



Oficina
del Rector

Universidad de Puerto Rico
Recinto de Ciencias Médicas

May 27, 2011

Marc C Ferdas, Chief
Medical Branch
Division of Nuclear Material Safety
US NRC, Region 1
475 Allendale Road
King of Prussia
Pennsylvania 19406-1415

**UNIVERSITY OF PUERTO RICO, MEDICAL SCIENCES CAMPUS,
RESPONSE TO NRC INSPECTION REPORT NO. 03013584/2011001**

The University of Puerto Rico, Medical Sciences Campus is authorized, under the broad scope license number 52-01946-07, to conduct research and medical activities in accordance with 10 CFR 35.100, 35.200, and 35.300. On March 23 and 24, 2011 we received an inspection visit by Ms Penny Lanzisera, Health Physicist of the Nuclear Regulatory Commission.

In the inspection report, five findings or "apparent violations" of NRC regulations are listed. The document also indicates that NRC has not made a final determination regarding these findings, thus a Notice of Violation has not been issued at this moment. UPR MSC immediately performed corrective actions, and documented these and sent them to Ms Lanzisera in letters dated April 13 and 14, 2011. These were reviewed by Ms Penny Lanzisera, who found the corrective measures to be prompt and comprehensive. The apparent violations are:

1. UPR did not calibrate a dose calibrator at the Isaac González Martínez Oncologic Hospital in accordance with the manufacturer's instructions, as required by 10 CFR 35.60(b). Specifically, the isotope keys were not tested monthly per the manufacturer's instructions.

Upon further investigation, UPR, MSC finds this "apparent violation" to be incorrect and attributes it mainly to a problems in semantics.

Dirección:

PO BOX 365067
SAN JUAN PR
00936-5067

Teléfono:

787-758-2525
Exts. 1708, 1709

Fax:

787-754-0474



During the inspection visit to the Nuclear Medicine Department Ms Lanzisera - asked the certified nuclear medicine technologist (CNMT), to provide documentation of the monthly "dial value tests". The CMNT was not familiar with this term and answered that they did not perform it. Several days later, when speaking to the CNMT supervisor about this finding, he indicated that his Department refers to these tests as "Self tests" and not "Dial value tests". He informed us that although the manufacturers instructions recommends monthly tests, the Nuclear Medicine Department performs these daily. We are enclosing copies of several pages of the log-book for your perusal. We can provide a copy of the rest of the log-book upon request. Thus, the Nuclear Medicine Department has the evidence to demonstrate compliance with 10- CFR 35.60(b).

2. UPR did not post the storage location for radiopharmaceutical returns with a "Caution Radioactive Material" sign, as required by 10 CFR 20.1902.

UPR accepts this finding.

The door leading to this storage room had a sign of "*Caution-Radioactive Area*". However, after Ms Lanzisera pointed this out, the sign was immediately replaced by one reading "*Caution, Radioactive Materials*".

3. UPR did not label syringe holders containing licensed material with a "*Caution Radioactive Material*" label, as required by 10 CFR 20.1904.

UPR accepts this finding.

Very rarely does the Nuclear Medicine Department save radioactive remnants, mainly because the department buys unit doses with the precise amount needed. The NRC inspector - Ms Lanzisera - arrived at the premises between the time the radioactive material was removed and before the remaining material was labeled as waste for disposal. After the finding, the container and syringe were immediately labeled to correct this.

4. UPR did not adequately monitor iodine-131 waste being held for decay-in-storage to ensure that its radioactivity cannot be distinguished from the background radiation levels before disposal, as required by 10 CFR 35.92(a)(1). Specifically, iodine-131 waste held for decay-in-storage was disposed of as non-radioactive prior to complete decay.

UPR accepts this finding, which was mainly due to human error.

This finding was discussed in an internal meeting between representatives of the Radiation Safety Committee and the Nuclear Medicine Department. This issue pertains to a situation with a pediatric patient that was given a dose of 108 mCi of ¹³¹Iodine on Sept 11, 2008. On Sept 25, 2008, the patient returned to our clinic for follow-up and a small contamination was detected on the patient's jacket. We assume it was saliva. The CNMT confiscated the jacket and erroneously entered 70 mR/hr instead of 7.0 mR/hr in the waste log book, this last value is consistent with the amount that should be present after 14 days of *biological decay* (Sept 11-Sept 25). After 13 additional days (Oct 8, 2008) the reading was less than background, (2.0 mR/hr), and the CNMT disposed of the jacket.

The other finding listed involves a container of ¹³¹Iodine waste that read 5 mR/hr on March 4, 2010. This container was disposed of on April 12, 2010. Although the technologist did not wait 10 half lives to dispose of the material, when monitored at the surface before disposal, the measurement was 0.17mR/hr, lower than that of laboratory background (2 mR/hr). A survey meter set on its most sensitive scale and with no interposed shielding, was used to obtain this measurement. According to 10 CFR 35.92(a)(1) this material no longer poses a health threat and can be disposed of in the regular trash.

Nonetheless, the CNMT was instructed to store radioactive waste with long and short half-lives separately. The RSO also designed a new log waste sheet for this purpose that was immediately implemented.

5. UPR did not retain records of the transfer of depleted uranium in a linear accelerator to an authorized recipient, as required by 10 CFR 40.61 (a)(2). Discussions with UPR staff indicated that the depleted uranium was likely disposed to an authorized recipient; however, neither the transferee nor the transferor can locate the paperwork to document the transfer.

UPR partly accepts this finding.

The University of Puerto Rico has exhausted all possibilities to provide NRC with information regarding the transfer of the linear accelerator to the Oncology Hospital Issac González Martínez. Unfortunately, the Radiation Safety Office lost many documents during Hurricane George due to flooding. However, we provided NRC with a handwritten document from the Property Office listing the transfer of several parts of the linear accelerator to the Oncology Hospital. We also provided depositions by UPR personnel that state that the equipment was transferred to the Oncology Hospital. Our personnel also contacted Varian Company to request documentation, but since so many years have passed, our attempts have been unsuccessful. At the time the linear accelerator was donated, it was not Institutional Policy to ask for a receipt of donated equipment and for this reason we do not have

any documents from the Oncology Hospital stating that they received the material. We also don't have documents accepting the linear accelerator as a donation from the Atomic Energy Commission. We will make this our policy in the future regarding all equipment.

If you should require additional information, do not hesitate to contact us.

Sincerely,



Rafael Rodríguez Mercado, MD, FAANS, FACS
Chancellor
University of Puerto Rico
Medical Sciences Campus