UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

April 23, 2021

Mr. Thomas Eiden
Chief Executive Officer
Atomic Alchemy Inc.
855 North Capital Ave, STE #3
Idaho Falls, ID 83402-3405

SUBJECT: ATOMIC ALCHEMY INC. – REQUEST FOR ADDITIONAL INFORMATION RE: VERSATILE ISOTOPE PRODUCTION REACTOR QUALITY ASSURANCE PROGRAM DESCRIPTION TOPICAL REPORT (EPID L-2020-LLL-0025)

Dear Mr. Eiden:

By letter dated October 16, 2020 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML20290A978), and enclosures (ADAMS Accession Nos. ML20290A979 and ML20290A980), Atomic Alchemy Inc. submitted a quality assurance program description as a topical report for the Atomic Alchemy Inc. Versatile Isotope Production Reactor for review and approval by the U.S. Nuclear Regulatory Commission (NRC) staff.

The NRC staff identified additional information needed to continue its review of the quality assurance program description topical report, as described in the enclosed request for additional information (RAI). As discussed by telephone with Atomic Alchemy Inc. staff on April 8, 2021, provide a response to the RAI or a written request for additional time to respond, including the proposed response date and a brief explanation of the reason, within 60 days of the date of this letter. Following receipt of the complete response to the RAI, the NRC staff will continue its review of the quality assurance program description topical report.

The response to the RAI must be submitted in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 50.4, "Written communications." Information included in the response that you consider sensitive or proprietary, and seek to have withheld from public disclosure, must be marked in accordance with 10 CFR 2.390, "Public inspections, exemptions, requests for withholding."

Based on the response date provided above, the NRC staff expects to complete its review of the quality assurance program description topical report by October 1, 2021. This date could change due to several factors including a need for further RAIs, unanticipated changes to the scope of the review, unsolicited supplements to the topical report, and others. If the forecasted date changes, the NRC staff will notify you in writing of the new date and an explanation of the reason for the change. In the case that the NRC staff requires additional information beyond that provided in the response to this RAI, the NRC staff will request that information by separate correspondence.

If you have any questions regarding the NRC staff's review or if you intend to request additional time to respond, please contact me at (301) 415-2313, or by electronic mail at William.Kennedy@nrc.gov.

Sincerely,

Signed by Kennedy, William
on 04/23/21

William B. Kennedy, Project Manager
Non-Power Production and Utilization Facility
Licensing Branch
Division of Advanced Reactors and Non-Power
Production and Utilization Facilities
Office of Nuclear Reactor Regulation

Project No. 99902080

Enclosure:
As stated

cc: See next page

cc:

Michael Grochowski
Regulatory Affairs & Compliance Licensing Manager
Atomic Alchemy Inc.
855 North Capital Ave, STE #3
Idaho Falls, ID 83402-3405

Test, Research and Training
Reactor Newsletter
Attention: Amber Johnson
Dept of Materials Science and Engineering
University of Maryland
4418 Stadium Drive
College Park, MD 20742-2115

SUBJECT: ATOMIC ALCHEMY INC. – REQUEST FOR ADDITIONAL INFORMATION RE: VERSATILE ISOTOPE PRODUCTION REACTOR QUALITY ASSURANCE PROGRAM DESCRIPTION TOPICAL REPORT (EPID L-2020-LLL-0025) DATED: APRIL 23, 2021

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ADAMS Accession No. ML21091A114 **NRR-088**

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NAME	WKennedy	NParker	DHardesty	WKennedy
DATE	4/16/2021	4/20/2021	4/23/2021	4/23/2021

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OFFICE OF NUCLEAR REACTOR REGULATION

REQUEST FOR ADDITIONAL INFORMATION

REGARDING THE QUALITY ASSURANCE PROGRAM DESCRIPTION

ATOMIC ALCHEMY INC.

PROJECT NO. 99902080

By letter dated October 16, 2020 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML20290A978), and enclosures (ADAMS Accession Nos. ML20290A979 and ML20290A980), Atomic Alchemy Inc. submitted for U.S. Nuclear Regulatory Commission (NRC) staff review AA0-VIPR-20-QAPD(NP), "Atomic Alchemy Inc. Topical Report: Quality Assurance Program Description," Revision 0. Atomic Alchemy Inc. requested NRC staff approval of the topical report to be used to satisfy quality assurance requirements for use in its applications submitted in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," and Part 70, "Domestic Licensing of Special Nuclear Material," related to facility design, procurement, construction, and operation.

The NRC staff reviewed the quality assurance program description (QAPD) topical report for compliance with 10 CFR using the following guidance and standard(s):

- NUREG-1537 Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (ADAMS) Accession No. ML042430055)
- NUREG-1537 Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996 (ADAMS Accession No. ML042430048)
- Regulatory Guide 2.5, Revision 1, "Quality Assurance Program Requirements for Research and Test Reactors" (ADAMS Accession No. ML093520099)
- Regulatory Guide 1.28, Revision 5, "Quality Assurance Program Criteria (Design and Construction)" (ADAMS Accession No. ML17207A293)
- American National Standard Institute/American Nuclear Society (ANSI/ANS)-15.8-1995, "Quality Assurance Program Requirements for Research and Test Reactors"

The NRC staff has completed an initial review of the topical report and determined additional information is required to complete its review.

1. The NRC staff has not endorsed the use of the 2017 revision of American Society of Mechanical Engineers (ASME) standard NQA-1, "Quality Assurance Requirements for Nuclear Facility Applications," (ASME NQA-1-2017) in Regulatory Guide (RG) 1.28. The NRC issues RGs to describe methods that the NRC staff considers acceptable for use in implementing specific parts of the agency's regulations and provides guidance to applicants. RGs are not substitutes for regulations and compliance with them is not

required. Methods and solutions that differ from those set forth in RGs will be deemed acceptable if they provide a basis for the findings required for the issuance or continuance of a permit or license by the Commission.

Provide Atomic Alchemy's basis for using ASME NQA-1-2017. This should include a comparison of the guidance in ASME NQA-1-2017 with the 2015 revision of ASME NQA-1 (ASME NQA-1-2015), the justification for using the newer version, and the basis for how conforming with ASME NQA-1-2017 will demonstrate compliance with the applicable regulations.

2. Clarification of References and Definitions:

    a. ANSI/ANS-15.8-1995, Section 1.3 defines safety-related items as "those physical structures, systems and components whose intended functions are to prevent accidents that could cause undue risk to the health and safety of workers and the public, or to the research reactor's programs; and to control or mitigate the consequences of such accidents." ASME NQA-1-2017, Part I, Introduction, 400, Terms and Definitions does not include a definition for safety-related. In Part IV, Regulatory Commitments you commit to RG 1.26, Revision 4, "Quality Group Classifications and Standards for Water, Steam, and Radioactive Waste Containing Components of Nuclear Power Plants," with the following statement "The Atomic Alchemy design is unique in its configuration and safety-related design feature functions. These unique design features and the equivalence of their design safety functions, including application to committed regulatory guidance, will be detailed in FSAR [final safety analysis report] Chapter 1, Appendix A."

        Clarify Atomic Alchemy's definition of safety-related structures, systems and components that will be covered by the QAPD.

    b. Section 2.1.1., "Definitions," refers to ASME NQA-1-2017, Part I, Section 400. Clarify if this reference is Part I, *Introduction*, Section 400.

    c. The Atomic Alchemy QAPD's "Executive Summary" lists a subset of regulations from Appendix A of NUREG-1537, Part 1. Clarify if 10 CFR 34(a)(6) should be 10 CFR 50.34(a)(6); 10 CFR 34(a)(7) should be 10 CFR 50.34(a)(7); and verify if 10 CFR 50.54 should have (j) listed twice.

    d. Section 2.1.5 of Atomic Alchemy's QAPD commits to compliance with NQA-1-2017, Part II, Section 600-604. Clarify if this reference is Part II, *Introduction*, Section 600-604.

    e. When referring to NQA-1-2017 in the Atomic Alchemy QAPD, use the term "Requirement" and a number consistent with NQA-1-2017 instead of the term "Basic Requirement" and a number.

    f. The Atomic Alchemy QAPD Section 3.1 references ASME QME-1-2017 and ASME B&PV Code Section III 2017 quality standards. The last paragraph of the "Policy Statement" states, "…and the *latest edition* of ASME BPV Code Section III 2017 quality standards." The term "latest edition" should be removed because the QAPD should reference a specific version of the Code.

g. The Atomic Alchemy QAPD Section 18.6 states, “Atomic Alchemy may delegate control of Part I, Criterion XVIII services, if necessary, to qualified suppliers through the contracts….” Clarify what is meant by Criterion XVIII services.

3. The organization chart provided shows the full organization including operation. Provide current or pre-submittal (construction permit) organization chart and proposed construction organization chart or submit them prior to use for review and approval. Explain how the pre-submittal (construction permit) organization chart and proposed construction organization chart are consistent with the guidance and demonstrate compliance with the applicable regulations.

4. Atomic Alchemy QAPD, Part IV, “Regulatory Commitments,” Section 1, “Regulatory Guides and Generic Letters,” includes RG 1.28. RG 1.28, Regulatory Position C.4.a. states, in part, “[a]pplicable elements of an organization’s QA program should be audited at least once each year or at least once during the life of the activity, whichever is shorter.” Part I of the Atomic Alchemy QAPD, Section 18 states, “Internal audits of selected aspects of licensing, design, construction phase, and operating activities are performed with a frequency commensurate with safety significance and in a manner that assures audits of safety-related activities are completed.” Section 18 also states, “During the facility’s operations phase audits are performed at a frequency commensurate with the safety significance of the activities and in such a manner to assure audits and assessments of all applicable QA [quality assurance] program elements are completed bi-annually.”

   Provide clarification on the frequency of audits of the applicable elements of Atomic Alchemy’s QA program as it relates to regulatory position C.4.

5. Part VI of the Atomic Alchemy QAPD addresses “Provisions for Changes to the Atomic Alchemy QAPD.” The provisions addressed in 10 CFR 50.54(a)(3) and 10 CFR 50.55(f)(4) are for a nuclear power plant or fuel reprocessing plant licensees or holders of an early site permit or manufacturing license under 10 CFR Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants.” The regulations in 10 CFR 50.4(b)(7)(ii) require that a change to an NRC-accepted quality assurance topical report from a non-licensee must be submitted to the NRC’s Document Control Desk. The reference to changes under 10 CFR 50.54(a)(3) and 10 CFR 50.55(f)(4) is not correct for Atomic Alchemy’s current application status.

   Clarify Atomic Alchemy’s regulatory change process to be used prior to receipt of a license and/or construction permit and how it satisfies the requirements of 10 CFR 50.4(b)(7)(ii).

6. The QAPD states that Part VII, “Exceptions and Alternatives to ASME NQA-1, ASME QME-1, and ASME B&PV Section III,” of the Atomic Alchemy QAPD will be provided with the FSAR. Clarify how these exceptions and alternatives will be controlled and implemented into the QAPD and reported to the NRC in accordance with 10 CFR 50.4(b)(7)(ii) prior to Atomic Alchemy becoming a license holder.

7. Figure 1, “Atomic Alchemy Organizational Chart,” of the Atomic Alchemy QAPD does not provide indication that quality assurance has a direct communication to a management level so that the required authority and organizational freedom, including sufficient independence from cost and schedule is achieved. Please explain how the quality assurance organization will have direct communication with management so that the required authority and organizational freedom is achieved.

8. In Table 2, “Atomic Alchemy QAPD Regulatory Commitments,” clarify if or which of these programs will be incorporated into the QAPD or which programs will be created and implemented in accordance with the controls and provisions of the Atomic Alchemy QAPD.