



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

April 27, 2020

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

SUBJECT: TEMPORARY EXEMPTION FROM TITLE 10 *CODE OF FEDERAL REGULATIONS* 30.34(e) AND LICENSE CONDITION 21.A OF NRC LICENSE 08-00386-19, HOWARD UNIVERSITY, MAIL CONTROL NO. 618593 AND WITHDRAWAL OF TEMPORARY EXEMPTION REQUEST, HOWARD UNIVERSITY HOSPITAL, MAIL CONTROL NO. 618599

Dear Dr. Wutoh:

By letter dated April 10, 2020 (Agencywide Document Access and Management System [ADAMS] Accession No. ML20105A109) Howard University, the licensee, requested an exemption from Title 10 of the *Code of Federal Regulations* (10 CFR) 30.34(e) and License Condition 21.A of NRC License No. 08-00386-19. Supplemental information for the request, in response to a Request for Additional Information, was provided in an email received April 17, 2020 (ML20112F382). By the above letter dated April 10, 2020, Howard University Hospital requested exemptions from parts of 10 CFR and certain license conditions. The request was withdrawn in an e-mail dated April 20, 2020 (ML20112F371).

In Howard University's request, the licensee stated that due to the COVID-19 public health emergency (PHE) all Principal Investigators were deemed to be non-essential personnel and all use of licensed material was discontinued.

The exemption provision in 10 CFR 30.11(a) states:

The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part and parts 31 through 36 and 39 of this chapter as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

The license conditions from which the licensee requested exemption were imposed upon the licensee by the U.S. Nuclear Regulatory Commission (NRC) per 10 CFR 30.34(e). The regulation in 10 CFR 30.34(c) requires that the licensee confine its use of the byproduct material to the locations and purposes authorized in the license. Therefore, exemptions to the requirement in 10 CFR 30.34(c) to comply with the terms of a license may be granted pursuant to 10 CFR 30.11.

The NRC staff reviewed the request in accordance with 10 CFR 30.11(a) and finds that the criteria contained therein are met. The regulation from which the licensee is requesting exemption is 10 CFR 30.34(c), which requires that the licensee confine its use of the byproduct material to the locations and purposes authorized in the license.

The license condition from which the licensee is requesting exemption is License Condition No. 21.A, which requires, in pertinent part, that the licensee shall conduct its program in accordance with the statements, representations and procedures contained in the application dated July 28, 2014 (ML14219A354). The specific parts of the application that are relevant to the exemption request are as follows:

- Page 10, Section 10.1, "Radiation Safety Program," Item A.4, "Quarterly Laboratory Inspections" requires, in pertinent part, that the Radiation Safety Officer and/or designee conduct an inspection of each radioisotope laboratory on a quarterly basis.
- Page 14, Section 10.4, "Occupational Dose" requires, in pertinent part, that badges must be exchanged according to the change date on the dosimetry.
- Appendix III, "Radiation Safety Officer Duties and Responsibilities," Item 6 requires that the Radiation Safety Officer survey all activities involving radioactive materials, including routine monitoring and special surveys of all areas in which radioactive materials are used. The licensee requested an exemption from:
 - A. Daily monitoring of the hospital loading dock radiation monitors including radioactive wastes.
 - B. Weekly wipe tests (surveys) for the Radiation Safety Office facilities/labs.
 - C. Semi-annual radiation surveys of the licensee's research laboratories not authorized to use or possess licensed materials.

The regulation in 10 CFR 30.11(a) authorizes granting of exemptions specific to Part 30. The NRC staff has determined that the granting of the requested exemption will not result in a violation of the Atomic Energy Act of 1954, as amended, or the Commission's regulations. The NRC staff, therefore, finds that the granting of the requested exemption is authorized by law.

The NRC also determined that:

1. This 90-day exemption from survey requirements - specifically the Quarterly Laboratory Inspections, the daily monitoring of the hospital loading dock (where Howard University's radioactive materials shipments are received) radiation monitors including radioactive wastes, weekly wipe tests (surveys) for the Radiation Safety Office facilities/laboratories, and the semi-annual radiation surveys of the licensee's research laboratories not authorized to use or possess licensed materials - is relatively short. Additionally, the extension of survey time does not constitute a significant increase in risk to public health and safety because the licensee suspended operations and Howard University Hospital is not accepting deliveries of licensed material from the loading dock.
2. This 90-day exemption from dosimetry exchange requirements is relatively short. Additionally, the extension of dosimetry exchange time does not constitute a significant increase in risk to public health and safety, because the licensee suspended operations and is not using equipment that would lead to accumulated dose.

The NRC also notes that, absent the requested exemption, the licensee may be required to take actions that may be contrary to guidance on preventing the spread of the virus that causes COVID-19. Therefore, the NRC staff finds that the requested exemption will not endanger life or property or the common defense and security and is otherwise in the public interest.

Based on the above findings, the NRC grants the following exemption for the specified period of time:

1. From the date of this letter for a period of 90 days, the licensee is temporarily exempt from the survey time interval required by license condition 21.A, specifically the Quarterly Laboratory Inspections, daily monitoring of the hospital dock radiation monitors including radioactive wastes, weekly wipe tests (surveys) of the Radiation Safety Office facilities/laboratories, and the semi-annual radiation surveys of the licensee's research laboratories not authorized to use or possess licensed materials. The licensee shall perform the required surveys within 30 days of the expiration of this exemption.
2. From the date of this letter for a period of 90 days, the licensee is temporarily exempt from the dosimetry exchange requirement in license condition 21.A. The licensee shall make the required dosimetry exchanges within 30 days of the expiration of this exemption.

An environmental assessment for this action is not required, because this action is categorically excluded under 10 CFR 51.22(c)(25)(vi)(C). In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's ADAMS, accessible from the NRC Web site at: <https://www.nrc.gov/reading-rm/adams.html>.

If you have questions, please contact Steven Courtemanche of my staff at Steven.Courtemanche@nrc.gov or 610-337-5075.

Sincerely,

Christopher Cahill, Chief
Commercial, Industrial, R&D
and Academic Branch
Division of Nuclear Materials Safety
Region I

License Nos. 08-00386-19 and 08-03075-07
Docket Nos. 03011063 and 03001321
Mail Control No. 618593 and 618599

cc: Satya R. Bose, Ph.D., DABR, Radiation Safety Of

TEMPORARY EXEMPTION FROM TITLE 10 *CODE OF FEDERAL REGULATIONS* 30.34(e) AND LICENSE CONDITION 21.A OF NRC LICENSE 08-00386-19, HOWARD UNIVERSITY, MAIL CONTROL NO. 618593 AND WITHDRAWAL OF TEMPORARY EXEMPTION REQUEST, HOWARD UNIVERSITY HOSPITAL, MAIL CONTROL NO. 618599 DATED APRIL 27, 2020

DOCUMENT NAME: G:\WBL Documents\WBL COVID letters\B2\TE08-00386-19.618593.final.docx
 SUNSI Review Complete: SCourtemanche

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/endl "E" = Copy w/ attach/endl "N" = No copy

OFFICE	RI:DNMS	N	OGC (NLO)	N	RI:ORA (NLO)	N	RI:DNMS	
NAME	SCourtemanche/src		EHouseman/eh		BKlukan/bk		CCahill/cgc	
DATE	4/24/2020		04/23/2020		04/27/2020		04/27/2020	

OFFICIAL RECORD COPY