



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

November 20, 2019

EA-19-120

John Gilstad, MD
CAPT MC USN
Institute Director
Uniform Services University of the
Health Sciences
Armed Forces Radiobiology Research Institute
8901 Wisconsin Avenue, Building 42, Room 3417
Bethesda, MD 20889-5603

SUBJECT: UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES, ARMED
FORCES RADIOBIOLOGY RESEARCH INSTITUTE - NRC INSPECTION NOS.
03004545/2019001 AND 03006931/2019002 AND NOTICE OF VIOLATION

Dear Captain Gilstad:

This letter refers to the inspection conducted on October 17, 2019, at your Bethesda, Maryland facility, and continued in-office review until November 18, 2019. This inspection examined activities conducted under your irradiator and broad scope licenses 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. We discussed the findings of the inspection with you during an inspection telephone exit meeting on November 18, 2019.

Based on the results of this inspection, the NRC has determined that one Severity Level IV violation of NRC requirements occurred on both your irradiator and broad scope licenses. The violation involved a failure to maintain an individual authorized by NRC to fulfill the duties and responsibilities of the radiation safety officer for your irradiator and broad scope licenses. In addition, the individual that you nominated to be the radiation safety officer for the broad scope license did not fully meet qualification requirements but was authorized by the NRC because you have a limited scope of work planned for the next year and you committed, by license condition, to have your proposed radiation safety officer mentored by another broad scope radiation safety officer for a period of one year.

The violation was evaluated 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>. The violation is cited in the enclosed Notice of Violation (Notice) because the violation was identified by the NRC.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and your response 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 Randolph Ragland of my staff at 610-337-5083 or via electronic mail at Randolph.Ragland@nrc.gov.

Thank you for your cooperation.

Sincerely,

/RA/

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

Docket Nos. 03004545 and 03006931
License No. 19-08330-02 and 19-08330-03

Enclosure:
Notice of Violation

cc w/Encl: Lt. J. Divis, Radiation Safety Officer

UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES, ARMED FORCES
 RADIOBIOLOGY RESEARCH INSTITUTE - NRC INSPECTION NOS. 03004545/2019001 AND
 03006931/2019002 AND NOTICE OF VIOLATION DATED November 20, 2019

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Leela Sreenivas

Michele Burgess

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OFFICE	Region I: DNMS	RI: OE	RI: DNMS		
NAME	RRagland/rcr	McLaughlin via email	CCahill/cgc		
DATE	11/19/19	11/19/19	11/20/19		

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NOTICE OF VIOLATION

Uniform Services University of the
Health Sciences
Armed Forces Radiobiology Research Institute
Bethesda, MD

Docket Nos. 030-04545
030-06931
License Nos. 19-08330-02
19-08330-03
EA-19-120

During an NRC inspection conducted on October 17, 2019, and continued in-office until November 18, 2019, one violation of NRC requirements was identified on both the AFFRI Irradiator license and the broad scope license. In accordance with the NRC Enforcement Policy, the violation is listed below:

NRC License Condition No. 12 of NRC License No. 19-08330-02, dated June 13, 2016, and NRC License No 19-08330-03, authorized a specific individual to fulfill the duties and responsibilities of the Radiation Safety Officer for the licenses.

Contrary to the above, from June 20, 2019, to July 26, 2019, the individual specifically authorized as the Radiation Safety Officer (RSO) in Condition 12 of NRC License Nos. 19-08330-02, dated June 13, 2016, and Condition 12 of NRC License No. 19-08330-03, dated January 11, 2017, did not fulfill the duties and responsibilities of the RSO. Specifically, the RSO left employment on June 20, 2019, AFRRRI appointed a new RSO on June 24, 2019, but did not submit license amendment requests to NRC until July 26, 2019. In addition, the individual nominated by AFRRRI to be the RSO for the broad scope license did not fully meet qualification requirements but was authorized by the NRC because AFRRRI only has a limited scope of planned work for the next year and AFRRRI committed, by license condition, to have the RSO mentored by another broad scope RSO for a period of one year.

This is a Severity Level IV Violation (NRC Enforcement Policy Section 6.3.d.8)

Pursuant to the provisions of 10 CFR 2.201, the Armed Forces Radiobiology Research Institute is hereby required to submit a written statement or explanation 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). This reply should be clearly marked as a "Reply to a Notice of Violation; EA-19-120" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

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 made available electronically for public inspection in the NRC Public Document Room or in 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>. 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 personal privacy or proprietary information is necessary to provide an acceptable response, then 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 material, 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). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21. If Classified Information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR Part 95.

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

Dated This 20th day of November 2019