



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

July 21, 2010

Docket No. 03036979
EA-10-091

License No. 52-31065-01

José E. Meléndez, M.D.
100 Roseville Drive, Box 22
San Juan, PR 00926

SUBJECT: NRC INSPECTION REPORT NO. 03036979/2010002, JOSÉ E. MELÉNDEZ
M.D., RÍO GRANDE NUCLEAR MEDICINE, RESPONSE TO DISPUTED
NOTICE OF VIOLATION

Dear Dr. Meléndez:

We have completed our review of your letters dated April 29 and June 4, 2010, in which you disputed a Notice of Violation (NOV), dated April 19, 2010.

The NOV described two Severity Level IV violations, identified during an NRC inspection, involving: (1) the failure to control and maintain constant surveillance of licensed materials in a controlled area (the Hot Lab) and that were not in storage as required by 10 CFR 20.1802; and, (2) the failure to post a room in which there was 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 bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)" as required by 10 CFR 20.1902. In your April 29 and June 4, 2010, responses, you stated that you did not accept the violations, because: (1) the Nuclear Medicine laboratory (which includes the Hot Lab) is located behind the reception area and the receptionists have been trained to escort patients to the room where they are being seen by the medical staff; and, (2) the Hot Lab is located inside the camera room, which has the required posting on the door, therefore all rooms located behind the posted door have the potential to contain radioactive materials.

Based on further review of the information submitted, the NRC has determined that a violation of 10 CFR 20.1802 did not occur. In your letters, you stated that the receptionists have been trained to control access to the areas where licensed material is used or stored. Specifically, the receptionists received training on November 16, 2009, which discussed the reception staff's responsibility to control access to areas where licensed material is used and stored and to escort patients to the room where they will be seen by the medical staff. The information presented in your letters related to the violation of 10 CFR 20.1802 was new information that was not provided to the inspectors at the time of the inspection. It demonstrates that you have established protocols to ensure that the receptionist staff is adequately trained to control access to areas where radioactive material is used and stored. Therefore, the violation of 10 CFR 20.1802 is retracted.

With regard to the second violation, the NRC has determined that a violation of 10 CFR 20.1902(e) did occur. 10 CFR 20.1902(e) states, in part, that the licensee shall post each area or 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)" or "DANGER, RADIOACTIVE MATERIAL(S)." Because greater than 10 millicuries of Technetium-99m (ten times the Appendix C value) is stored in the Hot Lab, a separate room from the camera room, it is required to be posted in accordance with 10 CFR 20.1902(e). The camera room may not be required to be posted based on the exception in 10 CFR 20.1903(a), which states, in part, that areas or rooms containing radioactive material for periods of less than 8 hours, need not be posted if the material is constantly attended and the area is under licensee control.

In the information you submitted, you stated that, "Many research facilities label the entrance to the hallway to restrict access to all of the research rooms and each of the rooms are not required to be labeled with a radiation sign." This practice is contrary to the guidance contained in NUREG-1736, "Consolidated Guidance: 10 CFR Part 20 –Standards for Protection Against Radiation." The guidance states that the intent of the posting regulation is to alert personnel to the presence of radiological hazards in their immediate vicinity and to aid them in minimizing exposures. It further states that posting the entrance to a large room is inappropriate if most of the area is not a radiation area and only individual rooms actually meet the criteria for a radiation area. If a room within a larger area can be reasonably posted to alert individuals to radiation areas, these rooms should be posted individually. Therefore, based on the above, the violation of 10 CFR 20.1902 remains as noted in the NOV that was issued. The NRC plans no further action regarding your request to retract this violation.

Although you did not agree that violations had occurred, you stated in the information submitted, that the Hot Lab door can now be locked and that it has been posted with the appropriate sign. The NRC has concluded that information regarding the reasons for the violation of 10 CFR 20.1902, and the corrective actions taken to correct the violation and prevent recurrence, are already addressed on the docket. Therefore, you are not required to submit an additional response to the violation. The corrective actions will be reviewed during a future NRC inspection.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC web-site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

If you have any further questions, please contact Marc S. Ferdas, Chief, Medical Branch at 610-337-5022.

Sincerely,

/RA/

John D. Kinneman, Director
Division of Nuclear Materials Safety

cc: Commonwealth of Puerto Rico

bearing the radiation symbol and the words, "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)." Because greater than 10 millicuries of Technetium-99m (ten times the Appendix C value) is stored in the Hot Lab, a separate room from the camera room, it is required to be posted in accordance with 10 CFR 20.1902(e). The camera room may not be required to be posted based on the exception in 10 CFR 20.1903(a), which states, in part, that areas or rooms containing radioactive material for periods of less than 8 hours, need not be posted if the material is constantly attended and the area is under licensee control.

In the information you submitted, you stated that, "Many research facilities label the entrance to the hallway to restrict access to all of the research rooms and each of the rooms are not required to be labeled with a radiation sign." This practice is contrary to the guidance contained in NUREG-1736, "Consolidated Guidance: 10 CFR Part 20 –Standards for Protection Against Radiation." The guidance states that the intent of the posting regulation is to alert personnel to the presence of radiological hazards in their immediate vicinity and to aid them in minimizing exposures. It further states that posting the entrance to a large room is inappropriate if most of the area is not a radiation area and only individual rooms actually meet the criteria for a radiation area. If a room within a larger area can be reasonably posted to alert individuals to radiation areas, these rooms should be posted individually. Therefore, based on the above, the violation of 10 CFR 20.1902 remains as noted in the NOV that was issued. The NRC plans no further action regarding your request to retract this violation.

Although you did not agree that violations had occurred, you stated in the information submitted, that the Hot Lab door can now be locked and that it has been posted with the appropriate sign. The NRC has concluded that information regarding the reasons for the violation of 10 CFR 20.1902, and the corrective actions taken to correct the violation and prevent recurrence, are already addressed on the docket. Therefore, you are not required to submit an additional response to the violation. The corrective actions will be reviewed during a future NRC inspection.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC web-site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

If you have any further questions, please contact Marc S. Ferdas, Chief, Medical Branch at 610-337-5022.

Sincerely,

/RA/

John D. Kinneman, Director
Division of Nuclear Materials Safety

cc: Commonwealth of Puerto Rico

Distribution:
OEMAIL
NHasan, OE

LSreenivas, OE
DHolody, RI

MMcLaughlin, RI
ADeFrancisco, RI

ML102040096

DOCUMENT NAME: G:\WordDocs\Current\Insp Letter\L52-31065-01.Disputed Violation.doc

SUNSI Review Complete: TWeidner After declaring this document "An Official Agency Record" it **will** be released to the Public.

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI	E	DNMS/RI	RA/OE
NAME	TWeidner/msf		MFerdas/msf		JKinneman/jdk	DHolody/mmm f/
DATE	07/08/10		07/08/10		07/09/10	07/14/10
OFFICE	RA/RC		HQ/OE		DNMS/RI	
NAME	KFarrar/klf		LSreenivas/LS via email		JKinneman/jdk	
DATE	07/14/10		07/19/10		07/21/10	