UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD., SUITE 100
KING OF PRUSSIA, PA 19406-2713

August 25, 2015

EA-15-078
EA-15-053

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

SUBJECT: HOWARD UNIVERSITY, NOTICE OF VIOLATION - INSPECTION REPORT NO. 03011063/2013001; AND HOWARD UNIVERSITY HOSPITAL, NOTICE OF VIOLATION – INSPECTION REPORT NO. 03001321/2013003; INVESTIGATION REPORT NO. 1-2014-002

Dear Dr. Frederick:

This letter provides you the U.S. Nuclear Regulatory Commission's (NRC's) enforcement decision for the apparent violations (AVs) identified during separate, onsite NRC safety inspections conducted on April 29-30, June 25 and September 18, 2013, at Howard University's (HU's) campus and on October 31, 2013, at the Howard University Hospital (HUH). Both facilities are located in Washington, DC, and each inspection involved continued in-office review through May 11, 2015. The inspections consisted of interviews with HU and HUH personnel and the examination of selective records to evaluate HU's and HUH's licensed activities as they relate to radiation safety and to compliance with NRC regulations. Messrs. James Dwyer and Robert Gallaghar of this office discussed the AVs with you during a telephonic exit meeting on May 11, 2015. The AVs were also described in NRC inspection reports sent to you with a letter dated July 8, 2015 (ML15194A370[1]).

In the July 8, 2015, letter transmitting the inspection reports, we informed you that we had sufficient information regarding the AVs and the corrective actions taken by HU and HUH to make an enforcement decision without the need for additional information from you. However, we provided you the opportunity to address the AVs by either attending a pre-decisional enforcement conference (PEC) or providing a written response. We also informed you that you could accept the violations as characterized in the reports. In an electronic mail message on July 22, 2015, Dr. Satya Bose of your organization indicated that HU and HUH did not require a PEC and did not intend to send a written response.

[1] Designation in parentheses refers to an Agency-wide Documents Access and Management System (ADAMS) accession number. Unless otherwise noted, documents referenced in this letter are publicly-available using the accession number in ADAMS

This letter also refers to the subject investigation by the NRC Office of Investigations (OI) conducted at HU. The investigation, which was completed on November 25, 2014, was conducted to determine whether HU staff willfully: (1) did not notify the NRC within 24 hours after discovery of an unplanned contamination event and/or provided inaccurate/incomplete information to the NRC regarding the event; (2) failed to keep records of information important to the decommissioning of a facility; (3) possessed byproduct material that was not authorized by a specific or general license; and (4) failed to conduct a physical inventory and maintain records of physical inventories.

Based on the evidence gathered during the OI investigation, the NRC has concluded that there was insufficient evidence to substantiate any of the specific concerns stated above. However, based on the information developed during the inspection and the investigation, the NRC has determined that two violations of NRC requirements occurred. The violations are cited in the Notice of Violation (Notice) provided as Enclosure 1 to this letter, and the circumstances surrounding them were described in detail in the subject inspection report.

The most significant violation involved HU's failure to notify the NRC within 24 hours after the discovery of an unplanned contamination event that: (1) required access to the contaminated area to be restricted for more than 24 hours for a reason other than to allow isotopes with a half-life less than 24 hours to decay prior to decontamination; and (2) involved a quantity of material greater than five times the lowest annual limit of intake specified in Appendix B of Title 10 of the Code of Federal Regulations (CFR) Part 20. Specifically, in February/March 2008, the HU Radiation Safety Office was preparing to ship radioactive waste material to an authorized disposal facility. The exterior surfaces of radioactive sources and source vials containing liquid radioactive materials were wipe tested for removable contamination, and one glass vial that HU believed had contained millicurie amounts of cesium-137 (Cs-137) in liquid form tested positive for contamination. HU staff surveyed the concrete vault in which the vial had been stored and the floor of the surrounding room, and identified additional contamination. HU staff restricted access to the room until the summer of 2008, following decontamination of the area. The HU staff involved informed OI and the NRC inspector that they had determined the event was not reportable based on a review of the reporting requirements in 10 CFR Part 20. However, they acknowledged that they had not reviewed the requirements in 10 CFR Part 30 and therefore had not identified that the event required 24 hour notification to the NRC, in accordance with 10 CFR 30.50(b).

This violation impacted the NRC regulatory process since the NRC did not receive information about the event in order to fully assess any safety impact to HU workers and/or the public and to monitor the effectiveness of HU's cleanup process. Based on HU's failure to report, for more than seven years, an event that required notification within one day, the violation has been cited at Severity Level (SL) III in accordance with the NRC Enforcement Policy. In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of $3,500 is considered for a SL III violation. Because HU has not been the subject of escalated enforcement action within the last two years or two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the NRC Enforcement Policy. The NRC has concluded that credit is warranted for HU's corrective actions taken to address the violation. Specifically, on May 7, 2015, HU reported the event to the NRC (Event Notification No. 51049) and the HU Radiation Safety Officer (RSO) has

provided training to the HU research staff and radiation safety staff on the proper reporting requirements. Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, after consultation with the Director, Office of Enforcement, I have been authorized not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this SL III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

One additional violation, also documented in the Notice, has been categorized in accordance with the NRC Enforcement Policy at SL IV. This violation involved HU's unauthorized possession of the Cs-137 source. Although it appears that the HU license did, at one time, permit possession of such material, this authorization had been removed from the license in December 1993. HU staff informed OI and the NRC inspector that the source had been in storage in the vault for years, and no one had realized HU was not authorized to possess the material. The circumstances surrounding this additional violation are documented in detail in the Notice as well as the aforementioned inspection report. The additional violation is being cited because it was identified by the NRC.

For the HUH license, based on the information developed during the inspection, the NRC has determined that two, related violations of NRC requirements occurred. The violations are cited in the Notice provided as Enclosure 2 to this letter, and the circumstances surrounding them were described in detail in the subject inspection report. Both violations resulted from the temporary loss of control of a radioactive material (RAM) package containing a 10.44 curie iridium-192 (Ir-192) sealed source. Specifically, on August 31, 2013, the package was delivered to the HUH loading dock and placed inside of the loading dock doors adjacent to the Central Supply Department (CSD). The CSD worker who was present at the time of delivery had not received training on the identification of a RAM shipment or the necessary actions to properly secure packages containing RAM, so the worker did not control or secure the package. The package was later moved by a second CSD worker to a location inside the CSD, behind locked doors near the HUH Mail Room, where it remained until September 3, 2013, when staff from the Mail Room notified the Radiation Safety Office. The HUH RSO surveyed the package, confirmed the source was not damaged, and secured the package.

The NRC has concluded that, contrary to 10 CFR 20.1802, while the package was in the loading dock area, HUH did not control or maintain constant surveillance of the package containing the Ir-192 source that was in a controlled or unrestricted area and was not in storage. The NRC also concluded that, contrary to 10 CFR 20.1801, when HUH stored the package inside the CSD, HUH did not secure the source from unauthorized removal or access, since unauthorized HUH staff had access to this temporary storage location. The NRC has concluded that both violations resulted from HUH's failure to provide adequate training to all CSD workers on how to identify and handle RAM packages. The package had been unexpectedly delivered to HUH over a holiday weekend, during which time the CSD was staffed with workers who were unaccustomed to dealing with RAM shipments, since HUH scheduled them to occur during normal work hours. However, this practice left HUH vulnerable to unplanned occurrences such as this one. Each violation resulted in the potential for unauthorized personnel to have access to, and potentially remove, the source, which could have resulted in unplanned radiation

exposure to members of the public. Consequently, each violation has been categorized at SL III. Given the shared root cause of both violations, they are being cited together as a SL III problem to emphasize the importance of providing adequate, defense-in-depth training on radiation safety.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of $3,500 is considered for a SL III problem. Because HUH has not been the subject of escalated enforcement action within the last two years or two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the NRC Enforcement Policy. The NRC has concluded that credit is warranted for HUH's corrective actions taken to address the violations. Specifically: (1) upon notification, the RSO immediately retrieved the package, determined that the package was not damaged, and secured it in the proper location; (2) the RSO trained all involved personnel on the proper procedures for RAM package receipt and security; and (3) the RSO established a policy, in writing, that the vendor only deliver such RAM shipments during normal business hours, and not on holidays or weekends. In addition, HUH clarified that if the vendor fails to comply with the written policy by delivering a RAM package during off-normal hours, security staff have been instructed to immediately secure the package. Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, after consultation with the Director, Office of Enforcement, I have been authorized not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this SL III problem constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding: (1) the reasons for the violations; (2) the actions planned or already taken to correct the violations and prevent recurrence; and, (3) the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report Nos. 03011063/2013001 and 03001321/2013003, and in this letter. 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 Notices.

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 document system (ADAMS), accessible from the NRC Website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response, if you choose to provide one, should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such information, you must specifically identify the portions of your response that you seek to have withheld, and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

The NRC also includes significant enforcement actions on its Web site at (http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/).

Please note that final NRC investigation documents, such as the OI report described in this letter, may be made available to the public under the Freedom of Information Act (FOIA) subject to redaction of information appropriate under the FOIA. Requests under the FOIA should be made in accordance with 10 CFR 9.23, "Requests for Records," a copy of which is enclosed for your information.

Sincerely,

for

Daniel H. Dorman
Regional Administrator

Docket Nos. 03011063
03001321

Enclosures:
1. Notice of Violation for Howard University
2. Notice of Violation for Howard University Hospital
3. Copy of 10 CFR 9.23, "Requests for Records"

cc w/enclosures:
District of Columbia

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Sincerely,

/RA David C. Lew for:/

Daniel H. Dorman
Regional Administrator

Docket Nos. 03011063
03001321

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District of Columbia

Distribution: see next page **ML15237A037**

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OFFICE	RI/ORA	RI/ORA	RI/DNMS	RI/DNMS	RI/ORA
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DATE	7/24/15	7/24/15	7/27/15	7/28/15	7/30/15
OFFICE	RI/ORA	OE**	RI/DNMS	RA	
NAME	B Bickett/ BAB*	L Sreenivas via email	D Collins/	D Dorman/dcl for	
DATE	7/31/15	8/05/15	8/21/15	8/24/15	

* See previous concurrence page ** OE to perform a quick review

OFFICIAL RECORD COPY

ENCLOSURE 1
NOTICE OF VIOLATION

Howard University
Washington, DC

Docket No. 03011063
License No. 08-00386-19
EA-15-078

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on April 29-30, June 25 and September 18, 2013, with continued in-office review through May 11, 2015, and during an NRC investigation by the NRC Office of Investigations, completed on November 25, 2014, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. ESCALATED VIOLATION

10 CFR 30.50(b) requires, in part, that each licensee notify the NRC within 24 hours after the discovery of an unplanned contamination event that (1) required the access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area; (2) involved a quantity of material greater than five times the lowest annual limit of intake specified in Appendix B of 10 CFR Part 20; and (3) access into the contaminated area was restricted for a reason other than to allow isotopes with a half-life less than 24 hours to decay prior to decontamination.

Contrary to the above, from February/March 2008 until May 7, 2015, Howard University (HU) did not notify the NRC within 24 hours after the discovery of an unplanned contamination event that required access to the contaminated area to be restricted for more than 24 hours for a reason other than to allow isotopes with a half-life less than 24 hours to decay prior to decontamination, and that involved a quantity of material greater than five times the lowest annual limit of intake specified in Appendix B of 10 CFR Part 20. Specifically, HU discovered that a storage room had been contaminated with material from a vial containing millicurie quantities of cesium-137 (which is more than five times the 10 CFR Part 20 Appendix B amount of 100 microcuries), and prohibited entry into the room for several months until decontamination was complete. The half-life of cesium-137 is 30 years.

This is a Severity Level III violation. (Enforcement Policy Section 6.9)

B. NON-ESCALATED VIOLATION

10 CFR 30.3(a) requires, in part, that no person shall transfer, receive, acquire, own, possess, or use byproduct material except as authorized by a specific or general license issued in accordance with the regulations in that chapter.

Contrary to the above, prior to June 2009, HU possessed byproduct material that was not authorized by a specific or general license. Specifically, HU possessed cesium-137 in a solution, and this material had not been authorized on the specific license since December 1993, and also was not authorized by a general license issued in accordance with 10 CFR Part 31.

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

The NRC has concluded that information regarding: (1) the reasons for the violations; (2) the actions planned or already taken to correct the violations and prevent recurrence; and (3) the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 03011063/2013001, and in the letter transmitting this Notice. Therefore, you are not required to respond to this Notice. 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 EA-15-078," 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, Region I, 2100 Renaissance Boulevard, Suite 100, King of Prussia, PA 19406, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

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

Dated this 25th day of August, 2015

ENCLOSURE 2
NOTICE OF VIOLATION

Howard University Hospital
Washington, DC

Docket No. 03001321
License No. 08-03075-07
EA-15-053

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on October 31, 2013, with continued in-office review through May 11, 2015, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 10 CFR 20.1802 requires licensees to control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

   Contrary to the above, on August 31, 2013, Howard University Hospital (HUH) did not control and maintain constant surveillance of licensed material that was in a controlled or unrestricted area and that was not in storage. Specifically, a 10.44 curie iridium-192 source was delivered to the hallway outside the HUH Central Supply Department (CSD) room (a controlled or unrestricted area) and the licensee did not control or maintain constant surveillance of the source for approximately 4.5 hours.

B. 10 CFR 20.1801 requires licensees to secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

   Contrary to the above, between August 31, 2013, and September 3, 2013, HUH did not secure from unauthorized removal or access licensed materials that were stored in a controlled or unrestricted area. Specifically, a 10.44 curie iridium-192 source was stored in a locked room (a controlled area) within the HUH CSD, and unauthorized HUH staff had access to the room.

This is a Severity Level III problem (Enforcement Policy Section 6.7).

The NRC has concluded that information regarding: (1) the reasons for the violations; (2) the actions planned or already taken to correct the violations and prevent recurrence; and (3) the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 03001321/2013003, and in the letter transmitting this Notice. Therefore, you are not required to respond to this Notice. 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 EA-15-053," 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, Region I, 2100 Renaissance Boulevard, Suite 100, King of Prussia, PA 19406, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. Therefore, to

the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

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

Dated this 25th day of August, 2015

§ 9.23 Requests for Records

(a)(1) A person may request access to records routinely made available by the NRC under § 9.21 in person, by telephone, by e-mail, facsimile, or U.S. mail from the NRC Public Document Room, One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland 20852-2738.

(i) Each record requested must be described in sufficient detail to enable the NRC Public Document Room staff to locate the record.

(ii) To obtain copies of records expeditiously, a person may open an account with the NRC Public Document Room reproduction contractor. Payment for reproduction services will be made directly to the contractor.

(2) [Reserved]

(b) A person may request agency records by submitting a request authorized by 5 U.S.C. 552(a)(3) to the Freedom of Information Act and Privacy Act Officer by an appropriate method listed in § 9.6 of this chapter. The request must be in writing and clearly state on the envelope and in the letter that it is a "Freedom of Information Act request." The NRC does not consider a request as received until the date it is actually received by the Freedom of Information Act and Privacy Act Officer.

(1) A Freedom of Information Act request covers only agency records that are in existence on the date the Freedom of Information Act and Privacy Act Officer receives the request. A request does not cover agency records destroyed or discarded before receipt of a request or which are created after the date of the request.

(2) All Freedom of Information Act requests for copies of agency records must reasonably describe the agency records sought in sufficient detail to permit the NRC to identify the requested agency records. Where possible, the requester should provide specific information regarding dates, titles, docket numbers, file designations, and other information which may help identify the agency records. If a requested agency record is not described in sufficient detail to permit its identification, the Freedom of Information Act and Privacy Act Officer will contact the requester within 10 working days after receipt of the request and inform the requester of the additional information or clarification needed to process the request.

(3) Upon receipt of a request made under paragraph (b) of this section, the NRC will provide written notification to the requester that indicates the request has been received, the name and telephone number of the NRC point of contact to find out the status of the request, and other pertinent matters regarding the processing of the request.

(4)(i) The NRC shall advise a requester that fees will be assessed if--

(A) A request involves anticipated costs in excess of the minimum specified in § 9.39; and

(B) Search and duplication is not provided without charge under § 9.39; or

(C) The requester does not specifically state that the cost involved is acceptable or acceptable up to a specified limit.

(ii) The NRC has discretion to discontinue processing a request made under this paragraph until--

(A) A required advance payment has been received;

(B) The requester has agreed to bear the estimated costs;

(C) A determination has been made on a request for waiver or reduction of fees; or

(D) The requester meets the requirements of § 9.39.

(c) If a requested agency record that has been reasonably described is located at a place other than at the NRC Web site, *http://www.nrc.gov,* the NRC Public Document Room, or the NRC headquarters, the NRC may, at its discretion, make the record available for inspection and copying at either of the locations.

(d) Except as provided in § 9.39--

(1) If the record requested under paragraph (b) of this section is a record available through the National Technical Information Service, the NRC shall refer the requester to the National Technical Information Service; and

(2) If the requested record has been placed on the NRC Internet Web site, under § 9.21, the NRC may inform the requester that the record is available at the NRC Web site, *http://www.nrc.gov,* and/or at the NRC Public Document Room, and that the record may be obtained in accordance with the procedures set forth in paragraph (a) of this section.

(e) The Freedom of Information Act and Privacy Act Officer will promptly forward a Freedom of Information Act request made under paragraph (b) of this section for an agency record to the head of the office(s) primarily concerned with the records requested, as appropriate. The responsible office will conduct a search for the agency records responsive to the request and compile those agency records to be reviewed for initial disclosure determination and/or identify those that have already been made publicly available at the NRC Web site, *http://www.nrc.gov,* and/or at the NRC Public Document Room.

[63 FR 2876, Jan. 20, 1998, as amended at 64 FR 48950, Sept. 9, 1999; 67 FR 67098, Nov. 4, 2002; 68 FR 58800, Oct. 10, 2003, 70 FR 34306, June 14, 2005]