

These two violations represent a Severity Level III problem (Supplement VI). Civil Penalty—\$3,250

*Summary of the Licensee's Response Regarding the Violations*

In its response, the licensee stated that it believed its license in the State of Florida allowed it to use and store the nuclear density gauge anywhere within Florida. The licensee stated that it did not know that the Indian Reservations of the Seminole Tribe of Florida are not under the State of Florida's jurisdiction and that it was required to file for reciprocity or obtain a separate license under NRC jurisdiction for storing and using a portable gauge on an Indian Reservation. The licensee also stated it immediately took corrective actions to file for a Federal license and paid the required fees. Further, the licensee stated that the management team understands the seriousness of the violations and described the corrective actions immediately taken to ensure two independent physical controls exist for securing the portable gauge from unauthorized removal. The actions included having the RSO or a member of the management team perform random checks to ensure the method of protection is strictly adhered to.

*NRC's Evaluation of the Licensee's Response Regarding the Violations*

The NRC has evaluated the licensee's statements regarding the violations. The NRC recognizes that these are the licensee's first violations of this type and that corrective actions were taken immediately to address the violations; however, not being aware that the Indian Reservations of the Seminole Tribe of Florida are under NRC jurisdiction is not a valid reason for not having filed for reciprocity nor obtaining an NRC license. NRC may not cite the licensee when a portable gauge is stolen under the condition that the licensee was in full compliance with all regulatory requirements regarding physical security, including the requirement to secure the gauge with two independent physical controls that form tangible barriers to secure the gauge from unauthorized removal. However, MC<sup>2</sup> was not in full compliance with all regulatory requirements and therefore, an adequate basis did not exist to not cite the violations.

*Summary of Licensee's Request for Negation or Significant Reduction of the Civil Penalty*

In its response, the licensee requested negating or significantly reducing the civil penalty, contending that specific mitigating circumstances surrounding the violations should be considered by the NRC, and that the fine will impose a significant financial hardship on their small company. The mitigating circumstances provided by the licensee included: (1) This is its first violation; (2) it did not know the Indian Reservations are separate entities; and, (3) immediate measures were taken to rectify the situation and prevent future violations. The licensee noted that the senior management team and the employees of MC<sup>2</sup> are committed to health and safety and place significant importance on supporting their Radiation Safety Officer and providing the

tools necessary to achieve safe operation of nuclear devices.

*NRC Evaluation of Licensee's Request for Negation or Significant Reduction of the Civil Penalty*

In accordance with section VI.C.2 of the Enforcement Policy, the base civil penalty amount for a Severity Level (SL) III violation involving the loss of this type of radioactive material is \$3,250. The licensee, while contending that a financial loss occurred, did not provide any evidence that payment of the civil penalty would create a financial hardship. Also, while the NRC acknowledges that the licensee took prompt and comprehensive corrective actions, a civil penalty was nonetheless warranted, consistent with the NRC Enforcement Policy, because the violation of 10 CFR 30.34(i) contributed to the theft of a gauge containing radioactive material. Issuance of this civil penalty is consistent with one of the purposes of the Enforcement Policy, which is to deter noncompliance, including for lost sources, by emphasizing to the licensee and other licensees the importance of compliance with NRC safety and security requirements. In addition, the NRC recognized that a contributing factor for these two violations was that MC<sup>2</sup> did not fully understand the NRC regulations regarding 10 CFR 150.20(b) and 10 CFR 30.34(i). The NRC took this into consideration and processed the two violations as one SL III problem, rather than citing two separate SL III violations, which could have each been individually considered for a civil penalty.

*NRC Conclusion*

The NRC has concluded that these violations occurred as stated in the Notice and that an adequate basis was not provided by the licensee for the NRC to negate or significantly reduce the civil penalty. Consequently, the proposed civil penalty in the amount of \$3,250 should be imposed.

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**NUCLEAR REGULATORY COMMISSION**

[Docket No. 030-19921]

**Notice of Availability of Environmental Assessment and Finding of No Significant Impact for License Amendment To Byproduct Materials License No. 52-13508-03 for Termination of the License and Unrestricted Release of the Pontifical Catholic University of Puerto Rico Facility in Ponce, Puerto Rico**

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Issuance of Environmental Assessment and Finding of No Significant Impact for License Amendment.

**FOR FURTHER INFORMATION CONTACT:** Dennis Lawyer, Health Physicist,

Commercial and R&D Branch, Division of Nuclear Materials Safety, Region I, 475 Allendale Road, King of Prussia, Pennsylvania; telephone 610-337-5366; fax number 610-337-5393; or by e-mail: [drl1@nrc.gov](mailto:drl1@nrc.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Introduction**

The U.S. Nuclear Regulatory Commission (NRC) is considering the issuance of a license amendment to Byproduct Materials License No. 52-13508-03. This license is held by Pontifical Catholic University of Puerto Rico (the Licensee), for its Ferré Science Building located near Avenue Las Americas in Ponce, Puerto Rico (the Facility). Issuance of the amendment would authorize release of the Facility for unrestricted use and termination of the NRC license. The Licensee requested this action in a letter dated June 16, 2006, and provided additional information in letters dated November 16, 2006, and August 22, 2007. The NRC has prepared an Environmental Assessment (EA) in support of this proposed action in accordance with the requirements of Title 10, Code of Federal Regulations (CFR), Part 51 (10 CFR Part 51). Based on the EA, the NRC has concluded that a Finding of No Significant Impact (FONSI) is appropriate with respect to the proposed action. The amendment will be issued to the Licensee following the publication of this FONSI and EA in the **Federal Register**.

**II. Environmental Assessment**

*Identification of Proposed Action*

The proposed action would approve the Licensee's June 16, 2006, license amendment request, resulting in release of the Facility for unrestricted use and the termination of its NRC materials license. License No. 52-13508-03 was issued on July 26, 1983, pursuant to 10 CFR Part 30, and has been amended periodically since that time. This license authorized the Licensee to use unsealed byproduct material for purposes of conducting research and development activities on laboratory bench tops and in hoods.

The Facility is a building containing 13,274 square feet of classroom, office, and laboratory space. Within the Facility, use of licensed materials was confined to rooms Fe-119 and Fe-120. The area of use totaled 468 square feet. The Facility is located in a mixed residential/commercial area.

In 1989, the Licensee ceased licensed activities at the Facility and initiated a survey and decontamination actions there. The request to release the facility

and terminate the license was delayed due to the difficulty in finding a waste vendor. Based on the Licensee's historical knowledge of the site and the conditions of the Facility, the Licensee determined that only routine decontamination activities, in accordance with their NRC-approved, operating radiation safety procedures, were required. The Licensee was not required to submit a decommissioning plan to the NRC because worker cleanup activities and procedures are consistent with those approved for routine operations. The Licensee conducted surveys of the Facility and provided information to the NRC to demonstrate that it meets the criteria in Subpart E of 10 CFR Part 20 for unrestricted release and for license termination.

#### *Need for the Proposed Action*

The Licensee has ceased conducting licensed activities at the Facility, and seeks the unrestricted use of its Facility and the termination of its NRC materials license. Termination of its license would end the Licensee's obligation to pay annual license fees to the NRC.

#### *Environmental Impacts of the Proposed Action*

The historical review of licensed activities conducted at the Facility shows that such activities involved use of the following radionuclides with half-lives greater than 120 days: hydrogen-3 and carbon-14. Prior to performing the final status survey, the Licensee conducted decontamination activities, as necessary, in the areas of the Facility affected by these radionuclides.

The Licensee conducted final status surveys on March 26 and during May 2007. This survey covered rooms Fe-119 and Fe-120. The Licensee elected to demonstrate compliance with the radiological criteria for unrestricted release as specified in 10 CFR 20.1402 by using the screening approach described in NUREG-1757, "Consolidated NMSS Decommissioning Guidance," Volume 2. The Licensee used the radionuclide-specific derived concentration guideline levels (DCGLs), developed there by the NRC, which comply with the dose criterion in 10 CFR 20.1402. These DCGLs define the maximum amount of residual radioactivity on building surfaces, equipment, and materials, that will satisfy the NRC requirements in Subpart E of 10 CFR Part 20 for unrestricted release. The Licensee's final status survey results were below these DCGLs and are in compliance with the As Low As Reasonably Achievable (ALARA) requirement of 10 CFR 20.1402. The NRC thus finds that the Licensee's final

status survey results are acceptable. Based on its review, the staff has determined that the affected environment and any environmental impacts associated with the proposed action are bounded by the impacts evaluated by the "Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC-Licensed Nuclear Facilities" (NUREG-1496) Volumes 1-3 (ML042310492, ML042320379, and ML042330385). The staff finds there were no significant environmental impacts from the use of radioactive material at the Facility. The NRC staff reviewed the docket file records and the final status survey report to identify any non-radiological hazards that may have impacted the environment surrounding the Facility. No such hazards or impacts to the environment were identified. The NRC has identified no other radiological or non-radiological activities in the area that could result in cumulative environmental impacts.

The NRC staff finds that the proposed release of the Facility for unrestricted use and the termination of the NRC materials license is in compliance with 10 CFR 20.1402. Based on its review, the staff considered the impact of the residual radioactivity at the Facility and concluded that the proposed action will not have a significant effect on the quality of the human environment.

#### *Environmental Impacts of the Alternatives to the Proposed Action*

Due to the largely administrative nature of the proposed action, its environmental impacts are small. Therefore, the only alternative the staff considered is the no-action alternative, under which the staff would leave things as they are by simply denying the amendment request. This no-action alternative is not feasible because it conflicts with 10 CFR 30.36(d), requiring that decommissioning of byproduct material facilities be completed and approved by the NRC after licensed activities cease. The NRC's analysis of the Licensee's final status survey data confirmed that the Facility meets the requirements of 10 CFR 20.1402 for unrestricted release and for license termination. Additionally, denying the amendment request would result in no change in current environmental impacts. The environmental impacts of the proposed action and the no-action alternative are therefore similar, and the no-action alternative is accordingly not further considered.

#### *Conclusion*

The NRC staff has concluded that the proposed action is consistent with the NRC's unrestricted release criteria specified in 10 CFR 20.1402. Because the proposed action will not significantly impact the quality of the human environment, the NRC staff concludes that the proposed action is the preferred alternative.

#### *Agencies and Persons Consulted*

NRC provided a draft of this Environmental Assessment to the Commonwealth of Puerto Rico for review on October 9, 2007. On November 26, 2007, the Division de Salud Radiologica responded by electronic mail. The Commonwealth agreed with the conclusions of the EA, and otherwise had no comments.

The NRC staff has determined that the proposed action is of a procedural nature, and will not affect listed species or critical habitat. Therefore, no further consultation is required under section 7 of the Endangered Species Act. The NRC staff has also determined that the proposed action is not the type of activity that has the potential to cause effects on historic properties. Therefore, no further consultation is required under section 106 of the National Historic Preservation Act.

#### **III. Finding of No Significant Impact**

The NRC staff has prepared this EA in support of the proposed action. On the basis of this EA, the NRC finds that there are no significant environmental impacts from the proposed action, and that preparation of an environmental impact statement is not warranted. Accordingly, the NRC has determined that a Finding of No Significant Impact is appropriate.

#### **IV. Further Information**

Documents related to this action, including the application for license amendment and supporting documentation, are available electronically at the NRC's Electronic Reading Room at <http://www.nrc.gov/reading-rm/adams.html>. From this site, you can access the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. The documents related to this action are listed below, along with their ADAMS accession numbers.

1. NUREG-1757, "Consolidated NMSS Decommissioning Guidance;"
2. Title 10 Code of Federal Regulations, Part 20, Subpart E, "Radiological Criteria for License Termination;"

3. Title 10, Code of Federal Regulations, Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions;"

4. NUREG-1496, "Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC-Licensed Nuclear Facilities."

5. Pontifical Catholic University of Puerto Rico Termination Request dated June 16, 2006 [ML072630543].

6. Pontifical Catholic University of Puerto Rico Additional Information letter dated August 22, 2007 [ML072420457].

7. Pontifical Catholic University of Puerto Rico Additional Information letter dated November 16, 2006 [ML070590570].

If you do not have access to ADAMS, or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to [pdr@nrc.gov](mailto:pdr@nrc.gov). These documents may also be viewed electronically on the public computers located at the NRC's PDR, O 1 F21, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852. The PDR reproduction contractor will copy documents for a fee.

Dated at Region I, 475 Allendale Road, King of Prussia, PA, this 3rd day of December 2007.

For the Nuclear Regulatory Commission.

**James P. Dwyer,**

*Chief, Commercial and R&D Branch, Division of Nuclear Materials Safety, Region I.*

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## NUCLEAR REGULATORY COMMISSION

### NUREG-1556, Volume 13, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacies"

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Notice of availability.

**SUMMARY:** The Nuclear Regulatory Commission (NRC) is announcing the completion and availability of NUREG-1556, Volume 13, Revision 1, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Commercial Radiopharmacies," dated November 2007.

**ADDRESSES:** Copies of NUREG-1556, Volume 13, Revision 1, may be purchased from the Superintendent of

Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328; [http://www.access.gpo.gov/su\\_docs](http://www.access.gpo.gov/su_docs); 202-512-1800 or The National Technical Information Service, Springfield, Virginia 22161-0002; [www.ntis.gov](http://www.ntis.gov); 1-800-533-6847 or, locally, 703-805-6000.

A copy of the document is also available for inspection and/or copying for a fee in the NRC Public Document Room (PDR), 11555 Rockville Pike, Rockville, Maryland. Publicly available documents created or received at the NRC after November 1, 1999, are available electronically at the NRC's Electronic Reading Room at <http://www.nrc.gov/NRC/ADAMS/index.html>. From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of the NRC's public documents. The ADAMS Accession Number for NUREG-1556, Volume 13, Revision 1, is ML073180179. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC PDR Reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to [pdr@nrc.gov](mailto:pdr@nrc.gov). The document will also be posted on NRC's public Web site at: <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/> on the "Consolidated Guidance About Materials Licenses (NUREG-1556)" Web site page, and on the Office of Federal and State Materials and Environmental Management Programs' NARM (Naturally-Occurring and Accelerator-Produced Radioactive Material) Toolbox Web site page at: <http://nrc-stp.ornl.gov/narmtoolbox.html> under the heading of "Licensing Guidance." Some publications in the NUREG series that are posted at NRC's Web site address <http://www.nrc.gov> are updated regularly and may differ from the last printed version.

A free single copy, to the extent of supply, may be requested by writing to the Office of the Chief Information Officer, Reproduction and Distribution Services, U.S. Nuclear Regulatory Commission, Printing and Graphics Branch, Washington, DC 20555-0001; facsimile: 301-415-2289; e-mail: [Distribution@nrc.gov](mailto:Distribution@nrc.gov).

#### FOR FURTHER INFORMATION CONTACT:

Torre Taylor, Division of Intergovernmental Liaison and Rulemaking, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-

7900, e-mail: [tmt@nrc.gov](mailto:tmt@nrc.gov); or Duane White, Division of Materials Safety and State Agreements, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6272, e-mail: [dew2@nrc.gov](mailto:dew2@nrc.gov).

**SUPPLEMENTARY INFORMATION:** On August 8, 2005, the President signed into law the Energy Policy Act of 2005 (EPAct). Among other provisions, Section 651(e) of the EPAct expanded the definition of byproduct material as defined in Section 11e. of the Atomic Energy Act of 1954 (AEA), placing additional byproduct material under the NRC's jurisdiction, and required the Commission to provide a regulatory framework for licensing and regulating these additional byproduct materials.

Specifically, Section 651(e) of the EPAct expanded the definition of byproduct material by: (1) Adding any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after the date of enactment of the EPAct for use for a commercial, medical, or research activity; or any material that has been made radioactive by use of a particle accelerator and is produced, extracted, or converted after extraction, before, on, or after the date of enactment of the EPAct for use for a commercial, medical, or research activity (Section 11e.(3) of the AEA); and (2) adding any discrete source of naturally occurring radioactive material, other than source material, that the Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of the Department of Energy, the Secretary of the Department of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and is extracted or converted after extraction before, on, or after the date of enactment of the EPAct for use in a commercial, medical, or research activity (Section 11e.(4) of the AEA).

NRC revised its regulations to provide a regulatory framework that includes these newly added radioactive materials. See **Federal Register** notice 72 FR 55864, dated October 1, 2007. As part of the rulemaking effort to address the mandate of the EPAct, the NRC also evaluated the need to revise certain licensing guidance to provide necessary guidance to applicants in preparing license applications to include the use of the newly added radioactive materials as byproduct material. Two