CUA

THE CATHOLIC UNIVERSITY OF AMERICA

Environmental Health and Safety
Washington, DC 20064
202-319-5206
Fax 202-319-4446

April 9, 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

Director, Office of Enforcement,
Unites States Nuclear Regulatory Commission
Washington, DC 20555-0001

Re: Reply to a Notice of Violation, License No. 08-02075-03, Docket No. 03000638

This letter is in response to NRC Inspection Report No. 03000638/2013001 dated March 11, 2013. The Catholic University of America (CUA) was requested to provide a written statement concerning the Notice of Violation issued to CUA dated March 11, 2013. CUA does not contest violation 1 and contests violation 2, and provides the following in support thereof.

Violation 1 – Failure to properly evaluate the dose to the skin of the extremity for a worker involved in an event in February 2011.

CUA acknowledges discrepancies in documented reports relating to the amount of contamination to the estimated radiation dose to the affected worker. Of particular note, the NRC's review highlighted the delay in receiving timely notification of the incident. CUA notes that the delay in receiving notice of the contamination event, combined with the lack of proper information from the person who was contaminated, led the Radiation Safety Officer (RSO) to estimate the highest possible exposure to the worker, with the intent to err on the side of caution and thereby assist CUA in determining if additional actions would be needed.

IE07

To prevent future occurrence of discrepancies in dose calculations CUA will provide additional training to its RSO. Since such occurrences are extremely rare at CUA the University may utilize the services of a consultant to assist with or review any radiation dose calculations performed, when the RSO deems it necessary. In addition, subsequent to this incident CUA entered into a professional services agreement with Dade Moeller & Associates (Dade Moeller) for prompt response should another exposure incident occur. CUA also contracted with Dade Moeller to provide assistance in estimating the radiation dose to the person contaminated in 2011 and submitted this information to the NRC. Although an agreement is in place with Dade Moeller, CUA reserves the right to use any qualified consultant to assist our radiation safety program.

CUA submits that full compliance with the NRC's requirements has been achieved in this matter, particularly in that Dade Moeller will be utilized should another exposure incident occur prior to the completion of additional training of the RSO. Accordingly, CUA confirms that it is currently in compliance with NRC license conditions and regulations.

Violation 2 – 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 stated in your letter dated June 7, 2005.

CUA acknowledges the discrepancy in accordance with the Radiation Safety Manual in-force at the time of the exposure incident **with the following understanding and exception:** In 2005 CUA sought renewal of License No. 08-02075-03. In the course of the renewal process CUA provided the NRC with information from the University's Radiation Safety Manual which "sets forth rules which are intended to assist authorized and individual users in conducting their work safely, in compliance with applicable regulations, and in a manner, which will ensure that ***exposures to ionizing radiation are maintained as low as is reasonably achievable (ALARA)***" [emphasis added]. Section 9.3.3 of the Radiation Safety Manual was provided to the NRC at that time and states that "[to] ***maintain CUA personnel exposures ALARA*** [emphasis added] and ensure compliance with federal limits, the annual CUA occupational dose limit for all individuals (minors, adults and declared pregnant women) shall be 500 mrem (5 mSv) TEDE."

The NRC has interpreted the foregoing as a specific exposure limit. However, the term "limit" does not restrict allowable occupational radiation doses to workers when conducting licensed activities. Rather, language from the Radiation Safety Manual reflects CUA's commitment to assuring occupational radiation doses to workers are as low as reasonably achievable (ALARA) in accordance with 10 CFR 20.1101(b). The internal requirement is also based on knowledge of CUA's operational experience in maintaining doses from routine operations to levels well below 10% of the regulatory limits specified in 10 CFR 20.1201(a)(ii).

Further, it is not reasonable to apply a lower dose "limit" to accidents. The establishment of any radiation safety program is intended to help assure licensees have adequate policies, procedures, proper safety equipment, and training to help assure the safe use of licensed radioactive materials and maintain doses to workers and members of the public that do not exceed regulatory limits and are ALARA. NRC Regulatory Guide 8.18 provides NRC guidance to medical licensees "and recommends methods that the staff of the U.S. Nuclear Regulatory Commission (NRC) considers acceptable to maintain exposures as low as is reasonably achievable (ALARA)." While CUA is not a medical licensee, the guidance provided in this Regulatory Guide is generally applicable to all licensees. This is particularly true for statements made in section C, subsection 34, "Low-Level Clinical or Medical Research Laboratory Activities,"

which are similar to many procedures conducted at CUA, which states:

> "Laboratories in medical institutions that use tracer amounts of the less radiotoxic nuclides may keep exposures ALARA by using the recommendations contained in regulatory positions previously described in this guide. ... **External and internal radiation exposures to personnel in such laboratories should ordinarily be maintained well below 10 percent of the permissible occupational exposure limits of 10 CFR Part 20 through careful initial planning of laboratory facilities, equipment, and procedures by the laboratory supervisor, in conjunction with qualified health physics personnel**" [emphasis added].

This statement indirectly acknowledges that maintaining doses below 10% of the regulatory limit is likely during normal operations. There is no expectation that radiation doses from accidents will be maintained below 10% of the regulatory limits. If this were the case it may be necessary to further limit the amount of licensed materials used to even lower levels, thus making the use of these materials ineffective for CUA's research and development programs. This is not consistent with the Atomic Energy Act of 1954, the purpose of which is, in part, to develop "[a] program of conducting, assisting, and fostering research and development in order to encourage maximum scientific and industrial progress" [Sec. 3.a.].

Further, the third paragraph of section 9.3.3 of CUA's Radiation Safety Manual, which describes CUA's radiation safety program at the time of the Notice of Violation in this matter, reads as follows:

> "[t]o maintain CUA personnel exposures ALARA and ensure compliance with federal limits, the annual CUA occupational *ALARA goal* [emphasis added] for all individuals (minors, adults and declared pregnant women) shall be 500 mrem (5 mSv) TEDE. Furthermore, the CUA occupational ALARA goals for dose to the lens of the eye, skin, and extremities shall be 10% of the applicable federal limits."

The language in section 9.3.3 was revised to show that CUA has established "ALARA Goals" to ensure compliance with federal occupation dose limits. CUA recognized the original language in the Radiation Safety Manual did not accurately reflect the spirit of the lower "limits" and made a change to better reflect the University's intent. Thus, the word "limit" was changed to "goal". In addition, the last paragraph in this section states the intended use of these "Goals" is, in part, to stimulate an investigation by the Radiation Safety Officer to determine the reason(s) for these unusually high doses and to document those reasons and any necessary corrective action to lower routine doses from licensed operations. When CUA applied for renewal of License No. SNM-164 in 2012 (which license applies to all licensed activities at CUA and not just those performed under License No. SNM-164) the renewal application included the above-referenced updated Radiation Safety Manual. In short, the above-referenced change occurred before the issuance of the Notice of Violation, and CUA submits that the issuance of the second violation is not warranted.

Notwithstanding the above comments, corrective actions taken to prevent high radiation doses in the future included retraining staff involved in the February 2011 contamination incident, along with other workers, regarding proper actions to take during and after accidents involving licensed radioactive material. This topic will be included in future radiation safety initial and refresher training sessions provided to CUA staff. Also, as noted above, CUA has updated its Radiation Safety Manual changing the language in section 9.3.3 to make it even more clear the lower dose values shown in the section are "goals" and not maximum "limits."

In conclusion, CUA confirms that the University is in compliance with NRC license conditions and

regulations. If you have any questions concerning this matter or require additional information, please feel free to contact the undersigned 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 of 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

March 11, 2013

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

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

SUBJECT: NRC INSPECTION REPORT NO. 03000638/2013001, THE CATHOLIC UNIVERSITY OF AMERICA, WASHINGTON, D.C. SITE AND NOTICE OF VIOLATION

Dear Mr. Alar:

On February 12, 2013, Dennis Lawyer and John Miller of this office conducted a safety inspection at 620 Michigan Avenue, N.E., Washington, D.C. of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspectors, interviews with personnel, and a selective examination of representative records. Additional information provided in your correspondence dated February 12 through March 1, 2013 and the telephone conversation on March 11, 2013 between you, Mahmound Haleem and this office were also examined as part of the inspection. The findings of the inspection were discussed with you and Mahmound Haleem at the conclusion of the inspection.

Based on the results of this inspection and in accordance with the NRC Enforcement Policy, the NRC has determined that 2 Severity Level IV violations of NRC requirements occurred. The violations involved: 1) Failure to properly evaluate the dose to the skin of the extremity for a worker involved in an event in February 2011; and 2) 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 stated in your letter dated June 7, 2005.

The violations are cited in the enclosed Notice of Violation (Notice) because the violations were identified by the NRC.

In addition, within the scope of this inspection, there was an occurrence of a Non-Cited Violation (NCV) for failing to follow your established emergency procedures. Specifically, your emergency procedures require that when there is an incident involving personnel contamination, the Radiation Safety Officer (RSO) must be notified. During the personnel contamination event in February 2011, the contaminated worker and his supervisor did not notify the RSO until two days following the incident. The inspectors reviewed the corrective actions, which included retraining

ML13071A563

staff members with regard to following emergency procedures, and determined that they were effective. This non-repetitive, licensee-identified and corrected violation is being treated as a Non-Cited violation consistent with Section 2.3.2 of the Enforcement Policy issued on January 28, 2013 (ADAMS Accession No. ML12340A295).

During our inspection exit meeting on March 11, 2013, you indicated that you are preparing a detailed response to this letter.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure(s), 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 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).

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Please contact Dennis Lawyer at 717-755-3266 if you have any questions regarding this matter.

Sincerely,

Judith A. Joustra, Chief
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc:
Mahmoud Haleem, Radiation Safety Officer
District of Columbia

NOTICE OF VIOLATION

The Catholic University of America
Washington, DC

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

During an NRC inspection conducted on February 12, 2013, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 10 CFR 20.1003 defines survey as an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation.

10 CFR 20.1501 requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present.

Contrary to the above, as of February 12, 2013, the licensee did not make surveys to assure compliance with 10 CFR 20.1201(a)(2)(ii), which limits radiation exposure to the skin of the whole body or to the skin of any extremity. Specifically, the licensee failed to properly evaluate the dose to the skin of the extremity for a worker involved in an event in February 2011, in which his skin was contaminated with approximately 13.5 microcuries of Tc-99m.

This is a Severity Level IV violation (Section 6.7).

B. 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.

Item 9.3.3 of the letter dated June 7, 2005, states that the Catholic University of America (CUA) will limit occupational doses to the skin of the extremity to 10% of the federal limit. It further stated 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 set forth above.

Contrary to the above, on February 8, 2011, a worker while performing operations in a restricted area, contaminated the skin of his extremity resulting in the individual receiving a dose of 8.3 Rads to the skin of the extremity, exceeding the 10% of the federal limit in 10 CFR 20.1201(a)(2)(ii).

This is a Severity Level IV violation (Section 6.7).

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 11 day of March 2013