UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

November 21, 2018

EA-18-076

Wayne A. I. Frederick, M.D., MBA
President
Howard University
2041 Georgia Avenue, N.W.
Washington, D.C. 20060

SUBJECT: HOWARD UNIVERSITY - NRC REACTIVE INSPECTION REPORT 03011063/2018001, WASHINGTON, DISTRICT OF COLUMBIA

Dear Dr. Frederick:

On February 16, 2018, July 25, 2018, and August 28, 2018, with continued in-office review through November 2, 2018, Randolph Ragland of this office conducted a reactive inspection of your activities performed under your NRC broad scope license No. 08-00386-19, at your facilities in in Washington, D.C. The purpose of this inspection was to review the events associated with the discovery of unlicensed Actinium-227 powder in lab 209 of your Physics Building. The enclosed report presents the results of this inspection. The inspector discussed the preliminary inspection findings with Dr. Satya Bose, Radiation Safety Officer, at the conclusion of the on-site portion of the inspection on August 28, 2018. A final exit briefing was conducted (telephonically) with Alice Mahan, Radiation Safety Committee Management Representative, Dr. Bose, and others on November 2, 2018.

Based on the results of this inspection, the NRC determined that one apparent violation of NRC requirements occurred, related to the possession of byproduct material (the Actinium-227 powder) that was not authorized on Howard University's license. This apparent violation is being considered for escalated enforcement action, including a civil penalty, in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. Since the NRC has not made a final determination in this matter, a Notice of Violation is not being issued at this time. Please be advised that the number and characterization of the apparent violation described herein may change as a result of further review. The circumstances surrounding the apparent violation, the significance of the issue, and the need for lasting and effective corrective actions were discussed with members of your staff at the inspection exit meeting at the conclusion of the on-site inspection and during the November 2, 2018, telephone call.

Before the NRC makes its enforcement decision regarding the apparent violation, we request that you provide additional information regarding Howard University's corrective actions for this event. Although we noted that your immediate corrective actions to control and secure the material and ensure its proper disposal and to inform the NRC of the event, appeared to be effective, it is not clear if adequate actions to prevent recurrence have been developed. In particular, the NRC notes that following discovery of the material, Howard University's Provost and Chief Academic Officer, sent a memorandum dated April 19, 2018, to all Department Chairs

notifying them of the issue. The memorandum requested all Department Chairs to verify that they did not possess unlicensed radioactive materials in their labs and to notify the Radiation Safety Department if they discovered any such material. But, the Provost's request did not require the Department Heads to provide a positive affirmation that they performed a detailed search of their labs. According to the Radiation Safety Officer, following issuance of the Provost's memorandum, no Department Heads besides the Physics and Engineering departments formally responded. The Radiation Safety Officer assumed that each department conducted a detailed review and did not find any unlicensed radioactive material.

The NRC considered that, in addition to this recent event, Howard University had previously (in 2008) discovered unlicensed material that had been in storage and not known by the licensee (see NRC inspection report No. 03011063/2013001, located in NRC's Agency Document Management System (ADAMS) Accession No. ML15237A037). In light of the reoccurrence of this apparent violation and the relative lack of comprehensiveness of the current corrective action, we are requesting you submit additional information associated with what specific actions have been taken or are planned to prevent further similar violations in the future. In particular, please include a list of any rooms that have been (or will be) checked for unlicensed radioactive materials, the schedule for completing such checks, and the results of completed checks, if any. Alternately, you may submit information about other corrective actions that were (or will be) performed.

The written response should be sent to the NRC within 30 days of the date of this letter. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. You should clearly mark the response as a "Response to Apparent Violation in NRC Inspection Report No. 03011063/2018001; EA-18-076," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, NRC Region I, 2100 Renaissance Boulevard, Suite 100, King of Prussia, PA 19406. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a pre-decisional enforcement conference (PEC).

In lieu of providing this written response, you may choose to provide your perspective on this matter, including the significance, cause, and corrective actions, as well as any other information that you believe the NRC should take into consideration by: (1) requesting a PEC to meet with the NRC and provide your views in person; or (2) requesting Alternative Dispute Resolution (ADR).

If you choose to request a PEC, the meeting should be held in our office in King of Prussia, PA, within 30 days of the date of this letter. The conference will include an opportunity for you to provide your perspective on these matters and any other information that you believe the NRC should take into consideration before making an enforcement decision. The topics discussed during the PEC may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned. Please note that if a PEC is held, the NRC would issue a press release to announce the conference time and date.

In lieu of a PEC or written response, you may request ADR with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC has decided to employ is mediation; a voluntary, informal process in which a trained neutral mediator works with parties

to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC ADR program can be obtained at http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC program as a neutral third party. Please contact ICR at 877-733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR. The ADR mediation session should be held in our Region I office in King of Prussia within 45 days of the date of this letter. The mediation session would be closed to public observation, but the time and date would be publicly-announced.

Please contact Arthur Burritt at 610-337-5069 within 10 days of the date of this letter to notify the NRC which of the above options you choose. If you do not contact the NRC within the time specified, and an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision.

In accordance with 10 CFR 2.390 of the NRC's Rules of Practice," a copy of this letter and its enclosure will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

If you have any questions concerning this matter, please contact Randolph Ragland of my staff at 610-337-5383.

Sincerely,

/RA/

James M. Trapp, Director
Division of Nuclear Materials Safety

Docket No. 03011063
License No. 08-00386-19

Enclosure:
Inspection Report 03011063/2018001

cc w/Encl: Satya R. Bose, Ph.D.
District of Columbia

HOWARD UNIVERSITY - NRC REACTIVE INSPECTION REPORT 03011063/2018001
DATED November 21, 2018 .

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S Woods, OE
M Burgess, NMSS
R Sun, NMSS
J Trapp, NMSS, RI
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U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03011063/2018001
Docket No.	03011063
License No.	08-00386-19
EA No.	EA-18-076
Licensee:	Howard University
Address:	2041 Georgia Avenue, N.W. Washington, D.C. 20060
Inspection Dates:	February 16, 2018, July 25, 2018, August 28, 2018, through November 2, 2018.
Exit Meeting:	November 2, 2018

Inspector:

/RA/ ***11/09/18***

Randolph C. Ragland, Jr. — date
Senior Health Physicist
Commercial, Industrial, R&D
and Academic Branch
Division of Nuclear Materials Safety

Approved By:

/RA/ ***11/13/18***

Arthur L. Burritt, Chief — date
Commercial, Industrial, R&D
and Academic Branch
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

Howard University
NRC Inspection Report No. 03011063/2018-001

On February 16, 2018, the NRC initiated a reactive inspection to review the events associated with the discovery of unlicensed Actinium-227 (Ac-227) powder in an inactive Howard University Physics Building Laboratory (Room 209).

No current information was available as to how and when the material was acquired and ended up in the Physics Building Laboratory, Room 209. Circumstantial evidence indicates that the unlicensed Ac-227 source was likely acquired by a University staff member before the existence of NRC licensing requirements and eventually stored in Howard University's Physics Building, Room 209, without the knowledge of the Howard University radiation safety staff.

With regard to safety, the material was present in a powdered form which represented a significant potential for over exposures due to inhalation or ingestion, if the material was improperly handled (e.g., spilled). However, the material was contained in a glass jar, inside a plastic bag, inside a clearly labeled lead shielded container, located in a locked inactive laboratory, and there is no indication that the material was mishandled. Radiological surveys determined that there was no spread of contamination; therefore, no measurable radiation exposures are attributed to the discovery, handling, and disposal of the unlicensed Ac-227.

Immediate corrective actions were effective and included conducting radiological surveys, placing the material in a ventilated hood in a locked laboratory, notifying the NRC, establishing a contract for analysis and disposal, and facilitating the shipment of the material from the University for disposal.

However, this discovery of unlicensed radioactive material was not prevented by the implementation of corrective actions from a previous discovery of unlicensed radioactive material (see NRC Inspection number 03011063/2013001, located in NRC's Agency Document Management System (ADAMS) Accession No. ML15237A037), and NRC considers the actions taken to prevent recurrence for this discovery to lack comprehensiveness.

We noted that that following the discovery of the material, the University Provost and Chief Academic Officer, sent a memorandum dated April 19, 2018, requesting all Department Chairs to verify that they do not possess unlicensed radioactive materials in their labs and to notify the Radiation Safety Office if they discovered any such material. But, the Provost's request did not require Department Chairs to provide a positive affirmation that they performed detailed searches of their laboratories. According to the Radiation Safety Officer, he only received responses from the Department of Physics and Engineering and therefore assumed that the other departments conducted detailed searches of their respective laboratories and did not find any unlicensed radioactive materials. Based on this information, it is unclear to the NRC if the actions you have taken to prevent recurrence were fully implemented.

One apparent violation of NRC requirements was identified for the possession of non-exempt byproduct material that was not authorized by NRC license number 08-00386-19.

REPORT DETAILS

1. Organization and Scope of the Program

a. Inspection Scope

The inspector reviewed the organization and scope of activities performed under Howard University's' NRC Broad-Scope License No. 08-00386-19. Information was gathered through interviews with licensee staff including selected Radiation Safety Committee members; through reviews of selected records; and through tours of selected Howard University laboratories.

b. Observations and Findings

Howard University maintains a broad-scope NRC license which authorizes specific radioactive materials for research and development. Currently, only four Howard University labs are authorized to purchase, possess, and use radioactive materials to carry out research activities. These include:

Cooper Hall, School of Pharmacy, Room 321
Adams Building Room 4104
Howard University Hospital Lab 3444
Howard University Hospital Lab 6-B-24.

The Radiation Safety Officer for Howard University's broad scope license is also the Radiation Safety Officer and Medical Physicist for Howard University Hospital's NRC medical license. The Radiation Safety Officer has a staff of two individuals and reports to the University's Provost and Chief Academic Officer. The Provost reports to the President of Howard University.

The inspector attended a portion of a Radiation Safety Committee meeting. Attendees included representatives from Management, the Departments of Radiology, Nursing, Medicine, Facilities, Dentistry, Cardiology, Oncology, and the Center for Sickle Cell Disease.

c. Conclusions:

No violations of NRC requirements were identified.

2. Review of the Activities Related to the Discovery of Ac-227 Powder

a. Inspection Scope

The inspector performed a reactive inspection to review the events associated with the discovery of unlicensed Ac-227 powder in a Howard University laboratory. The inspector used NRC Inspection Procedure 87103, "Inspection of Materials Licensees Involved in an Incident or Bankruptcy Filing," to conduct the inspection. Information was gathered through interviews with cognizant personnel, review of records, tours of the facility, and through the performance of independent radiation surveys.

b. Observations and Apparent violations

On January 31, 2018, while cleaning out a lab in Howard University's Physics Building, Room 209, the Howard University Chemical Safety Officer discovered a lead container labeled as "Radioactive Material." The Physics staff moved the material to a locked safe and contacted the Radiation Safety Officer (RSO).

In early February 2018, the RSO examined the container and conducted radiological surveys. The RSO opened the lead container and found a baby food sized jar wrapped in a plastic bag. The jar contained a gray powder and the label on the jar read "Actinium" and "received on July 31, 1942." The radiation safety staff performed a radiation survey of the jar and measured an exposure rate of 10 mR/h on contact. The material was taken to a Radiation Safety Laboratory at the University Cancer Center, Room B101, where it was placed in a negative pressure hood, and the lab door was locked. The radiation safety staff performed contamination surveys and reported that there was no spread of contamination during the transfer. Surveys showed no radiological contamination in the laboratory where the material was initially found (Physics Building Room 209) or in the safe where the material was temporarily stored by physics department staff.

The RSO notified the NRC Region I office (ref ADAMS Accession No. ML18045A021) and immediately submitted an amendment request to add Ac-227 to Howard University's broad-scope NRC license No. 08-00386-19.

In an attempt to gather more information about the radioactive material, the RSO interviewed Howard University Physics Department staff members who reported that Room 209 is an inactive lab that was formerly controlled by a Physics Professor who left the University due illness in 2014 and subsequently passed away on June 30, 2015. Since that time, the lab was unused and the door was locked. Further, they reported that the lab space had not been used as an active lab and had only been used for storage for the last, approximately, 15 years. None of the individuals interviewed had any knowledge of the material and could not provide any additional information about the origin, acquisition, or use of the material labeled as Actinium.

The label on the container indicated that the material was Actinium [presumably Ac-227] and was received on July 31, 1942. This date is before NRC licensing requirements. The earliest readily retrievable NRC license in the NRC Region I docket room for Howard University is dated July 11, 1975, and no actinium isotopes were authorized by this or any later amendment to the license. The label on the source gives no indication of who received it or if it was even initially received by anyone at Howard University. Therefore, it is unknown if the material was acquired by the Physics professor who controlled the lab or some other scientist at the University. Given that the Physics professor would have been a child in 1942, it is highly unlikely that he was the initial recipient of the material.

On February 16, 2018, NRC conducted a reactive inspection to review the details associated with the discovery of the powdered radioactive material labeled as actinium. The inspector conducted interviews with selected staff members including the Radiation Safety Officer and his staff, selected members of the Radiation Safety Committee, and selected members of the Physics department. The inspector also conducted tours of

locations where the material was handled and the inspector conducted independent radiological surveys.

The inspector examined the material which was stored in the Radiation Safety laboratory (University Cancer Center, Room B101), inside a negative pressure vent hood. The RSO opened the lead container and removed a small jar of gray powder. The jar was double wrapped in plastic. The inspector performed a radiation survey of the jar and attempted to perform isotopic scans using a Ludlum Model 702i Isotope Identifier. The inspector measured 8 mR/h on contact with the jar. Attempts to identify the specific radioisotopes in the jar were unsuccessful. The inspector noted that Ac-227 and its daughter products decay by alpha and beta emission and typically cannot be identified using hand held survey instruments that identify isotopes by measuring the energy of emitted gamma rays.

The inspector also performed contamination surveys with a Ludlum Measurements, Inc. Model 26 Integrated Pancake Frisker. No radioactive contamination was found in the Physics Building lab, Room 209, or the Radiation Safety laboratory (University Cancer Center, Room B101) using the Ludlum Model 26 frisker.

Following the initial on-site NRC inspection, Howard University contracted with RSO, Inc. to have the material disposed of. RSO, Inc. contracted with GEL Laboratories, LLC, to have the material analyzed and they determined that the material contained 79.5 microcuries of Ac-227 (half-life (t ½) = 21.77 y), and that it was in secular equilibrium with its short lived daughter products including Th-227 (t ½ = 18.7 d), Ra-223 (t ½ = 11.4 d), Rn-219 (t ½ 3.9 sec), Pb-211 (t ½ = 36 min), and Bi-211 (t ½ = 2.1 min).

Risk Significance

Howard University's' contractor estimated the total quantity of Ac-227 in the container to be 79.5 microcuries. The most limiting Annual Limit of Intake (ALI) for inhalation of Act-227 is listed in Appendix B of 10 CFR Part 20, as 4 E-4 microcuries for bone surfaces. The material was present in a powdered form which was readily dispersible. If this material was mishandled (e.g., spilled in the lab), significant internal exposures above regulatory limits could have occurred.

However, based on Howard University's review and the independent NRC review, there is no indication that the material was mishandled and no loose contamination was identified in the laboratory environments. The material was present in a powdered form within a glass jar, within a plastic bag, and stored in a clearly labeled lead shielded container. The container was stored in a locked laboratory that had not been actively used for at least 15 years, and was accessible only to a limited number of Department of Physics staff members. Therefore, no measureable radiation exposures are attributed to the discovery, handling, and disposal of the unlicensed Ac-227 material.

Summary of Corrective Actions

In response to the discovery of unlicensed Ac-227, the radiation safety staff at Howard University conducted radiological surveys, confirmed that there was no spread of contamination, placed the material into secure storage, notified the NRC, established a contract for the analysis and disposal of the material, and facilitated the shipment of the material from the university. Because Howard University transferred the material for

disposal before NRC processed the license amendment request, the NRC determined that it was not necessary for Howard University to add Ac-227 to their broad-scope material license, and the license amendment request was voided.

On April 11, 2018, the Radiation Safety Committee unanimously agreed to request a memorandum from the Office of the Provost to all Department Chairs requesting them to verify there are no unauthorized radioactive materials present in Howard University laboratories. In response, Howard University's Provost and Chief Academic Officer, sent a memorandum dated April 19, 2018, to all Department Chairs notifying them of the issue and requested all Department Chairs to verify that they do not possess unlicensed radioactive materials in their labs, and to immediately notify the Radiation Safety Office if they discovered any such material.

According to the Radiation Safety Officer, following the issuance of the Provost's memorandum, he was notified by the Engineering department that they did not possess any unlicensed materials and was notified by the Department Physics that they possessed 84 exempt quantity sources. Follow-up radiological surveys of Physics Building room 209, performed by the radiation safety staff, identified five naturally occurring uranium rocks, which were not required to be on the Howard University license, and one 0.5 microcurie sealed Co-60 source which was authorized by NRC license 08-00386-19.

In an attempt to evaluate the scope and thoroughness of actions taken to prevent recurrence, the inspector requested the RSO to provide any electronic or hard copy documentation of responses from the Department Chairs who were directed by the University Provost to verify that there is no unlicensed radioactive materials present in their labs. The Radiation Safety Officer stated that besides the Departments of Physics and Engineering, he did not receive any additional responses and therefore assumed that each department conducted detailed searches of their respective laboratories and did not find any unlicensed radioactive materials. The RSO could not provide any additional information regarding the scope or thoroughness of the searches performed by the recipients of the Provost's memorandum.

Previous Discovery of Unlicensed Radioactive Material

During NRC Inspection No. 03011063/2013001, initiated at Howard University on April 29, 2013, inspectors determined that sometime prior to June of 2009, Howard University possessed a glass vial that contained "millicuries" of cesium-137 (Cs-137) in a liquid form, in Howard University's Adams Building, Room 4104, and that material was not authorized by Howard University's NRC Broad-Scope License No. 08-00386-19.

During the current NRC inspection, the inspector inquired about the effectiveness of the corrective actions taken to address the previous discovery of unlicensed liquid Cs-137. The RSO reported that the discovery of the unlicensed liquid Cs-137 and its disposal occurred prior to him being named as the current Radiation Safety Officer. He stated that when NRC issued the violation, no additional corrective or preventative actions were taken because the unlicensed liquid Cs-137 that was the subject of the violation was disposed of in 2009 and based on his staff's surveillances, there were no unlicensed radioactive materials present in the laboratories that were authorized to possess radioactive materials.

Current Discovery of Unlicensed Material

Based on circumstantial evidence, it appears that:

- The unlicensed Ac-227 source was likely acquired by a University staff member before NRC licensing requirements and was eventually stored in Howard University's Physics Building, Room 209, without the knowledge of the University's radiation safety staff;

- Howard University's radiation safety staff was apparently never notified about the existence of the Ac-227 source when they applied for the original NRC license.

Upon discovery, Howard University's radiation safety staff took appropriate immediate corrective actions to properly control and dispose of the the Ac-227 source. There is no evidence that the unlicensed Ac-227 was mishandled and therefore, no radiation exposures are attributed to the discovery, handling, or disposal of the material.

Corrective actions to address a previous NRC violation related to the possession of unlicensed radioactive material (see NRC inspection report No. 03011063/2013001), were not effective in preventing this recurrence, in that they did not include a robust extent-of-condition review, which would have included detailed searches of scientific laboratories that were not authorized to possess radioactive materials, for the potential presence of unlicensed radioactive materials.

To prevent recurrence, the University's Provost directed Howard University Department Chairs to verify that they do not possess unlicensed radioactive materials in their labs. However, details regarding the scope or thoroughness of the searches performed by the various Howard University departments was not available.

c. Conclusions

One apparent violation was identified and is being considered for escalated enforcement:

10 CFR 30.3 requires, in part, that except for persons exempted, no person shall possess or use byproduct material except as authorized by a specific or general license issued in accordance with the regulations in 10 CFR Part 30.

Contrary to the above, from an unknown period through March 2018, Howard University possessed byproduct material that was not authorized by a specific or general license issued in accordance with the regulations in 10 CFR Part 30, and without being exempt from licensing. Specifically, Howard University possessed 79.5 microcuries of Ac-227 powder, and that material was not exempt from licensing requirements and was not authorized on NRC License No. 08-00386-19.

4. Exit Meeting

On November 2, 2018, the inspector presented the results of the inspection by telephone. The licensee acknowledged the apparent violations.

ATTACHMENT: SUPPLEMENTAL INFORMATION

PARTIAL LIST OF PERSONS CONTACTED

Licensee
#* Satya R. Bose, Ph. D, Radiation Safety Officer
* Alice Mahan, Management Representative
*Sergei Nekhai, Ph.D., Radiation Safety Committee Chair
Deepsa Sarker, Radiation Safety Staff
Kanwal Gambhir, Ph.D.
Quinton Williams, Chair- Department of Physics
Marcus Alfred, Department of Physics
Oladapo Bakare, Chair – Department of Chemistry

#Present at entrance meeting on February 16, 2018
*present at telephone exit meeting on November 2, 2018

INSPECTION PROCEDURES USED

1) Manual Chapter 2800, "Materials Inspection Program"
2) Inspection Procedure 87103, "Inspection of Materials Licensees Involved in an Incident or Bankruptcy Filing"

LIST OF DOCUMENTS REVIEWED

1. Notification to NRC Regarding the Discovery of Unlicensed Ac-227, dated 2/12/2018, (ML18045A021)
2. Howard University Amendment request letter dated 2/13/2018, to add Ac-227 to NRC License No. 08-00386-19 (ML18045A021).
3. Memorandum from Anthony K. Wutoh, Ph.D., R. Ph., to all Howard University Department Chairs requesting a verification that there is no unlicensed radioactive material in department laboratories, dated April 19, 2018.
3. List of Radioactive Material collected from the Physics Department, Room 209, dated 6/8/2018
4. Howard University Physics Department Inventory of Check Source 6/18/2018
5. GEL Laboratories, LLC, Analysis of Howard University Actinium Sample, dated March 28, 2018

LIST OF NRC SURVEY INSTRUMENTS USED

1) Ludlum Model 702i Isotopic Identifier, serial number. 25013458, calibration date 12/21/2017,

2) Ludlum Measurements, Inc. Model 26 Integrated Pancake Frisker, serial number PF001744, calibration date: 01/11/2018.

LIST OF ACRONYMS USED

Ac-227	actinium-227
ALI	Annual Limit of Intake
Cs-137	cesium-137
mR/h	milliRoentgen per hour
RSO	Radiation Safety Officer
t ½	half-life