The licensee states that there appears to be a mistake in the violation as stated in the Notice. The licensee indicates that the survey instrument was calibrated on February 28 and November 18, 1992, not on May 1, 1992. The licensee also indicates that the calibration records included the indicated exposure rates, and that since readings were within accepted values, no correction factor was given. The licensee further stated that a form will be designed to include all information required to be maintained by the licensee's procedure.

NRC evaluation of licensee's response to Violation I.A.2.d:

The NRC agrees that the correct survey instrument calibration date should have been February 28, 1992, and that the records included the indicated exposure rates. NRC records will be adjusted to reflect these changes in the Notice of Violation.

Action required by licensee:

None.

Restatement of Violation I.B:

10 CFR 35.320 requires, in part, that a licensee authorized to use byproduct material for radiopharmaceutical therapy have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirems per hour to 100 millirems per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirems per hour.

Contrary to the above, between April and November 1992, the licensee did not possess a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirems per hour. Specifically, the licensee possessed a portable radiation measuring and detection survey instrument capable of measuring up to 17 millirems per hour.

This is a Severity Level IV violation (Supplement VI).

Summary of licensee's response to Violation I.B:

The licensee does not deny the violation but states that there was a survey instrument with the required capability located in the RSO's office, and that the nuclear medicine staff is now aware of the availability of the instrument in case of need.

NRC evaluation of licensee's response to Violation I.B:

Inherent in the requirement that the licensee possess a survey instrument with a specified capability is that the instrument be available for use. The inspection revealed that, during the period in question, nuclear medicine

personnel: (1) were not aware of the existence of the referenced instrument, (2) routinely needed an instrument with the required capability to perform radiation surveys of incoming packages and areas with elevated radiation levels and, (3) instead used an inadequate instrument, incapable of measuring the expected radiation levels, to perform required radiation surveys and produce unacceptable survey results. The licensee also stated that they have acquired a new survey instrument with the required capability. The NRC concludes that the violation occurred as stated in the Notice.

Action required by licensee:

None.

Restatement of Violation II.C:

10 CFR 35.634(f) requires, in part, that the licensee retain a record of each spot-check required by paragraphs (a) and (d) of this section for three years. The records must include, among others, an assessment of the timer linearity and constancy and the calculated on-off error.

10 CFR 35.632(g) states, in part that the licensee shall retain a record for each calibration for the duration of the teletherapy unit source. The record must include, among others, an assessment of the timer linearity.

Contrary to the above, the licensee's monthly spot-check records for the period between February and November 1992 did not include an assessment of the timer linearity and constancy and the calculated on-off error, and the record of the full calibration performed on February 15, 1992, did not include an assessment of the timer linearity.

This is a Second Repeat Severity Level V violation (Supplement VI).

Summary of licensee's response to Violation II.C:

The licensee stated that records showed an OK for constancy, linearity and on-off error.

NRC evaluation of licensee's response to Violation II.C:

Based on discussions between the inspector and licensee personnel, it is the NRC's understanding that the licensee's response to this violation is in error, and that the licensee will resubmit a response.

Action required by licensee:

The licensee should follow the instructions contained at the end of the Notice when preparing its response, providing information regarding admission or denial, corrective steps and date of full compliance.