CUA

THE CATHOLIC UNIVERSITY OF AMERICA

Environmental Health and Safety
Washington, DC 20064
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July 31, 2013

United States Nuclear Regulatory Commission
ATTN: Document Control Desk,
Washington, DC 20555

United States Nuclear Regulatory Commission
Regional Administrator, Region 1
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713

Subject: CUA response to NRC July 5, 2013 correspondence regarding notice of violation 03000638/2013001, The Catholic University of America Washington, D.C. Site and revised Notice of Violation (NOV).

License No. 08-02075-03 **Docket No. 03000638**

Thank you for the detailed information contained within the NRC staff review of the April 9, 2013 correspondence. CUA does not contest the revised NOV and offers the corrective steps delineated in this letter. As per the enclosed instructions, copies of this response will not be forwarded to the Director, Office of Enforcement.

Since the original NOV and in conjunction with our response to the revised NOV; The Environmental Health and Safety Director and Radiation Safety Officer have approached this incident in a collaborated review of CUA's application of the appropriate radiation safety manual with the appropriate license, the training program and engineering controls in the laboratory setting. The overall safety culture and radiation safety program have improved as a result of this incident.

The reason for the violation: The worker involved in the incident was not wearing adequate protective clothing to fully protect his skin from becoming contaminated, thus leading to the accidental skin contamination and radiation dose. Further, the worker failed to conduct adequate decontamination of the skin in order to keep radiation doses as low as reasonably achievable and below the applicable dose limit. Finally, the worker did not follow the appropriate emergency procedures to immediately notify the Radiation Safety Officer.

Corrective steps that have been taken: As indicated in our April 9, 2013 response to the original Notice of

IE07

Violation, (see enclosed attachment) a refresher training session covering radiation safety requirements specifically focusing on the Tc-99m work was held on February 11, 2011 with another training session held in May, 2011. A subsequent refresher training to the melter staff is in progress. The training included the following topics: adherence to established procedures, proper actions to take during and after accidents involving licensed radioactive material, and use of protective clothing to prevent contamination of the skin. These topics have been included in the University's initial radiation safety training and refresher training provided to our staff as appropriate. This training session was attended by all melter operators and others laboratory technicians involved in this work.

CUA continually evaluates and reviews protective clothing and equipment to be utilized by staff to prevent personal contamination and contamination of clothing, equipment, and work and public areas. The radiation safety manual addresses personal protective equipment. This includes gloves, labcoats, Tyvek® or similar coveralls, rubber aprons, shoe covers, and sleeve covers. Protective glasses or goggles shall be worn if there is a possibility of contamination of the eyes. Protective clothing to be worn will be chosen based on the hazards posed by the radioactive material and the procedures to be followed.

Although not detailed in our previous correspondence, specific engineering modifications were made in 2011 to engineer out potential exposure hazards. Additional actions taken involved replacing some of the hardware used to deliver the radioactive solution to the vitrification melter. Routine inspections of the hardware and, when necessary, replacement of hardware, continued until April 2011. After this, additional modifications to the experimental system were made, including:

- Replacing parts of the delivery system with stainless steel components to improve the overall durability of the system.

- Installation of a new all-metal construction syringe pump to deliver radioactive material using rugged stainless steel syringes, completely eliminating the possibility of leakage due to the use of plastic syringes. Both syringe barrels and plungers are made from #316 stainless steel and are equipped with Viton O-ring seals between the top and the end of the barrel which insures against leakage. Syringes are guaranteed to be leak free for pressures up to 7000 psi.

- Replacing the existing luer lock end fitting with Genuine Swagelok™ syringe to tube fittings, thus reducing the possibility of leakage.

- Replacing the radioactive material delivery line, previously made of Teflon tubing, with a stainless steel coil.

- Replacing all valves with metallic Swagelok™ fittings.

The experimental system may be further modified to accommodate the research needs, but all modifications will be made only after careful consideration of the safety implications of such changes.

Finally, CUA has issued the RSO a dedicated cell phone at which he may be reached on a 24 hours basis. The continued issuance of this cell phone may be re-examined in the future and eliminated if other methods of reaching the RSO in a timely manner are available.

Corrective action steps to be taken to avoid future violations: CUA will be submitting license amendment request to License No. 08-02075-03 to modify the statements made in the license renewal application documents. In addition, we will continue to inform all workers involved in licensed activities of regulatory and license commitments concerning the safe use of licensed materials, prompt reporting of accidents to the RSO, and actions to take in the event of personal contamination. These matters will be

conducted in consultation with the Radiation Safety Committee for scheduled completion during the fall 2013 academic semester.

The date when full compliance will be achieved: CUA is in full compliance with NRC regulations found in 10 CFR 20 and applicable license conditions.

CUA is committed to a safety culture in accordance with NRC regulations and best practices. The University approached this response from a personnel training, engineering improvements and personal protective equipment perspective. Furthermore, CUA acknowledges error in the application of the appropriate directives of the radiation safety manual in-force at the time of the incident. We submit this experience, the corrective steps taken and the planned license amendment are instrumental to improve CUA's overall Radiation Safety Program.

If you have any questions concerning this matter or require additional information, please feel free to contact me or the University's RSO, Mr. Mahmoud Haleem, by phone at 202-319-5206 or by email to Haleem@cua.edu.

Sincerely,

Mr. Louis P. Alar
Director, Environmental Health & Safety

Cc: Mr. Jerry Conrad, Associate Vice President, Facilities and Operations

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PENNSYLVANIA 19406-2713

July 5, 2013

Docket No. 03000638 License No. 08-02075-03
EA-13-088

Louis P. Alar
Director, Environmental Health & Safety
The Catholic University of America
Marist Annex Building
Cardinal Station
Washington, DC 20064

SUBJECT: NRC RESPONSE TO THE CATHOLIC UNIVERSITY OF AMERICA REPLY TO NOTICE OF VIOLATION 03000638/2013001, THE CATHOLIC UNIVERSITY OF AMERICA WASHINGTON, D.C. SITE AND REVISED NOTICE OF VIOLATION

Dear Mr. Alar:

This letter refers to your April 9, 2013, [ML13101A188], correspondence, in response to our letter and Notice of Violation (Notice) dated March 11, 2013. The NRC Notice described two Severity Level IV violations identified during an inspection conducted at your Washington, D.C. facility on February 12, 2013. In your April 9, 2013, letter, you provided clarifying information and denied that Violation B occurred. Violation A in the Notice involved a failure to properly evaluate the dose to the skin of the extremity for a worker involved in an event in February 2011. Violation B involved the failure to maintain the dose to the skin of the extremity to less than one tenth of the value in 10 CFR 20.1201 as required by Condition 23 of License No. 08-02075-03.

Our letter dated April 17, 2013: (1) acknowledged the corrective and preventive actions described in your April 9, 2013, letter with regard to Violation A; and (2) indicated that the NRC was still evaluating the merits of your dispute of Violation B. Based on the NRC staff's review (Enclosure 1) of the points raised in your letter dated April 9, 2013, Violation B has been reviewed and determined to remain valid. However, the violation has been revised to provide additional detail supporting our conclusion that a staff member failed to implement fundamental radiation safety work practices, and as a result, his extremity exposure exceeded the limit required by Condition 23 of License No. 08-02075-03. The revised Notice of Violation (Enclosure 2) provides additional detail related to this event.

We also reviewed your corrective actions for Violation B and found them to be narrowly focused on a single aspect of the violation. Specifically, the corrective actions only provided worker training on the proper response to future events involving skin contamination. Your corrective actions however, did not address any actions (i.e. training on the proper use of protective clothing) to prevent future skin contamination events. As a result, you are required to respond to this letter within 30 days and should follow the instructions specified in the enclosed Notice when preparing your response. In particular, you should include the reason for the violation and the corrective steps you have taken to prevent further violations. This violation will remain open until the NRC has verified implementation of your corrective actions during a subsequent inspection. This violation was evaluated in accordance with the NRC Enforcement Policy and is

categorized at Severity Level IV. The current Enforcement Policy is included on the NRC's Web site (http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html). If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC's 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, its enclosures, 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 website 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.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses;** then **Regulations, Guidance and Communications.** The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents;** then **Enforcement Policy (Under 'Related Information').** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

Please contact Judith Joustra at 610-337-5355 if you have any questions regarding this matter.

Sincerely,

/RA/

Raymond K. Lorson, Director
Division of Nuclear Materials Safety

Enclosures:
1. NRC Staff Review of April 9, 2013 Correspondence
2. Notice of Violation

cc w/enclosures: Mahmoud Haleem, Radiation Safety Officer
District of Columbia

NRC Staff Review of April 9, 2013, Correspondence

In your letter dated April 9, 2013 (ADAMS Accession No. ML13101A188), you disputed Violation B. A summary of your points and the NRC's responses are as follows:

Catholic University Issue 1

Section 9.3.3 of the Radiation Safety Manual, which is incorporated by reference in Condition 23 of License No. 08-02075-03, was provided to the NRC by the Catholic University of America (CUA) to maintain personnel exposures as low as reasonable achievable (ALARA) and ensure compliance with federal limits. CUA's use of "limit" was offered as a commitment to ALARA to serve as a goal but was not intended as a license limit.

NRC Response

Catholic University of America must comply with all regulatory requirements and license conditions. The non-compliance was specific to License Condition 23 for CUA. Condition 23 requires that CUA maintain exposures below the limits specified in the regulations, the application dated October 27, 2004, or letters dated November 4, 2003, and June 7, 2005. In particular, the June 7 letter requires that CUA control operations so that no individual working in a controlled or restricted area receives from sources in the possession of CUA an occupational dose equivalent that is above 10% of the applicable federal limits (10 CFR 20.1201). As a result, CUA was required to adhere to the explicit limits specified in License Condition 23.

Catholic University Issue 2

Regulatory Guide 8.18 was provided as the basis for the ALARA limits documented in your Radiation Safety Manual. Regulatory Guide 8.18 states that, "external and internal radiation exposures to personnel in such laboratories should ordinarily be maintained below 10 percent of the permissible occupational exposure limits of 10 CFR 20." The inference is that "ordinarily" applies only to normal operations and not an accident scenario.

NRC Response

The NRC regulatory framework does not differentiate between non-routine and ordinary operations nor does it provide a different dose limit for "accidents" or non-routine operations.

This event demonstrated multiple deficiencies in the radiation safety work practices associated with your activities. Specifically, the worker did not contact radiation safety personnel and did not decontaminate to the fullest extent following the accidental skin contamination to mitigate his dose consequence. In addition, the licensee failed to ensure the proper use of protective clothing prior to the event. Specifically, the worker wore protective clothing in a manner that failed to prevent the skin of the extremity from becoming contaminated while handling nuclear materials. Therefore, the NRC determined that the root cause for the personnel overexposure event was multiple human performance errors and not an accident scenario.

Catholic University Issue 3

You indicated in your response that during the renewal of License No. SNM-164, you had revised the Radiation Safety Manual to stipulate ALARA goals instead of limits. You asserted that this revision of the Radiation Safety Manual is applicable to all CUA licenses not just License No. SNM-164.

NRC Response

CUA must meet all regulatory requirements and license commitments. Since the revised Radiation Safety Manual was not submitted for this particular license as an amendment request, it does not change the commitment as stated in your June 7, 2005 letter, which is incorporated by reference in Condition 23 of License No. 08-02075-03.

Catholic University Issue 4

You further stated the Radiation Safety Manual had been changed before the issuance of the Notice of Violation and you submit that the issuance of the second violation is not warranted.

NRC Response

CUA must meet all regulatory requirements and license commitments at the time of the event. The change to the Radiation Safety Manual was submitted for License No. SNM-164 in an application dated April 3, 2012, which occurred after the contamination event of February 8, 2011. The Notice of Violation was issued based on the regulatory requirements at the time of the incident in 2011. The fact that you changed your license commitment for License No.SNM-164 (a different license from that associated with the event) after the event had occurred does not provide a basis for not complying with the license conditions that were in effect during this event.

NOTICE OF VIOLATION

The Catholic University of America
Washington, DC

Docket No. 03000638
License No. 08-02075-03
EA-13-088

During an NRC inspection conducted on February 12, 2013, two violations of NRC requirements were identified. During an in-office review completed on May 2, 2013, in response to your letter dated April 9, 2013, one violation of NRC requirements was revised to provide additional clarification and information regarding the violation. This Notice of Violation revises the initial Violation B identified in NRC Inspection Report No. 03000638/2013001, The Catholic University of America, Washington, D.C. Site and Notice of Violation dated March 11, 2013. In accordance with the NRC Enforcement Policy, the violation is listed below:

Condition 23 of License No. 08-02075-03 requires that, except as specifically provided otherwise in the license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the letter dated June 7, 2005, where they are more restrictive than the regulations.

Item 9.3.3 of the letter dated June 7, 2005, states that the Catholic University of America (CUA) occupational doses limit for exposure to the extremities shall be 10% of the federal limit. It states that each authorized user shall control operations so that no individual working in a controlled or restricted area receives from sources in the possession of CUA an occupational dose equivalent that is above the limits of 10% of the applicable federal dose limits. Table 9.3.3 of the letter dated June 7, 2005, states the CUA annual shallow dose limit to any extremity is 5,000 millirem. It further states that each individual shall be responsible for ensuring that his/her occupational exposure is maintained as low as reasonably achievable (ALARA).

Contrary to the above, on February 8, 2011, the licensee did not control operations such that no individual working in a controlled or restricted area received from sources in possession of CUA an occupational dose equivalent to the skin of the extremity above 10% of the federal limit or 5,000 millirem. Specifically, the licensee did not ensure that protective clothing was properly used which resulted in the individual contaminating the skin of his extremity while performing operations with 15.6 millicuries of technetium-99m in a restricted area. In addition, the individual performing work washed the contaminated area in an effort to decontaminate the skin, informed the next shift supervisor by phone, and left the facility without completing the decontamination of his skin or alerting radiation safety personnel to evaluate and ensure the individual had been properly decontaminated. As a result, the licensee did not conduct further decontamination which resulted in the individual receiving a dose of approximately 8,300 millirem to the skin of the extremity, an amount greater than 10% of the federal limit or 5,000 millirem.

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

Pursuant to the provisions of 10 CFR 2.201, The Catholic University of America 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" 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 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 5th day of July 2013