



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

August 10, 2018

Anthony K. Wutoh, Ph.D., R.Ph.
Provost & Chief Academic Officer
Howard University Hospital
2041 Georgia Avenue, N.W.
Cancer Center, Room 323
Washington, D.C. 20060

**SUBJECT: HOWARD UNIVERSITY HOSPITAL - NRC INSPECTION NO.
 03001321/2018001, AND NOTICE OF VIOLATION**

Dear Dr. Wutoh:

This letter refers to the inspection conducted on April 10, 2018, at your Washington, D.C. facility. This inspection examined activities conducted under your license as they relate to public health and safety, and to confirm compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel. The inspection also included evaluation of communications provided by your Radiation Safety Officer on April 13, April 23, May 24, and August 7, 2018.

Based on the results of this inspection, the NRC has determined that three Severity Level IV violations of NRC requirements occurred. These violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at (<http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>). The violations are cited in the enclosed Notice of Violation (Notice) because the violations were identified by the NRC.

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance will be achieved is already adequately addressed on the docket and include: as of the July 2018 meeting, a 35.400 user was added to the Radiation Safety Committee until the authorization for 35.400 materials is removed from your license; on April 13, 2018, the RSO provided training on emergency operating procedures for the two 10 CFR 35.600 Authorized Users who had not received the training in the past twelve months; and on April 11, 2018, the RSO/AMP performed a linearity evaluation for the High Dose Rate Remote Afterloader out to maximum time permitted by the unit. Therefore, you are not required to respond to this letter unless the description herein 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 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 Web site 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.

If you have any questions regarding this matter, please contact Robin Elliott of my staff at (610) 337-5076 or via electronic mail at robin.elliott@nrc.gov.

Thank you for your cooperation.

Sincerely,



Donna M. Janda, Chief
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety
Region I

Docket No. 030-01321
License No. 08-03075-07

Enclosure:
Notice of Violation

cc w/Encl: Satya Bose, Ph.D., Radiation Safety Officer
District of Columbia

HOWARD UNIVERSITY HOSPITAL - NRC INSPECTION NO. 03001321/2018001, AND
NOTICE OF VIOLATION DATED August 10, 2018

DOCUMENT NAME: G:\WBL Documents\WBL Inspection Letter\L08-03075-07.2018001.docx

SUNSI Review Complete: RElliott

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	RI:DNMS	N	RI:DNMS	N			
NAME	RElliott/rle		DMJanda	<i>DMJ</i>			
DATE	8/8/18		<i>8/10/18</i>				

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Howard University Hospital
Washington, DC

Docket No. 030-01321
License No. 08-03075-07

During an NRC inspection conducted on April 10, 2018, three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 35.24(f) requires, in part, that licensees that are authorized for two or more different types of uses of byproduct material under subparts E, F, and H of this part, shall establish a Radiation Safety Committee to oversee all uses of byproduct material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license.

Contrary to the above, between June 2017 and April 2018, Howard University did not include an authorized user for each type of use permitted by the license on the Radiation Safety Committee. Specifically, the Howard University Radiation Safety Committee did not include an authorized user for 35.400 materials, a use permitted by their license.

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

- B. 10 CFR 35.610 requires, in part, that licensees shall provide instruction, initially and at least annually, to all individuals who operate the unit, and shall ensure that operators, authorized medical physicists, and authorized users participate in drills of emergency procedures, initially and at least annually.

Contrary to the above, as of April 10, 2018, Howard University did not provide instruction, at least annually, to all authorized users who operate the unit and did not ensure that all authorized users participate in drills of emergency procedures at least annually. Specifically, as of April 10, 2018, two authorized users for 35.600, High Dose Rate (HDR) Remote Afterloader Units, had not received the annual instruction and did not participate in annual drills of the emergency procedures within the last twelve months.

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

- C. 10 CFR 35.633(b)(5) requires, in part, that licensees must perform full calibration measurements on each (HDR) unit to include timer linearity over the typical range of use.

Contrary to the above, between June 2017 and April 2018, Howard University did not perform full calibration measurements on their HDR unit to include timer linearity over the typical range of use. Specifically, Howard University conducted timer linearity measurements on their HDR unit out to 8 minutes, and treatments were performed out to 20 minutes.

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

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations 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.

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

Dated This 10th day of August 2018