ATOMIC ALCHEMY INC. TOPICAL REPORT:

QUALITY ASSURANCE PROGRAM DESCRIPTION (QAPD)

NON-PROPRIETARY (NP)

** The "-A" designates NRC acceptance via issued Safety Evaluation, appended after this page.*

NRC SAFETY EVALUATION FOR THIS QAPD

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

Atomic Alchemy Inc. Docket No. 99902080

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

T. Eiden - 3 -

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

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,

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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Date: August 10, 2022

REVISION LOG

REVISION NO.	DESCRIPTION OF CHANGES
Rev. 0-A	This revision is the initial version of the Atomic Alchemy Inc. QAPD accepted by the NRC via issuance of their Safety Evaluation (SE) dated 8/10/22, which is appended to this QAPD after the title page, as requested by the NRC in their transmittal letter of the SE. As described in the NRC SE, Atomic Alchemy provided responses for two NRC Requests for Additional Information (RAI) with a total of nine items—the NRC RAI letters and Atomic Alchemy Inc.'s formal responses are referenced in the NRC transmittal letter for the SE. The changes described in the RAI responses were incorporated in this Rev. 0-A. The changes made between the QAPD version submitted to the NRC for review and this version which incorporates the changes made to address the RAIs, are noted by sidebars in the margin. Because the NRC SE for the Atomic Alchemy QAPD does not approve use of Part II, Subpart 2.19 in either NQA-1-2017 or NQA-1-2019, Atomic Alchemy has noted such in the applicable portion of its QAPD. Also, the SE states that the NRC does not approve the Atomic Alchemy QAPD insofar as it relates to operations or decommissioning, as it is not required for review of the construction permit application. As such, this is also noted in the applicable portions of the QAPD. These changes are marked by sidebars in the margin. A few additional minor or inconsequential changes insofar as the conclusions reached by the SE were made to: • correct formatting or grammatical errors (not marked by sidebars), • update the table of contents, and page and revision numbering (not marked by sidebars), • add this Revision Log (not marked by sidebars), and • update subsections and lists of planned implementing programs to be addressed in the FSAR that were inadvertently left off in the version submitted for review (marked with sidebars).

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ATOMIC ALCHEMY INC. QUALITY ASSURANCE PROGRAM DESCRIPTION

EXECUTIVE SUMMARY

This Quality Assurance Program Description defines the Atomic Alchemy Inc., Quality Assurance Program for safe and reliable production of radioisotopes, silicon transmutation doping, neutron activation analysis, and radiography. Title 10 of Code of Federal Regulations (10 CFR), Section 50.34(a)(6), and (7) requires each applicant for a non-power production and utilization facility construction permit to include, in its preliminary safety analysis report, a description of the quality assurance program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility.

Furthermore, 10 CFR50.34(b)(6)(ii) requires that each applicant for a license to operate a non-power production & utilization facility include, in the final safety analysis report, a description of the managerial and administrative controls to be used to assure safe operations.
NUREG-1537, “Guidelines for Pre-paring and Reviewing Applications for the Licensing of Non-Power Reactors”, Section 12.9 “Quality Assurance” recommends the applicant consider the guidance in Regulatory Guide 2.5, Rev 1, “Quality Assurance Program Requirements for Research and Test Reactors” and American National Standard, ANSI/ANS 15.8-1995, “Quality Assurance Program Requirements for Research and Test Reactors”.

Regulatory Guide 2.5, Rev. 1 states that ANSI/ANS 15.8-1995 provides an acceptable method of complying with the program requirements of 10 CFR 50.34.

NUREG-1537, Appendix A also directly invokes compliance with the following regulatory criterion requirements related to a safety / quality assurance program:

a) 10 CFR50.34(a)(6)
b) 10 CFR50.34(a)(7)
c) 10 CFR50.34(b)(6)(i), (ii), (iii), and (iv)
d) 10 CFR50.40
e) 10 CFR50.50
f) 10 CFR50.54(i), (j), (k), (l), and (m)
g) 10 CFR50.55a.

All reactors, both power and non-power, are licensed to operate as utilization facilities under Title 10 in accordance with the Atomic Energy Act of 1954, as amended (AEA or Act). The AEA was written to promote the development and use of atomic energy for peaceful purposes and to control and limit its radiological hazards to the public.

NUREG-1537 was published in 1996. At the time it was written, the only non-power reactors were AEA Chapter 10, Section 104 licensed facilities (test and research), reactors that utilized very low power (<2.0 MW) reactor designs.

In Chapter 10 Section 104(b) of the Act for non-power reactors, it is stated that nuclear utilization facilities for research and development should be regulated to the minimum extent consistent with protecting the health and safety of the public.

There does not appear to be any similar implication expressed in Chapter 10, Section 103 of the Act, that a nuclear utilization facility dedicated solely for commercial use should also be so minimally regulated.

NUREG-1537, NUREG-1537 Appendix A, NUREG-0800 SRP 17.5, 10 CFR50.55a, 10 CFR50 Appendix A, 10 CFR50 Appendix B, 10 CFR71 Subpart H, 10 CFR70.61, ANSI/ANS-45.2, Regulatory Guide 1.28, Rev 5, and NEI 06-14 "Quality Assurance Program Description," were all reviewed extensively in development of the Atomic Alchemy Quality Assurance Program.

Based on the complexity of the design of the Atomic Alchemy facility (multiple site nuclear non-power reactors; staged construction; multiple radiological processes; and both 10 CFR Part 50 and 10 CFR Part 70 licenses) it was concluded by management that the Atomic Alchemy Quality Assurance Program should exceed the minimum requirements outlined for test and research reactors in NUREG-1537 (ANSI/ANS-15.8) for the design, procurement, fabrication, construction, testing, and operation of the Atomic Alchemy facility.

POLICY STATEMENT

The primary goal of Atomic Alchemy Inc. (Atomic Alchemy) is to provide a domestic, secure, and reliable supply for radioisotopes of commercial interest. To achieve this goal, Atomic Alchemy is committed to establishing, implementing, and maintaining a quality assurance program to ensure that all Atomic Alchemy activities and processes are planned, reviewed, controlled, and verified for compliance with applicable Code of Federal Regulations (CFR), the applicable U.S. Nuclear Regulatory Commission (NRC) construction permit and operating license, national standards, applicable laws and regulations of the state and local governments, and contractual requirements. In addition, the management of Atomic Alchemy believes that sound safety, quality, security, and environmental programs are essential to our business's success and are personally engaged in their implementation.

The Atomic Alchemy Quality Assurance Program is the Quality Assurance Program Description (QAPD) provided in this document and the associated documents. They provide for control over Atomic Alchemy activities that affect quality of nuclear facility structures, systems, and components, and include all planned and systematic safety-related activities necessary to provide adequate confidence that such items will perform satisfactorily in service. The QAPD may also be applied to certain items and activities that are not safety-related, but support safe and reliable facility operations, enable the business mission to be completed more efficiently and effectively, or where NRC guidance establishes program requirements.

This QAPD is the top-level policy document that establishes the manner in which quality is to be achieved and presents the Atomic Alchemy overall philosophy regarding achievement and assurance of quality. Implementing programs and procedures assigns more detailed responsibilities and requirements and defines organizational interfaces involved in conducting activities within the scope of the quality assurance program. Compliance with the QAPD and the associated documents is mandatory for personnel directly or indirectly associated with implementation of the Atomic Alchemy Quality Assurance Program.

The Atomic Alchemy QAPD is incorporated by reference into the Atomic Alchemy FSAR.
The Atomic Alchemy QAPD implementing policies and procedures are therefore designed and administered to meet the applicable requirements and standards of ASME NQA-1 2017 "Quality

Assurance Requirements for Nuclear Facility Applications, ASME QME-1-2017 “Qualification of Active Mechanical Equipment Used in Nuclear Power Plants” and the ASME BPV Code Section III 2017 quality standards.

Digitally signed by Thomas Eiden
Date: 2023.01.03 13:26:46 -07'00'

Thomas Eiden
Chief Executive Officer

PART I - QUALITY ASSURANCE PROGRAM DESCRIPTION

Atomic Alchemy’s Quality Assurance Program Description is the top-level policy document that establishes the quality assurance program and assigns major functional responsibilities for design, procurement, construction, operating, and testing activities conducted by or on the behalf of Atomic Alchemy.

Regulatory Guide 1.26, Rev 4, "Quality Group Classification, and Standards for Water, Steam, and Radioactive Waste Containing Components of Nuclear Power Plants", Regulatory Guide 1.28, Rev 5, “Quality Assurance Program Criteria (Design and Construction)”, Regulatory Guide 1.29, Rev 5, "Seismic Design Classification" and Regulatory Guide 1.33, Rev 3, Quality Assurance Program Requirements (Operations),” describes methods that the staff of the U.S. Nuclear Regulatory Commission considers acceptable for complying with the provisions of Title 10, of the Code of Federal Regulations, Part 50, “Domestic Licensing of Production and Utilization Facilities,” 10 CFR Part 50, Appendix B, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,” for establishing and implementing a quality assurance (QA) program for the design and construction of nuclear power plants and fuel reprocessing plants.

The Atomic Alchemy QAPD also satisfies the requirements of 10 CFR 70 Subpart G and 10 CFR 71 Subpart H by Atomic Alchemy’s commitment to follow the guidelines of the American Society of Mechanical Engineers (ASME) Quality Assurance (QA) standard NQA-1-2017, “Quality Assurance Program Requirements for Nuclear Facilities” and QME-1-2017, “Qualification of Active Mechanical Equipment Used in Nuclear Power Plants.”

The version of NQA-1-2017 is not endorsed by a regulatory guide but its use should not result in deviation from the design philosophy otherwise stated in Regulatory Guide 1.28 Rev 5.
Most of the application text is written in the present tense, active voice, including discussions of processes associated with advanced stages of the licensing process. It should be understood, however, that statements regarding these processes typically address activities that may have not yet been performed and will not be performed until it is reasonable and appropriate to do so.

1 ORGANIZATION (CRITERION I)

Atomic Alchemy has established an organizational structure designed to ensure that quality work is performed safely and cost-effectively, while meeting or exceeding regulator expectations and requirements. The responsibility for establishing the overall expectations for effective implementation of the QAPD and obtaining the desired end results lies with the CEO and Atomic Alchemy Officers.

However, all Atomic Alchemy employees are individually responsibly for achieving and maintaining the established quality of products and services provided to customers within their respective areas of responsibility.

Atomic Alchemy describes in this section and associated programs and procedures that implement the requirements of Criterion I, Organization, of 10 CFR 50, Appendix B and Requirement 1, Sections 100-300 of NQA-1-2017.

1.1 ORGANIZATIONAL STRUCTURE

This section describes the Atomic Alchemy organizational structure, functional responsibilities, levels of authority, and interfaces for establishing, executing, and verifying QAPD implementation. The organizational structure includes internal and external functions for Atomic Alchemy, including interface responsibilities for multiple organizations that perform quality-affecting functions. Implementing procedures assign more specific responsibilities and duties, and define the organizational interfaces involved in conducting activities and duties within the scope of the QAPD. Design & engineering, construction, testing, and licensing services can be delegated to suppliers who conduct activities in accordance with their quality assurance program that will be approved by Atomic Alchemy.
The Atomic Alchemy organization consists of personnel with responsibility for design, procurement, construction, testing, operation, and maintenance of the facility. The significant functional levels of the organization are described below.

1.1.1 Key Atomic Alchemy Management Authorities and Responsibilities

Atomic Alchemy Chief Executive Officer (CEO)

The Atomic Alchemy CEO is responsible for all aspects of design, construction and operation of the Atomic Alchemy Non-Power Production and Utilization Facility (NPUF). The CEO is also responsible for all technical and administrative support activities provided by Atomic Alchemy and its consortium partners and contractors. The Atomic Alchemy CEO directs the Chief Operating Officer and Chief Nuclear Officer and reports to the board of directors.

Atomic Alchemy Chief Operating Officer (COO)

During construction and operations, this position reports to the Chief Executive Officer and is responsible for all operational aspects of the company including safety, quality, environmental stewardship, regulatory affairs, security, plant management, information technology and supply chain management.

The COO is also responsible for all external operations of Atomic Alchemy, including supplier organizations. The COO delegates sufficient responsibility and authority to the Vice President, Nuclear Process Operations, Atomic Alchemy Chief Nuclear Officer, Vice President, Nuclear Reactor Operations, and Vice President, Nuclear Regulatory Affairs & Compliance. The COO is ultimately responsible for integrating all quality requirements as defined in this QAPD across the internal and external organization.

Atomic Alchemy Chief Financial Officer (CFO)

During construction and operations, this position reports to the Chief Executive Officer and is responsible for all financial matters for Atomic Alchemy. In addition, the CFO will partner with senior leadership to develop and implement financial strategies across the organization. The CFO will oversee all compliance and recognition for government (federal and state) contracts and private grants. The CFO is also responsible for financial accounting and human resources for the organization.

Atomic Alchemy Chief Nuclear Officer (CNO)

This position reports to the Chief Operating Officer, and is responsible for the overall corporate policy, for the implementation of the quality assurance program and provides executive direction and guidance as well as promulgates corporate nuclear policy through the Company's senior management staff.

General Manager, Nuclear Process Operations (GMNPO)

During the operations phase, this position is responsible for overall plant nuclear radioisotope process safety, operation, maintenance, training, and operations support including business operations areas of document control and records management. This position reports to the Chief Nuclear Officer and is responsible for the station's compliance with its NRC Operating License, governmental regulations and ASME Code requirements.

General Manager, Nuclear Reactor Operations (GMNRO)

During the operations phase, this position is responsible for overall plant nuclear reactor safety, operation, maintenance, training, and operations support including business operations areas of document control and records management. This position reports to the CNO and is responsible for the station's compliance with its NRC Operating License, governmental regulations and ASME Code requirements.

General Manager, Nuclear Regulatory Affairs & Compliance (GMRAC)

During both the operations phase and construction phase, this position reports to the CNO, and is responsible for all licensing and regulatory affairs & compliance matters and provides organizational support and management oversight of the facilities to ensure prompt and proper disposition of regulatory issues, develops regulatory positions and advises senior management on priorities and activities affecting regulatory issues at the Atomic Alchemy facility.

General Manager, Nuclear Design Engineering Services (GMNDES)

During the operations phase, the GMDES reports to the COO. The GMNDES is responsible for managing the Design Engineering organizations such as Mechanical, I&C, Electrical. The Engineering Services organization is responsible for support of the Atomic Alchemy facility by providing engineering services using qualified personnel.

General Manager, Construction Services (GMCS)

Prior to the operations phase, this position reports to the COO, and is responsible for all of Atomic Alchemy's and their consortium partners construction activities.
During the Operations phase, this position is responsible for day-to-day engineering and technical services to support plant operations and maintenance including engineering programs, equipment reliability, system engineering, and nuclear fuel services. This position is also responsible for developing and managing any future Atomic Alchemy construction activities and modifications.

General Manager, Nuclear Support Services (GMNSS)

During the operations phase, the GMNSS reports to the COO. The GMNSS is responsible for managing the review of the design of plant systems (including human factors engineering), modifications, testing, configuration control, Emergency Preparedness (EP) organizations, Training, and technical support programs. The GMNSS is also responsible for the safe and efficient operation of the reactor units.

General Manager, Quality Assurance Program (GMQAP)

During the operations phase, the GMQAP reports to the COO. There are several organizations within Atomic Alchemy which implement and support the QAPD. These organizations include, but are not limited to Procurement Group, Engineering, Training, Security, Emergency Preparedness, and Environmental Services. This position oversees the implementation and adherence to Quality Control standards throughout these organizations.

Reactor Operations Shift Manager (ROSM)

A licensed senior reactor operator (SRO) provides general supervision for the operation of each respective nuclear reactor unit, and coordinates radioisotope process facility operations with the Process Operations Shift Manager. As stipulated in Technical Specifications (or in Appendix B) the Ops-Shift Manager holds the appropriate reactor operator license. The Ops-Shift Manager assures the safe and efficient operation of the assigned unit in accordance with applicable licenses, operating instructions and procedures, emergency procedures and safety rules and regulations.

Process Operations Shift Manager (POSM)

A licensed reactor operator (RO) provides general supervision for the operation of the radioisotope process facility operations with maintenance, work management, and other groups. As stipulated in Technical Specifications the Ops-Shift Manager holds the appropriate reactor operator license. The Ops-Shift Manager assures the safe and efficient operation of the assigned unit in accordance with applicable licenses, operating instructions and procedures, emergency procedures and safety rules and regulations.

1.1.2 Key Atomic Alchemy Organizations, Groups, and Committees

Nuclear Design Engineering Services Group

The Nuclear Design Engineering Services Group is responsible for multi-discipline design engineering functions, supporting activities, engineering programs, and configuration management including design and configuration control, engineering technical support, systems engineering, and material engineering. The Nuclear Design Engineering group is also responsible for engineering activities in safety analysis and nuclear fuel. These activities include reactor, radiological and radwaste engineering.

Maintenance Group

The Maintenance group is responsible for on-line preventative and repair maintenance, cost and scheduling, outage activities, installation, alterations, adjustment and calibration, replacement and repair of plant electrical and mechanical equipment, and instruments and controls. Responsibilities include scheduling of surveillances required by Technical Specifications, establishing standards and frequency of calibration for instrumentation, and ensuring instrumentation and related testing equipment are properly used, inspected, and maintained.

Nuclear Training Services Group

The Nuclear Training Services group is responsible for reactor operators, process hot cell operators, and technical plant equipment training. The operator training group reports directly to the General Manager, Nuclear Design Engineering Services to provide sufficient organizational freedom and independence.

Emergency Planning Group

The Emergency Planning group is responsible for development and maintenance of the on-site radiological emergency plan and the development and coordination of required off-site radiological emergency response plans.

Licensing and Regulatory Affairs & Compliance Group

The Licensing and Regulatory Affairs & Compliance Group responsibilities include developing policies and standardized processes and procedures for the maintenance of the licensing basis, and the preparation of submittals to the NRC and other regulatory organizations. This position is also responsible for security, and the emergency preparedness departments. Responsibilities for nuclear security include facility physical security, nuclear access programs, and fitness for duty programs.

Radiation Protection and Waste Services Group

Radiation Protection and Waste Services group carries out health physics functions and reports to the General Manager, Nuclear Design Engineering Services to provide sufficient organizational freedom and independence. Radiation protection services include the following:

a) Scheduling and conducting radiation surveys including contamination sample collection.
b) Determining contamination levels and assigning work restrictions through radiation worker permits.
c) Maintaining records and reports on radioactive contamination levels.
d) Administering the personnel monitoring program and maintaining required records in accordance with federal and state codes.

Radiation Protection and Waste Services is also responsible for radioactive waste services.

Plant Nuclear Safety Review Committee (PNSRC)

Activities occurring during the construction and operational phase shall be independently reviewed on a periodic basis for nuclear safety. The independent review committee shall be functional prior to the commencement of construction activities.

This committee also functions as the Atomic Alchemy Plant Operations Review Committee (PORC) and Site Operations Review Committee (SORC).

The composition and minimum qualifications of the PNSRC members is described in Part I, Section 2 Scope of the Quality Assurance Program Section of this QAPD.

Configuration Control Board Organization (CCBO)

The Atomic Alchemy Configuration Control Board provides a structured review process of design engineering changes, requirement changes, system changes, procedural changes, problem areas, and work in progress.

The Atomic Alchemy Configuration Control Organization is responsible for verifying the development and effective implementation of changes and modifications of the Atomic Alchemy facility, including but not limited to engineering, licensing, document control, the corrective action program and procurements that support ongoing construction.

The minimum qualifications of CCBO members shall be that all members have a 4-year academic degree in an engineering or physical science field, or hold a management position, and have a minimum of five years nuclear technical experience in their respective field of expertise.

The CCBO shall be composed of seven to nine members. Members shall collectively have experience and expertise in the following areas:

a) Nuclear Plant Operations
b) Nuclear Engineering
c) Reactor Engineering
d) Nuclear Maintenance
e) Instrumentation and Controls
f) Health Physics
g) Chemistry
h) Nuclear Work Planning
i) Quality Assurance

Corporate Services Group

The Atomic Alchemy Corporate Services Group is an enterprise-wide organization that is responsible for supporting the Atomic Alchemy Facility by performing activities related to safety and health, food service, gym, janitorial, human resources, financial and environmental services as applicable. Financial and Human resources report to the CFO while the remaining services report to the COO.

1.1.3 Quality Related Responsibilities Common to all Organizational Managers

The head of each department performing quality activities is responsible for:

a) Administering those activities within their organization which are required by this QAPD.
b) Ensuring implementation of the Atomic Alchemy Quality Assurance Program.
c) Establishing and clearly defining the duties and responsibilities of personnel within their organization who perform quality related activities.
d) Planning, selecting, and training personnel to meet the requirements of the QAPD.
e) Performing and coordinating quality activities within their organization and interfacing with the PNSRC.
f) Each individual performing or verifying activities affecting quality is responsible to conduct those activities in accordance with the requirements of this QAPD and implementing programs. These individuals shall have direct access to such levels of management as may be necessary to perform this function.
g) The responsibility, authority, and organizational relationship for performing quality activities within each organization is established and delineated in the Atomic Alchemy organizational charts, policy statements, and written job or functional descriptions.

1.2 APPLICANT FOR CERTIFICATION

1.2.1 License Application

Atomic Alchemy and its Design Authority Consortium Partner (to be identified in the FSAR) provides engineering & design services for the development of the 10 CFR part 50 and 10 CFR part 70 application and construction license. These engineering services include site specific license engineering, and design engineering activities necessary to support development of the application and planning and support for preconstruction and construction of a Non-Power Reactor and Production and Utilization Facility.

1.3 AUTHORITY TO STOP WORK

Quality assurance and inspection personnel have the authority, and the responsibility, to stop work in progress which is not being performed in accordance with approved procedures or where safety or SSC integrity may be jeopardized. This extends to off-site work performed by suppliers furnishing safety-related materials and services to Atomic Alchemy.

Every individual has an obligation to identify concerns using the corrective action process described in Part I, Section 18 of this QAPD whenever the health and safety of workers, the public, or the environment could be compromised or QAPD requirements are not satisfied.

1.4 QUALITY ASSURANCE ORGANIZATIONAL INDEPENDENCE

For the 10 CFR Part 50, and Part 70 application and construction, independence shall be maintained between the organization or organizations performing the checking (quality assurance and control) functions and the organizations performing the design functions. This provision is not applicable to design review/verification by the organization creating the items.

1.5 RESOLUTION OF DISPUTES

Disputes involving differences of opinion on quality matters or issues are brought to the attention of line management, and if not resolved by the individual's manager, are elevated progressively through the Atomic Alchemy management.

1.6 PROGRAMS THAT IMPLEMENT THE ATOMIC ALCHEMY QAPD

In addition to the program requirements of the Technical Specifications, Technical Requirements Manual (TRM), and the Offsite Dose Calculation Manual (ODCM), Atomic Alchemy establishes additional programs by which to implement the requirements of this QAPD. Some regulatory-required programs will be used to satisfy criterion of the QAPD, as indicated by an asterisk in the “Implementing Programs” subsections for each criterion herein.

2 QUALITY ASSURANCE PLAN (CRITERION II)

2.1 SCOPE OF QUALITY ASSURANCE PLAN

This QAPD applies to the Atomic Alchemy construction/pre-operation and operations[1] activities of a Non-Power Production and Utilization Facility (NPUF), affecting the quality and performance of safety-related structures, systems, and components, including, but not limited to:

a) Designing
b) Construction
c) Procuring
d) Fabricating
e) Cleaning
f) Handling
g) Tests
h) Pre-operational activities
i) Licensing
j) Startup
k) Siting
l) Operations
m) Maintenance
n) Receiving
o) Storing
p) Erecting
q) Installations
r) Repairs
s) Training
t) Decommissioning
u) Modifications
v) Inspecting
w) Refueling
x) Shipping

During initial preliminary design and development, pre-application, Atomic Alchemy will implement the design and document control programs. The applicability of these programs to preliminary design is further described in Part I, Criterion III and Criterion VI.

2.1.1 Definitions

The definitions provided in ASME NQA-1-2017, Part I, Introduction, Section 400, apply to the terms and definitions used in this document.

2.1.2 Requirements

Safety-related systems, structures, and components under the control of the QAPD are identified by design engineering documents. The technical aspects of these items are considered when determining the QA program applicability, including, as appropriate, the item's design safety function.

As described in PART II and Part III of this document, specific program controls are applied to non-safety related SSCs that are significant contributors to plant safety, for which 10 CFR50, Appendix B is not applicable. The specific program controls consistent with applicable sections of the QAPD are applied to those items in a selected manner, targeted at those characteristics or critical attributes that render the SSC a significant contributor to plant safety.

2.1.3 Responsibilities

The policy of Atomic Alchemy is to assure a high degree of reliability of its nuclear processing facility and operation of its nuclear reactors while ensuring the health and safety of its workers and the public.

[1] See NRC Safety Evaluation conclusion with regard to operations and decommissioning.

To this end, selected elements of the QAPD are also applied to certain equipment and activities that are not safety-related but support safe, economic, and reliable plant operations, or where other NRC guidance establishes quality assurance requirements. Implementing documents establish program element applicability.

2.1.4 Multiple Organizations

Atomic Alchemy QAPD is implemented across multiple organizations that are assigned different aspects of quality assurance responsibility. Atomic Alchemy recognizes that quality assurance is an interdisciplinary function involving many organizational components and, therefore, should not be regarded as the sole domain of a single quality assurance group.

For example, it may be more appropriate for nuclear engineers to perform reviews of plant nuclear engineering activities rather than quality assurance engineers because of the specialized competence required to perform these reviews. Quality related responsibilities common to all organizations are promulgated throughout the appropriate programs and procedures.

2.1.5 Multi-Unit Facility Provisions

In establishing QA/QC provisions for ongoing construction at a multi-unit reactor facility, Atomic Alchemy commits to compliance with NQA-1-2017, Part II, Introduction, Sections 600-604.

2.1.6 Interface Responsibilities

The Atomic Alchemy design interface ensures that design input items and activities subject to the provisions of this QAPD are promulgated between the various Design Authority Consortium Partners and Departments suitable for their intended application, consistent with their effect on safety.

Atomic Alchemy design interfaces shall be identified and procedurally controlled. Design efforts shall be coordinated among interfacing consortium partners and sub-organizations as detailed in the Atomic Alchemy design control program.

2.1.7 Delegation of Work

Delegated responsibilities may also be performed by a supplier’s QAP, provided that supplier has been approved as a supplier in accordance with the Atomic Alchemy QAPD. Periodic audits and assessments of a supplier’s QA programs are performed to assure compliance with the supplier's QAP and implementing procedures.

2.1.8 Periodic Review of the Quality Assurance Program

Activities occurring during both the construction and operational phase shall be independently reviewed on a periodic basis. The Atomic Alchemy independent review committee, Plant Nuclear Safety Review Committee (PNSRC), shall be functional prior to the commencement of construction activities. This committee also functions as the Atomic Alchemy Plant Operations Review Committee (PORC) and the Site Operations Review Committee (SORC).

2.1.9 Plant Nuclear Safety Review Committee (PNSRC)

The PNSRC is composed of no less the 6 persons; the majority of members are from the on-site operating organizations.

Additional consultants and contractors may be added and used as required for the review of complex problems beyond the expertise of the offsite/on site independent review committee.

The PNSRC performs the following:

a) Reviews proposed tests and experiments not described in the FSAR.
b) Changes to proposed tests and experiments not described in the FSAR that do require a technical specification change must be reviewed by the PNSRC prior to NRC submittal and implementation.
c) Reviews proposed technical specification changes and license amendments requests prior to NRC submittal and implementation.
d) Reviews violations, deviations, and reportable events that are required to be reported to the NRC in writing within 24 hours. This review includes the results of investigations and recommendations resulting from such investigations to prevent or reduce the probability of recurrence of the event.
e) Reviews NRC issuances, industry advisories, Licensee Event Reports etc.
f) Reviews any matter related to nuclear safety that is requested by the Site Vice President, Plant Manager, or any PNSRC member.
g) Reviews corrective actions for significant conditions adverse to quality
h) Makes detailed recommendations for revised procedures, equipment modifications, maintenance activities, operations activities, or other means of improving unit safety to appropriate station/corporation management.
i) Reviews the adequacy of the audit program every 24 months.

2.1.9.1 Qualifications

Chairman of the PNSRC

Education: Baccalaureate (or higher) in engineering or a related science.

Minimum experience: 10 years combined managerial and nuclear technical support.

PNSRC Committee Members

Education: Baccalaureate in engineering or a related science, or in lieu of the degree, at least 12-years of nuclear engineering experience.

Minimum required experience shall be no less than: 5 years' nuclear experience in their own area of responsibility (e.g., nuclear power plant operations, nuclear engineering, chemistry and radiochemistry, metallurgy, nondestructive testing, instrumentation and control, radiological safety, mechanical, I&C, electrical engineering, administrative control and quality assurance, training, emergency plans and related procedures and equipment.

2.1.10 Maintenance Rule Expert Panel

Atomic Alchemy will assemble an Expert Panel that will determine the SSC's to be included in the Maintenance Rule program. The program applies to safety-related and non-safety-related SSCs identified as being significant to safety. A deterministic approach and industry lessons learned is used as the guide in the analysis to determine the safety significance of non-safety related components and systems.

The expert panel members must have an accredited 4-year degree in engineering, science, or other related field with a minimum of 5 years of nuclear experience or in lieu of the 4-year degree, a combined 12 years of nuclear engineering experience in one or more of the following disciplines or areas:

a) Reliability Analysis
b) Safety Analysis
c) Licensing or Regulatory Affairs
d) Design Engineering
e) Power Plant Operations or Maintenance
f) Previous Commercial Senior Reactor Operator License

2.1.11 Personnel Qualifications

Personnel assigned to implement elements of the QAPD shall be capable of performing their assigned tasks. To this end Atomic Alchemy establishes and maintains formal indoctrination and training programs for personnel performing, verifying, or managing activities within the scope of the QAPD to assure that suitable proficiency is achieved and maintained.

Plant and support staff minimum qualification requirements are as delineated in each site's Technical Specifications. Other qualification requirements may be established but will not reduce those required by Technical Specifications.

Sufficient managerial depth is provided to cover absences of incumbents. When required by code, regulation, or standard, specific qualification and selection of personnel is conducted in accordance with those requirements as established in the applicable Atomic Alchemy procedures.

The minimum qualifications of the Operational Quality Assurance Manager are to hold an engineering or related science degree and a minimum of five years of related experience including two years of nuclear facility experience, one year of supervisory or management experience, and two years of experience performing quality verification activities.

Special requirements shall include management and supervisory skills and experience or training in leadership, interpersonal communication, management responsibilities, motivation of personnel, problem analysis and decision making, and administrative policies and procedures.

The minimum qualifications of the individuals responsible for planning, implementing, and maintaining the programs for the QAPD are that each has a high school diploma or equivalent and has a minimum of 5-years of related experience.

2.1.12 Identification of Specific Safety-Related Design Basis Information

The development of the Atomic Alchemy 10 CFR 50 and 10 CFR 70 construction application will involve site testing, data collection, engineering design inputs, and calculations that determine and bound the safety-related design basis data. This information will be inclusive to the indoctrination training programs as required.

2.1.13 Management Participation

The COO & CNO assures that a management review of the Atomic Alchemy QAPD is conducted on an annual basis by the CCBO to assess the scope, status, implementation, and effectiveness, and to assure compliance with NRC licensing commitments.

2.1.14 Status Report to Management

Management is regularly informed by the PNSRC of adverse trends and lessons learned as a result of reviews conducted on audit reports, surveillance reports, corrective action reports, management assessments, and Focus Area Self Assessments.

2.1.15 Implementing Organizations

- Plant Nuclear Safety Review Committee (PNSRC) (to be provided in the FSAR)
- Configuration Control Board Organization (CCBO) (to be provided in the FSAR)
- Maintenance Rule Expert Panel (to be provided in the FSAR)

2.2 QA TRAINING AND QUALIFICATION CRITERIA (CRITERION II)

Atomic Alchemy describes in this section the associated programs and procedures that implement the requirements of Criterion II, Training and Qualification Criteria, of 10 CFR 50, Appendix B and Requirement 2, Sections 100-500 of NQA-1-2017.

Personnel assigned to implement elements of the QAPD shall be capable of performing their assigned tasks. To this end, Atomic Alchemy establishes and maintains formal indoctrination and training programs for personnel performing, verifying, or managing activities within the scope of the QAPD to assure that suitable proficiency is achieved and maintained.

2.2.1 Requirements

Proficiency of personnel performing and verifying activities affecting quality is established and maintained.

Personnel proficiency is established and maintained by training, examination/testing, and/or certification based upon the requirements of the activity. Acceptance criteria are developed to determine If individuals are properly trained and qualified.

Training for positions identified in 10 CFR 50.120 is accomplished according to programs accredited by the National Nuclear Accrediting Board of the National Academy of Nuclear Training that implements a systematic approach to training.

Atomic Alchemy training indoctrination includes the administrative and technical objectives, requirements of the applicable codes and standards, and the QAPD elements to be employed.

Records of personnel training and qualification are maintained.

In establishing QA/QC qualification and training programs, Atomic Alchemy commits to compliance with NQA-1-2017, Requirement 2, Sections 100-500.

2.2.2 Implementing Programs

Configuration Control Training Program (to be provided in the FSAR)

2.3 TRAINING AND QUALIFICATION – INSPECTIONS AND TESTS (CRITERION II)

Atomic Alchemy describes in this section the associated programs and procedures that implement the requirements of Criterion II, Training and Qualification – Inspection and Tests, of 10 CFR 50, Appendix B and Requirement 2 of NQA-1-2017.
Personnel assigned to implement elements of the QAPD shall be capable of performing their assigned tasks. To this end Atomic Alchemy establishes and maintains formal indoctrination and training programs for personnel performing, verifying, or managing activities within the scope of the QAPD to assure that suitable proficiency is achieved and maintained

2.3.1 Requirements

Proficiency of personnel performing and verifying activities affecting quality is established and maintained.

Personnel proficiency is established and maintained by training, examination/testing, and/or certification based upon the requirements of the activity. Acceptance criteria are developed to determine If individuals are property trained and qualified.

Training for positions identified in 10 CFR50.120 is accomplished according to programs accredited by the National Nuclear Accrediting Board of the National Academy of Nuclear Training that implement a systematic approach to training.

Atomic Alchemy training indoctrination includes the administrative and technical objectives, requirements of the applicable codes and standards, and the QAPD elements to be employed.

Records of personnel training and qualification are maintained.

In establishing qualification and training programs, Atomic Alchemy commits to compliance with NQA-1-2017, Requirement 2.

2.3.2 Non-Destructive Testing (NDT) and Non-Destructive Examination (NDE) Training

During construction and operational phases, Atomic Alchemy may delegate control of Part I, Criterion II NDT services, if necessary, to the qualified suppliers of NDT/NDE training services and design consortium partners who retain an NDT/NDE department or organization through the contracts in accordance with the requirements in Part II, Criterion II of this document.

All qualification and certification of NDT/NDE personnel who perform such services for the Atomic Alchemy facility shall meets the requirements of NQA-1-2017, and shall include the following:

a) Visual Testing (VT)
b) Radiographic Testing (RT)

c) Ultrasonic Testing (UT)
d) Magnetic Particle Testing (MT)
e) Liquid Penetrant Testing (PT)
f) Electromagnetic Testing (ET)
g) Leak Testing (LT)

2.3.3 NDE/NDT Instructors

Instructors develop appropriate classroom and laboratory materials for initial and supplemental training of NDE/NDT personnel. Instructors' responsibilities include the following:

a) Conducts classroom and laboratory training sessions for all levels of NDE/NDT personnel.
b) Conducts classroom and laboratory testing sessions for all levels of NDE/NDT personnel.
c) Conducts qualification testing for all levels of NDE/NDT personnel.

2.3.4 Non-License Plant Staff Training Program

2.3.5 NUPF Reactor Operator and Radioisotope Process Operator Training and Requalification Program

2.3.6 Security Training and Requalification Program

The security training and requalification program complies with 10 CFR 73.55(c)(4) and 10 CFR 73 App. B

2.3.7 Implementing Programs

- QA/QC Inspector Training Program (to be provided in the FSAR)
- Non-Destructive Examination & Testing Training Program (to be provided in the FSAR)
- Non-Licensed Plant Staff Training Program (to be provided in the FSAR)
- NUPF Reactor Operator and Radioisotope Process Operator Training and Requalification Program (to be provided in the FSAR)
- Security Training and Requalification Program (to be provided in the FSAR)

3 DESIGN CONTROL (CRITERION III)

Atomic Alchemy describes in this section and associated programs and procedures that implement the requirements of Criterion III, Design Control, of 10 CFR 50, Appendix B and Requirement 3, Sections 100-900 of NQA-1-2017.

Implementing programs and procedures identify the process and include provisions for the control of design, development, verification, approval, release, status, distribution, revisions, review of calculations, control of software, and implementation of required rules, regulations, codes, and standards.

The Atomic Alchemy Design Control program assures a complete and accurate transfer of the high-level design information and performance requirements specified in the Final Safety Analysis Report (FSAR) into detailed procedures, specifications, calculations, drawings, procurement, and/or

construction documents, in a manner consistent with the requirements of Appendix B to 10 CFR Part 50.

3.1 REQUIREMENTS

As part of the design control, the design review program has been developed to meet the requirements of ASME NQA-1-2017 “Quality Assurance Requirements for Nuclear Facility Applications, ASME QME-1-2017, “Qualification of Active Mechanical Equipment Used in Nuclear Power Plants” and ASME BPV Code Section III 2017 quality standards. While these versions are not endorsed by a Regulatory Guide their use should not result in deviation from the design philosophy otherwise stated in the Regulatory Guides.

3.2 DESIGN INPUT CONTROL

Applicable design inputs (such as design basis, conceptual design reports, performance requirements, regulatory requirements, codes, and standards shall be controlled by the Atomic Alchemy Design Authority Consortium Partner (to be provided in the FSAR) according to the following requirements:

a) Design inputs shall be identified and documented, and their selection reviewed and approved.
b) Design inputs shall be specified and approved in a manner to support the schedule.
c) Design inputs shall provide the necessary details to permit design to be carried out in a manner that provides a consistent basis for making design decisions, accomplishing design verification, and evaluating design changes.
d) Changes from approved design inputs and reasons for the changes shall be identified, approved, documented, and controlled.
e) Design inputs based on assumptions that require re-verification shall be identified and controlled by the appropriate procedures.
f) Atomic Alchemy design input analyses documentation shall include:
    i. Definition of the objective of the analyses.
    ii. Definition of design inputs and their sources.
    iii. Results of literature searches or other applicable background data.
    iv. Identification of assumptions and designation of those that must be verified as the design proceeds.
    v. Identification of any computer calculation, including computer type, computer program (e.g., name), revision identification, inputs, outputs, evidence of reference to computer program verification and the bases (or reference thereto) supporting application of the computer program to the specific physical problem.
    vi. Review and approval.

3.3 DESIGN PROCESS

The design process shall be controlled by the Atomic Alchemy Design Authority Consortium Partner (to be provided in the FSAR) according to the following requirements:

a) Design documents shall be adequate to support design, construction, and operation.
b) Appropriate quality standards shall be identified and documented, and their selection reviewed and approved.

c) Changes from specified standards, including the reasons for the change, shall be identified, approved, documented, and controlled.
d) Design methods, materials, parts, equipment, and processes that are essential to the function of the structure, system, or component shall be selected and reviewed for and suitability of application.
e) Applicable information derived from experience as set forth in reports or other documentation, shall be made available to cognizant design personnel.
f) Final design documents (i.e., approved design output documents and approved changes thereto) shall be sufficiently detailed as to purpose, method, assumptions, design input, references, and units such that a person technically qualified in the subject/engineering discipline can understand the documents and verify their adequacy without recourse to the originator of the design document.
g) Procedural controls for identifying sub-assemblies or components on final design documents that are part of the item being designed shall be established. When a commercial grade item is modified and/or tested to new requirements that are different from the supplier's published product description, the component part shall be traceable to documentation noting that it is different from the originally approved commercial grade item.
h) Atomic Alchemy design drawings, specifications or other design output documents shall contain appropriate inspection, examination, and testing acceptance criteria.
i) Design analysis documents shall be legible, in a form suitable for reproduction, filing and retrieval, and under configuration management control. Atomic Alchemy design calculations shall be identifiable by subject (including structure, system or component to which the calculation applies), originator, reviewer and date, or by other designators in order that approved calculations are retrievable.

3.4 DESIGN VERIFICATION

The Atomic Alchemy design processes provide for design verification to ensure that items and activities subject to the provisions of this QAPD are suitable for their intended application, consistent with their effect on safety. The design verification shall be controlled by the Atomic Alchemy and its Design Authority Consortium Partner (to be provided in the FSAR) according to the following requirements:

a) Design changes are subjected to these controls, which include verification measures commensurate with those applied to original plant design.
b) Design verifications are performed by competent individuals or groups other than those who performed the original design but who may be from the same organization. The verifier shall not have taken part in the selection of design inputs, the selection of design considerations, or the selection of a singular design approach, as applicable.
c) This verification may be performed by the originator's supervisor provided the supervisor did not specify a singular design approach, rule out certain design considerations, and did not establish the design inputs used in the design, or if the supervisor is the only individual in the organization competent to perform the verification. If the verification is performed by the originator's supervisor, the justification of the need is documented and approved in advance by management.

d) The extent of the design verification required is a function of the importance to safety of the SSC under consideration, the complexity of the design, the degree of standardization, the state-of-the-art, and the similarity with previously acceptable designs.
e) Design verification procedures are established and implemented to assure that an appropriate verification method is used, the appropriate design parameters to be verified are chosen, the acceptance criteria are identified, and the verification is satisfactorily accomplished and documented.

Design verification shall be performed in a timely manner at appropriate times during the design process. Verification shall be performed before release for procurement, manufacture or construction, or release to another organization for use in other design work. In some cases (such as when insufficient data exists) it may be necessary to release unverified designs to other engineering organizations or disciplines to support schedule requirements. Unverified portions of the design shall be clearly identified and procedurally controlled. In all cases, design verification shall be completed before relying on the item or computer program to perform its function.

f) Computer programs may be utilized for design analysis or verification without additional individual verification of the program for each application provided:
    i. The computer program has been verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed.
    ii. The encoded mathematical model has been shown to produce a valid solution to the physical problem associated with the particular application.
    iii. Computer programs shall be controlled to assure that changes are documented and approved by authorized personnel. Where changes to previously verified computer programs are made, verification shall be required for the change, including evaluation of the effects of these changes on the above.

3.5 DESIGN VERIFICATION METHODS

Acceptable verification methods include, but are not limited to, any one of the following or a combination of the following:

3.5.1 Design Reviews

Design reviews are critical reviews to provide assurance that the final design is correct and satisfactory. The following items shall be addressed, as applicable during the review:

a) Were the design inputs correctly selected and incorporated into the design?
b) Are assumptions necessary to perform the design activity adequately described, reasonable and, where necessary, re-verified?
c) Was an appropriate design method used?
d) Is the design output reasonable compared to the applicable design inputs?
e) Are the necessary design input and verification requirements for interfacing organizations specified in the design documents or in supporting procedures and instructions?

3.5.2 Alternate Calculations

The appropriateness of assumptions, input data, and the computer program or other calculation methods used, shall be evaluated and the results shall be checked through the use of alternate calculation methods to verify the correctness of the original calculations or analyses.

3.5.3 Qualification Testing

If design adequacy is to be verified by qualification testing, the tests shall be identified, procedurally controlled, and documented according to the following:

a) The test configuration shall be defined and documented.
b) Testing shall demonstrate the adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions in which the item must perform satisfactorily shall be considered in determining the most adverse design conditions.
c) If the tests verify only specific design features, then the other features of the design shall be verified by other means.
d) Test results shall be documented and evaluated to ensure that test requirements have been met.
e) If qualification testing indicates that a modification to an item is necessary to obtain acceptable performance, then the modification shall be documented, and the item modified and re-tested or otherwise verified to ensure satisfactory performance.
f) Scaling laws shall be established, verified, and documented when tests are being performed on models or mockups.
g) The results of model test work shall be subject to error analysis, where applicable, before using the results in final design work.

3.6 DESIGN RECORDS

Atomic Alchemy maintains records sufficient to provide evidence that the design was properly accomplished. These records include the final design output and any revisions thereto, as well as record of the important design steps (e.g., verifications, calculations, analyses, and computer programs).

3.7 DESIGN CONTROL – INITIAL DRAFT DESIGN AND PRE-CONSTRUCTION PHASE

Design changes during the initial draft design and pre-construction phase shall be controlled according to the following requirements:

a) During the initial draft design phase of design all documents are considered to be in an “Open Revision” state. Preliminary studies, analysis and layouts are being evaluated, various design inputs and processes are being reviewed and examined. Equipment vendor inputs are being reviewed and selected. While in these design phase states the documents are not considered quality control documents. ANSI N45.2.9-1974, paragraph 1.4, definition of "Quality Assurance Records" states in part: "For the purposes of this standard, a document is considered a quality assurance record when the document has been completed."
b) Numerous extensive changes to layouts and calculations are anticipated during this phase therefore changes to these documents during this “Open Revision” state is not controlled.

c) Once a technical design input document has reached a “Revision 0” status the control of that document then falls under the requirements of the design control programs outlined in this criterion. New documents which evolve during new construction shall be transmitted to records department within 90 days of completion.

3.8 DESIGN CONTROL – CONSTRUCTION AND OPERATIONAL PHASE

Design changes during the construction and operational phase shall be controlled according to the following requirements:

a) Changes to final designs, field changes, modifications to the operating facility and nonconforming items dispositioned as "use-as-is" or "repair," as described in the Atomic Alchemy QAPD Section XV.
b) Nonconforming Items shall have documented justification for use and are subject to the same design control measures and reviews as those applied to the original design.
c) Design control measures for changes shall include provisions to determine that the design analyses for the item are still valid.
d) Changes shall be reviewed and approved by the affected groups or organizations that reviewed and approved the original design documents.
e) The interface between the design organization responsible for finalizing a design change and other organizations either involved in the review of the change, such as the QA and configuration management organizations, and those affected by the change, such as the operations and maintenance organizations, shall be maintained.
f) The design process and design verification practices and procedures shall be reviewed and modified, as necessary, when a significant design change is required because of an incorrect design. These design deficiencies shall be documented according to the Atomic Alchemy QAPD Section XVI, Corrective Actions.
g) If these deficiencies cause constructed or partially constructed items (systems, structures, or components) to be deficient, the affected items shall be controlled in accordance with the Atomic Alchemy QAPD Section XV, Nonconforming Items.
h) When a design change is approved other than revision to the affected design documents, field changes shall be incorporated into affected design documents when such incorporation is appropriate.

3.9 DESIGN INTERFACE

The Atomic Alchemy design interface ensures that design input items and activities subject to the provisions of this QAPD are promulgated between the various Design Authority Consortium Partners and Departments suitable for their intended application, consistent with their effect on safety.

Atomic Alchemy design interfaces shall be identified and procedurally controlled. Design efforts shall be coordinated among interfacing consortium partners and sub-organizations as detailed in the Atomic Alchemy design control program.

Interface controls shall include the assignment of responsibility and the establishment of procedures among interfacing design consortium partners’ organizations for the review, approval, release, distribution, and revision of documents involving design and licensing basis inputs.

Atomic Alchemy design information transmitted across interfaces shall be documented and procedurally controlled.

Atomic Alchemy transmittals of design information and/or documents shall reflect the status of the transmitted information and documents. Incomplete designs that require further evaluation, review or approval shall be so identified. When it is necessary to initially transmit the design information orally or by other informal means, design information shall be promptly confirmed through a controlled document or by electronic means.

During the operational phase that begins after final acceptance and turnover of all SSC's, and design and licensing basis documents from the design authority consortium partner(s) to Atomic Alchemy, the Atomic Alchemy General Manager, Nuclear Design Engineering Services (GMNDES), General Manager, Construction Services (GMCS), General Manager, Nuclear Support Services (GMNSS), Vice President, Nuclear Regulatory Affairs & Compliance (GMRAC), and General Manager, Quality Assurance Program (GMQAP) are responsible for ensuring the facility complies with all applicable regulatory requirements including the requirements of this QA Program.

3.10 COMPUTER APPLICATION AND DIGITAL EQUIPMENT SOFTWARE

The QAPD shall govern the acquisition, development, procurement, testing, maintenance, and use of computer application and digital equipment software when used in safety-related applications and designated non-safety-related applications.

3.11 IMPLEMENTING PROGRAMS

- Design Control Program (to be provided in the FSAR)
- Design Basis Documentation (DBD) Program (to be provided in the FSAR)
- Commitment Management Program (to be provided in the FSAR)
- *Setpoint Control Program (to be provided in the FSAR)
- I&C Software Development Program (to be provided in the FSAR)
- *Software Verification and Validation Program (to be provided in the FSAR)

4 PROCUREMENT DOCUMENT CONTROL (CRITERION IV)

Atomic Alchemy describes in this section the associated programs and procedures that implement the requirements of Criterion IV, Procurement Document Control, of 10 CFR 50, Appendix B, Requirement 4, Sections 100-400 of NQA-1-2017, Part II, Subpart 2.7, Sections 100-700 of NQA-1-2017, and Part II, Subpart 2.19, Sections 100-200 of NQA-1-2019[2].

Procedures shall be established to ensure that procurement documents will contain sufficient technical and quality requirements to ensure that the items or services satisfy the needs of Atomic Alchemy.

4.1 REQUIREMENTS

Procurement documents at all procurement levels shall identify the documentation required to be submitted for information, review, or approval by Atomic Alchemy. At each level of procurement, the

[2] See NRC SE related to use of Subpart 2.19—commercial grade dedication of calibration and testing services is not approved for implementation without additional controls per Revision 1 of NEI 14-05A, as described in the SE.

procurement documents shall provide for access to the supplier's facilities and records, for inspection or audit by Atomic Alchemy, a designated representative, or other parties authorized by Atomic Alchemy.

Atomic Alchemy procurement documents shall include Atomic Alchemy's requirements for reporting and approving disposition of supplier's nonconformances associated with the items or services being procured. The procurement documents for safety items will prohibit the supply of sub-standard or counterfeit parts or materials.

Applicable technical, regulatory, administrative, quality and reporting requirements (such as specifications, codes, standards, tests, inspections, special processes, and 10 CFR 21) are invoked for procurement of items and services. 10 CFR 21 requirements for posting, evaluating, and reporting will be followed and imposed on suppliers when applicable.

4.2 PROCUREMENT DOCUMENT CONTENT

To the extent necessary, procurement documents shall require suppliers to have a documented QA program that is determined to meet the applicable requirements of 10 CFR 50, Appendix B, as appropriate to the circumstances of procurements.

Atomic Alchemy procurement documents issued for items or services shall include the following provisions, as applicable to the procured material, equipment or service as described in approved procedures controlled under the QAPD:

a) Statement of the scope of work to be performed by the supplier.
b) Technical requirements including the design bases, identified, or referenced in the procurement documents
c) Specific Atomic Alchemy documents (such as drawings, codes, standards, regulations, procedures, or instructions) describing the technical requirements of the material, equipment, or services to be furnished, shall be specified along with their revision level, or change status of those documents.
d) Identification of the tests, inspections, or acceptance requirements that Atomic Alchemy will use to monitor and evaluate the performance of the supplier shall be specified.
e) Provisions for establishing witness/inspection hold points beyond which work cannot proceed by the supplier without Atomic Alchemy authorization.
f) Provisions for identifying spare and replacement parts or assemblies and the appropriate delineation of technical and quality assurance data required for ordering these parts or assemblies.
g) Provisions for requiring the suppliers to report to Atomic Alchemy in writing adverse quality conditions resulting in nonconformances.
h) Allowances for commercial grade substitutions shall also be identified in procurement documents.

Further details are presented in the Atomic Alchemy Procurement Document Control Program.

4.3 PROCUREMENT DOCUMENT REVIEW AND APPROVAL

Reviews of procurement documents shall be performed by Atomic Alchemy personnel who have access to pertinent information and who have an adequate understanding of the requirements and

intent of the procurement documents. Further details are presented in the Atomic Alchemy Vendor Inspection Program.

4.4 PROCUREMENT DOCUMENT CHANGE

Changes to the scope of work, technical requirements, quality assurance program requirements, right of access, documentation requirements, work stoppage and nonconformance, hold points and lists of spare and replacement parts delineated in procurement documents, shall be subject to the same degree of control as used in the preparation of the original procurement document.

4.5 IMPLEMENTING PROGRAMS

- Procurement Document Control Program (to be provided in the FSAR)
- Vendor Inspection Program (to be provided in the FSAR)

5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS (CRITERION V)

Atomic Alchemy describes in this section the associated programs and procedures that implement the requirements of Criterion V, Instructions, Procedures and Drawings, of 10 CFR 50, Appendix B, and Requirement 5, Section 100 of NQA-1-2017.

Activities affecting quality shall be performed in accordance with documented instructions, procedures, or drawings appropriate to the circumstances. These documents shall include or reference appropriate quantitative or qualitative acceptance criteria for determining that activities have been satisfactorily accomplished.

These documents shall be prepared to prescribe performance expectations and define the proper sequence and detail to accomplish the work. Copies of applicable and necessary procedures, instructions and drawings shall be available to the appropriate Atomic Alchemy internal and external organizations to accomplish work in an efficient and safe manner.

5.1 REQUIREMENTS

Procedures, instructions, specifications, calculations, and drawings shall include appropriate quantitative and qualitative acceptance criteria for determining satisfactory work performance and quality compliance.

All procedures and instructions that delineate requirements for implementing quality activities shall be reviewed, approved, signed by the Quality Assurance Manager.

Project Procedures are prepared by specific Project Engineering staff under the direction of the Atomic Alchemy Project Manager. Project Procedures include systems, methods, and procedures that define the review, approval, and control of the engineering documents.

5.2 PROCEDURES

The Atomic Alchemy Procedure Writer’s Guideline promotes the standardization and application of human factors engineering principles to the Atomic Alchemy procedures. Atomic Alchemy uses four types of procedures to ensure that activities are carried out in compliance with the requirements of this QAPD, they are defined as: administrative, normal, abnormal, and emergency procedures. These

comprise the highest echelon of the Atomic Alchemy hierarchy of procedures. As an example, each can be further subdivided as follows:

a) Administrative (to be provided in the FSAR)
   - Engineering & Design Control Procedures
   - Corrective Action Program Procedures
   - Organizational Procedures
   - Regulatory Compliance Procedures
   - Human Resources Procedures
   - FFD Procedures
   - Writer's Guide Procedures
   - General Plant Staff Training Procedures

b) Normal (to be provided in the FSAR)
   - Start-Up/Shutdown, Reactor Operations Procedures
   - Hot Cell Operational Procedures
   - Training Manuals and Procedures
   - Non-T/S Inspection, Surveillance, and Modification Procedures
   - Hot Cell and Reactor Process Monitoring Procedures
   - Material Control Procedures
   - Special Nuclear Material (SNM) Material Control and Accounting Procedures
   - Technical Specification Surveillance Procedures
   - Maintenance Manuals and Procedures
   - SSC Calibration and Testing Procedures
   - Radioactive Waste Management Procedures
   - Plant Radiation Protection Procedures
   - Chemistry Procedures
   - Security and Cyber Security Procedures
   - Reactor Refueling Procedures
   - Health Physics Procedures

c) Abnormal (to be provided in the FSAR)
   - Alarm Response Procedures
   - Off-Normal Condition Procedures
   - Fire Protection Procedures

d) Emergency (to be provided in the FSAR)
   - Emergency Operations Manuals and Procedures (EOP)
   - Function Restoration Procedures (FRP)
   - FLEX Support Guidelines (FSG)
   - Severe Accident Management Guidelines (SAMG)
   - Extensive Damage Mitigation Guidelines (EDMG)

5.3 PROCEDURE DEVELOPMENT PROCESS

The Atomic Alchemy procedure development process follows the requirements delineated in the Atomic Alchemy Procedure Writer's Guidelines.

5.4 PROCEDURE ADHERENCE

The Atomic Alchemy policy is that procedures are followed and the requirements for use of procedures have been established in administrative procedures. Where procedures cannot be followed as written, depending on the complexity, alternate provisions are established within those procedures for making changes.

Additionally, in accordance with Part I, Criterion VI of this QAPD provisions for making necessary revisions to procedures are also implemented and controlled.

Requirements are established to identify the manner in which procedures are to be implemented, including identification of those tasks that require:

a) Written procedure to be present and followed step-by-step while the task is being performed.
b) Verification of completion of significant steps, by initials or signatures or use of check-off lists.
c) Procedures that are required to be present and referred to directly are those developed for extensive or complex jobs where reliance on memory cannot be trusted, tasks that are infrequently performed, and tasks where steps must be performed in a specified sequence.

5.5 PROCEDURE STANDARDIZATION

The overall goal of Atomic Alchemy is to develop procedures integrating industry best practices and standards. The standards and guidance from the NRC and industry organizations such as INPO and NEI have been incorporated into the QAPD program for procedure development.

5.6 PROCEDURE CONTENT

The established measures address the applicable content of procedures as described in Part II Section 402, of NQA-1-2017.

5.7 DRAWINGS AND OTHER DOCUMENTS

Drawings, specifications, and calculations assure that design inputs (such as design bases and the performance, regulatory, quality, and quality verification requirements) are correctly translated into design outputs so that the final design output can be related to the design input in sufficient detail to permit verification and validation of the design and conformance to the regulations.

Drawings, specifications, and calculations shall be prepared and revised in accordance with program procedures.

Drawings shall be isometric or orthographic, showing sufficient detail to describe all materials of construction, dimensions, methods of fabrication.

All drawings should have a drawing number, revision number, company name, title, scale, and date. The designer, drafter, checker, and approver should also be denoted on the drawing.

Certified for Construction (CFC) drawings shall be stamped by the appropriate discipline engineer licensed in the state of Idaho. If drawings have been reduced or enlarged, this should be clearly indicated so that the scale may be applied properly.

All specifications and calculations should have an identification number, revision number, company name, title, and date. The preparer, checker, and approver should also be denoted on the document.

Certified for Construction (CFC) design documents shall also be stamped by the appropriate discipline engineer licensed in the state of Idaho.

A separate set of drawings shall be produced and maintained for ASME XI components which include the examination boundary for each component. Further ASME component drawing requirements shall be detailed in a program procedure.

5.8 IMPLEMENTING PROGRAMS

- Configuration Management and Change Control Program (to be provided in the FSAR)
- Configuration Control Training Program (to be provided in the FSAR)
- Human Factors/Performance Program (to be provided in the FSAR)

6 DOCUMENT CONTROL (CRITERION VI)

Atomic Alchemy describes in this section the associated programs and procedures that implement the requirements of Criterion VI, Document Control, of 10 CFR 50, Appendix B, and Requirement 6, Sections 100-300 of NQA-1-2017.

The preparation, issue, and change of documents which specify requirements that affect quality or prescribe activities affecting quality, shall be controlled to ensure that correct documents are used. The document control system shall be documented, and provide for:

a) Identification of documents to be controlled and their specified distribution.
b) Identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents.
c) Review of documents for adequacy, completeness, and correctness prior to approval and issuance.

6.1 REQUIREMENTS

Major changes to controlled documents shall be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated.

The control systems (including electronic systems used to make documents available) are documented and provide for the following:

a) Identification of documents to be controlled and their specified distribution.
b) A method to identify the correct document (including revision) to be used and control of superseded documents.
c) Identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents.
d) Review of documents for adequacy, completeness, and correctness prior to approval and issuance.
e) A method for providing feedback from users to improve procedures and work instructions.
f) Coordinating and controlling interface documents and procedures.

The types of documents to be controlled include:

a) Drawings such as design, diagrams, etc.
b) Engineering calculations
c) Design specifications
d) Purchase orders and related documents
e) Supplier-supplied documents
f) Audit, surveillance, and quality verification/inspection procedures
g) Inspection and test reports
h) Instructions and procedures for activities covered by this QAPD
i) Technical specifications
j) Nonconformance reports and corrective action reports

6.2 REVIEW AND APPROVAL OF DOCUMENTS

Drawings, procedures, specifications, and calculations shall be reviewed for adequacy by qualified persons other than the preparer. Documents shall also be subject to an interdisciplinary review and comment phase as part of the approval process.

During the construction phase, procedures for design, construction, and installation shall also be reviewed by Quality Assurance to ensure quality assurance measures have been appropriately applied. The documented review signifies satisfactory incorporation of comments and concurrence.

During the operations phase, documents affecting the configuration or operation of the station as described in the FSAR shall be screened to identify those that require additional review by the CCOB prior to implementation as described in Section II of this QAPD.

To ensure effective and accurate procedures during the operational phase, applicable procedures shall be reviewed, and updated as necessary, based on the following conditions:

a) Following any modification to a system.
b) Following an unusual incident, such as an accident, significant operator error, or equipment malfunction.
c) When procedure discrepancies are found.
d) Prior to use if not used in the previous two years.
e) Results of QA audits conducted in accordance with Section XVIII of this QAPD.
f) As requested by the Site Vice President, Plant Manager, or any PNSRC member.

6.3 DOCUMENT CONTROL – INITIAL DRAFT DESIGN AND PRE-CONSTRUCTION PHASE

Document control during the initial draft design and pre-construction phase shall be coordinated according to the following requirements:

a) During the initial draft design phase of design all documents are considered to be in an “Open Revision” state. Preliminary studies, analysis and layouts are being evaluated, various design inputs and processes are being reviewed and examined. Equipment vendor inputs are being reviewed and selected. While in these design phase states the documents are not considered quality control documents. ANSI N45.2.9-1974, paragraph 1.4, definition of "Quality Assurance Records" states in part: "For the purposes of this standard, a document is considered a quality assurance record when the document has been completed."

b) Numerous extensive changes to layouts and calculations are anticipated during this phase therefore changes to these documents during this “Open Revision” state is not controlled.
c) Once a technical design input document has reached a “Revision 0” status the control of that document then falls under the requirements of the document control programs outlined in this criterion. New documents which evolve during new construction shall be transmitted to records department within 90 days of completion.

6.4 CHANGES TO DOCUMENTS

Changes to documents, other than those defined in implementing procedures as minor changes, shall be reviewed, and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated. The reviewing organization shall have access to pertinent background data or information upon which to base their approval.

6.5 MINOR CHANGES

Minor changes such as inconsequential pagination, editorial, or spelling corrections may be made to documents without being subject to the review and approval of the requirements specified above as described in the Document Control program procedures.

6.6 DELEGATION OF WORK

Atomic Alchemy may delegate control of Criterion VI services, if necessary, to the qualified suppliers through the contracts in accordance with the requirements in Part I, Criterion IV of this document.

6.7 IMPLEMENTING PROGRAMS

Document Control Program (to be provided in the FSAR)

7 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES (CRITERION VII)

Atomic Alchemy describes in this section the associated programs and procedures that implement the requirements of Criterion VII, Control of Purchased Material, Equipment, and Services, of 10 CFR 50, Appendix B, Requirement 7, Sections 100-800, of NQA-1-2017, and Part II, Subpart 2.14, Sections 100-900 of NQA-1-2017.

The procurement of items and services shall be controlled to ensure appropriate procurement planning, source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, source inspection, audit, and examination of items or services for acceptance upon delivery or completion. Atomic Alchemy has established the necessary measures and governing procedures to control the procurement of items and services to assure conformance with specified requirements.

7.1 REQUIREMENTS

Procurement of material, equipment, and services is controlled to assure conformance with specified requirements. Such control requirements include pre-award evaluations of suppliers' QA programs, annual evaluations, periodic audits/source inspections and surveillance. Atomic Alchemy will assess the quality of purchased items and services, whether purchased directly or through contractors, at

intervals and to a depth consistent with the item's or service's importance to safety, complexity, quantity, and the frequency of procurement.

7.2 PROCUREMENT PLANNING

Procurements shall be planned and documented to ensure a systematic approach to the procurement process exists and supports the schedule. Procurement planning shall be performed in accordance with the requirements defined in approved procedures controlled under the QAPD program. Procurement planning shall be accomplished as early as possible.

7.3 SOURCE EVALUATION

Atomic Alchemy may accept material, equipment, or service by monitoring, witnessing, or observing activities performed by the vendor/supplier. This method of acceptance is called source evaluation. Source evaluation shall be implemented consistent with the supplier's planned inspections, examinations or tests at predetermined points and performed at intervals consistent with the importance and complexity of the SSC being supplied.

7.4 SOURCE EXCEPTIONS

Atomic Alchemy considers that other 10 CFR 50 licensees, Authorized Nuclear Inspection Agencies, National Institute of Standards and Technology, or other State and Federal agencies which may provide items or services to the Atomic Alchemy Facility are not required to be evaluated or audited.

7.5 BID EVALUATION

For proposals and bids, technically qualified personnel from the Atomic Alchemy QA/QC and procurement organizations along with other Atomic Alchemy stake holder or design authority consortium partner organizations shall perform an evaluation to determine if the bid/proposal meets the Atomic Alchemy QAPD procurement document requirements. As a minimum, this evaluation shall review the following subjects consistent with the importance, complexity and quantity of items or services being procured:

a) Technical considerations
b) QA program requirements
c) Supplier personnel qualifications
d) Supplier production capability and past performance
e) Alternatives and exceptions

7.6 ACCEPTANCE OF ITEMS OR SERVICES

Atomic Alchemy establishes and implements measures to assess the quality of purchased items and services, whether purchased directly or through contractors, at intervals and to a depth consistent with the item's or service's importance to safety, complexity, quantity, and the frequency of procurement. Verification actions include testing, as appropriate, during design, fabrication, and construction activities. Verifications occur at the appropriate phases of the procurement process as delineated in the Atomic Alchemy Program.

7.7 CERTIFICATION OF CONFORMANCE

Atomic Alchemy establishes provisions for accepting purchased items and services, such as source verification, receipt inspection, pre- and post-installation tests, certificates of conformance, and document reviews including Certified Material Test Reports, (CMTR).

Acceptance actions/documents are established by Atomic Alchemy with appropriate input from the subject matter expert engineering departments and are completed to ensure that procurement, inspection, and applicable test requirements have been satisfied before relying on the item to perform its intended safety function.

For commercial grade items, special quality verification requirements are established and described in the Atomic Alchemy Commercial Grade Dedication Program to provide the necessary assurance an item will perform satisfactorily in service.

7.8 COMMERCIAL GRADE ITEMS

Where the Atomic Alchemy design allows for the utilization of commercial grade material and/or equipment, the following requirements are imposed in addition to other requirements of this Section:

a) Not subject to design or specification requirements that are unique to nuclear facilities.
b) The commercial grade material/equipment is identified in an approved design output document. An alternate commercial grade material/equipment may be applied, provided there is verification that the alternate commercial grade material/equipment will perform the intended function and will meet design requirements applicable to both the replaced material/equipment and its application.
c) Supplier evaluation and selection, where determined necessary by Atomic Alchemy on complexity and importance to safety, shall be in accordance with source evaluation section of this document.
d) Commercial grade items shall be identified in the purchase order by the manufacturer's published product description (e.g., catalog number).
e) One or a combination of the following methods shall be utilized to provide reasonable assurance that the item meets the acceptance criteria for the characteristics identified to be verified for acceptance:
    i. Special test(s) or inspection (s) or both.
    ii. Commercial grade survey of the supplier.
    iii. Source verification.
    iv. Acceptable supplier/item performance records.
    v. Prior to acceptance of a commercial grade item, the Atomic Alchemy QA/QC organization shall determine that:
        1. Damage was not sustained during shipment.
        2. The item received has satisfied the specified acceptance criteria.
        3. Inspection and/or testing is accomplished, as required, to assure conformance with critical characteristics.
        4. Documentation, as applicable to the item, was received and is acceptable.

Any additional requirements are as described in the Atomic Alchemy Commercial Grade Dedication Program.

7.9 LIKE-FOR-LIKE ITEM REPLACEMENTS

The critical characteristics for design of the original item should be identified first. Determination of the critical characteristics for design begins with identifying the requirements of the original part being replaced. This is found by review of the original procurement documents, original specifications prepared by the Atomic Alchemy, or original shop drawings provided by the vendor/supplier.

Replacement items that can be shown to be like-for-like replacements (see definition) do not require a full technical evaluation. If a supplier can furnish a like-for-like replacement, only minimal technical evaluation may be required (See EPRI NP-5652, Rev 1)

The original manufacturer designed the component to perform its intended function in the equipment when it was included in the equipment's original design. If the replacement part can be demonstrated to be identical to the original part, there is no need to perform an equivalency evaluation by comparing design requirements to critical characteristics for design (See NRC Generic Letter 91-05 and EPRI NP-6406.)

Spare and replacement parts for use in safety-related applications will be procured from vendors who maintained established, documented, and audited Quality Assurance Programs acceptable to nuclear industry standards.

7.10 COMMERCIAL GRADE SERVICES

Where the Atomic Alchemy design allows for the use of commercial grade services[3] from domestic laboratories and vendors the following additional conditions shall be satisfied:

a) The vendor or laboratories shall be accredited by a nationally recognized authority having jurisdiction for accreditation.
b) A technical evaluation shall be performed by Atomic Alchemy Engineering for the specific M&TE or other services being provided to identify any additional technical requirements that need to be included in the purchase order (e.g., tolerances, accuracies, ranges, specific industry standards to be used, etc.).
c) Minimum critical characteristics to include in the purchase order shall include use of NQA-1 quality program, all technical requirements identified in the technical evaluation, and identification of all equipment and standards used.
d) The accrediting body shall be an NRC recognized agency.

Any additional requirements are as described in the Atomic Alchemy Commercial Grade Dedication Program.

7.11 COMMERCIAL-GRADE DEDICATION PACKAGE

Atomic Alchemy shall maintain a collection of documents that is the result of the commercial-grade dedication process for specific safety related components that perform specific safety functions. These documents will contain the technical and quality basis for satisfying the commercial-grade item

[3] See footnote under Criterion 4 previously in this Part.

dedication process and will provide that there is sufficient objective evidence to reasonably assure that the dedicated commercial-grade component will perform its required safety function.

7.12 RECEIVING INSPECTION

When receiving inspection is used to accept an item:

a) The inspection shall verify any source verifications/audits and the demonstrated quality performance of the supplier.
b) The inspection shall be performed in accordance with the established Atomic Alchemy QAPD inspection program procedures.
c) The inspection shall verify, as applicable, proper configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage; and cleanliness.
d) The inspection shall be planned and executed according to the requirements of the established Atomic Alchemy Inspection program procedures.
e) Receiving inspection shall be coordinated with a review for adequacy and completeness of any required supplier documentation submittals.

7.13 POST INSTALLATION TESTING AS A METHOD OF ACCEPTANCE

When post-installation testing is used as a method of acceptance the affected/involved Atomic Alchemy organization manager and the vendor/supplier, when possible, shall mutually establish test requirements and acceptance documentation. The Atomic Alchemy consortium design authority is ultimately responsible for ensuring appropriate test requirements and acceptance documentation are established.

7.14 APPROVED VENDOR LIST (AVL)

The Atomic Alchemy Quality Assurance Manager is responsible for the development and maintenance of the Atomic Alchemy Approved Vendor List. The AVL contains those suppliers with acceptable QA Programs that have been evaluated and accepted by the Atomic Alchemy QA/QC organization in accordance with approved procedures. The Atomic Alchemy QA/QC organization shall perform and document an annual evaluation of each supplier.

7.15 DELEGATION OF WORK

Atomic Alchemy may delegate control of M&TE services, if necessary, to the qualified suppliers through the contracts in accordance with the requirements in Part I, Criterion IV of this document. For the delegated tests to the Suppliers, the Suppliers shall provide the same level of control of M&TE as Atomic Alchemy does as describe in the Part I, Criterion IV.

7.16 IMPLEMENTING PROGRAMS

- Commercial Grade Dedication Program (to be provided in the FSAR)
- Vendor Inspection Program (to be provided in the FSAR)
- Receipt Inspection Program (to be provided in the FSAR)
- Materials, Equipment, and Parts List (MEPL) Program (to be provided in the FSAR)
- Software Safety Hazards Program (to be provided in the FSAR)
- *Software Verification and Validation Program (to be provided in the FSAR)

8 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS (CRITERION VIII)

Atomic Alchemy describes in this section the associated programs and procedures that implement the requirements of Criterion VIII, Identification and Control of Materials, Parts and Components, of 10 CFR 50, Appendix B, and Requirement 8, Sections 100-300 of NQA-1-2017.

8.1 REQUIREMENTS

When specified by codes, standards, or specifications that include identification or traceability requirements, the item identification and control process shall be capable of providing identification and traceability control.

Items' identification shall be maintained from the initial receipt or fabrication of the items up to and including installation and use.

Where physical identification on the item is either impractical or insufficient, physical separation, procedural control, or other appropriate means shall be employed. Identification markings shall be applied through the use of materials and methods which provide clear and legible identification and do not detrimentally affect the function or service life of the item.

Markings shall be transferred to each part of an identified item when the item is subdivided and shall not be obliterated or hidden by surface treatment or coatings unless substitute means are provided.

Non-conforming items shall be identified as described in Part I, Criterion XV.

8.2 LIMITED LIFE ITEMS

Where specified, items having limited calendar or operating life shall be identified and controlled to preclude use of items whose shelf life or operating life is expired.

8.3 DELEGATION OF WORK

Atomic Alchemy may delegate control of Part I, Criterion VIII services, if necessary, to the qualified suppliers through the contracts in accordance with the requirements in Part I, Criterion IV of this document.

8.4 IMPLEMENTING PROGRAMS

- Material Control and Accountability Program (to be provided in the FSAR)
- Special Nuclear Material Accounting and Control Program (to be provided in the FSAR)
- Materials, Equipment, and Parts List (MEPL) Program (to be provided in the FSAR)

9 CONTROL OF SPECIAL PROCESSES (CRITERION IX)

Atomic Alchemy describes in this section the associated programs and procedures that implement the requirements of Criterion IX, Control of Special Processes, of 10 CFR 50, Appendix B and Requirement 9, Sections 100-400 of NQA-1-2017.

Special processes include any in which the results are highly dependent on the control of the process or skill of the personnel. These are also those processes in which the specified quality cannot be readily determined by inspection or nondestructive testing of the product. The control of these processes will be provided in the FSAR Chapter 17.

9.1 REQUIREMENTS

Special processes shall be controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means.

Personnel responsible for performance, inspection, and control of special processes and operations, which require special skills and have an effect upon quality, shall be certified (e.g., welding, nondestructive examination, heat treating, etc.).

Atomic Alchemy and its suppliers are responsible to adhere to the approved procedures and processes for performing the special process.

The requirements of applicable codes and standards, including acceptance criteria for the process, shall be specified, or referenced in the procedures or instructions that control the process. Records shall be maintained as appropriate for the currently qualified personnel, processes, and equipment associated with special processes.

9.2 IMPLEMENTATION

During quality-controlled activities performed at the Atomic Alchemy Facility, the responsible engineering manager assures that the special process data and documentation is reviewed, and that if any vendor special process procedures are utilized, they too are qualified and approved.

9.3 IMPLEMENTING PROGRAMS

- Welding Quality Assurance Program (to be provided in the FSAR)
- Electrical Equipment Qualification Program (EEQ) (to be provided in the FSAR)
- Fuel Loading Conditions Surveillance Program (to be provided in the FSAR)
- ALARA Program (to be provided in the FSAR)
- Operator Work Around Program (to be provided in the FSAR)
- *Radiation Protection Program (to be provided in the FSAR)
- Physical Security Program (to be provided in the FSAR)
- Insider Mitigation Program (to be provided in the FSAR)
- Security Training and Requalification Program (to be provided in the FSAR)
- FFD for Security Personnel Program (to be provided in the FSAR)
- FFD and Access Authorization Program (to be provided in the FSAR)
- FFD and Access Authorization for Construction Personnel (to be provided in the FSAR)
- Safeguards Contingency Program (to be provided in the FSAR)
- Emergency Planning Program (to be provided in the FSAR)
- Cyber Security Program (to be provided in the FSAR)
- Behavior Observation Program (to be provided in the FSAR)
- Construction Area Behavior Observation Program (to be provided in the FSAR)

10 INSPECTION (CRITERION X)

Atomic Alchemy describes in this section the associated programs and procedures that implement the requirements of Criterion X, Inspections, of 10 CFR 50, Appendix B, Requirement 10, Sections 100-800 of NQA-1-2017 and Part II, Subpart 2.8, Sections 100-700 of NQA-1-2017.

Inspections are required to verify conformance of an item or activity are planned and executed according to specified requirements. Characteristics to be inspected and inspection methods to be employed are specified in procedures. The inspection program shall apply to procurement, construction, operations, modification, and maintenance.

10.1 REQUIREMENTS

Inspection of items in-process or under construction shall be performed for work activities where product quality cannot be determined by inspection of the completed product. The final inspection shall be planned to arrive at a conclusion regarding conformance of the item to specified requirements.

Completed items shall be inspected for completeness, markings, calibration, adjustments, protection from damage, or other characteristics as required to verify the quality and conformance of the item to specified requirements.

Associated quality records shall be examined for adequacy and completeness. Only items that have passed the required inspections and tests shall be used, installed, or operated.

Measuring and Test Equipment (M&TE) used to perform inspections shall be identified in inspection documentation for traceability of inspection results.

Inspection results shall be documented.

Acceptance of items shall be documented and approved by authorized personnel.

Inspection shall be performed by persons other than those who performed the work being inspected but may be from the same organization. Each person who verifies conformance of work activities for purposes of acceptance shall be qualified to perform the assigned inspection task.

The need for formal training shall be determined and training activities conducted as required to qualify personnel who perform inspections and tests. On-the-job training shall be included, with emphasis on firsthand experience gained through actual performance of inspection.

Records of inspection personnel’s qualification shall be established and maintained by their employer.

10.2 INSPECTION PLANNING

Inspection planning shall be performed and documented in accordance with approved Atomic Alchemy program and procedures.

10.3 INSPECTION HOLD POINTS

When mandatory hold points are used to control work processes or inspections that shall not proceed without the specific consent of the organization responsible or authority having jurisdiction for the hold point, the specific hold points shall be specified in implementing documents. Waiver of specified

hold points shall be documented and approved before continuing work beyond the designated hold point.

10.4 STATISTICAL SAMPLING INSPECTION

When statistical sampling is used to verify the acceptability of a group of components the statistical sampling method used shall be based on recognized standard industry practices and these practices shall be implemented through applicable approved Atomic Alchemy program and procedures.

10.5 INSPECTION DOCUMENTATION

Inspection documentation shall identify:

a) The item inspected, date of inspection, the name of the inspector who documented, evaluated, and determined acceptability.
b) Name of data recorder, as applicable and type of observation or method of inspection.
c) The inspection criteria, sampling plan, or reference documents (including revision levels) used to determine acceptance.
d) Results or acceptability of characteristics inspected.
e) Measuring and test equipment used during the inspection including the identification number and the most recent calibration date.
f) Reference to information on actions taken in connection with nonconformances, as applicable.

10.6 INSPECTOR QUALIFICATION

The individuals who perform QA/QC inspections to verify conformance of an item to specified acceptance criteria shall be qualified to perform the assigned inspection tasks in accordance with the requirements of the Atomic Alchemy relevant QA/QC program.
Atomic Alchemy has established a qualification training program for personnel performing quality inspections. The qualification program requirements Inspection personnel shall not report directly to the immediate supervisors who are responsible for performing the work being inspected.

10.7 PRE-SERVICE INSPECTION AND TESTING

The NRC regulations in 10 CFR50.55a(g)(3)(ii) require, in part, that ASME Safety Class 1, 2, and 3 components (Equivalent of Atomic Alchemy Safety Class A, B, and C respectively) and their supports must meet the pre-service examination requirements set forth in the editions and addenda of Section III or XI of the ASME B&PV Code incorporated by reference in 10 CFR 50.55a that apply to the construction of the particular component(s).

During the design phase, Atomic Alchemy and its consortium design authority partners will ensure that each SSC and its associated elements that require an ASME B&PV Code, Section III pre-service inspection will be evaluated to determine accessibility, inspectable geometry, exposure, etc., to determine if inspections are feasible with inspection methods prescribed by current codes and standards. For SSC, whose inspection geometries, access issues, ALARA, or other safety concerns for performing current inspection and testing requirements, alternate pre-service inspection or monitoring techniques will be developed and documented in the Atomic Alchemy ISI/IST and Pre-Service Inspectability program.

10.8 IN-SERVICE INSPECTIONS AND TESTING

During the design phase, Atomic Alchemy and its consortium design authority partners will ensure that each SSC and its associated elements that require an ASME Section XI inspection will be evaluated to determine accessibility, inspectable geometry, exposure, etc., to determine if inspections are feasible with inspection methods prescribed by current codes and standards. For SSC, whose inspection geometries, access issues, ALARA, or other safety concerns for performing current inspection and testing requirements, alternate inspection or monitoring techniques will be developed and documented in the Atomic Alchemy ISI/IST and Pre-Service Inspectability Program.

Where existing ASME and industry standards can be meaningfully employed for the Atomic Alchemy First of a Kind (FOAK) components design, those codes, and standards, as endorsed or modified by the NRC under 10 CFR 50.55a, will be utilized.

Where existing codes and industry standards are not appropriate or cannot be safely implemented to address any Atomic Alchemy FOAK design features, Atomic Alchemy will provide proposed alternatives that provide an acceptable level of quality and safety and that will also demonstrate that compliance with the specified existing current requirements would result in hardship or unusual difficulty without a compensating increase in the level of quality and safety.

10.9 DELEGATION OF WORK

Atomic Alchemy may delegate control of Criterion X services, if necessary, to the qualified suppliers through the contracts in accordance with the requirements in Part I, Criterion IV of this document.

10.10 IMPLEMENTING PROGRAMS

- QA/QC Inspector Training Program (to be provided in the FSAR)
- ISI/IST and Pre-Service Inspectability Program (to be provided in the FSAR)
- Reactor Pool Liner Inspection Program (to be provided in the FSAR)
- Hot Cell Maintenance and Inspection Program (to be provided in the FSAR)
- Buried Tank, Piping and Conduit Inspection Program (to be provided in the FSAR)
- Reactor Coolant System Material Surveillance Program (to be provided in the FSAR)
- Aging Evaluation Program (to be provided in the FSAR)
- Structures Monitoring Program (to be provided in the FSAR)
- Maintenance Rule Program (to be provided in the FSAR)
- Overhead Heavy Loads Equipment Inspection Program (to be provided in the FSAR)
- Pre-Service Inspection Program (to be provided in the FSAR)
- Pre-Service Testing Program (to be provided in the FSAR)
- Confinement and Radioisotope Penetrations Appendix J Program (to be provided in the FSAR)
- *Reactor Coolant Pump Flywheel Inspection Program (to be provided in the FSAR)
- *RCS Heat Exchanger Tube Inspection Program (to be provided in the FSAR)
- *Inservice Inspection Program (to be provided in the FSAR)
- *Inservice Testing Program (to be provided in the FSAR)
- *Electromagnetic Compatibility and Radio Frequency (EMC/RFI) Program (to be provided in the FSAR)

11 TEST CONTROL (CRITERION XI)

Atomic Alchemy describes in this section the associated programs and procedures that implement the requirements of Criterion XI, Test Control, of 10 CFR 50, Appendix B, and Requirement 11, Sections 100-600 of NQA-1-2017.

Formal testing shall be required to verify conformance of designated structures, systems, or components to specified requirements and demonstrate satisfactory performance for service or to collect data in support of design or fabrication.

The Atomic Alchemy test control program identifies the quality structures, systems, and components to be tested, method of conducting tests, evaluation of tests and documentation of tests by qualified personnel to assure requirements have been satisfied.

11.1 REQUIREMENTS

The Atomic Alchemy Test Control program includes criteria for determining when testing is required, such as proof tests before installation, pre-operational tests, post-maintenance tests, post modification tests, in-service tests, and operational tests (such as surveillance tests required by Plant Technical Specifications), to demonstrate that performance of plant systems is in accordance with design.

Testing shall include prototype qualification tests, proof tests prior to installation, and functional tests. Test results shall be documented and evaluated by a responsible authority to ensure that test requirements have been satisfied.

Computer programs used for operational control shall be tested in accordance with an approved verification and validation plan and shall demonstrate required performance over the range of operation of the controlled function or process.

11.2 TESTING PROCEDURES AND PREPARATION

The test program procedure documents include the following as a minimum:

a) Test prerequisites that address calibrated instrumentation, appropriate and adequate test equipment/instrumentation, trained personnel, condition of test equipment and the item to be tested, suitably controlled environmental conditions and provisions for data acquisition.
b) Test requirements, such as acceptance criteria.
c) Hold, notification, inspection points, if required, and data collection points.
d) Mandatory hold points and methods to record data and results.
e) Provisions for ensuring that prerequisites for the given test have been met.
f) Selection and identification of the measuring and test equipment to be used to perform the test to ensure that the equipment is of the proper type, range, accuracy, and tolerance to accomplish the intended function.

11.3 PERFORMANCE REQUIREMENTS

Specific performance requirements shall be addressed in the Atomic Alchemy Test Control program and the Post Maintenance Test programs.

11.4 TESTING EQUIPMENT

The Atomic Alchemy program procedures provide the criteria for determining when a test is required and the accuracy requirements of test equipment. The following steps are taken for the control of test equipment:

a) To assure accuracy, test equipment is checked and calibrated in accordance with Atomic Alchemy procedures.
b) Plant instrumentation used in testing is calibrated. It is maintained in calibration at regular intervals in accordance with established surveillance and/or preventative maintenance procedures.
c) Where special instrumentation is required for testing, the requirements are stated in the procedures.

11.5 MONITORING AND OVERSIGHT OF VENDOR/SUPPLIER TESTING

The Atomic Alchemy QA Manager shall establish measures to routinely interface with the supplier and to verify supplier performance. Atomic Alchemy may accept material, equipment, or service by monitoring, witnessing, or observing activities performed by the supplier.

11.6 USE OF TESTING DOCUMENTS AND METHODS BY OTHERS

Other testing documents (e.g., American Society for Testing and Materials (ASTM)), specifications, supplier manuals, or other related documents containing acceptance criteria may be used instead of preparing special test procedures. If used, the information shall be incorporated by reference in the approved test program procedure. Implementing documents shall include adequate supplemental instructions as required to ensure the required quality of the testing work.

11.7 INITIAL STARTUP TEST PROGRAM

The initial start-up test program (See also FSAR Chapter 14) is planned and scheduled to permit safe fuel loading and startup; to increase power in safe increments; and to perform major testing at specified power levels. If tests require the variation of operating parameters outside of their normal range, the limits within which such variation is permitted will be prescribed. The scope of the testing demonstrates, insofar as practicable, that the plant is capable of withstanding the design transients and accidents.

The suitability of facility operating procedures is checked to the maximum extent possible during the pre-operational and initial start-up test programs.

The tests are performed, and results documented in accordance with applicable technical and regulatory requirements including those described in the Technical Specifications and FSAR. The test programs ensure appropriate retention of test data in accordance with the records requirements of this QAPD. The personnel performing or evaluating tests are qualified in accordance with the requirements established in this QAPD

11.8 OPERATIONAL READINESS ASSESSMENT PROGRAM

The operational readiness assessment program (See also FSAR Chapter 14) evaluates the status of the facility's completion of system turnovers, punch lists, pre-operational testing, inspections, etc. to

establish the basis for supporting the conclusion that 10 CFR50.57(a)(1), (2), (3) has been satisfied and there are no outstanding issues for which Atomic Alchemy has not developed adequate corrective actions, in preparation for the NRC's Operational Readiness Assessment Team (ORAT) Inspections.

The scope of the operational readiness assessment focuses on four major areas: system readiness, functional area readiness, programmatic readiness, and equipment readiness. The scope will be expanded to include any emergent issues. A multi-discipline Engineering Review Board (ERB) will be assembled to perform a technical review of any potential readiness issues.

11.9 POST MAINTENANCE TESTING

Required post maintenance testing for SSCs is identified in each component maintenance procedure, and is performed according to those applicable procedures that include, consistent with the effect on safety, instructions and prerequisites to perform the test, use of proper test equipment, acceptance criteria, and mandatory verification points as necessary to confirm satisfactory test completion. Test results are documented as part of the maintenance program and evaluated by the organization performing the test and reviewed by a responsible authority to assure that the test requirements have been satisfied.

11.10 INTERFACE WITH OTHER PROGRAMS

The Atomic Alchemy program interface ensures that program activities subject to the provisions of this QAPD are promulgated between the various Design Authority Consortium Partners and Departments suitable for their intended application, consistent with their effect on safety.

Atomic Alchemy program interfaces shall be identified and procedurally controlled. Programmatic efforts shall be coordinated among interfacing consortium partners and sub-organizations as detailed in the Atomic Alchemy QAPD program.

Atomic Alchemy program information transmitted across the interfaces shall be documented and procedurally controlled.

During the operational phase that begins after final acceptance and turnover of all SSC's, and design and licensing basis documents from the design authority consortium partner(s) to Atomic Alchemy, the Atomic Alchemy General Manager, Nuclear Design Engineering Services (GMNDES), General Manager, Construction Services (GMCS), General Manager, Nuclear Support Services (GMNSS), Vice President, Nuclear Regulatory Affairs & Compliance (GMRAC), and General Manager, Quality Assurance Program (GMQAP) are responsible for ensuring the facility complies with all applicable regulatory requirements including the requirements of this QA Program.

11.11 IMPLEMENTING PROGRAMS

- Test Control Program (to be provided in the FSAR)
- Post Maintenance Test Program (to be provided in the FSAR)
- Start-Up Test Program (to be provided in the FSAR)
- Operational Readiness Assessment Program (to be provided in the FSAR)
- ISI/IST Inspectability Program (to be provided in the FSAR)
- QA/QC Inspector Training Program (to be provided in the FSAR)

- Maintenance Rule Program (to be provided in the FSAR)
- *Ventilation Filter Test Program (to be provided in the FSAR)

12 CONTROL OF MEASURING AND TESTING EQUIPMENT (CRITERION XII)

Atomic Alchemy describes in this section the associated programs and procedures that implement the requirements of Criterion XII, Control of Measuring and Testing Equipment, of 10 CFR 50, Appendix B, and Requirement 12, Sections 100-400 of NQA-1-2017.

12.1 REQUIREMENTS

Tools, gauges, instruments, and other M&TE used for activities affecting quality shall be controlled and calibrated or adjusted, at specified periods to maintain accuracy within specified limits.

Out-of-calibration devices shall be tagged or segregated, and not used until they have been recalibrated.

Records shall be maintained of calibration data traceable to the individual piece of M&TE. Calibration and control measures are not required when normal commercial equipment provides adequate accuracy.

12.2 INSTALLED INSTRUMENTATION AND DEVICES

For the operations phase of the facility, Atomic Alchemy has established and implements a control program and procedures for the calibration and adjustment of instrument and control devices installed in the facility. The calibration and adjustment of these devices is accomplished through the facility maintenance programs to ensure the facility is operated within design and technical requirements. Appropriate documentation will be maintained for these devices to indicate the control status, when the next calibration is due, and identify any limitations on use of the device.

12.3 QA/QC TESTING DEVICES

This QAPD and implementing program also provides the requirements for the control of measuring and testing equipment (M&TE) used as the basis for acceptance during QA/QC inspection, testing, and measurement of materials, equipment, and parts affecting quality structures, systems, and components. Periodic calibration and adjustment of M&TE is performed and controlled to assure accuracy is maintained within limits necessary to verify that design and operating condition requirements have been met. Documentation is retained such that all items of M&TE are traceable to their calibration records.

12.4 CALIBRATION STANDARDS

Measuring and test equipment is calibrated at specified intervals based on the required accuracy, purpose, degree of usage, stability characteristics, and other conditions affecting the measurement. Measuring and test equipment shall be permanently marked or tagged with a unique Identification number and the date calibrated and next calibration date indicated on the M&TE.

12.5 OUT OF TOLERANCE CONTROL

M&TE and reference standards when found out of tolerance are so identified and removed from service. A timely review is conducted to determine the validity of previous inspection or test results gained through use of the instrument, and of the acceptability of items previously measured or tested. Where it is determined that use of out of tolerance measuring and test equipment may have resulted in a condition adverse to quality, the condition is promptly identified, and corrective action is implemented.

M&TE shall be considered to be out-of-calibration and not be used until calibrated if any of the following conditions exist:

a) The calibration due date or interval has passed without re-calibration.
b) The device produces results known or suspected to be in error.

If any M&TE is consistently found out-of-calibration during the re-calibration process, it shall be repaired or replaced.

When M&TE is lost, the validity of results obtained using that equipment since its last valid calibration shall be evaluated to determine acceptability of previously collected data, processes monitored, or items previously inspected or tested.

12.6 DELEGATION OF WORK

Atomic Alchemy may delegate control of Criterion XII services, if necessary, to the qualified suppliers through the contracts in accordance with the requirements in Part I, Criterion IV of this document.

12.7 IMPLEMENTING PROGRAMS

- Calibration and Control Program (to be provided in the FSAR)
- *Safety Function Program (to be provided in the FSAR)

13 RECEIVING, HANDLING, STORAGE, PACKAGING, AND SHIPPING (CRITERION XIII)

Atomic Alchemy describes in this section the associated programs and procedures that implement the requirements of Criterion XIII, Receiving, Handling, Storage, Packaging and Shipping, of 10 CFR 50, Appendix B, Requirement 13, Sections 100-600 of NQA-1-2017, Part II, Subpart 2.1, Sections 100-1100 of NQA-1-2017, Subpart 2.2 Sections 100-800 of NQA-1-2017, Part II, Subpart 2.3, Sections 100-400 of NQA-1-2017, and Part II, Subpart 2.15, Sections 100-900 of NQA-1-2017.

Additionally, described in this section are the programs that implement the requirements of 10 CFR 71 Subpart H.

Handling, storage, packaging, and shipping of items shall be in accordance with work and inspection instructions, drawings, specifications, shipping instructions, and other pertinent documents or procedures for conducting the activity.

13.1 REQUIREMENTS

These requirements include specific programs and their respective procedures, that maintain acceptable quality of the items important to the safe operations of the plant. Items are appropriately

marked and labeled during packaging, shipping, handling, and storage to identify, maintain, and preserve the item's integrity and indicate the need for special controls.

Special controls (such as containers, shock absorbers, accelerometers, inert gas atmospheres, specific moisture content levels and temperature levels, etc.) are provided when required to maintain acceptable quality.

Special or additional handling, storage, shipping, cleaning, and preservation requirements are identified and implemented as specified in procurement documents and applicable procedures.

Where additional special requirements are specified, the items and containers (where used) are suitably marked. Special handling tools and equipment shall be used and controlled as necessary to ensure safe and adequate handling.

Special handling tools and equipment shall be inspected and tested at specified time intervals and in accordance with the program procedures to verify that the tools and equipment are adequately maintained.

13.2 TRAINING

Training for all QA personnel involved in the shipment, transport and/or receipt of hazardous materials shall be in accordance with 49CFR172.700. Hazardous Materials Training commensurate with the guidance of 49CFR172.701 through 704 (Subpart H) shall be conducted and the scope and content of the training shall be commensurate with the duties and hazards associated with the personnel anticipated functions.

Additional OSHA and EPA required training shall be conducted in accordance with the Atomic Alchemy training program.

13.3 RECEIVING

Visual inspections by designated QA personnel will be performed upon receipt of packaging to ensure compliance with procurement documentation. The criteria for acceptance of each of these inspections and action to be taken if non-compliance is encountered will be determined by procedure. Arrival times will be recorded, and, if required, the package will be under periodic surveillance until used. These inspections will include an inspection of the following:

a) Surface conditions
b) Weld and structural integrity
c) Condition of any flanges or sealing faces
d) Condition of any gaskets and seals
e) Condition of any gauges, rupture disks, valves, pressure relief devices
f) Condition of any tiedown members
g) Legibility of labeling and marking
h) Leak tightness of the packaging

13.4 HOISTING, RIGGING, AND TRANSPORTING ITEMS

For the construction and operations phase of the facility, Atomic Alchemy has established and implements a heavy load program and a hoisting and rigging program with respective procedures.

Operators of special handling, rigging, and lifting equipment shall be experienced or trained in the use of the equipment.

The purpose of these programs is to provide requirements and guidance to support safe rigging and handling of loads.

Guidance is included for identification, control, storage, issuance, usage and prior to use inspections of lifting and rigging equipment (cranes, mobile cranes, hand operated hoists, wire ropes, chains, slings, rigging tackle), and for determining the center of gravity, safe working load, and signals.

Rigging and lifting plans are reviewed, evaluated, or approved by Engineering. Additional reviews, evaluations, or approvals are required if the plan is revised.

A Pre-use visual inspection by a qualified person is required to be performed prior to the start of each use of rigging and lifting equipment.

Consistent with Paragraph 10 of NUREG-0554, the Atomic Alchemy QAPD covers the procurement, design, fabrication, installation, inspection, testing, and operation of Atomic Alchemy facility cranes.

13.5 HOUSEKEEPING

Housekeeping practices are established by Atomic Alchemy to account for conditions or environments that could affect the quality of structures, systems, and components within the facility. This includes control of cleanliness of facility and materials, fire prevention and protection, disposal of combustible material and debris, control of access to work areas, protection of equipment, radioactive contamination control and storage of solid radioactive waste.

Additionally, adherence to good housekeeping practices is included throughout the respective Atomic Alchemy relevant programs. Necessary procedural steps or work instructions, such as for electrical bus and motor control center cleaning, cleaning of control consoles, are developed and included in Atomic Alchemy program procedures.

13.6 SPECIAL HANDLING AND STORAGE

Special Handling and Storage procedures are established by Atomic Alchemy to account for handling and storing packages, materials and other items that will require special handling and lifting equipment to move the items from one station to another.

Special storage provisions for items (e.g., shock absorbers, tags, or markings, radiation shielding, etc. to adequately protect and identify critical components) will be identified and used. Special protective environments (e.g., inert gas atmosphere, specific moisture content levels, and temperature levels) shall also be specified and provided where required by these procedures.

Atomic Alchemy shall employ specific methods and procedures to monitor and remove the presence of removable contamination on packaging and shipping containers in storage prior to use.

Atomic Alchemy shall employ specific methods and procedures to ensure that all liquid and wet wastes in storage will be stabilized in accordance with the Radwaste Program before processing for offsite shipment.

Atomic Alchemy onsite waste storage facilities provide sufficient storage capacity to allow time for shorter lived radionuclides to decay before packaging and shipping.

13.7 PACKAGING AND SHIPPING

13.7.1 Radioisotopes

Radioisotope shipping containers will be provided to Atomic Alchemy by other entities that have established an appropriate QA Program and are licensed by the NRC for manufacturing and transporting them. These containers will be subjected to a procedural inspection prior to use to detect any non-compliant container or damage done to the container during shipping to the Atomic Alchemy Facility.

Before packaging the Radioisotope products into the shipping container, Atomic Alchemy shipping personnel will perform a final procedural visual inspection of the products and the packaging to discover if any defects occurred during the assembly process. Upon acceptance, the package will then be closed according to the detailed instructional requirements of the Atomic Alchemy procedure.

The completed package will be inspected by Atomic Alchemy QA personnel for damage that may have occurred during closure. Atomic Alchemy QA personnel will also verify that all closure devices, such as bolts, washers, nuts, lock nuts, and, if applicable, lock rings have been properly installed and tightened. Atomic Alchemy QA personnel will certify that the completed package is suitable for transport, including all DOT required marking, labeling, and seals.

The status of these inspections and tests performed on each individual transport item will be indicated by the use of markings such as stamps, tags, labels, or other suitable means. These markings shall provide for the identification of items that have satisfactorily passed required inspections and tests.

The objectives of this final inspection will also be described in the Atomic Alchemy Shipping and Packaging procedures.

13.7.2 Radioactive Waste (Liquid or Solid)

The processing, packaging and disposal of radioactive waste is controlled under the Atomic Alchemy Radwaste Program.

Radioactive Waste shipping containers will be provided to Atomic Alchemy by other entities that have established an appropriate QA Program and are licensed by the NRC for manufacturing and transporting them. These containers will be subjected to a procedural inspection prior to use to detect any non-compliant container or damage done to the container during shipping to the Atomic Alchemy Facility.

A High Integrity Container (HIC) may be used to provide stability in lieu of the requirement for waste form stability for sludges, resins, filters, etc. HICs shall meet applicable regulatory packaging and transportation disposal requirements.

Contaminated cartridge filter waste elements and depleted resins are planned to be shipped for off-site processing and disposal.

Solid Wastes consist of miscellaneous solidified liquid/wet wastes and Dry Active Waste (DAW). DAW waste will be typically packaged into boxes, intermodal containers and shipped to a licensed vendor that processes DAW for final disposal.

Atomic Alchemy does not plan to process mixed waste on-site and will ship its mixed waste inventory to licensed and permitted facilities for processing prior to disposal.

Verification of suitability for disposal, packaging, and transportation of radwaste shall be determined through Atomic Alchemy procedural controls.

Radioactive waste streams are sampled and/or assessed prior to packaging and shipment as required or after any evolution that may affect the distribution of radionuclides by a factor of ten in waste streams for Class A, B, and C waste defined in 10 CFR 61.55.

Before transferring the radioactive waste into these shipping containers, Atomic Alchemy shipping personnel will perform a final procedural visual inspection of the waste products and the packaging to discover if any defects occurred during the waste product assembly process. Upon acceptance, the waste package container will then be closed according to the detailed instructional requirements of the Atomic Alchemy procedure.

The completed waste package container will undergo a final inspection by Atomic Alchemy QA personnel for damage that may have occurred during closure. Atomic Alchemy QA personnel will also verify that all closure devices, such as bolts, washers, nuts, lock nuts, and, if applicable, lock rings have been properly installed and tightened. Atomic Alchemy QA personnel will certify that the completed waste package container is suitable for transport, including all DOT required marking, labeling, and seals.

The status of these inspections and tests performed on each individual transport item will be indicated by the use of markings such as stamps, tags, labels, or other suitable means. These markings shall provide for the identification of items that have satisfactorily passed required inspections and tests.

The objectives of this final inspection will also be described in the Atomic Alchemy Shipping and Packaging procedures.

13.7.3 Non-Radioactive Waste

Non-Radioactive fluid and solid wastes that are capable of being incinerated (e.g. hydraulic fluids, lubricating oils, etc.) will be processed and packaged per specific Atomic Alchemy procedures for these types of wastes and shipped to a processor that is licensed to perform the appropriate disposal activity.

All other Non-Radioactive wastes shall be processed in accordance with Atomic Alchemy procedures in compliance with local, state, and federal DEP requirements.

13.7.4 Shipping Releases

The release of each new Atomic Alchemy product package or waste package for shipment is required by the program procedure. This procedure contains a checklist of the required inspections for each authorized package. This assures that an inspection required for the item has not been bypassed before delivery of a package(s) to a carrier. As appropriate, procedures will be established-to control the application and removal of status indicators (e.g., tags, inspection sheets, markings, stamps). Departure times will be recorded and, if required, the package will be under periodic surveillance until delivered to the carrier.

13.8 INTERFACE WITH OTHER PROGRAMS

The Atomic Alchemy program interface ensures that program activities subject to the provisions of this QAPD are promulgated between the various Design Authority Consortium Partners and Departments suitable for their intended application, consistent with their effect on safety.

Atomic Alchemy program interfaces shall be identified and procedurally controlled.

Programmatic efforts shall be coordinated among interfacing consortium partners and sub-organizations as detailed in the Atomic Alchemy QAPD program.

Atomic Alchemy program information transmitted across the interfaces shall be documented and procedurally controlled.

During the operational phase that begins after final acceptance and turnover of all SSC's, all design and licensing basis documents are transmitted and turned over from the design authority consortium partner(s) to Atomic Alchemy.

The Atomic Alchemy General Manager, Nuclear Design Engineering Services (GMNDES), General Manager, Construction Services (GMCS), General Manager, Nuclear Support Services (GMNSS), Vice President, Nuclear Regulatory Affairs & Compliance (GMRAC), and General Manager, Quality Assurance Program (GMQAP) are responsible for ensuring the facility complies with all applicable regulatory requirements including the requirements of this QA Program.

13.9 IMPLEMENTING PROGRAMS

- Package Design Control Program (to be provided in the FSAR)
- QA/QC Inspector Training Program (to be provided in the FSAR)
- Heavy Load Handling Program (to be provided in the FSAR)
- Lifting and Rigging Program (to be provided in the FSAR)
- Radioactive Waste Program (to be provided in the FSAR)
- Receipt Inspection Program (to be provided in the FSAR)
- *Chemical Process Safety & Surveillance Program (to be provided in the FSAR)

14 INSPECTION, TEST, AND OPERATING STATUS (CRITERION XIV)

Atomic Alchemy describes in this section the associated programs and procedures that implement the requirements of Criterion XIV, Inspections, Test, and Operating Status, of 10 CFR 50, Appendix B, Requirement14, Section 100 of NQA-1-2017, Part II, Subpart 2.5, Section 100-1000 of NQA-1-2017, and Part II, Subpart 2.18, Sections 100-500 of NQA-1-2017.

The status of inspection and test activities shall be identified on the items or in documents traceable to the items, to ensure that required inspections and tests are performed and to ensure that items which have not passed the required inspections and tests, are not inadvertently installed or operated.

14.1 REQUIREMENTS

This QAPD and implementing programs provides the requirements for the inspections, tests, and operating status of the facility systems, structures, and components during quality-controlled activities.

These procedures and instructions delineate the requirements, methods, and responsibilities for indicating the status of the affected SSCs.

Status is indicated either on the SSCs directly or in documents traceable to these SSCs where it is necessary to assure that required inspections and tests are performed and to assure that SSCs which have not passed the required inspections and tests are not inadvertently installed, used or operated.

Atomic Alchemy process control procedures, as well as test and inspection procedures and installation records and checklists are used as applicable to control the installation of structures, system, and components. These documents contain hold points, activity checklists, and in many cases, step-by-step signoffs which indicate the status of fabrication, installation, inspections, and test. Operating status and documentation of tests of components are additionally controlled through the normal facility operating procedures.

Requirements also include the control of temporary design changes (temporary modifications), such as temporary bypass lines; electrical jumpers and lifted wires; and temporary trip-point settings, that are controlled by programs and procedures that include requirements for appropriate installation and removal, independent/concurrent verifications, and status tracking.

Atomic Alchemy will ensure that contractors are familiar with the Atomic Alchemy ASME Section XI ISI/NDE and IST/NDT programs being used.

14.2 NON-DESTRUCTIVE TESTING (NDT) AND NON-DESTRUCTIVE EXAMINATION (NDE)

During construction and operational phases, Atomic Alchemy may delegate control of Part I, Criterion XIV NDE and NDT services, if necessary, to the qualified suppliers of NDT/NDE testing services and design consortium partners who retain an NDT/NDE department or organization through the contracts in accordance with the requirements in Part I, Criterion XIV of this document.

Atomic Alchemy will ensure that contractors are certified and maintain surveillance of contractor preservice or in-service activities to verify compliance with the contract and applicable Atomic Alchemy ASME Section XI lSI/NDE and IST/NDT program requirements.

Inspection plans submitted by outside contractors shall be reviewed and approved by Atomic Alchemy prior to use.

Contractor's written practices for qualification and certification of NDE and NDT personnel shall be reviewed and approved by Atomic Alchemy prior to use.

Atomic Alchemy Site Document Control and Records Management will be responsible for issuing controlled copies of the ASME Section XI ISI/IST drawings to specified distribution lists.

14.3 MAINTENANCE RULE PROGRAM (SEE ALSO QAPD PART V)(TO BE PROVIDED IN THE FSAR)

Atomic Alchemy SSCs are determined by an expert panel to be included within the scope of the Maintenance Rule program. These designated components and systems will undergo routine preventive maintenance. These components are monitored for operability or availability either at the system level or the component level depending upon the SSC’s importance to safety.
In accordance with the rule, Atomic Alchemy utilizes structural and aging monitoring programs to provide reasonable assurance that in scope structures are capable of fulfilling their intended design functions.

14.4 INTERFACE WITH OTHER PROGRAMS

The Atomic Alchemy program interface ensures that program activities subject to the provisions of this QAPD are promulgated between the various Design Authority Consortium Partners and Departments suitable for their intended application and consistent with their effect on safety.

Atomic Alchemy program interfaces shall be identified and procedurally controlled.

Programmatic efforts shall be coordinated among interfacing consortium partners and sub-organizations as detailed in the Atomic Alchemy QAPD program.

Atomic Alchemy program information transmitted across the interfaces shall be documented and procedurally controlled.

During the operational phase that begins after final acceptance and turnover of all SSC's, all design and licensing basis documents are transmitted and turned over from the design authority consortium partner(s) to Atomic Alchemy.

The Atomic Alchemy General Manager, Nuclear Design Engineering Services (GMNDES), General Manager, Construction Services (GMCS), General Manager, Nuclear Support Services (GMNSS), Vice President, Nuclear Regulatory Affairs & Compliance (GMRAC), and General Manager, Quality Assurance Program (GMQAP) are responsible for ensuring the facility complies with all applicable regulatory requirements including the requirements of this QA Program.

14.5 IMPLEMENTING PROGRAMS

- Pre-Service Inspection/NDE Program (to be provided in the FSAR)
- Pre-Service Testing/NDT Program (to be provided in the FSAR)
- Test Control Program (to be provided in the FSAR)
- Maintenance Rule Program (to be provided in the FSAR)
- Confinement and Radioisotope Penetrations Appendix J Program (to be provided in the FSAR)
- Structures Monitoring Program (to be provided in the FSAR)
- Aging Evaluation Program (to be provided in the FSAR)
- Overhead Loads Handling Equipment Inspection Program (to be provided in the FSAR)
- Operational Readiness Assessment Program (to be provided in the FSAR)
- Initial Start-Up Test Program (to be provided in the FSAR)
- Functional Capability Assurance Program (to be provided in the FSAR)
- *Main Control Room Habitability Program(to be provided in the FSAR)
- Seismic Instrumentation Program (to be provided in the FSAR)
- Health Physics (to be provided in the FSAR)
- Emergency Response and Data System Implementing Program (to be provided in the FSAR)

15 NON-CONFORMING MATERIALS, PARTS, OR COMPONENTS (CRITERION XV)

Atomic Alchemy describes in this section the associated programs and procedures that implement the requirements of Criterion XV, Non-Conforming Materials, Parts or Components, of 10 CFR 50, Appendix B, 10 CFR Part 21, and Requirement 15, Sections 100-400 of NQA-1-2017.

Activities, services, and items that do not conform to design requirements shall be controlled to prevent inadvertent installation or use. Conditions adverse to quality is an all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances.

Controls on nonconforming items shall provide for identification, documentation, evaluation, segregation from like conforming items when practical, and disposition of nonconforming items. Nonconforming conditions shall be evaluated for further reporting to appropriate regulatory agencies. Nonconforming characteristics shall be reviewed, and recommended dispositions of nonconforming items proposed and approved in accordance with documented procedures.

15.1 REQUIREMENTS

Nonconformance documentation shall clearly identify and describe the characteristics that do not conform to specified criteria.

Nonconformance documentation shall be reviewed by the responsible affected organization and recommended dispositions of nonconforming items shall be proposed in accordance with procedures.

Nonconforming components and items shall be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned. See also Part I, Criterion VIII for identification of items.

Personnel performing evaluations of recommended dispositions shall have demonstrated competence in the specific area they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information.

The responsibility and authority for reviewing, evaluating, approving the disposition, and closing nonconformances shall be specified in program procedures.

The disposition (use-as-is, reject, repair, or rework) of nonconforming items shall be identified and documented.

Nonconformance to design requirements of items dispositioned “use-as-is” or “repair” shall be subject to design control measures commensurate with those applied to the original design.

The as-built records shall reflect the accepted deviation.

Reports of non-conforming materials and conditions adverse to quality are analyzed to identify trends.

Atomic Alchemy performs audits and surveillances, as appropriate, to verify that dispositions for reports documenting nonconforming conditions are adequate.

15.2 VERIFICATION OF REWORK OR REPAIR ACCEPTABILITY

Repaired or reworked items shall be re-examined in accordance with applicable procedures and with the original acceptance criteria unless the nonconforming item disposition has established alternate acceptance criteria.

Technical justification for the acceptability of a nonconforming item disposition “repair” or “use-as-is” shall be documented.

15.3 DELEGATION OF WORK

Atomic Alchemy may delegate control of Criterion XV services, if necessary, to the qualified suppliers through the contracts in accordance with the requirements in Part I, Criterion IV of this document.

15.4 INTERFACE WITH REPORTING PROGRAMS

The Atomic Alchemy program interface ensures that program activities subject to the provisions of this QAPD are promulgated between the various Design Authority Consortium Partners and Departments suitable for their intended application, consistent with their effect on safety.

Atomic Alchemy program interfaces shall be identified and procedurally controlled.

Programmatic efforts shall be coordinated among interfacing consortium partners and sub-organizations as detailed in the Atomic Alchemy QAPD program.

Atomic Alchemy program information transmitted across the interfaces shall be documented and procedurally controlled.

During the operational phase that begins after final acceptance and turnover of all SSC's, all design and licensing basis documents are transmitted and turned over from the design authority consortium partner(s) to Atomic Alchemy.

The Atomic Alchemy General Manager, Nuclear Design Engineering Services (GMNDES), General Manager, Construction Services (GMCS), General Manager, Nuclear Support Services (GMNSS), Vice President, Nuclear Regulatory Affairs & Compliance (GMRAC), and General Manager, Quality Assurance Program (GMQAP) are responsible for ensuring the facility complies with all applicable regulatory requirements including the requirements of this QA Program.

Atomic Alchemy has in-place the necessary measures and governing procedures that implement a program to identify, evaluate and report defects and non-compliances in accordance with 10 CFR50.55(e) and/or 10 CFR Part 21, as applicable.

15.5 IMPLEMENTING PROGRAMS

- Light Water Pool Foreign Material Exclusion (FME) Surveillance Program (to be provided in the FSAR)
- Light Water Pool Loose Parts Monitoring Program (to be provided in the FSAR)
- Moly 99 Transfer Canal Pool Foreign Material Exclusion (FME) Surveillance Program (to be provided in the FSAR)
- Corrective Action Program (to be provided in the FSAR)
- Material Control and Accountability Program (to be provided in the FSAR)

16 CORRECTIVE ACTIONS (CRITERION XVI)

Atomic Alchemy describes in this section the associated program and procedures that implement the requirements of Criterion XVI, Corrective Actions, of 10 CFR 50, Appendix B and Requirement16, Section 100 of NQA-1-2017.

The Atomic Alchemy program assure that the remediation of conditions discovered adverse to quality are documented in compliance with regulatory requirements and applicable design and quality standards. In the case of a significant condition adverse to quality, the root cause of the condition as well as any extending conditions shall also be investigated, and additional corrective actions are prescribed to preclude recurrence. Reports of conditions adverse to quality are analyzed to identify trends.

16.1 REQUIREMENTS

Personnel performing evaluations of recommended corrective actions shall have demonstrated competence in the specific area they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information.

The responsibility and authority for reviewing, evaluating, approving the corrective actions, and closing nonconformance tracking documents shall be specified in program procedures.

The program establishing the corrective actions shall include a requirement for management to take follow-up action to verify implementation of corrective action taken to address significant conditions adverse to quality

The significance level of the adverse condition determines the need for a root cause determination and for establishing the necessary action to prevent recurrence.

16.2 IDENTIFYING AND CLASSIFYING CONDITIONS ADVERSE TO QUALITY

Conditions adverse to quality shall be classified in one of two categories in regard to their significance, and corrective actions shall be taken accordingly. The two categories of significance include:

a) Conditions adverse to quality.
b) Significant conditions adverse to quality.

Significant condition adverse to quality shall be defined as

a) A deficiency that would seriously impact an item, activity or service from meeting or performing its intended function or output of assuring public health and safety.
b) A deficiency in design that has been approved for fabrication or construction where the design deviates extensively from design criteria and bases.
c) A deficiency in the fabrication or construction of, or significant damage to, structures, systems or components that require extensive evaluation, re-design or repair in order to establish the adequacy of the structure, system or component to perform its intended function of assuring public health and safety.
d) A deviation from performance specifications that shall require extensive evaluation, redesign, or repair to establish the adequacy of the structure, system, or component to perform its intended function.
e) A significant error in a computer program used to support activities affecting quality after it has been released for use.
f) A deficiency, repetitive in nature, related to an activity or SSC subject to the Atomic Alchemy QA Program.

16.3 EVENT RECURRENCE CONTROL

The significance level determines the need for a root cause determination and for establishing the necessary action to prevent a recurrence of the adverse condition. In cases of significant conditions adverse to quality, the immediate corrective action, the cause, and recurrence control actions must be documented. Procedures establish the responsibilities and measures taken to accomplish these actions.

16.4 FOLLOW-UP ACTIONS

The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management. Follow-up action shall be taken to verify implementation of the corrective action.

16.5 TRENDING

The program establishing the CAP shall assign organizational responsibility for trending conditions adverse to quality and the criteria for determining adverse trends. Trend evaluation shall be performed in a manner and at a frequency that provides for prompt identification of adverse quality trends.

Adverse trends concerning specific vendors shall be reported to the affected vendor for resolution and relapse control, as appropriate.

16.6 INTERFACE WITH REPORTING PROGRAMS

The Atomic Alchemy program interface ensures that program activities subject to the provisions of this QAPD are promulgated between the various Design Authority Consortium Partners and Departments suitable for their intended application, consistent with their effect on safety.

Atomic Alchemy program interfaces shall be identified and procedurally controlled.

Programmatic efforts shall be coordinated among interfacing consortium partners and sub-organizations as detailed in the Atomic Alchemy QAPD program.

Atomic Alchemy program information transmitted across the interfaces shall be documented and procedurally controlled.

During the operational phase that begins after final acceptance and turnover of all SSC’s, all design and licensing basis documents are transmitted and turned over from the design authority consortium partner(s) to Atomic Alchemy.

The Atomic Alchemy General Manager, Nuclear Design Engineering Services (GMNDES), General Manager, Construction Services (GMCS), General Manager, Nuclear Support Services (GMNSS), Vice President, Nuclear Regulatory Affairs & Compliance (GMRAC), and General Manager, Quality Assurance Program (GMQAP) are responsible for ensuring the facility complies with all applicable regulatory requirements including the requirements of this QA Program.

In the case of vendors or consortium partners working on safety-related activities, or other similar situations, Atomic Alchemy may choose to delegate specific responsibilities of the Corrective Action program, but Atomic Alchemy maintains responsibility for the program's effectiveness.

16.7 IMPLEMENTING PROGRAMS

- Corrective Action Program (to be provided in the FSAR)

17 QUALITY ASSURANCE RECORDS (CRITERION XVII)

Atomic Alchemy describes in this section the associated programs and procedures that implement the requirements of Criterion XVII, Quality Assurance revision, of 10 CFR 50, Appendix B, Requirement 17, Sections 100-800 of NQA-1-2017, Part II, Subpart 2.17, and Sections 100-800 of NQA-1-2017. Additionally, Atomic Alchemy complies with the NRC guidance Generic Letter 88-18, "Plant Record Storage on Optical Disks."

A records management system and/or program shall be established at the earliest practical time consistent with the schedule for accomplishing work activities. The records system or systems shall be defined, implemented, and enforced in accordance with written procedures, instructions, or other documentation.

The records shall include as a minimum: design and licensing basis documents, drawings, calculations, specifications, facility procedures, corrective action reports, inspection and test results, results of QA/QC reviews and audits, QA/QC implementing procedures, and engineering reviews and analyses in support of designs or changes and modifications.

17.1 REQUIREMENTS

Required records include but are not limited to operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and material analyses. These records also include closely related data such as qualifications of personnel, procedures, and equipment.

Additional provisions shall be made for special processed records such as radiographs, photographs, negatives, microfilm, and magnetic media, to prevent damage from excessive light, stacking, electromagnetic fields, temperature, and humidity.

Design documentation and records, which provide evidence that the design and design verification processes were properly performed, are collected, stored, and maintained in accordance with documented procedures.

The documentation includes not only final design documents, such as drawings and specifications, and revisions thereto but also documentation which identifies the important steps, including sources of design inputs that support the final design.

Records maintained by a supplier shall be accessible to Atomic Alchemy at all times.

17.2 RECORD RETENTION

Some records shall be maintained by or for the facility owner for the life of the particular item while it is installed in the facility or stored for future use. Such records shall be classified in accordance with the following criteria:

a) Those which would be of value in demonstrating capability for safe operation.
b) Those which would be of value in maintaining, reworking, repairing, replacing, or modifying an item.

c) Those which would be of value in determining the cause or results of an accident or malfunction of a basic component.
d) Those which provide required baseline data for in-service inspections.
e) Those which would be of value in planning for facility decommissioning.

Other records shall be retained for a shorter period as determined by Atomic Alchemy. The records shall be stored in a location or locations that prevent damage from moisture, temperature, and pestilence.

Should instances be discovered where more than one licensing basis document specifies a record retention requirement and they are different (e.g., QA Program commitment versus the Atomic Alchemy Technical Specifications) the more restrictive requirement shall apply.

17.3 INDEXING AND CLASSIFICATION OF RETAINED RECORDS

Records are classified as Lifetime or Nonpermanent.

Lifetime records are required to be maintained for the life of the particular item while it is installed in the plant or stored for future use. Nonpermanent records are those required to show evidence that an activity was performed in accordance with the applicable requirements but need not be retained for the life of the item because they do not meet the criteria for lifetime records. The retention period for nonpermanent records is established in writing in the program procedures.

17.4 RECORD MIGRATION

An electronic record migration/regeneration program is implemented for electronic records stored in media with a standard life expectancy that fails to meet the specific retention period. This program is implemented in accordance with documented procedures that provide for appropriate record authentication, quality verification of the completion, and accuracy of the data transferred.

17.5 RECORD CORRECTIONS

Records are corrected in accordance with program procedures which provide for appropriate review or approval by the originating organization. The correction includes the date and the identification of the person authorized to issue such correction. For records stored in electronic media, a new record is generated when substantial corrections or changes to previous electronic records are required.

17.6 RECEIPT CONTROL OF RECORDS

The Atomic Alchemy organization is responsible for organizing and implementing a system of receipt control of records for permanent and temporary storage, and for providing protection from damage or loss. For electronic records, in addition to the requirements described above, the organization is also responsible for organizing and implementing an inventory of system applications, record formats, and programs required to process and retrieve electronic records. The receipt control system is structured to permit a current and accurate assessment of the status of records during the receiving process.

17.7 AUTHENTICATION

Documents are considered valid records only if stamped, initialed, authenticated, or signed and dated by authorized personnel. This authentication may take the form of a statement by the responsible

individual or organization. Handwritten signatures are not required if the document is clearly identified as a statement by the reporting individual or organization. These records may be originals or reproduced copies. For electronic records, authentication is accomplished by manually affixing a seal, signature, an electronic representation (Atomic Alchemy user ID/password combination, digital signature), or other acceptable process control that ensures genuineness, validity, or reliability.

17.8 ELECTRONIC RECORDS

For records in electronic media, the Atomic Alchemy program includes provisions for the generation, distribution, use, maintenance, storage, and disposition of electronic records. The program provides for all acceptable media on which electronic records are created and stored.

Also, the program includes provisions to verify that the media is appropriate, suitable for the capture or storage of records, and error/defect free.

Periodic inspections of systems, software applications, and media are performed to ensure electronic records retrievability, integrity, and retention period.

When using electronic records storage and retrieval systems, Atomic Alchemy complies with the NRC guidance Generic Letter 88-18, "Plant Record Storage on Optical Disks", Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guide (TG) 11-1998, "Authentication of Records and Media", NIRMA TG 15-1998, "Management of Electronic Records", NIRMA TG 16-1998, "Software Configuration Management and Quality Assurance", and NIRMA TG 21-1998, "Electronic Records Protection and Restoration".

17.9 IMPLEMENTING PROGRAMS

- Document Control Program (to be provided in the FSAR)
- Nuclear Document Records Retention Program (to be provided in the FSAR)
- Configuration Management and Change Control Program (to be provided in the FSAR)

18 AUDITS/ASSESSMENTS (CRITERION XVIII)

Atomic Alchemy describes in this section the associated programs and procedures that implement the requirements of Criterion XVIII, Audits/Assessments, of 10 CFR 50, Appendix B and Requirement 18, Sections 100-800 of NQA-1-2017.

Atomic Alchemy will conduct periodic assessments of quality-affecting activities during design, construction, modification, and operations to evaluate the effectiveness of the as-implemented quality program. Assessments and Audits shall be performed in accordance with written procedures or checklists.

During the construction phase, internal audits of selected aspects of licensing, design, and construction activities are performed with a frequency to assure that an audit of all applicable QA program elements is completed for each functional area at least once each year, or at least once during the life of the activity, whichever is shorter.

During the early portions of Atomic Alchemy initial design and licensing phase activities audits will focus on areas including, but not limited to, site investigation, procurement, design engineering, design control, document control and corrective actions.

During the facility's operations phase internal audits are performed at a frequency commensurate with the safety significance of the activities and in such a manner to assure audits of all applicable QA program elements are completed bi-annually.

18.1 REQUIREMENTS

Assessment results shall be documented and should be reviewed by management personnel who have responsibility for the area assessed.

Conditions requiring prompt corrective action shall be reported immediately to the appropriate management of the assessed organization.

Management of the assessed organization or activity shall investigate adverse findings, schedule corrective action (including measures to prevent recurrence) and notify the appropriate assessing organization in writing of action taken or planned. The adequacy of the responses shall be evaluated by the assessing organization.

Assessment records include assessment plans, reports, written replies, and the record of completion of corrective action.

Assurance of the authority and organizational independence of the auditor personnel.

Personnel selected for assessment assignments shall have experience or training commensurate with the scope, complexity, or special nature of the activities to be assessed. The assessor shall have the capability to communicate effectively, both in writing and orally.

A documented QA audit plan shall be developed for each audit. This plan shall identify the audit scope, requirements for performing the audit, type of audit personnel needed, work to be audited, organizations to be notified, applicable documents, audit schedule, and implementing documents or checklists to be used.

QA Audits may also be used to meet the periodic review requirements of the code for the Security, Emergency Preparedness, and Radiological Protection programs within the provisions of the applicable code.

Approved vendors utilized to perform quality activities for the Atomic Alchemy facility are responsible for developing and implementing a system of planned and periodic audits to verify compliance with and to determine the effectiveness of all aspects of their own quality assurance program.

18.2 QUALIFICATIONS OF AUDITORS

The audits are conducted by trained personnel not having direct responsibilities in the area being audited and in accordance with preplanned and approved audit plans or checklists, under the direction of a qualified lead auditor and the cognizance of the Quality Assurance Program Supervisor.

Technical specialists may be used to assist in assessing the adequacy of technical processes. Before commencing the audit, the lead auditor shall ensure the personnel assigned to the audit team are

prepared and collectively have experience and/or training commensurate with the scope, complexity, or special nature of the work to be audited

The audit of the Fire Protection Program and its implementing procedures are conducted utilizing either a qualified off-site licensed fire protection engineer or an outside qualified fire protection consultant.

18.3 REPORTING AUDIT RESULTS

The audit report shall be prepared and signed by the audit team leader and issued to the management of the audited organization in a timely manner after completion of the audit. The audit report shall include the following information:

a) A description of the audit scope.
b) Identification of the auditors.
c) Identification of persons contacted during the audit.
d) A summary of audit results and the documents reviewed, persons interviewed and the specific results of the reviews and interviews (i.e., a summary of the checklist contents).
e) Statement as to the effectiveness of the implementation of the QA Program elements audited.
f) A description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization.

18.3.1 Management Response to Audits

Atomic Alchemy Management of the audited organizations or activities shall:

a) Investigate adverse audit findings in accordance with the program requirements a timely manner.
b) Determine and evaluate corrective actions, including measures to prevent recurrence.
c) Develop a schedule for implementing corrective actions.
d) Prior to or by the requested response date, notify the Atomic Alchemy Manager responsible for the Quality and Performance Improvement in accordance with program requirements of the actions taken or scheduled.

18.4 FOCUS AREA SELF ASSESSMENTS (FASA)

The Atomic Alchemy Focus Area Self-Assessment program evaluates the overall effectiveness of the implementing QAPD programs as well as other organizations through its success in meeting pre-established goals and intended outcomes. Program guidance and procedures are developed for the self-assessment program to collect data and user experience from all sources that is then consolidated to facilitate analysis.

Data analysis consists of comparing performance metric data with preestablished criteria and writing a determination of its programmatic impact. The assessment analysis will determine the significance of identified performance issues and recommend the following:

a) Adjust resources to focus on significant performance issues.
b) Evaluate the adequacy of prior corrective actions for performance issues.
c) Recommend necessary regulatory actions for significant performance issues.

d) Communicate inspection and assessment results to upper management.
e) Suggest program improvements based on stakeholder feedback and lessons learned.

18.5 SCHEDULING OF AUDITS AND FASA

Audits and focus area self-assessments are performed at a frequency commensurate with the safety significance of the activities. At a minimum, the program assures all audits and assessments of all applicable QA program and organizational elements are completed bi-annually. Regularly scheduled audits are supplemented by audits for one or more of the following reasons or conditions:

a) When significant changes are made in functional areas of the quality assurance program, such as significant reorganization or procedure revisions.
b) When it is suspected that the quality of the item or process is in jeopardy due to deficiencies in the quality assurance program.
c) Whenever a systematic, independent assessment of program or organizational effectiveness is considered necessary.
d) When necessary to verify implementation of required corrective actions.
e) At the request of the GMNRO or GMNPO.

18.6 DELEGATION OF WORK

Atomic Alchemy may contract performance of program audits and assessments to external firms that specialize in such audits to qualified suppliers via contracts in accordance with the requirements in Part I, Criterion IV herein.

18.7 IMPLEMENTING PROGRAMS

- Reactor and Process Oversight Program (to be provided in the FSAR)
- Focus Area Self-Assessment Program (to be provided in the FSAR)

PART II - NON-SAFETY RELATED SSC QUALITY CONTROL

Specific program controls are applied to non-safety related SSCs, for which 10 CFR 50, Appendix B is not applicable, that are significant contributors to plant safety. The specific program controls consistent with applicable sections of this QAPD are applied to those components in a selected manner. The following clarify the applicability of the QA Program to the non-safety related SSCs and related activities.

1 ORGANIZATION (CRITERION I)

The organizational verification activities described in this part may be performed by the Atomic Alchemy line organization. The QA organization described in Part I is not required to perform these functions.

2 QA PROGRAM (CRITERION II)

Atomic Alchemy QA requirements for non-safety related SSCs are contained in this QAPD and appropriate procedures. Suppliers of these SSCs or related services describe the quality controls applied in their appropriate procedures. Performance of other QA program functions may be performed by personnel outside of the QA organization.

Specific requirements of Part IV will apply to fire protection, ATWS, and SBO activities.

3 DESIGN CONTROL (CRITERION III)

Atomic Alchemy shall establish design control procedural measures to ensure that contractually established design control requirements are included in the design. These measures ensure that applicable design inputs are included or correctly translated into the design documents, and deviations from those requirements are controlled.

Design verification is provided through the normal supervisory review of the designer's work. The design control may be performed by personnel in the line organization that utilizes knowledgeable personnel to perform these functions.

Specific requirements of Part IV will apply to fire protection, ATWS, and SBO activities.

4 PROCUREMENT DOCUMENT CONTROL (CRITERION IV)

Procurement documents for items and services obtained by or for Atomic Alchemy shall include or reference the design documents describing applicable design bases, design requirements, and other industry requirements necessary to ensure component performance. The procurement documents are controlled to address deviations from the specified requirements.

Design verification of the procured components is provided through the Section II, Criterion IV receipt inspection.

Specific requirements of Part IV will apply to fire protection, ATWS, and SBO activities.

5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS (CRITERION V)

Atomic Alchemy shall provide documents such as, but not limited to, written instructions, plant procedures, drawings, vendor technical manuals, and special instructions in work orders, to direct the performance of activities affecting quality. The method of instruction employed shall provide an appropriate degree of guidance to the personnel performing the activity to achieve acceptable functional performance of the SSC.

Specific requirements of Part IV will apply to fire protection, ATWS, and SBO activities.

6 DOCUMENT CONTROL (CRITERION VI)

Specific requirements of Part I, Criterion VI will be used to provide an overall program for non-safety related SSC's.

7 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES (CRITERION VII)

Atomic Alchemy shall establish measures, such as inspection of items or documents upon receipt or acceptance testing, to ensure that all purchased items and services conform to appropriate procurement documents.

Specific requirements of Part IV will apply to fire protection, ATWS, and SBO activities.

8 IDENTIFICATION AND CONTROL OF PURCHASED ITEMS (CRITERION VIII)

Atomic Alchemy shall establish measures where necessary, to identify purchased items and preserve their functional performance capability. Storage controls consider appropriate environmental, maintenance, or shelf-life restrictions for the items.

9 CONTROL OF SPECIAL PROCESSES (CRITERION IX)

Atomic Alchemy shall establish process and procedure controls for special processes, including welding, heat treating, and nondestructive testing. These controls are based on applicable codes, standards, specifications, criteria, or other special requirements for the special process. The control of these special processes may be performed by personnel in the line organization that utilizes knowledgeable personnel to perform these functions.

Specific requirements of Part IV will apply to fire protection, ATWS, and SBO activities.

10 INSPECTION (CRITERION X)

Atomic Alchemy shall establish procedural instructions to ensure necessary inspections are performed to verify conformance of an item or activity to specified requirements and/or to verify that the activities are satisfactorily accomplished. These inspections and verification may be performed by personnel in the line organization that utilizes knowledgeable personnel to perform the inspection and verification functions.

Specific requirements of Part IV will apply to fire protection, ATWS, and SBO activities.

11 TEST CONTROL (CRITERION XI)

Atomic Alchemy shall establish procedural instructions and measures to identify required testing that demonstrates that equipment conforms to design requirements. These tests are performed in accordance with these test instructions or procedures. The test results are recorded, and authorized individuals evaluate the results to ensure that test requirements are met. These tests may be performed by personnel in the line organization that utilizes knowledgeable personnel to perform the testing.

Specific requirements of Part IV will apply to fire protection, ATWS, and SBO activities.

12 CONTROL OF MEASURING AND TEST EQUIPMENT (M&TE) (CRITERION XII)

Atomic Alchemy shall establish procedural measures to control M&TE use, and calibration and adjustment at specific intervals or prior to use. This control may be performed by personnel in the line organization that utilizes knowledgeable personnel to perform the specified functions.

Specific requirements of Part IV will apply to fire protection, ATWS, and SBO activities.

13 HANDLING, STORAGE, AND SHIPPING (CRITERION XIII)

Atomic Alchemy shall establish procedural measures to control the handling, storage, cleaning, packaging, shipping, and preservation of items to prevent damage or loss and to minimize deterioration. These measures include appropriate marking or labels, and identification of any special storage or handling requirements. These measures may be performed by personnel in the line organization that utilizes knowledgeable personnel to perform the specified tasks.

Specific requirements of Part IV will apply to fire protection, ATWS, and SBO activities.

14 INSPECTION, TEST, AND OPERATING STATUS (CRITERION XIV)

Atomic Alchemy shall establish procedural measures to identify items that have satisfactorily passed required tests and inspections and to indicate the status of inspection, test, and operability as appropriate. These measures may be performed by personnel in the line organization that utilizes knowledgeable personnel to perform the specified functions.

Specific requirements of Part IV will apply to fire protection, ATWS, and SBO activities.

15 CONTROL OF NONCONFORMING ITEMS (CRITERION XV)

Atomic Alchemy shall establish procedural measures to identify and control items that do not conform to specified requirements to prevent their inadvertent installation or use. These measures may be performed by personnel in the line organization that utilizes knowledgeable personnel to perform the specified tasks.

16 CORRECTIVE ACTION (CRITERION XVI)

Specific requirements of Part I, Criterion XVI will be used to provide an overall corrective actions program for non-safety related SSC's.

17 RECORDS (CRITERION XVII)

Specific requirements of Part I, Criterion XVII will be used to provide an overall record keeping program for non-safety related SSC's.

18 AUDITS (CRITERION XVIII)

Atomic Alchemy shall establish procedural measures for line management to periodically review and document the adequacy of the process, including taking any necessary corrective action. Audits independent of line management are not required. Line management is responsible for determining whether reviews conducted by line management or audits conducted by any organization independent of line management are appropriate. When performed, audits are conducted and documented to verify compliance with design and procurement documents, instructions, procedures, drawings, and inspection and test activities. Where the measures of this part (Part II) are implemented by the same programs, processes, or procedures as the comparable activities of Part I, the audits performed under the provisions of Part I may be used to satisfy the review requirements of this Section.

Additionally, fire protection audits shall be performed by a qualified audit team. The team shall include at least a lead auditor from the Atomic Alchemy QA organization, a system engineer, and a fire protection engineer. The lead auditor shall be qualified, per ASME NQA-1. The systems engineer shall be knowledgeable in safety systems, operating procedures, and emergency procedures. The fire protection engineers (or engineering contractor/consultant) shall meet the qualifications for membership in the Society of Fire Protection Engineers at the grade of member. The fire protection engineer can be the Atomic Alchemy employee who is directly responsible for the site fire protection program but shall be an outside independent fire protection consultant every third year. This audit team approach will ensure that the technical requirements as well as the QA requirements are adequately assessed.

PART III - NON-SAFETY RELATED SYSTEMS, STRUCTURES AND COMPONENTS CREDITED FOR REGULATORY EVENTS

The following criteria apply to fire protection (10 CFR 50.48), anticipated transients without scram (ATWS) (10 CFR 50.62), the station blackout (SBO) (10 CFR 50.63) SSCs that are not safety related.

Atomic Alchemy shall implement quality requirements for the fire protection system in accordance with Regulatory Position 1.7, “Quality Assurance,” in Regulatory Guide 1.189 Rev 3, “Fire Protection for Operating Nuclear Power Plants.”

Atomic Alchemy shall implement the quality requirements for ATWS equipment in accordance with Generic Letter 85-06, "Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related."

Atomic Alchemy shall implement quality requirements for SBO equipment in accordance with Regulatory Position 3.5, "Quality Assurance and Specific Guidance for SBO Equipment That Is Not Safety Related," and Appendix A, "Quality Assurance Guidance for Non-Safety Systems and Equipment," in Regulatory Guide 1.155, Rev 0, "Station Blackout."

PART IV REGULATORY COMMITMENTS

This section identifies the NRC Regulatory Guides and the other quality assurance standards that have been selected to supplement and support the Atomic Alchemy QAPD. Atomic Alchemy complies with these standards to the extent described or referenced within this Part IV description as they apply to the Construction Application activities.

Part VIII, Table 2 contains the list of regulatory commitments that Atomic Alchemy makes in the QAPD.

1 REGULATORY GUIDES AND GENERIC LETTERS

RG 1.8, Rev 4, “Qualification and Training of Personnel for Nuclear Power Plants."

Atomic Alchemy conformance and exceptions for the applicable regulatory position guidance will be provided for this regulatory guide in FSAR Chapter 1, Appendix A.

RG 1.26, Rev 4, “Quality Group Classifications and Standards for Water, Steam, and Radioactive Waste Containing Components of Nuclear Power Plants.”

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 Chapter 1, Appendix A.

RG 1.28, Rev 5, “Quality Assurance Program Requirements (Design and Construction)."

Atomic Alchemy commits to the applicable regulatory position guidance as indicated in the Atomic Alchemy FSAR Chapter 1, Appendix A.

RG 1.29, Rev 4, “Seismic Design Classification.”

Atomic Alchemy commits to the applicable regulatory position guidance as indicated in the Atomic Alchemy FSAR Chapter 1, Appendix A.

RG 1.33, Rev 3, “Quality Assurance Program Requirements (Operations),”

Atomic Alchemy commits to the applicable regulatory position guidance as indicated in the Atomic Alchemy FSAR Chapter 1, Appendix A.

R.G. 1.39, Rev 2, "Housekeeping Requirements for Water-Cooled Nuclear Plants"

Atomic Alchemy commits to the applicable regulatory position guidance as indicated in the Atomic Alchemy FSAR Chapter 1, Appendix A.

GL 89-02, “Actions to Improve the Detection of Counterfeit and Fraudulently Marked Products.”

Atomic Alchemy commits to this guidance as indicated in the Atomic Alchemy QAPD in Part I.

GL 91-05, “Licensee Commercial-Grade Dedication Programs.”

Atomic Alchemy commits to this guidance as indicated in the Atomic Alchemy QAPD in Part I.

GL 88-18, "Plant Record Storage on Optical Disks."

Atomic Alchemy commits to this guidance as indicated in the Atomic Alchemy QAPD in Part I.

2 INDUSTRY STANDARDS

Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guide (TG) 11-2011, “Authentication of Records and Media.”

Atomic Alchemy commits to this guidance as indicated in the Atomic Alchemy QAPD in Part I, Criterion XVII.

Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guide (TG) TG 15-2011, “Management of Electronic Records.”

Atomic Alchemy commits to this guidance as indicated in the Atomic Alchemy QAPD in Part I, Criterion XVII.

Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guide (TG) 16-2011, “Software Configuration Management and Quality Assurance.”

Atomic Alchemy commits to this guidance as indicated in the Atomic Alchemy QAPD in Part I, Criterion XVII.

Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guide (TG) 21-2011, “Electronic Records Protection and Restoration.”

Atomic Alchemy commits to this guidance as indicated in the Atomic Alchemy QAPD in Part I, Criterion XVII.

ASME NQA-1-2017

Atomic Alchemy commits to this industry guidance as described in Part I and Part II in this document with any specific identification of exceptions or clarifications as noted in Part VII of this QAPD.

ASME QME-1-2017

Atomic Alchemy commits to this industry guidance as described in Part I and Part II in this document with any specific identification of exceptions or clarifications as noted in Part VII of this QAPD.

ASME BPV Section III 2017 Quality Classification

Atomic Alchemy commits to this industry guidance as described in Part I and Part II in this document with any specific identification of exceptions or clarifications as noted in Part VII of this QAPD.

3 ATOMIC ALCHEMY REGULATORY COMMITMENTS

Regulatory commitments are appropriate for matters that are of significant interest to the NRC staff, but do not warrant either legally binding license condition requirements or inclusion in Final Safety Analysis Reports (FSARs) or programs subjected to a formal regulatory change control mechanism.

Atomic Alchemy will implement regulatory commitments and will be responsible for creating and maintaining configuration control of all regulatory commitments made to the NRC. Regulatory Commitments will be controlled in accordance with the appropriate Atomic Alchemy program which include controls for evaluating changes and, when appropriate, reporting them to the NRC.

Commitments made in this QAPD will be controlled under 10 CFR 50.54(a) and 10 CFR 50.55(f)(4). All other commitments will be controlled in accordance with guidance in NEI 99-04 and NRC RIS 00-017.

Other Atomic Alchemy regulatory commitments will be made to the NRR staff in the form of docketed formal correspondence. At the appropriate time Atomic Alchemy will expressly submit their respective regulatory commitment to the NRR in writing.

3.1 IMPLEMENTING PROGRAM

- Regulatory Commitment Management Program (To be provided in the FSAR)

PART V - MAINTENANCE RULE COMPLIANCE

To be provided with the FSAR.

PART VI – PROVISIONS FOR CHANGES TO THE ATOMIC ALCHEMY QAPD

The Atomic Alchemy QAPD is reviewed and revised as necessary to reflect any changes that occur during siting, fabrication, design, construction, operation, including maintenance and modification. In addition, this QAPD is revised when corrective actions, regulatory, organizational, or work scope changes warrant changes to the QAPD Program. The Atomic Alchemy QAPD is maintained current through design, construction, and operation.

Any changes that reduce commitments described in this QAPD or that are incorporated by reference in the approved QAPD, including those commitments that affect any QA Level requirements in this QAPD, will be submitted to the NRC for review and approval prior to implementation as required by 10 CFR 50.54(a) and 10 CFR 50.55(f)(4). Changes that do not reduce commitments will be submitted in accordance with 10 CFR 50.54(a) and 10 CFR 50.55(f)(4), as applicable.

For the purposes of 10 CFR 50.54(a)(3) and 10 CFR 50.55(f)(4) the following are not considered a reduction in commitment:

a) Quality assurance program changes involving administrative improvements and clarifications, spelling corrections, punctuation, or editorial items.
b) The use of a QA standard subsequently endorsed or approved by the NRC which is more recent than the QA standard in the Atomic Alchemy current QA program at the time of the change.
c) The use of a quality assurance alternative or exception endorsed or approved by an NRC safety evaluation, provided that the bases of the NRC approval are applicable to the Atomic Alchemy facility.
d) The use of generic organizational position titles or the replacement of titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles.
e) The use of generic organizational charts or the replacement of charts, to indicate functional relationships, authorities, and responsibilities, or, alternately, the use of descriptive text.
f) The elimination of quality assurance program information that duplicates language in quality assurance regulatory guides and quality assurance standards to which Atomic Alchemy is committed to.

PART VII – EXCEPTIONS AND ALTERNATIVES TO ASME NQA-1, ASME NQE-1, AND ASME BPV SECTION III

Number	Regulation or Standard	Atomic Alchemy Exceptions/Alternatives	Source / Basis for Acceptance
1	NQA-1-2017	In lieu of the applicable requirements of NQA-1-2017, Part II, Subpart 2.19 for controls for approving commercial grade services (either through performance of commercial grade surveys or through accreditation in lieu of the performance of commercial grade surveys, including laboratory calibration and testing services) shall be based on the requirements of NQA-1-2019, Part II, Subpart 2.19 which accounts for the later endorsed version of ISO/IEC 17025.	This alternate is acceptable because ISO/IEC 17025:2005 was referenced in the NQA-1-2017 version, which has been superseded by ISO/IEC 17025:2017. In NQA-1-2019, ASME states in NQA-1-2019 that a supplier of services may be accredited to either ISO/IEC version. The NEI ILAC Taskforce performed a gap analysis between ISO/IEC 17025:2005 and ISO/IEC 17025:2017 and concluded the newer version (2017) of the standard is equivalent to the older version (2005) which was previously recognized by the NRC.

PART VII -TABLES AND FIGURES

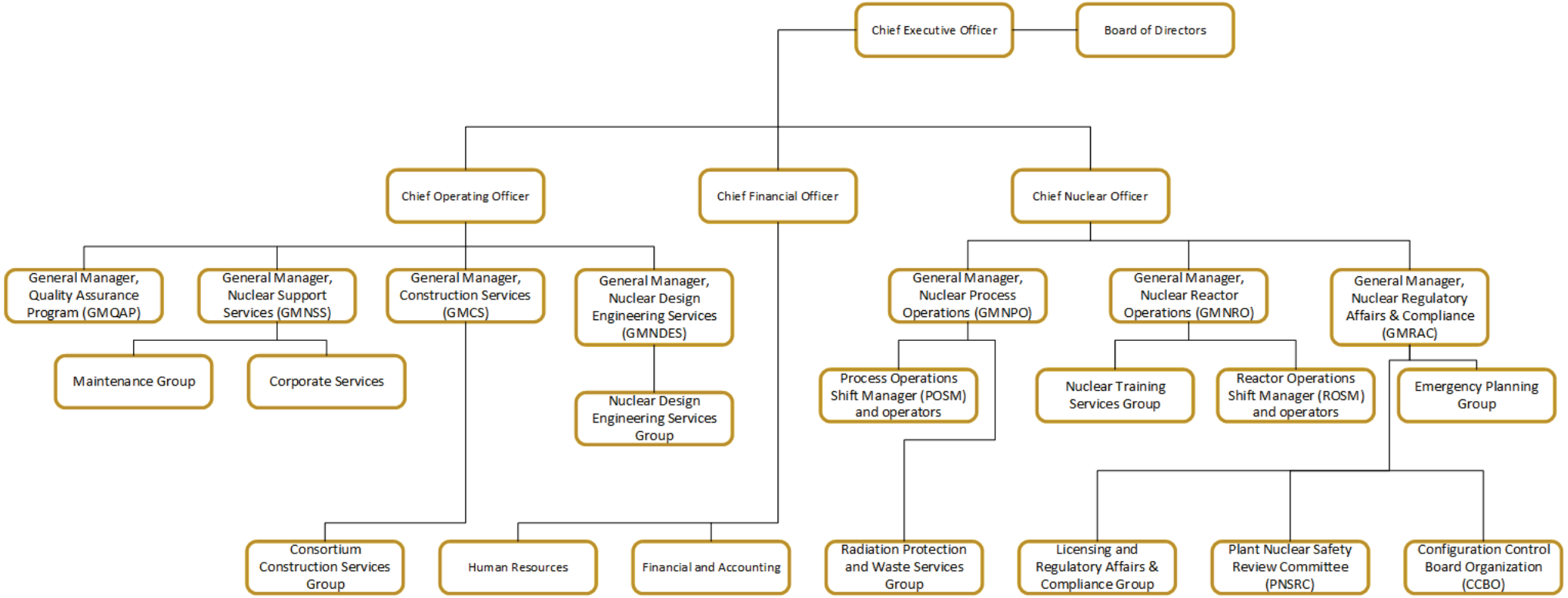

FIGURE 1: ATOMIC ALCHEMY ORGINIZATIONAL CHART

Table 1: Atomic Alchemy QAPD Criterion-program interface matrix

The purpose of this table is to establish the Atomic Alchemy programs that will be placed under the change control process (10 CFR 50.54(a) and 10 CFR 50.55(f)(4)) of the QAPD after they have been evaluated to the criteria of 10 CFR50.36(C)(2)(ii).

Quality Assurance Section	Program
Training and Qualification Section II	QA/QC Inspector Training Program
	Configuration Management and Change Control Training Program
	Non-Destructive Examination & Testing Training Program
	Non-Licensed Plant Staff Training Program
	NUPF Reactor Operator and Radioisotope Process Operator Training and Requalification Program
	Security Training and Requalification Program
Design Control Section III	Design Basis Documentation (DBD) Program
	Commitment Management Program
	*Setpoint Control Program
	I&C Software Development Program
	*Software Verification and Validation Program
	Design Control Program
Procurement Document Control Section IV	Procurement Document Control Program
	Vendor Inspection Program
Instructions, Procedures, and Drawings Section V	Configuration Management and Change Control Program
	Configuration Control Training Program
	Human Factors/Performance Program
Document Control Section VI	Document Control and Records Management
Control of Purchased Material, Equipment, and Services Section VII	Commercial Grade Dedication Program
	Receipt Inspection Program
	Materials, Equipment, and Parts List (MEPL) Program
	Software Safety Hazards Evaluation Program
	Software Verification and Validation Program
Identification and Control of Materials, Parts, and Components Section VIII	Special Nuclear Material Accounting and Control Program
	Material Control and Accountability Program
	Special Nuclear Material Accounting and Control Program
	Receipt Inspection Program
	Materials, Equipment, and Parts List (MEPL) Program
Control of Special Processes Section IX	Welding Quality Assurance Program
	Electrical Equipment Qualification Program (EEQ)
	Fuel Loading Conditions Surveillance Program
	QA/QC Inspector Training Program
	ALARA Program

Quality Assurance Section	Program
Control of Special Processes Section IX	Operator Work Around Program
	Physical Security Program
	*Radiation Protection Program
	Insider Mitigation Program
	Security Training and Requalification Program
	FFD for Security Personnel Program
	*Emergency Planning Program
	FFD and Access Authorization Program
	FFD and Access Construction Personnel Program
	Cyber Security Program
	Safeguards Contingency Program
	Behavior Observation Program
	Construction Area Behavior Observation Program
Inspection Section X	Reactor Pool Liner Inspection Program
	Hot Cell Maintenance and Inspection Program
	Buried Tank, Piping and Conduit Inspection Program
	Reactor Coolant System Material Surveillance Program
	Aging Evaluation Program
	Structures Monitoring Program
	Maintenance Rule Program
	*Reactor Coolant Pump Flywheel Inspection Program
	*RCS Heat Exchanger Tube Inspection Program
	Pre-Service Inspection Program (ASME B&PV Code, Section III)
	Pre-Service Testing Program (ASME B&PV Code, Section III)
	ISI/IST and Pre-Service Inspectability Program
	*Inservice Inspection/ NDE Program
	*Inservice Testing/ NDT Program
	QA/QC Inspector Training Program
	Overhead Loads Handling Equipment Inspection Program
	Confinement and Radioisotope Penetrations Appendix J Program
	*Electro-magnetic Compatibility and Radio Frequency interference (EMC/RFI) Program
	*Battery Monitoring and Maintenance Program
Test Control Section XI	ISI/IST Inspectability Program
	QA/QC Inspector Training Program
	Test Control Program

Quality Assurance Section	Program
	Initial Start-Up Test Program
	Post Maintenance Test Program
Test Control Section XI	Operational Readiness Assessment Program
Control of Measuring and Test Equipment (M&TE) Section XII	Calibration and Control Program
	*Safety Function Program
Handling, Storage, and Shipping Section XIII	Package Design Control Program
	QA/QC Inspector Training Program
	Heavy Load Handling Program
	Lifting and Rigging Program
	Radioactive Waste Program
Inspection, Test, and Operating Status Section XIV	Pre-Service Inspection Program
	Pre-Service Testing Program
	Test Control Program
	Maintenance Rule Program
	Aging Evaluation Program
	Structures Monitoring Program
	Electrical Equipment Qualification Program (EEQ)
	Overhead Loads Handling Equipment Inspection Program
	Operational Readiness Assessment Program
	Initial Start-Up Test Program
	Confinement and Radioisotope Penetrations Appendix J Program
	Functional Capability Assurance Program
	*Main Control Room Habitability Program
	*Seismic Instrumentation Program
	Health Physics Program
	Emergency Response Data System (ERDS) Implementation Program
Non-conforming Materials, Parts, or Components Section XV	Light Water Pool Foreign Material Exclusion (FME) Surveillance Program
	Light Water Pool Loose Parts Monitoring Program
	Moly 99 Transfer Canal Pool FME Surveillance Program
	Corrective Action Program
	Material Control and Accountability Program
Corrective Action Section XVI	Corrective Action Program
Quality Assurance Records Section XVII	Document Control and Records Management Program
	Nuclear Document Records Retention Program
	Configuration Management and Change Control Program
Audits Section XVIII	Focus Area Self-Assessment Program

Quality Assurance Section	Program
	Reactor and Process Oversight Program

Table 2: Atomic Alchemy QAPD regulatory commitments

Atomic Alchemy Commitment Number	Category/Type; Completion Method [1] or [2] (See Table 2 Endnote for Discussion)	Commitment	Discussion
AA0-RC-0001	[1]	QAPD to be based on ASME NQA-1-2017 "Quality Assurance Requirements for Nuclear Facility Applications, ASME QME-1-2017 "Qualification of Active Mechanical Equipment Used in Nuclear Power Plants" ASME BPVC Section III 2017 quality standards, Regulatory Gide 1.8, Regulatory Guide 1.26, Regulatory Guide 1.28, Regulatory Guide 1.29, Regulatory Guide 1.33, Regulatory Guide 1.39, Generic Letter 89-02, Generic Letter 91-05, and Generic Letter 88-18.	While there is not a requirement by the NRC under NUREG-1537 Appendix A, based on the complexity of the design of the Atomic Alchemy facility (multiple site nuclear non-power reactors; staged construction; multiple radiological processes; and both 10 CFR Part 50 and 10 CFR Part 70 licenses) Atomic Alchemy recognizes that the Quality Assurance Program should exceed the minimum requirements outlined for test and research reactors in NUREG-1537 (ANSI/ANS-15.8) for the design, procurement, fabrication, construction, testing, and operation.
AA0-RC-0002	[2]	Light Water Confinement Pool Leakage Rate Test Program	While there is not a requirement by the NRC under NUREG-1537 Appendix A, Atomic Alchemy recognizes the good business practice of applying a similar leakage requirement of 10 CFR 50.54(o); 10 CFR 50, App. A (GDC 53); 10 CFR 50, App. J to the light water confinement pool.
AA0-RC-0003	[2]	Radioisotope Transfer Canal Pool Leakage Rate Test Program	While there is not a requirement by the NRC under NUREG-1537 Appendix A, Atomic Alchemy recognizes the good business practice of implementing a similar leakage requirement of 10 CFR 50.54(o); 10 CFR 50, App. A (GDC 53); 10 CFR 50, App. J to the Moly99 transfer canal pool.

Atomic Alchemy Commitment Number	Category/Type; Completion Method [1] or [2] (See Table 2 Endnote for Discussion)	Commitment	Discussion
AA0-RC-0004	[2]	NUPF Reactor Operator and Radioisotope Process Operator Training and Requalification Program will be in place within 3 months of the issuance of an operating license.	While there is not a requirement by the NRC under NUREG-1537 Appendix A, Atomic Alchemy recognizes the good business practice of implementing similar requirements of 10 CFR 55.13; 10 CFR 55.31; 10 CFR 55.41; 10 CFR 55.43; 10 CFR 55.45; 10 CFR 50.54(i); 10 CFR 55.59 to the radioactive process hot cell operators. See also 10 CFR55.40(d), 10 CFR 55.53(j), 10 CFR 55.53(k), 10 CFR 55.61(b)(5)).
AA0-RC-0005	[2]	Hot Cell Maintenance and Inspection Program	While there is not a requirement by the NRC under NUREG-1537 Appendix A, Atomic Alchemy recognizes the good business practice of applying a similar requirement that would meet the NRC Inspection Program (IP 87127) goals for this.
AA0-RC-0006	[2]	Radioisotope Transfer Canal Pool FME Surveillance Program	While there is not a requirement by the NRC under NUREG-1537 Appendix A, Atomic Alchemy recognizes the good business practice of applying a similar requirement of 10 CFR50.60 and 10 CFR50 Appendix H to the Molly99 transfer canal pool.

Atomic Alchemy Commitment Number	Category/Type; Completion Method [1] or [2] (See Table 2 Endnote for Discussion)	Commitment	Discussion
AA0-RC-0007	[2]	Electrical Equipment Qualification Program (EEQ)	While there is not a requirement by the NRC under NUREG-1537 Appendix A, Atomic Alchemy recognizes the good business practice of implementing the requirements of 10 CFR50.49; GDC 1, 2, 4, 23; 10 CFR50 Appendix B, Criteria III, XI, XVII; and R.G. 1.89.
AA0-RC-0008	[2]	Aging Evaluation Program	While there is not a requirement by the NRC under NUREG-1537 Appendix A, Atomic Alchemy recognizes the good business practice of applying a similar requirement of NUREG-1801.
AA0-RC-0009	[2]	Structures Monitoring Program	While there is not a requirement by the NRC under NUREG-1537 Appendix A, Atomic Alchemy recognizes the good business practice of applying a similar requirement of NUREG-1801.
AA0-RC-0010	[2]	Buried Tank, Piping and Conduit Inspection Program	While there is not a requirement by the NRC under NUREG-1537 Appendix A, Atomic Alchemy recognizes the good business practice of applying a similar requirement of NUREG-1801.

Atomic Alchemy Commitment Number	Category/Type; Completion Method [1] or [2] (See Table 2 Endnote for Discussion)	Commitment	Discussion
AA0-RC-0011	[2]	RCS Heat Exchanger Tube Inspection Program	While there is not a requirement by the NRC under NUREG-1537 Appendix A, Atomic Alchemy recognizes the good business practice of implementing similar requirements for Inspecting the RCS primary/secondary water HX tubes.
AA0-RC-0012	[1]	Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guides (TGs)	While there is not a requirement by the NRC under NUREG-1537 Appendix A, Atomic Alchemy recognizes the good business practice of implementing the requirements of NIRMA.
AA0-RC-0013	[2]	Atomic Alchemy will develop a radioactive waste control program in compliance with 10 CFR61.55 and 10 CFR61.56 for wet solid wastes and 10 CFR71 for both wet and dry wastes.	While there is not a requirement by the NRC under NUREG-1537 Appendix A, Atomic Alchemy recognizes the good business practice of implementing similar requirements of 10 CFR61 and 10 CFR71 for radioactive waste.
AA0-RC-0014	[2]	Overhead Loads Handling Equipment Inspection Program	While there is not a requirement by the NRC under NUREG-1537 Appendix A, Atomic Alchemy recognizes the good business practice of applying a similar requirement to Generic Letter 81-07
AA0-RC-0015	[2]	Maintenance Rule Compliance	While there is not a requirement by the NRC under NUREG-1537 Appendix A, Atomic Alchemy recognizes the good business practice of applying a similar requirement of 10 CFR 50.65 (a) and (b).

Atomic Alchemy Commitment Number	Category/Type; Completion Method [1] or [2] (See Table 2 Endnote for Discussion)	Commitment	Discussion
AA0-RC-0016	[2]	Reactor Coolant System Material Surveillance Program	While there is not a requirement by the NRC under NUREG-1537 Appendix A, Atomic Alchemy recognizes the good business practice of applying a similar requirement of 10 CFR 50 Appendix H to its RCS piping system and Reactor Pool Materials.
AA0-RC-0017	[2]	Light Water Pool Liner Inspection Program	While there is not a requirement by the NRC under NUREG-1537 Appendix A, Atomic Alchemy recognizes the good business practice of applying similar surveillances and inspections of known problem areas identified in NUREG/CR-7111 and Regulatory Guide 1.127, “Inspection of Water Control Structures Associated with Nuclear Power Plants”.

Table 2 Endnote:

[1] Will be QAPD-controlled by 10 CFR 50.4(b)(7)(ii) until Atomic Alchemy receives a construction permit, at which point it will be controlled under 10 CFR 50.54(a)(3) and 10 CFR 50.55(f)(4).

[**2**] Programs that will be created and implemented in accordance with the controls and provisions of the QAPD. These commitments will be controlled in accordance with guidance in NEI 99-04 and NRC RIS 00-017.

PART IX – REFERENCES

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