CENTRO MEDICO DE MAYAGUEZ

DEPARTAMENTO DE SALUD
MAYAGUEZ, PUERTO RICO

BO. SABALOS
CARRETERA NUM. 2
KM. 157
MAYAGUEZ, P.R. 00708
TEL. 834-8686

February 12, 1991

United States
Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 2 555

Subject: Reply to a "Notice of Violation"
Inspection Report No.
52-13598-01/90-02

Gentlemen:

Your "Notice of Violation" letter dated on January 23, 1991 was received on January 30, 1991 at Mayagüez Medical Center. Each item indicated in your report has been evaluated with the corresponding responsible personnel involved. This represents our reply to each item indicated.

Item A: The room radiation monitor was inoperable between Oct. 31, 1989 and November 1, 1990. A portable survey instrument was available at the operators console to be used in case of emergency. The technologist is aware if the source exposure mechanism has the source exposed, because he sees at the T.V. monitor the "red extractor bar coming out" of the head cover. Also the operator can see thru the T.V. monitor, as well as thru the entrance door the red warning pilot light at the machine arc frame indicating the beam condition. The technologist were instructed to use the survey meter in cases of emergency or suspicion of a unit malfunction.

The room radiation monitor is operational since November 1990. Personnel has been oriented to enter the room with the survey meter in case of radiation monitor malfunction. In compliance since November 1990.

Item B: Replacement of the inoperable radiation monitor was made by November 1990. A purchase order for a new monitor was made on Jan. 30, 1991 in order to have at all times a back-up instrument.

The delay in replacing the monitor was due to economic reasons in the hospital. At the present time we are in full compliance.

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Item C: The annual full calibration was not performed on Sept. 1989 as required because our calibration equipment was in the states for its own calibration and a delay in delivery existed. The monthly spot checks were carried out using borrowed instrumentation from other institution.

This situation no longer exist and calibration measurements will be carried at intervals not exceeding one year. In compliance at present time.

Item D: The management representative was not present in two Radiation Safety Committee Meetings but all other members represented a quorum for our purposes. The managements is aware of all business discussed because copy of the meeting minutes are distributed to each member, the hospital management and the Faculty Quality Assurance Committee. The administration is naming an alternate management representative to avoid future meeting abcenses. We will be in compliance for next meeting.

Item E: The R.S.O. explains the instruments calibration situation as follows. The Nucor Model CS-40A was only use as a back-up survey instrument to verify at the teletherapy unit if the source was "on" or "off". It was an old ionization chamber appropriate to indicate the presence of high radiation levels. This instrument has been replaced and evaluation for possible repair is under consideration.

The Xetex Model 305B survey meter is a new instrument used at the nuclear medicine laboratory. The sticker or chart attached to the instrument had a correction factor of 0.87 when the correct number should be 0.77 in order to be within the 20 percent difference. That was a mistake made when the chart was attached.

At the present time the Xetex-305B is re-calibrated and the correct data obtained. In compliance at the present time.

Item F: Records of calibration for the Nucor-CS-40 were not retained because this instrument had very limited use as indicated in item E. Only the correction chart was attached due to the short expected use of the instrument.

Afterwards all calibration records will be retain for three years.

Item G: Records of each full calibration of the teletherapy unit were retained but some data was not included as required. For example the difference between the last full calibration and the mathematically correction for radioactive decay. The reason for this discrepancy was the obvious nature of the data availabe that demonstrated not a significant variation from the accepted values. Future calibrations will follow the requirements of 10CFR 35.632 (a) (b) (q).

Item H: Monthly spot-checks records were retained but all required information was not specifically detailed. As in item G above, future spot-check records will be kept as required.

As discussed with the inspectors after the visit this Government Hospital has a heavy load of indigent cancer patients receiving treatment daily. Some of the violations indicated are a direct result of the amount of work to be done daily with a limitation of human resourses and equipment. Safety is always our concern and we look forward to keep our safety record the best possible within our limitations.

At present time none of the activities carried out represents a risk of radiation exposure. The record-keeping activities will receive special attention by all the radiotherapy staff in order to fullfill the details involve in the regulations.

Please advise us if the reply to each notice of violation satisfies the requirements.

Sincerely,

Angel Franceschi

Angel Franceschi, MSHA
Hospital Administrator