



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

June 7, 2011

Docket No. 03013584
EA No. 11-107

License No. 52-01946-07

Rafael Rodriquez Mercado, M.D.
Chancellor
University of Puerto Rico
Office of the Chancellor
Attention: Radiation Safety Officer
P.O. Box 365067
San Juan, PR 00936

SUBJECT: NOTICE OF VIOLATION – NRC INSPECTION REPORT NO. 03013584/2011001

Dear Dr. Rodriquez Mercado:

This refers to the U.S. Nuclear Regulatory Commission (NRC) inspection conducted between March 23 and 24, 2011, at the University of Puerto Rico (UPR) facilities authorized by the above listed NRC license. The results of the safety inspection were discussed with you and other members of your organization by telephone during an exit meeting on May 2, 2011, and were transmitted to you in a letter dated May 3, 2011, which enclosed the NRC Inspection Report No. 03013584/2011001.

In our letter dated May 3, 2011, the NRC identified five apparent violations of NRC requirements. Specifically, the letter documented that UPR: 1) did not calibrate a dose calibrator at the I. González Martínez Oncologic Hospital in accordance with the manufacturer's instructions, as required by 10 CFR 35.60(b); 2) did not post the storage location for radiopharmaceutical returns with a "Caution Radioactive Material" sign, as required by 10 CFR 20.1902; 3) did not label syringe holders containing licensed material with a "Caution Radioactive Material" label, as required by 10 CFR 20.1904; 4) 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 level before disposal, as required by 10 CFR 35.92(a)(1); and 5) did not maintain a record of the transfer of depleted uranium in a linear accelerator to an authorized recipient, as required by 10 CFR 40.61(a)(2).

On May 27, 2011, UPR submitted additional information regarding dose calibrator testing performed at the I. González Martínez Oncologic Hospital, and indicated that the testing was conducted in compliance with the manufacturer's instructions. The NRC reviewed the test results submitted; and concluded that based on the additional information provided that the testing was performed in accordance with the manufacturer's instructions, as required by 10 CFR 35.60(b). Therefore, the NRC has concluded that no violation of regulatory requirements occurred. UPR stated in their submittal that they agreed with the other apparent violations documented in NRC Inspection Report No. 03013584/2011001.

The remaining four violations associated with the inspection are cited in the enclosed Notice of

Violation (Notice), because the violations were identified by the NRC. The circumstances surrounding the violations were described in detail in the inspection report issued on May 3, 2011. Also, please note, that contrary to statements UPR made in its May 27, 2011 letter, surveys of radioactive waste after being held for decay-in-storage should be conducted in a low background area (e.g., 0.02 mR/hour) instead of in your nuclear medicine department which would have a higher background (e.g., 2 mr/hour) radiation level.

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken to correct the violations and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket, in NRC Inspection Report No. 03013584/2011001, and in correspondence provided to the NRC dated April 13 and 14 and May 27, 2011 by UPR. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC document system (ADAMS), accessible from the NRC website at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Med, Ind, & Academic Users**; then **Regulations, Guidance and Communications**. The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents**; then **Enforcement Policy (Under 'Related Information')**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 7:00 a.m. to 6:30 p.m. EST, Monday through Friday (except Federal holidays).

Please contact Penny Lanzisera at 610-337-5169 if you have any questions regarding this matter.

Sincerely,

Original signed by Marc Ferdas

Marc S. Ferdas, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

R. Rodriguez Mercado

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cc:

Jossian J. Pagan-Lisboa, Radiation Safety Officer
Commonwealth of Puerto Rico

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Sincerely,

/RA/

Marc S. Ferdas, Chief
 Medical Branch
 Division of Nuclear Materials Safety

Enclosure:
 Notice of Violation

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NOTICE OF VIOLATION

University of Puerto Rico (UPR)
San Juan, PR
EA No. 11-107

Docket No. 03013584
License No. 52-01946-07

During an NRC inspection conducted on March 23-24, 2011, as well as in-office review of information provided by UPR on April 13 and 14, and May 27, 2011, four violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 20.1902(e) requires, in part, that a licensee shall post each room in which there is used or stored an amount of licensed material exceeding 10 times the quantity of such material specified in appendix C to part 20 with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)."

Contrary to the above, as of March 24, 2011, UPR did not post a room in which licensed material exceeding 10 times the quantity of material specified in appendix C to part 20 was stored with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)." Specifically, a room located near the nuclear medicine department at I. Gonzalez Martinez Oncologic Hospital was not posted with a conspicuous sign as required. The room was used to store various radiopharmaceuticals, in quantities exceeding 10 times the quantity specified in appendix C to part 20, prior to return to the radiopharmacy.

This is a Severity Level IV violation (Section 6.7).

- B. 10 CFR 20.1904(a) requires, in part, that a licensee shall ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL." The label must also provide sufficient information (such as the radionuclide present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, and kinds of materials) to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

Contrary to the above, as of March 24, 2011, UPR did not label each container of licensed material with a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL," and sufficient information to permit individuals handling or working in the vicinity of the containers to take precautions to avoid or minimize exposure. Specifically, syringes containing licensed material were placed in shielded syringe holders prior to use and the holders were not properly labeled with the required information.

This is a Severity Level IV violation (Section 6.7).

- C. 10 CFR 35.92(a)(1) requires, in part, that a licensee may hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal if

the licensee monitors the byproduct material's surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level.

Contrary to the above, on October 8, 2008 and April 12, 2010, UPR did not adequately monitor byproduct material held for decay-in-storage before disposal and determine that its radioactivity cannot be distinguished from the background radiation level. Specifically, UPR monitored byproduct material being held for decay in storage in their nuclear medicine department, an area with elevated background radiation levels; and as a result disposed of material as non-radioactive prior to complete decay and at levels greater than background radiation.

This is a Severity Level IV violation (Section 6.3).

- D. 10 CFR 40.61(a)(2) requires, in part, that a licensee who transferred source material shall retain each record of transfer of source material until the Commission terminates the license that authorizes the activity that is subject to the recordkeeping requirement.

Contrary to the above, as of March 24, 2011, UPR did not retain a record of transfer of source material until the Commission terminated their license that authorized the activity that was subject to the recordkeeping requirement. Specifically, UPR transferred depleted uranium contained within a Siemens Mevatron 12 linear accelerator to an authorized recipient in 1993; however, UPR could not locate paperwork to document the transfer.

This is a Severity Level IV violation (Section 6.3).

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violation and prevent recurrence and the date when full compliance will be achieved is already adequately addressed on the docket. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

Notice of Violation
University of Puerto Rico

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In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated This 6 day of June 2011