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

August 10, 2022

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

SUBJECT: ATOMIC ALCHEMY INC. - FINAL SAFETY EVALUATION FOR ATOMIC ALCHEMY INC. TOPICAL REPORT AA0-VIPR-20-QAPD-NP, REVISION 0, "VERSATILE ISOTOPE PRODUCTION REACTOR QUALITY ASSURANCE PROGRAM DESCRIPTION" (EPID L-2020-LLL-0025)

Dear Mr. Eiden:

This letter provides the final safety evaluation for the Quality Assurance Program Description Topical Report, AA0-VIPR-20-QAPD-NP, Revision 0, "Versatile Isotope Production Reactor Quality Assurance Program Description." By letter dated October 16, 2020 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML20290A978), Atomic Alchemy Inc. (AA), submitted Revision 0, for U.S. Nuclear Regulatory Commission (NRC) staff review. As part of its review the NRC staff sent two requests for additional information (RAIs) to AA on April 26, 2021, and August 31, 2021 (ADAMS Accession Nos. ML21091A114, and ML21228A040), respectively). By letters dated June 22, 2021, and October 8, 2021 (ADAMS Accession Nos. ML21173A001 and ML21281A279, respectively), AA provided responses to the RAIs. Enclosed is a copy of the NRC staff's final safety evaluation (SE) for "Versatile Isotope Production Reactor Quality Assurance Program Description," Revision 0.
The NRC staff's final safety evaluation for topical report, "Versatile Isotope Production Reactor Quality Assurance Program Description", Revision 0, is enclosed. The NRC staff provided AA a draft of the safety evaluation for the purpose of identifying proprietary information on April 5, 2022 (ADAMS Accession No. ML22067A168). On June 30, 2022, AA confirmed that the SE does not include proprietary information.

The NRC staff requests that AA publish an accepted version of this topical report within 3 months of receipt of this letter. The accepted version shall incorporate this letter and the enclosed safety evaluation after the title page. The accepted version shall include an "-A"

(designating accepted) following the topical report identification symbol. If you have any questions, please contact Holly Cruz at holly.cruz@nrc.gov.

Sincerely,


Signed by Borromeo, Joshua
on 08/10/22

Joshua Borromeo, Chief
Non-Power Production and Utilization
Facility Licensing Branch
Division of Advanced Reactors and Non-Power
Production and Utilization Facilities
Office of Nuclear Reactor Regulation

Docket 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. - FINAL SAFETY EVALUATION FOR ATOMIC ALCHEMY INC. TOPICAL REPORT AA0-VIPR-20-QAPD-NP, REVISION 0, "VERSATILE ISOTOPE PRODUCTION REACTOR QUALITY ASSURANCE PROGRAM DESCRIPTION" (EPID L-2020-LLL-0025)
DATED: AUGUST 10, 2022

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SAFETY EVALUATION BY

THE OFFICE OF NUCLEAR REACTOR REGULATION

REGARDING ATOMIC ALCHEMY INC.

TOPICAL REPORT AA0-VIPR-20-QAPD-NP, REVISION 0,

"VERSATILE ISOTOPE PRODUCTION REACTOR

QUALITY ASSURANCE PROGRAM DESCRIPTION"

1.0 INTRODUCTION

By letter dated October 16, 2020 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML20290A978), with enclosures (ADAMS Accession Nos. ML20290A79 and ML20290A980), supplemented by letter dated June 22, 2021 (ADAMS Accession No. ML21173A001), with enclosures (ADAMS Accession Nos. ML21173A002 and ML21173A003) and letter dated October 8, 2021 (ADAMS Accession No. ML21281A279), with enclosures (ADAMS Accession Nos. ML21281A280, ML21281A281, and ML21281A282), Atomic Alchemy Inc. (AA), submitted its Quality Assurance Program Description (QAPD) Topical Report (TR), AA0-VIPR-20-QAPD, Revision 0, for review by the U.S. Nuclear Regulatory Commission (NRC) staff in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR), 50.34, "Contents of applications; technical information," paragraph (a)(7).

AA has advised the NRC that it plans to apply for a construction permit (CP) for four non-power, pool type reactors to irradiate targets of various materials, and the associated chemical extraction and purification facility to produce radioisotopes of commercial interest in accordance with 10 CFR Part 50. Because the proposed facility is classified as a non-power reactor, the Commission regulations require AA to obtain both a CP and an operating license (OL) in order to construct and operate the facility. The Commission's regulatory requirements for CP applications related to quality assurance (QA) programs set forth in 10 CFR 50.34(a)(7) govern the QA aspects of the CP application. This regulation requires a description of the QA program to be applied to the design, fabrication, construction, and testing of structures, systems, and components (SSCs) of the facility. The NRC staff reviewed the proposed QAPD for acceptability to ensure the appropriate quality controls will be satisfied during the design and construction. AA has requested the NRC staff to review the QAPD separately from the CP application through the topical report process. AA plans to reference the AA QAPD TR, if approved, in the CP application.

The AA QAPD TR is based on NQA-1-2017, "Quality Assurance Requirements for Nuclear Facility Applications." Specifically, the AA QAPD TR commits to Part I and Subparts 2.1, 2.2,

Enclosure

2.3, 2.4, 2.5, 2.7, 2.8, 2.14, 2.15, 2.17, 2.18 and 2.19 of Part II of NQA-1. In reviewing the AA QAPD TR, the staff used the QA controls in American National Standards Institute/American Nuclear Society Standard (ANSI/ANS) 15.8-1995, "Quality Assurance Program Requirements for Research Reactors," as review guidance, consistent with the regulatory requirements for non-power production and utilization facilities (NPUFs). The staff does not endorse the use of NQA-1-2017 in this safety evaluation (SE). Additionally, the staff does not approve of the use of NQA-1-2017 or NQA-1-2019, Part II, Subpart 2.19 without the use of the additional controls identified in Sections 3.3.1, "Subcontracting of Services", and 3.3.2, "Remote Accreditation Assessments", of the staff SE to Revision 1 of Nuclear Energy Institute (NEI) 14-05A dated November 23, 2020 (ADAMS Accession No. ML20322A019).

2.0 REGULATORY BASIS

As indicated above, 10 CFR 50.34(a)(7) requires each application include a description of the quality assurance program to be applied to the design, fabrication, construction, and testing of the SSCs of the facility. Section 12.9, Quality Assurance, of NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors," Part 1, "Format and Content," and Part 2, "Standard Review Plan and Acceptance Criteria," provides guidance on how an application for an NPUF should address NRC QA requirements. NUREG-1537, Parts 1 and 2, and interim staff guidance dated October 17, 2012, augmenting NUREG-1537 refer to Regulatory Guide 2.5, "Quality Assurance Program Requirements for Research and Test Reactors," Revision 1, which endorses ANSI/ANS 15.8-1995, "Quality Assurance Program Requirements for Research Reactors," as providing an acceptable method of complying with the requirements of 10 CFR 50.34(a) for NPUFs.

The NRC staff used established guidance documents to determine the acceptance criteria for demonstrating compliance with regulatory requirements for NPUFs. The NRC staff used:

- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," (ADAMS Accession No. ML042430055) dated February 1996

- NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," (ADAMS Accession No. ML042430048) dated February 1996

- "Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," (ADAMS Accession No. ML12156A069) dated October 17, 2012

- "Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," (ADAMS Accession No. ML12156A075) dated October 17, 2012

- RG 2.5, “Quality Assurance Program Requirements for Research and Test Reactors,” (ADAMS Accession No.), Revision 1, dated June 2010
- ANSI/ANS-15.8-1995, “Quality Assurance Program Requirements for Research Reactors,” (Reaffirmed 2005, 2013) dated May 10, 2013

ANSI/ANS-15.8-1995 states acceptance criteria for NPUF QA measures that the staff applied in evaluating the AA QAPD, as described below.

3.0 EVALUATION

The NRC staff will review the aspects of the AA facility CP application related to QA programs under the Commission’s regulatory requirements set forth in 10 CFR 50.34(a)(7). This regulation requires a description of the QA program to be applied to the design, fabrication, construction, and testing of the SSCs of the facility. Because AA proposes to reference the TR in the CP application, the NRC staff will review the QAPD measures described in the AA QAPD TR to determine their acceptability in accordance with the applicable quality assurance requirements.

In evaluating the adequacy of the proposed AA QAPD TR, the NRC staff considered the guidance of NUREG 1537 Parts 1 and 2, Section 12.9, the final interim staff guidance, and RG 2.5, which endorses ANSI/ANS 15.8-1995.

3.1 Quality Assurance Program Overview for Design and Construction

The AA QAPD TR provides a description of the QA program to be applied to design, fabrication, construction, and testing of SSCs of the facility. The NRC staff’s review is broken down into the introduction followed by 19 quality assurance criteria listed in ANSI/ANS 15.8-1995, Section 2, “Design, Construction and Modification.”

3.1.0 Introduction

The AA QAPD TR describes the QA program for safe and reliable production of radioisotopes, silicon transmutation doping, neutron activation analysis, and radiography. Based on the complexity of the design of the AA facility, involving four non-power nuclear reactors; staged construction; multiple radiological processes; and both 10 CFR Part 50 and 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material,” licenses, AA decided it should exceed the minimum standards outlined for research and test reactors in NUREG-1537 Parts 1 and 2 and the final interim staff guidance. Therefore, AA chose to model its QAPD after NQA-1-2017.

3.1.1 Organization

The AA QAPD TR is the top-level policy document that outlines the activities and tasks assigned to the various organizational elements to achieve AA’s stated QA objectives. Overall policies on quality are established and implemented by the General Manager, Quality Assurance Program (GMQAP).

Chapter 1 of the AA QAPD TR describes the organizational structure, levels of authority, lines of communication, and functional responsibilities for the control of activities affecting quality. The

quality management function reports to an adequately authoritative level of management. The GMQAP is responsible for assisting with identification of quality measures, ensuring such measures are understood across the program team, assessing the effectiveness of the QAPD implementation, and reporting results to program and senior management.

The NRC staff reviewed the QA measures to be employed by AA, its consortium, and its contractors and determined that the organizational controls. described in AA QAPD TR, Chapter 1 conforms to the controls addressed in ANSI/ANS 15.8, Section 2.1, “Organization,” and is therefore acceptable.

3.1.2 Quality Assurance Program

The AA QAPD TR documents the measures for establishing, implementing, and managing the QA program. Chapter 2 of the AA QAPD TR identifies the activities and items that will be controlled by the program. These activities will be performed in accordance with appropriate policies, procedures, instructions and controlled documents. The program provides for indoctrination and training of personnel performing activities that affect quality and ensures that suitable proficiency is achieved and maintained.

The NRC staff reviewed the QA activities and items to which the AA QAPD TR applies. The staff verified that the AA QAPD TR addresses the appropriate activities and items to which the program applies. The NRC staff reviewed the QA measures and determined that the information described in Chapter 2 of the AA QAPD TR conforms to the controls addressed in ANSI/ANS 15.8, Section 2.2, “Quality Assurance Program,” and is therefore acceptable.

3.1.3 Design Control

Chapter 3, “Design Control,” of the AA QAPD TR addresses AA’s controls for engineering and design control. These controls cover the following processes: design requirements, design inputs, design process, design verification, design verification methods, design interfaces, software, and design records. This chapter addresses the applicability of standardized or previously proven designs, with respect to meeting design inputs that will be verified for each application. The QAPD in Chapter 3 includes the following provisions for design control. Deviations from the established design inputs will be documented and controlled. The design organization will ensure that the final design is relatable to the design input by adequate documentation. Computer design programs used to develop any portion of the facility design or to analyze the design will be controlled. The design program will be controlled to ensure that it is fully documented and validated. QAPD also assigns to AA personnel the responsibility for identifying and controlling design interfaces and coordinating activities among participating organizations.

In regard to design verification, Chapter 3 of the QAPD calls for the QA measures described below. Design verification for an item will be performed by competent persons other than those who designed the item. Design verification will be completed prior to reliance upon the component, system, structure, or computer program to perform its function in operations. Qualification testing will be defined in formal test plans and will include appropriate acceptance criteria. Testing will simulate the most adverse design conditions under which an SSC must perform its safety function to demonstrate the adequacy of the SSC’s performance. Test results

will be documented and verified to have met the test acceptance criteria. Such documents and records will be collected, stored, and maintained for the life of the safety-related item. This chapter describes how changes to design inputs for final designs, field changes, and temporary and permanent modifications to SSCs or computer codes shall be documented, justified, and subject to design control measures commensurate with those applied to the original design. These measures include evaluation of effects of those changes on the overall design and on any analysis on which the design is based.

The NRC staff compared the QA measures to be employed by AA to those identified in ANSI/ANS 15.8 Section 2.3, "Design Control," and determined that the design controls described in Chapter 3 of the QAPD include all the design controls identified in ANSI/ANS 15.8, Section 2.3. Therefore, the controls in Chapter 3 of the AA QAPD TR conform to the controls in ANSI/ANS 15.8, Section 2.3 and are therefore acceptable.

3.1.4 Procurement Document Control

Chapter 4, "Procurement Document Control," of the AA QAPD TR establishes controls to ensure that technical and quality standards necessary to ensure adequate quality of material, equipment, and services are included or referenced in procurement documents. Chapter 4 of the QAPD calls for the procurement QA measures described below. Correct quality measures for procurement will be formally and effectively communicated to AA suppliers of items and services. Procurement documents at all procurement levels will identify the documentation to be submitted for information, review, or approval by AA. The procurement document controls include sufficient technical information and quality measures to ensure that the items or services will satisfy the needs of the purchase order and that the purchaser reviews all documents at all procurement levels. Procurement documents will provide that the supplier report non-conformances associated with the items or services being procured.

The NRC staff requested AA to use the approved process for implementing the International Laboratory Accreditation Cooperation accreditation process in lieu of a commercial grade survey as part of the dedication process for calibration and test services. The NRC staff recommended that AA review the approved alternative addressed in the NRC staff SE to Revision 1 of NEI 14-05A dated November 23, 2020. In its response, AA requested the use of NQA-1-2019, Part II, Subpart 2.19, "Quality Assurance Requirements for the Use of Supplier Accreditation for Calibration or Testing Services." The NRC staff has determined that the use of the 2017 or 2019 versions of Subpart 2.19 is unacceptable without the additional controls identified in Sections 3.3.1, "Subcontracting of Services", and 3.3.2, "Remote Accreditation Assessments", of the staff SE to Revision 1 of Nuclear Energy Institute (NEI) 14-05A dated November 23, 2020 (ADAMS Accession No. ML20322A019).

The NRC staff determined that the AA procurement document controls described in Chapter 4 of the AA QAPD TR conform with the guidance provided in ANSI/ANS Section 2.4 and are therefore acceptable, with the exception of commercial grade dedication. The NRC staff does not approve of the use of NQA-1-2017 or NQA-1-2019, Part II, Subpart 2.19, as acceptable for use for dedication of commercial grade components without the use of the additional controls identified in Revision 1 of NEI 14-05A. Therefore, AA QAPD is not approved to use either NQA-1-2017 or NQA-1-2019, Subpart 2.19 for the dedication of commercial grade calibration and testing services.

3.1.5 Procedures, Instructions, and Drawings

The AA QAPD TR Chapter 5, “Instructions, Procedures and Drawings,” describes the measures to ensure that quality activities are based on documented instructions, procedures, or drawings, as appropriate. Specifically, these documents will include or reference appropriate quantitative or qualitative acceptance criteria for determining that activities have been satisfactorily accomplished. Further, these documents will prescribe performance expectations and define the proper sequence and detail to accomplish each quality activity.

The NRC staff determined that the controls for instructions, procedures, and drawings described in Chapter 5 of the AA QAPD TR conform to the controls in ANSI/ANS 15.8, Section 2.5, “Procedures, Instructions and Drawings,” and are therefore acceptable.

3.1.6 Document Control

Chapter 6, “Document Control,” of the AA QAPD describes the process to control the review, approval, and distribution of documents, including changes thereto, which prescribe activities affecting quality. It indicates that the program and implementing procedures will establish the measures for identification, review and approval, and distribution of documents. Major changes to controlled documents will be reviewed and approved by the same organizations that performed the review of the original issue.

The NRC staff determined that the AA document controls described in Chapter 6 of the AA QAPD TR conform to the controls in ANSI/ANS 15.8, Section 2.6, “Document Control,” and are therefore acceptable.

3.1.7 Control of Purchased Items and Services

Chapter 7, “Control of Purchased Material, Equipment, and Services,” of the AA QAPD describes the measures to ensure that purchased items and services conform to procurement documents. These measures include supplier evaluation and selection, source surveillance and inspection, and audits and review of supplier documents, as applicable.

The AA QAPD TR sets for the following measures for control of purchased material, equipment, and services. The QAPD indicates that the procurement of material, equipment and services is controlled to assure conformance with applicable quality measures. The selection of suppliers will be based on evaluation of their capabilities to provide items or services in conformance with the specifications of the procurement documents. In addition, the QAPD includes measures to evaluate supplier performance. The QAPD provides for review of supplier plans and procedures, source surveillance or inspection, QA assessments, receipt inspections, deviations, and corrective actions. AA will also implement controls and procedures to approve supplier generated documents and items. The controls also state that the QA manager is responsible for the development and maintenance of the AA approved suppliers list using approved procedures and shall perform annual evaluations of each supplier.

The NRC staff determined that the QA measures described in QAPD Chapter 7 for purchased material, equipment and services conform to the controls in ANSI/ANS 15.8, Section 2.7, “Control of Purchased Items and Services,” and are therefore acceptable.

3.1.8 Identification and Control of Items

The AA QAPD Chapter 8, “Identification and Control of Material, Parts, and Components,” describes the measures to ensure that only correct and accepted items are used or installed. Identification will be maintained on the items or in documents traceable to the items, or in a manner that ensures identification is established and maintained as described in the QAPD.

The NRC staff determined that the AA controls for identification and control of items described in QAPD Chapter 8 conform to the controls in ANSI/ANS 15.8, Section 2.8, “Identification and Control of Items,” and are therefore acceptable.

3.1.9 Control of Special Processes

AA QAPD Chapter 9, “Control of Special Processes,” describes the measures to ensure that approved special process procedures are used by qualified personnel, and consistent with specified codes and standards, including acceptance criteria for the process. The AA QAPD TR states that special processes will be controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means. Records for qualified personnel, processes, and equipment associated with special processes will be maintained, as appropriate.

The NRC staff determined that the AA controls for special processes described in AA QAPD TR Chapter 9 conform to the controls in ANSI/ANS 15.8, Section 2.9, “Control of Special Processes,” and are therefore acceptable.

3.1.10 Inspections

The AA QAPD Chapter 10, “Inspections,” describes the inspection process for verifying the quality and conformance of items or activities to specified quality standards. The inspection process will be applicable to procurement, construction, modification, maintenance, and maintenance. Inspections will be performed by persons other than those who performed the work being inspected but may be from the same organization. Inspection activities will be documented and controlled by instructions, procedures, drawings, checklist, travelers, or other appropriate means.

The NRC staff determined that the AA controls for inspections described in AA QAPD TR Chapter 10 conform to the controls in ANSI/ANS 15.8, Section 2.10, “Inspections,” and are therefore acceptable.

3.1.11 Test Control

The AA QAPD Chapter 11, “Test Control,” describes the AA controls for planning, conducting, and documenting tests according to specific quality standards that ensure SSCs or computer program acceptability. Test results will be documented and evaluated by a responsible authority to ensure that test procedures and acceptance criteria have been satisfied. Computer programs to be used for operational control will be tested consistent with an approved verification and validation plan and will demonstrate acceptable performance over the range of operation of the controlled function or process.

The NRC staff determined that the AA controls for testing described in AA QAPD TR Chapter 11 conform to the controls in ANSI/ANS 15.8, Section 2.11, “Test Control,” and are therefore acceptable.

3.1.12 Control of Measuring and Test Equipment

The AA QAPD Chapter 12, “Control of Measuring and Test Equipment,” describes the measures to ensure that tools, gauges, instruments, and other measuring and test equipment (M&TE) used for activities affecting quality are controlled, calibrated, or adjusted at specified periods, to maintain accuracy within specified limits. Chapter 12 of the QAPD provides for defining the frequency of the calibration of M&TE based on the type of equipment, stability characteristics, necessary accuracy, intended use, and other conditions that might affect measurement control.

Out-of-tolerance devices will be tagged and segregated until calibration has been restored. Records of calibration and repair, including as-found conditions, will be maintained to indicate calibration and the capability of the M&TE.

The NRC staff determined that the AA controls for M&TE described in AA QAPD TR Chapter 12 conform to the controls in ANSI/ANS 15.8, Section 2.12, “Control of Measuring and Testing Equipment,” and are therefore acceptable.

3.1.13 Handling, Storage, and Shipping

The AA QAPD Chapter 13, “Receiving, Handling, Storage, and Shipping,” describes the controls for receiving, handling, storage, and shipping of items. QAPD chapter 13 specifies that these activities be performed in accordance with instructions, drawings, specifications, or other pertinent documents specified for use in conducting the activity.

The NRC staff determined that the receiving, handling, storage, and shipping measures to be employed by AA described in QAPD Chapter conform to the controls in ANSI/ANS 15.8, Section 2.13, “Handling, Storage, and Shipping,” and are therefore acceptable.

3.1.14 Inspection, Test, and Operating Status

The AA QAPD Chapter 14, “Inspections, Test, and Operating Status,” provides for the identification of the status of inspection and test activities on items covered by the QAPD or in documents traceable to the items. Identification of inspection and test status will ensure that the specified inspection and test activities were performed and will prevent inadvertent installation or operation of items that have not passed the applicable inspections or tests. Specifically, the AA QAPD TR states that inspection, test, and operating status will be controlled by procedures, installation records and checklists. These documents contain hold points, activity checklists, and step-by-step signoffs to indicate the status of fabrication, installation, inspection, and test, as appropriate. Operating status and documentation of tests of components are controlled through the normal facility operating procedures.

The NRC staff determined that the controls for inspections, test, and operating status to be employed by AA described in QAPD Chapter 14 conform to the controls in ANSI/ANS 15.8, Section 2.14, “Inspection, Test, and Operating Status,” and are therefore acceptable.

3.1.15 Control Nonconforming Items and Services

The AA QAPD Chapter 15, “Nonconforming Materials, Parts, or Components,” describes the necessary measures to control nonconforming items and prevent their inadvertent use or installation. These controls include measures for identification, documentation, evaluation, segregation (as appropriate), and disposition of nonconforming items. Recommended dispositions, such as “use-as-is,” “reject,” “repair,” or “rework,” will be identified, documented, and approved.

The AA QAPD TR addresses measures for nonconforming items dispositioned as “repair” or “use-as-is,” including a documented technical justification identifying the reasons for acceptance. Items that do not conform to design specifications, but which are dispositioned as “repair” or “use-as-is” will be subject to design control measures commensurate with those applied to the original design. Nonconforming items dispositioned as “repair” or “rework” will be re-examined consistent with applicable procedures and appropriate acceptance criteria.

The NRC staff determined that the measures to be employed by AA described in AA QAPD TR Chapter 15 conform to the controls in ANSI/ANS 15.8, Section 2.15, “Control of Nonconforming Items and Services,” and are therefore acceptable.

3.1.16 Corrective Actions

The AA QAPD Chapter 16, “Corrective Actions,” provides that conditions adverse to quality be identified promptly and corrected as soon as practical. In the case of a significant condition adverse to quality, the cause of the condition will be investigated and corrective action to prevent recurrence will be taken.

The NRC staff determined the measures for corrective action to be employed by AA described in QAPD Chapter 16 conform to the controls in ANSI/ANS 15.8, Section 2.16, “Corrective Actions,” and are therefore acceptable.

3.1.17 Quality Records

The AA QAPD Chapter 17, “Quality Assurance Records,” specifies procedures that describe the necessary measures to ensure that, at minimum, sufficient records of the following activities be maintained and appropriately stored: inspection and test results, results of QA reviews, QA procedures, and engineering reviews and analyses for design or changes and modifications. The AA QAPD TR records management will be implemented and enforced in accordance with written procedures, instructions, or other documentation.

The NRC staff determined that the QA record controls to be employed by AA described in AA QAPD TR Chapter 17 conform to the controls in ANSI/ANS 15.8, Section 2.17, “Quality Records,” and are therefore acceptable.

3.1.18 Assessments

The AA QAPD TR Chapter 18, “Audits/Assessments,” describes the process to implement a system of audits and assessments of activities affecting quality. Chapter 18 of the AA QAPD TR describes measure relating to audits and assessments as follows. Audit and assessment results will be documented and reviewed by the management personnel responsible for the area assessed. Management of the audited or assessed organization will investigate adverse findings and schedule corrective actions. The adequacy of the responses will be evaluated by the auditing or assessing organization. Audit and assessment records will include plans, reports, written replies, and records of completion of corrective actions.

The AA QAPD TR also specifies that personnel conducting audits or assessments have experience and training of the activities being audited or assessed. The audits will be performed by trained personnel not having direct responsibilities in the area being audited.

The NRC staff determined that the controls for audits and assessments to be employed by AA described in AA QAPD TR Chapter 18 conform to the controls in ANSI/ANS 15.8, Section 2.18, “Assessments,” and are therefore acceptable.

3.1.19 Experimental Equipment

The AA QAPD does not specifically address experimental equipment. The NRC staff reviewed the AA QAPD TR and responses to requests for information to identify information relating to experimental equipment. The AA QAPD TR provides measures and controls for safety-related items and items that are significant contributors to plant safety in regard to experimental equipment.

The NRC staff determined that the controls for safety-related items or items that are significant contributors to plant safety conform to the controls in ANSI/ANS 15.8, Section 2.19, “Experimental Equipment,” and are therefore acceptable.

3.2 Facility Operations

The AA QAPD TR states that the TR is applicable during the Facility Operations. However, the NRC staff is deferring review of the QAPD controls for operation until the NRC receives an application for construction and/or operation, including a preliminary safety analysis report or final safety analysis report (FSAR).

3.3 Decommissioning

The AA QAPD TR states that decommissioning is an activity applicable to the controls in the TR. The NRC staff is deferring review of the QAPD controls for decommissioning until the NRC receives the AA FSAR supporting decommissioning.

4.0 CONCLUSION

Based on its review as set forth above, the NRC staff concludes that the AA QAPD meets the guidance in ANSI/ANS 15.8 except in regard to commercial dedication and, with that exception, is acceptable for use in developing the AA construction permit application. The staff further

concludes that, except for the commercial dedication QA measures in NQA-1-2017 or NQA-1-2019, Part II, Subpart 2.19, the AA QAPD addresses 10 CFR 50.34(a)(7), which requires that an applicant for a construction permit provide a description of the QA program to be applied to the design, fabrication, construction, and testing of the SSCs of the facility. Therefore, except for the subject of dedication of commercial-grade calibration and testing services, the NRC staff concludes that the AA TR has met the applicable guidance and regulatory requirements for the acceptance of the AA QAPD and is acceptable for referencing in an application for a construction permit for the AA production facility. However, the NRC staff is not approving the AA quality assurance program set forth in the TR insofar as it might relate to the conduct of operations or decommissioning. This information is not necessary for the review of a construction permit application. The NRC staff will review any updates, changes, or modification to the AA QAPD submitted by AA to the NRC in accordance with 10 CFR 50.4, "Written communications," paragraph (b)(7)(ii) prior to the issuance of a license or CP.

5.0 REFERENCES

1. Letter from Thomas Eiden, Chief Executive Officer, Atomic Alchemy, Inc. to the NRC Document Control Desk, "Atomic Alchemy Versatile Isotope Production Reactor Quality Assurance Program Description," dated October 16, 2020 (ADAMS Accession No. ML20290A978)
2. Letter from Thomas Eiden, Chief Executive Officer, Atomic Alchemy, Inc. to the NRC Document Control Desk, "Atomic Alchemy's Response to NRC Questions Related to Quality Assurance Program Description for Atomic Alchemy's Non-Power Production and Utilization Facility," dated June 22, 2021 (ADAMS Accession No. ML21173A001)
3. Letter from Thomas Eiden, Chief Executive Officer, Atomic Alchemy, Inc. to the NRC Document Control Desk, "Atomic Alchemy's Response to NRC Questions to the Quality Assurance Program Description Topical Report for Atomic Alchemy's Non-Power Production and Utilization Facility," dated October 8, 2021 (ADAMS Accession No. ML21281A279)
4. NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," dated February 1996 (ADAMS Accession No. ML042430055)
5. NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," dated February 1996 (ADAMS Accession No. ML042430048)
6. "Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors") dated October 17, 2012 (ADAMS Accession No. ML12156A069)
7. "Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (ADAMS Accession No. ML12156A075)
8. Regulatory Guide (RG) 2.5, "Quality Assurance Program Requirements for Research and Test Reactors," Revision 1, dated June 2010 (ADAMS Accession No. ML093520099)
9. ANSI/ANS-15.8-1995, "Quality Assurance Program Requirements for Research Reactors," (Reaffirmed 2005, 2013) dated May 10, 2013

10. American Society of Mechanical Engineers NQA-1-2017, “Quality Assurance Requirements for Nuclear Facility Applications.” New York, NY, dated January 18, 2018
11. Revision 1 of NEI 14-05A, “Guidelines for the Use of Accreditation in Lieu of Commercial-Grade Surveys for Procurement of Laboratory Calibration and Test Services,” dated September 2020 (ADAMS Accession No. ML20259B731)
12. Final Safety Evaluation by the Office of Nuclear Reactor Regulation for the Nuclear Energy Institute Technical Report NEI 14-05A, “Guidelines for the Use of Accreditation in Lieu of Commercial-Grade Surveys for Procurement of Laboratory Calibration and Test Services,” Revision 1, February 19, 2021 (ADAMS Accession No. ML20322A019)

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