Chapter 12 - Appendix A:

PDD-001 Rev 2 Quality Assurance Program

ATOMIC ALCHEMY INC.

NOTE: The following document is an internal AAI Program Description and retains its original numbering and formatting. As a result, the section headings do not follow the same convention as the PSAR chapters.

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TERMS

ACRONYMS AND ABBREVIATIONS

Common acronyms, abbreviations, and units of measurements may not be included here as it is assumed the reader is familiar with their meaning.

AAI	Atomic Alchemy Inc.
CFR	*Code of Federal Regulations*
FSAR	final safety analysis report
IRC	Independent Review Committee
KPI	key performance indicator
MEL	Master Equipment List
PSAR	preliminary safety analysis report
Q-Level	Quality-Level
QAP	Quality Assurance Program
SSC	structure, system, and component

GLOSSARY

Definitions listed to promote uniform interpretation of terms by users. Sources noted in brackets.

graded approach – regulatory requirements, analyses, and controls are scaled in rigor according to safety, security, product quality, and other risk significance factors, as deemed important to the *management* of the implementing organization. [AAI]

important-to-safety[1] – those items and activities whose intended functions help prevent accidents that could cause undue risk to health and safety of workers and the public; and help to control or mitigate the consequences of such accidents. [ANSI/ANS-15.8; AAI]

Master Equipment List – an electronic list used for configuration control of all equipment used in facilities that includes important information such as procurement, installation, testing, maintenance, spare parts, etc. [AAI]

quality-level – a designation assigned to an item or activity indicating that it is subject to the AAI Quality Assurance Program. The designation is listed in the Master Equipment List for items or in the

[1] AAI uses the term "*important-to-safety*" commensurate with the ANSI/ANS-15.8 definition of "safety-related," however the definition is more encompassing and allows flexibility in terms of QAP applicability as it can also involve items and activities that are non-safety but have been augmented in quality. As such, it is nuanced from the definition of "safety-related" per 10 CFR 50.2, which is used throughout the PSAR. Safety-related items and activities are a subset of those considered *important-to-safety* as defined herein.

controlling procedure's metadata for activities. Unless so designated, items or activities are considered Non-Quality and are not subject to AAI's QA Program. [AAI]

safety-related[1] – means those structures, systems, and components (SSCs) that are relied upon to remain functional during and following design basis events to assure:

1. The capability to shut down the reactor and maintain it in a safe shutdown condition, or
2. The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to the applicable guideline exposures set forth in 10 CFR 50.34(a)(1) or 10 CFR 100.11, as applicable. [10 CFR 50.2; AAI]

technical authority – the AAI CEO, COO, or other authorized functional position as having the responsibility and authority for approving the design bases, configuration, and changes thereto. [AAI]

1 INTRODUCTION

1.1 SCOPE AND APPLICABILITY

This Quality Assurance Program (QAP) description provides criteria for QA in the design, construction, operation, and decommissioning of research reactors. Quality assurance is those planned and systematic actions necessary to provide adequate confidence that structure, systems, or components (SSCs) will perform satisfactorily in service. Atomic Alchemy Inc. (AAI) also utilizes this program, applied using a *graded approach* (see Glossary), for other company projects and facilities, when deemed appropriate. This QAP is also applicable to AAI items and activities subject to Title 10 of the *Code of Federal Regulations* (CFR) Part 71, "Packaging and Transportation of Radioactive Material." Appendix A supplements this QAP to address additional requirements imposed by 10 CFR 71.37, and Subpart H, "Quality Assurance."

The QAP applied by AAI to its items and activities shall be consistent with the importance of these items and activities to safety and reliability. Activities subject to the QAP shall be, as a minimum, those related to the reactor safety and protection system, engineered safety features, and the applicable radiation monitoring systems as identified in the Limiting Conditions for Operations section in the Technical Specifications for the facility. The QAP is applied using a graded approach to those items and activities which are considered *important-to-safety* (see Glossary). These include siting, designing, purchasing, fabrication, handling, shipping, receiving, storing, cleaning, erecting, installing, repairing, maintaining, modifying, inspecting, testing, operating, and decommissioning. AAI personnel shall consider the tangible and intangible attributes of replacement costs, schedule delays, and facility availability in terms of QAP applicability.

AAI developed and implemented the QAP beginning with the design and construction planning phase for the Meitner-1 facility. This phase focuses on the development of appropriate controls that ensure the facility is properly designed and fabricated to meet owner/operator requirements. The majority of these controls provide documentation of quality to support the application for an operating license. Design and construction program requirements are defined in Section 2 of the ANSI/ANS-15.8-1995, "Quality Assurance Program Requirements for Research Reactors," standard.

Following facility construction and commissioning, the focus of the quality program will shift to establishing controls that ensure proper and reliable facility operation. All the program provisions established during the design and construction phase remain in place but will change in level of implementation appropriate to support facility operations. Each portion of ANSI-15.8 Section 2 will be implemented as necessary. The operating phase license imposes additional requirements related to the conduct of operations. Additional program requirements are described in Section 3.

1.2 REGULATORY BASES

10 CFR 50.34 "Contents of applications; technical information" requires each applicant for a Non-power Production and Utilization Facility (NPUF) construction permit to include in its preliminary safety analysis report (PSAR) a description of the QAP to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility. Furthermore, 10 CFR

50.34(b)(6)(ii) requires that each applicant for a license to operate a NPUF include, in its final safety analysis report (FSAR), a description of the managerial and administrative controls to be used to ensure safe operations.

The NRC's guidance document, NUREG-1537 Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content" Section 12.9 "Quality Assurance," recommends the applicant consider the guidance in Regulatory Guide (RG)-2.5, Rev 1, "Quality Assurance Program Requirements for Research and Test Reactors," which states that ANSI-15.8 provides an acceptable method of complying with the program requirements of 10 CFR 50.34.

1.3 CHANGES TO QAP

Changes to the AAI QAP that do not reduce the commitments in the QAP will be submitted to NRC as required per 10 CFR 50.71, "Maintenance of records, making of reports." NRC provides direction in 10 CFR 50.54, "Conditions of licenses" regarding changes that are not considered to be reductions in commitment. Minor changes include those involving administrative improvements and clarifications, spelling corrections, punctuation, or editorial items. The following changes also do not reduce commitments:

- Changing to a QA standard approved by the NRC which is more recent than the QA standard in the licensee's current QAP at the time of the change.
- Changing to a quality assurance alternative or exception approved by an NRC safety evaluation, provided that the bases of the NRC approval are applicable to the licensee's facility.
- Changing generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles.
- Changing generic organizational charts to indicate functional relationships, authorities, and responsibilities, or, alternately, the use of descriptive text.
- Eliminating QAP information that duplicates language in quality assurance regulatory guides and quality assurance standards to which the licensee is committed.
- Changing the organizational structure to ensure that persons and organizations performing quality assurance functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.

Changes to the AAI QAP that reduce commitments from the previously accepted revision, will be formally submitted to the NRC prior to implementation of the changes per 50.54(a)(4).

2 QA ELEMENTS AND IMPLEMENTATION

This section contains the 19 QA subsections within ANSI-15.8, Section 2. AAI commits to adherence and implementation of ANSI-15.8 for its planned activities and items, as described herein.

2.1 ORGANIZATION

This section describes the AAI organization for those portions whose personnel perform activities important to the QA Program. The structure is based on the guidance in ANSI-15.1-2007, "The Development of Technical Specifications for Research Reactors," Section 6, and ANSI-15.4-2016, "Selection and Training of Personnel for Research Reactors," Section 3, which refer to organization Levels 1 through 4. As shown in these guidance documents, the general responsibilities for each Level are shown as follows:

- Level 1: Individual responsible for the reactor facility license
- Level 2: Individual responsible for reactor facility operation
- Level 3: Individual responsible for day-to-day or shift operations (i.e., supervisor)
- Level 4: Operating staff

Figure 1 below shows the AAI organization, including the corresponding level of the position. The AAI internal organization levels represent the hierarchical chain of command. These levels do not represent gradations in job categories, experience, education, pay, etc. For example, a Level 4 staff member could be an entry-level operator with only a high school diploma or could be an experienced scientist with a post-doctoral degree. Additional details about the organization and staffing are called out as needed in the PSAR, policies, procedures, etc. AAI's Training and Qualification Program is described in the Section **Error! Reference source not found.**.

The following are fundamental to the AAI organization:

- Quality and safety shall be achieved and maintained by those who have been assigned responsibility for performing work.
- Quality and safety achievement shall be verified by people not directly performing the work. Verification activities shall not be hindered by cost or schedule pressure or interference.
- Persons responsible for ensuring that appropriate controls have been established and for verifying that activities have been correctly performed shall have sufficient authority, access to work areas, personnel, and freedom to do the following without the risk or threat of retaliation:
    - Identify problems
    - Initiate a time-out or stop work when an immediate threat to safety or quality is perceived
    - Communicate concerns, questions, problems, etc. with direct supervision and up through the chain of command to the CEO or COO to resolve such
    - Communicate concerns, questions, problems, etc. anonymously if uncomfortable going through the direct chain of command, via the Employee Concerns Program
    - Recommend corrective action
    - Have questions, concerns, or both adequately addressed before continuing work
    - Verify corrective action implementation

Key expectations and responsibilities for the positions shown in **Figure 1** are listed and described in the following sections.

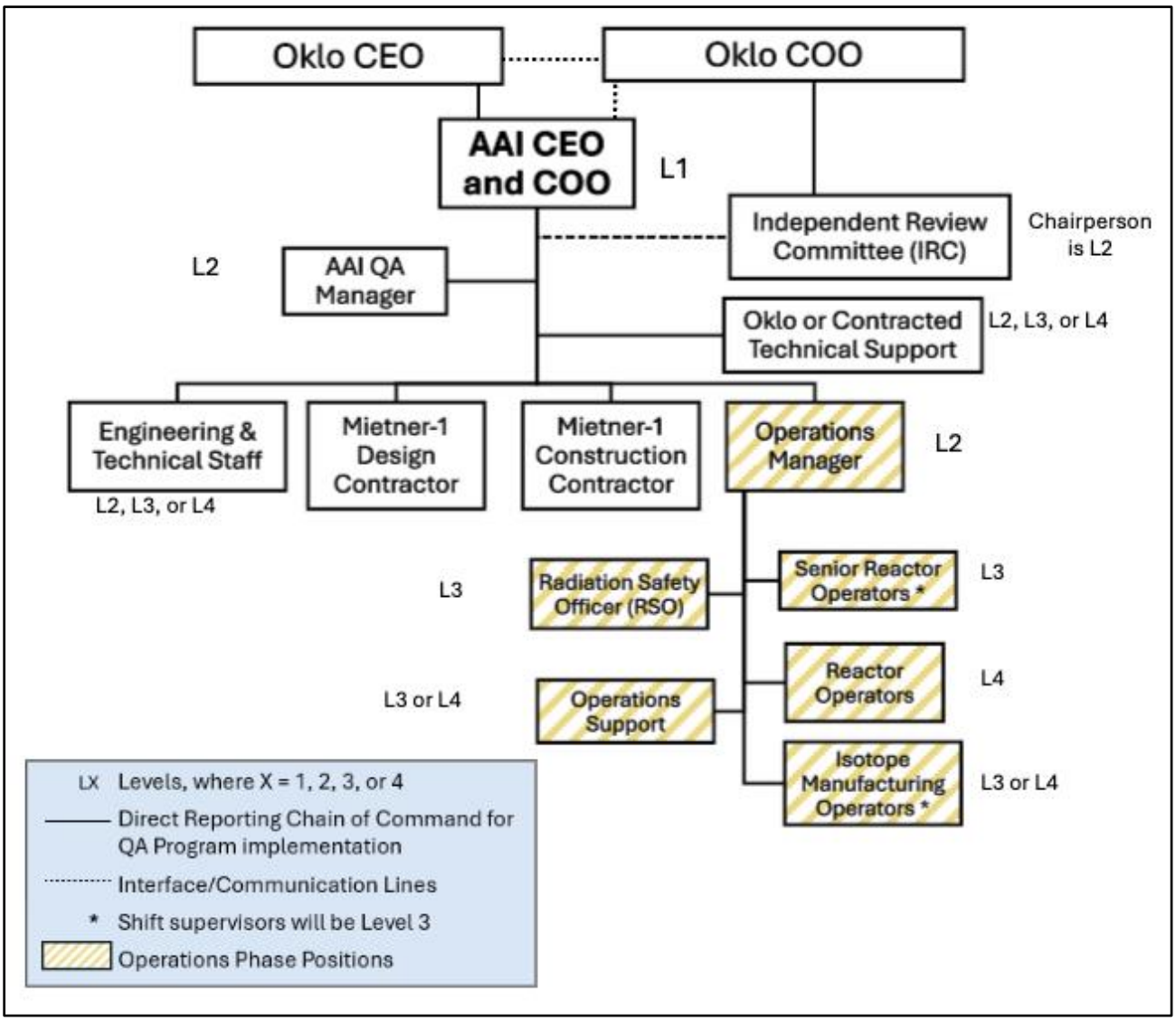

Figure 1: AAI Organization

2.1.1 Level 1—AAI Chief Executive Officer (CEO)

The AAI CEO is responsible for all aspects of the Meitner-1 facility. The CEO is also responsible for all technical and administrative support activities provided by AAI and its contractors. The CEO directs the AAI team in fulfillment of their responsibilities. The AAI CEO has overall responsibility for the Quality Assurance (QA) Program and delegates the necessary responsibility and authority to his direct reports to ensure quality is achieved and maintained by those who have been assigned the responsibility for performing the work. Quality achievement is verified by persons not directly performing the work.

The CEO is directly accountable to the CEO of AAI's parent company, Oklo, for AAI's performance in all aspects. The AAI CEO also interacts frequently with the Oklo Chief Operations Officer (COO). The CEO may obtain additional personnel resources from Oklo or from contractors to perform certain activities for AAI.

2.1.2 Level 1—AAI Chief Operating Officer (COO)

As the second senior-most, onsite authority, the COO collaborates with the AAI CEO for the safe operation of the facility, communications with Oklo senior management as well as NRC. In the absence of the CEO, the COO maintains oversight of the facility and coordinates operation and emergency activities with the facility's staff.

2.1.3 Level 2—QA Manager

The QA Manager is a Level 2 senior management position that reports directly to the CEO or designee. The QA Manager is responsible for the following:

- Preparing and maintaining the QAP description
- Verifying implementation of the QAP by AAI staff, and contractors when applicable
- Assuring compliance with regulatory requirements and procedures through audits, assessments and technical reviews
- Monitoring organization processes to ensure conformance to commitments and licensing requirements
- Developing and overseeing AAI's review, assessment, issues, corrective action, and reporting programs and processes
- Ensuring that vendors providing quality services, parts, and materials to AAI are meeting the requirements of this QAP as flowed down in contractual documents through vendor evaluations, surveillances, and audits
- Providing guidance and assistance to AAI staff in developing procedures and processes to implement the QAP within their respective areas of responsibility

The QA Manager has sufficient independence from other priorities to bring forward issues affecting safety and quality and makes judgments regarding quality in all areas necessary regarding AAI's activities. The QA Manager may make recommendations to management regarding improving the quality of work practices. The QA Manager has access to bring matters directly to the AAI CEO or COO, as well as the Oklo CEO or COO if the QA Manager disagrees with actions taken by the AAI organization and is unable to obtain a resolution.

2.1.4 Level 2—Independent Review Committee (IRC)

AAI shall utilize an IRC to perform independent reviews and assessments related to *quality-level* (see Glossary) structures, systems, and components and associated activities as directed by the CEO or COO to provide an independent, objective snapshot of AAI conformance and performance regarding the topic being reviewed or audited. These may include Safety Authorization Bases Reviews of changes to

the SSCs and applicable documents, including procedures, per 10 CFR 50.59, “Changes, tests and experiments.”

The IRC members shall be selected to collectively represent a broad spectrum of knowledge and expertise in appropriate NPUF technology. They can be selected from various organizations within the company (Oklo and AAI) or from external entities as needed. All selected members shall be approved by the AAI CEO or COO. The IRC Chairperson, members, and alternates may hold other positions within the Oklo or AAI organizations or an external organization. For duties associated with the IRC, the Chairperson shall report directly to the AAI CEO or COO and shall coordinate IRC member activities. IRC members shall report results of their reviews to the Chairperson but may elevate concerns or conflicts pertinent to their IRC duties to the AAI CEO or COO, then to the Oklo CEO or COO if unresolved within the IRC. IRC personnel shall recuse themselves from participation in reviews or assessments for activities which they supervised, performed, or have approval authority.

2.1.5 Engineering and Other Technical Staff

AAI has developed and implemented specific administrative procedures to guide engineering and other QAP-implementing activities.

AAI Engineering has been delegated responsibility and authority from the AAI CEO for construction contractor oversight during pre-construction and construction as defined in 10 CFR 50.10, and for eventual decommissioning.

2.1.6 Level 2—Meitner-1 Operations Manager

The operations organization for the Meitner-1 facility will be staffed in sufficient time to ensure the operations manager and staff are knowledgeable in the design and licensing bases for the facility, and are involved in preparation, validation, and reviews and approval of operating procedures. A more refined operations organization will be provided with the FSAR.

The Meitner-1 Operations Manager is a Level 2 senior management position that will report directly to the CEO or COO; responsibilities and authorities are delegated to this position accordingly. Primarily this individual will be responsible for all day-to-day facility operations, beginning with receipt of nuclear material onsite. They are responsible for and have authority to operate and maintain Meitner-1 facilities within the license conditions and technical specifications to ensure the safety of workers, the public, and the environment.

This organization element will be staffed with senior reactor operators, reactor operators, and isotope manufacturing operators—these positions require an NRC-approved training and qualification program, which will be further described in Section 12.10 of the Meitner-1 FSAR.

Additionally, a Level 3 supervisor that reports to the CEO or COO will oversee operations support services for all the Meitner-1 facilities, including

- radiation safety,
- waste management,
- general laboratory, industrial, and chemical safety,

- security, and
- emergency response.

2.1.7 External Design and Construction Contractors

AAI has selected external contractors for the final design and construction of the Meitner-1 facility. AAI QAP requirements are flowed down via contractual documents. Contractors report directly to the AAI CEO or designee for their respective contract performance. The CEO delegates oversight of and coordination with the external contractors for specific activities, such as an onsite construction field representative, to AAI Engineering.

A more refined organization chart for the Meitner-1 facility construction phase as defined in 10 CFR 50.10, “License required; limited work authorization” shall be developed and provided separately to the NRC prior to the start of construction.

2.2 QA PROGRAM

AAI is committed to adhering to the applicable requirements of ANSI-15.8 as its QA and conduct of operations standard as described herein for all items and activities that are safety-related and those important-to-safety. All items and activities that are safety-related and those important-to-safety shall be designated quality-level (Q-Level). Items and activities that are not safety-related or important-to-safety may also utilize the QAP when deemed appropriate by management responsible for such items and activities, such as for the protection of key assets and products or for the safety of workers, the public, or the environment.

2.2.1 Quality Level

The determination of whether an item or activity is subject to the QAP is based on engineering judgement and qualitative assessment of key attributes, utilizing a graded approach. Those items and activities that are subject to the QAP are specifically designated as Q-Level. Items and activities not covered are either designated as non-quality or not designated at all. AAI’s initial development and implementation of its QAP and implementing processes and procedures are based on the technical knowledge and experience of its senior management team—which is used to “bootstrap” subsequent activities.

An item or activity designated as Q-Level does not require the highest level of rigor for all QAP elements. The level of rigor for each QAP element will be applied as appropriate on a case-by-case basis to items and activities considering their importance to the criteria that define the graded approach. Generally, the documents associated with a Q-Level item (e.g., drawings, procedures that direct its use, specifications, etc.) will also be Q-Level. Documents called out to meet regulatory requirements, such as the Safety Analysis Report, QAP, and implementing procedures shall also be Q-Level. Q-Level controlled documents will be marked as such. The designation of an item as Q-Level shall be documented by AAI Engineering in the Master Equipment List (MEL) for items.

2.2.3 Criteria for Determining and Implementing Control Measures

AAI utilizes a standard process for assessing, planning, and performing work. Control measures for work involving hazardous materials and activities are established and implemented via utilization of the QA Program. Specific control measures are determined, implemented, and verified or validated prior to the start of hazardous activities. The priority for control measures, from highest choice to lowest choice, is

1. avoid the hazard if practicable,
2. engineering controls (e.g., use of gloveboxes, hot cells, and ventilation designs to ensure the most hazardous areas have the most negative pressure),
3. use of protective equipment, and
4. administrative controls.

2.2.4 Training and Qualification

AAI personnel shall be trained and qualified to ensure suitable proficiency is achieved and maintained. ANSI-15.4 was used in development of AAI's Training and Qualification Program, along with the systems approach to training as defined in 10 CFR 55.4, "Definitions." This program addresses selection and training of personnel in positions associated with safe operations of AAI facilities, at all levels of the organization, commensurate with the level of responsibility, which provides reasonable assurance that decisions and actions during all modes of operation will result in safe operations of the facility. The Training and Qualification Program addresses the roles described previously in Section 2.1. The program includes selection and training requirements for all key technical, managerial, and operational positions, from cradle to grave, including, but not limited to:

- Definition of specific job functions, tasks, responsibilities, skills, and physical and mental attributes necessary, and minimum requirements for academic education, job-related experience, training, qualification, licensing, and requalification
- Types of training, e.g., classroom, on-line or computer-based, hands-on or on-the-job-training, practical demonstrations, written and oral examinations, qualification and licensing, and requalification
- Content of training, e.g., purpose, learning objectives, fundamental knowledge, hazards, lessons learned, etc.
- Frequency of training, e.g., initial, continuing, or remedial
- Identification and selection of potential candidates, interviews, verification of credentials, and hiring
- Violations and penalties
- Health requirements
- Fitness for duty aspects
- Potential radiological, chemical, and industrial hazards, safety and health programs, monitoring, notifications, reporting, records, associated worker responsibilities and rights

2.3 DESIGN CONTROL

Design control is the process AAI uses to ensure that facility structures, systems, components, and software are designed, modified, and documented in a deliberate and traceable manner. This process requires that design inputs be clearly identified, changes be justified and reviewed, and verification be performed before items are relied upon in operation. In practice, design control means that no modification, whether permanent, temporary, or software-based, is implemented unless its basis is documented, independently verified, and records are preserved for the life of the item. Design control is conducted under the provisions of the QA Program. It establishes a defined process for controlling the design, design changes, and temporary modifications.

2.3.1 Design Requirements

Applicable design inputs, such as design bases, performance requirements, regulatory requirements, codes, and standards shall be identified and documented.

2.3.2 Design Process

Design interfaces shall be identified and controlled. Design efforts shall be coordinated by the design organization among the participating organizations. Interface controls will include the assignment of responsibility and establishment of implementing documents among the interfacing design organizations for the review, approval, release, distribution and revision of documents involving design interfaces.

The applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, shall be verified for each application. Known problems affecting the standardized or previously proven designs, and their effects on other features, shall be considered. Deviations from the established and documented design inputs, including the reasons for the changes, shall be documented and controlled.

The design organization is responsible to ensure that the final design shall (1) be documented in sufficient detail to trace back to the design input, and (2) identify assemblies, components, or both that are part of the item being designed.

When a computer design program is used to develop portions of the facility design or to analyze a design for acceptability, that program shall be fully documented, validated, and controlled to ensure the correctness of its output. When a design program must be developed, the program shall be controlled to ensure that it is fully documented and validated. Where changes to previously valid computer programs are made, documented revalidation shall be required for the change. Verification of design-unique computer programs shall include appropriate benchmark testing.

2.3.3 Design Verification

Independent design reviews shall be used to verify the adequacy of design by one or more of the following:

- Performance design reviews
- Use of alternate calculations

- Performance of qualification tests
- Comparison of similar proven systems

The responsible design organization shall identify and document the design verification method(s) used. Design verification will be performed by competent individuals or groups other than those who performed the design, but whom may be from the same organization. In all cases the design verification shall be completed prior to reliance upon the component, system, structure, or computer program to perform its function in operations.

If qualification testing is needed to verify a design, the qualification tests will be defined in a formal test plan that shall include appropriate acceptance criteria and shall demonstrate the adequacy of performance under conditions that simulate the most adverse design conditions. Test results will be documented and evaluated by the responsible design organization to ensure that test requirements have been met.

2.3.4 Design Documents and Records

Design documents and records, which provide evidence that the design and design verification process were performed, shall be collected, stored, and maintained for the life of safety-related items.

2.3.5 Commercial Grade Items

The use of commercial-grade equipment in important-to-safety applications shall be reviewed to ensure that it can adequately perform its intended function. Procedures shall be implemented to provide guidance on how to evaluate commercial grade items for suitability in applications covered by the QA Program. In some cases, a commercial grade item must meet requirements that are more restrictive than the supplier's published product description. When this occurs, the item shall be inspected to determine whether it can meet the stricter requirements and modified if necessary. After modification, testing shall be performed to verify compliance. Thereafter, the item shall be identified as different from the original commercial grade item, and documentation shall be created to clearly and traceably define the difference.

2.3.6 Change Control

Procedures shall be established to ensure that modifications to important-to-safety SSCs or computer codes shall be based on a defined "as-exists" design. Changes to verified designs shall be documented, justified, and subject to design control measures commensurate with those applied to the original design. The control measures shall include assurance that the design analyses for the structure, system, component, or computer code are still valid. Where a significant design change is necessary because of an incorrect design, the design process and verification procedure shall be reviewed and modified as necessary.

2.4 PROCUREMENT DOCUMENT CONTROL

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 AAI. Procurement documents at all procurement levels shall identify the documentation required to be submitted for

information, review, or approval by AAI. At each level of procurement, the procurement documents shall provide for access to the supplier's plant facilities and records, for inspection or assessment by AAI or a designated representative or other parties authorized by AAI.

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

2.5 PROCEDURES, INSTRUCTIONS, AND DRAWINGS

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.

2.6 DOCUMENT CONTROL

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 shall provide for

- identification of documents to be controlled and their distribution,
- assignment of responsibility for preparing, reviewing, approving, and issuing documents,
- review of documents for adequacy, completeness, and correctness prior to approval and issuance, and
- controls to prevent use of obsolete documents.

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.

2.7 CONTROL OF PURCHASED ITEMS AND SERVICES

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, assessment and examination of items or services for acceptance upon delivery or completion.

2.7.1 Supplier Selection

The selection of suppliers shall be based on evaluation of their capability to provide items or services in accordance with requirements of the procurement documents.

2.7.2 Work Control

AAI shall establish measures to control the supplier's performance to ensure that purchased items and services meet quality requirements. Controls may include test plans, review of supplier's submitted

documents, arrangements for source surveillance or inspection, and other technical and administrative interfaces with the supplier in accordance with procurement documents.

2.7.3 Verification Activities

The supplier shall be responsible for the quality of his product and shall verify and provide evidence of that quality. Supplier-generated documents shall be controlled, handled, and approved in accordance with established methods. Means shall be implemented to provide for the acquisition, processing, and recorded evaluation of technical, inspection and test data against acceptance criteria. Based on complexity of the product and importance to safety, AAI shall consider independently verifying the quality of a supplier's product through source surveillances, inspections, assessments or review of the supplier's nonconformances, dispositions, waivers and corrective actions.

2.7.4 Item or Service Acceptance

Acceptance of items or services provided to AAI shall require a system to provide assurances that purchased items and services conform to procurement specifications. Methods used to accept an item or related service from a supplier shall be a supplier Certificate of Conformance, source verification, receiving inspection, post-installation test or a combination thereof. Receiving inspection shall be performed in accordance with established procedures and instructions, to verify by objective evidence such features as proper configuration, to ensure proper identification and cleanliness, and to determine any shipping damage, fraud or counterfeit.

2.8 IDENTIFICATION AND CONTROL OF ITEMS

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. The identification items 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 using 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. 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.

2.9 CONTROL OF SPECIAL PROCESSES

Special processes are those in which results depend heavily on process control or personnel skill, and where the specified quality cannot be readily verified by inspection or non-destructive testing. These processes shall be conducted in accordance with approved instructions, procedures, drawings, travelers, or other suitable controls. AAI and its suppliers are responsible for complying with these controls. Applicable codes and standards, including acceptance criteria, shall be incorporated into the governing documents. Records shall be maintained for qualified personnel, processes, and equipment associated with special processes.

2.10 INSPECTIONS

Inspections to verify conformance of items and activities to requirements shall be planned, documented, and performed. The inspection program applies to procurement, construction, modification, and maintenance. In-process inspections shall be conducted when product quality cannot be verified by examining the completed item. Final inspections shall determine whether items conform to specified requirements.

Completed items shall be inspected for characteristics such as completeness, markings, calibration, adjustments, protection from damage, and any other features necessary to verify quality. Associated quality records shall be reviewed for adequacy and completeness. Only items that have passed required inspections and tests may be used, installed, or operated. Measuring and test equipment used in inspections shall be identified in the inspection documentation to ensure traceability of results.

Inspection results and acceptance decisions shall be documented and approved by authorized personnel. Inspections shall be performed by individuals independent of the work being inspected, although they may belong to the same organization. Inspectors shall be qualified for their assigned tasks. Formal training, including hands-on experience, shall be provided as necessary. Records of inspector qualifications shall be established and maintained by AAI. When inspection services are contracted, AAI shall review and approve inspector qualifications, as specified in the applicable procurement documents.

2.11 TEST CONTROL

Formal testing shall be required and planned 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 test procedures shall include provisions for assuring that all prerequisites for the given test are met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions. Testing shall include at least one of the following tests:

- Prototype qualification tests
- Proof tests prior to installation
- Functional tests

Test results shall be documented and evaluated by a responsible authority to ensure that test requirements have been satisfied prior to use with licensed material. 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.

2.12 CONTROL OF MEASURING AND TEST EQUIPMENT

Tools, gauges, instruments and other measuring and test equipment used for activities affecting quality shall be controlled and calibrated 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 measuring and test

equipment. Calibration and control measures are not required when normal commercial equipment provides adequate accuracy.

2.13 HANDLING, STORAGE, AND SHIPPING

Specific controls shall be established for handling, storage, shipping, cleaning, and preservation of materials and equipment to be used in packaging to prevent damage or deterioration. Special protective environments, such as inert gas atmosphere, and specific moisture and temperature levels shall be specified and provided for all items that require them. Items and activities important-to-safety shall be controlled in accordance with work, inspection and test instructions, drawings, specifications, shipping instructions, or other pertinent documents or procedures for conducting the activity.

2.14 INSPECTION, TEST, AND OPERATING STATUS

The status of inspections and tests shall be clearly identified on the item itself or in documents traceable to the item. This ensures that required inspections and tests are completed, and that items which have not successfully passed them are not inadvertently installed or operated.

2.15 CONTROL OF NONCONFORMING ITEMS AND SERVICES

Items that do not conform to requirements shall be controlled to prevent inadvertent installation or use. Control of nonconforming items shall provide for identification, documentation, evaluation, segregation from like conforming items when practical, disposition of nonconforming items, and notification to affected organizations. 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.

The disposition (use-as-is, reject, repair, or rework) of nonconforming items shall be identified and documented. Technical justification for the acceptability of a nonconforming item disposition "repair" or "use-as-is" shall be 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. 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.

2.16 CORRECTIVE ACTION

Conditions adverse to quality are items and activities that do not meet internal or external requirements or expectations and shall be identified promptly and corrected as soon as practical. The corrective actions are measures taken to rectify conditions adverse to quality and shall be performed in accordance with the design requirements unless those requirements were faulty. A condition significantly adverse to quality is any item or activity that does not meet requirements in an external permit or license and has caused, or could cause if uncorrected (1) failure of items and activities designed to prevent or mitigate failures, (2) an abnormal event or condition exceeding regulatory consequence limits for workers or the public, or (3) an environmental condition requiring remediation under Federal or State environmental regulations. In the case of a condition significantly adverse to

quality, the cause of the condition shall be investigated and corrective action taken to preclude recurrence. The identification of the condition significantly adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management.

2.17 QUALITY RECORDS

AAI's Records Management Procedure has been established to specify instructions for preparing, storing, completing, authenticating, uploading, retaining, accessing, and disposing of records. At a minimum, the following records shall be managed as QA records:

- Those which provide evidence that applicable QA requirements are met, e.g.: inspection and test results, results of QA reviews, QA procedures, engineering reviews and analyses in support of designs or changes and modifications, etc.
- Those which are required by applicable regulations, regulator guidance documents, codes, standards, licenses, and permits.
- Those not meeting criteria a) or b) above but are otherwise deemed appropriate by AAI management.

Records shall be

- protected from loss or damage during their preparation until completed,
- verified and authenticated for completeness and readability,
- uploaded to the AAI electronic records system,
- searchable and retrievable from the AAI electronic records system,
- stored to protect from loss or degradation for the required retention period, and
- dispositioned in accordance with requirements.

Records shall be retained for periods of time in accordance with applicable regulations, regulator guidance documents, codes, standards, licenses, and permits. Record retention periods are outlined in the Records Type List.

Some records shall be retained for the life of a particular item while it is installed in the plant or stored for future use, i.e., "Lifetime" records. Such records shall be classified in accordance with the following criteria:

- those which would be of value in demonstrating capability for safe operation,
- those which would be of value in maintaining, reworking, repairing, replacing, or modifying an item,
- those which would be of value in determining the cause or results of an accident or malfunction of a safety-related item,
- those which provide required baseline data for in-service inspections, or
- those which would be of value in planning for facility decommissioning.

Other records shall be retained for a shorter period as determined by the owner/operator and in accordance with the Records Type List.

Physical records shall be stored in locations that protect them from damage caused by moisture, temperature, or pest activity. Additional provisions shall be implemented for special processed records, such as radiographs, photographs, etc., which require distinct handling and storage to protect them from the unique environmental and physical threats associated with their media.

AAI shall maintain an electronic Records List which includes all records maintained and dispositioned by AAI, with various metadata fields that facilitate indexing and searching. Records management shall be routinely assessed. Records maintained by a supplier shall remain accessible to AAI.

2.18 ASSESSMENTS

AAI shall conduct periodic assessments of quality-affecting activities (i.e., those important-to-safety) during design, construction, modification and operations to evaluate the effectiveness of the as-implemented QAP. Assessments shall be performed in accordance with written procedures or checklists. Assessment results shall be documented and 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, implement corrective actions (including measures to prevent recurrence), and notify the assessing organization in writing of the actions taken or planned. Follow-up actions, including reaudit of deficient areas, shall be performed as appropriate. The assessing organization shall evaluate the adequacy of responses, as agreed upon during assessment planning.

Assessment records shall include assessment plans, reports, written replies, and documentation of corrective action completion.

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

2.19 EXPERIMENTAL EQUIPMENT

The QAP shall provide controls over the design, fabrication, installation, and modification of experimental equipment to the extent that these impact important-to-safety items. Additional information about experiments is provided in the Meitner-1 PSAR, Chapter 10.

3 CONDUCT OF OPERATIONS ELEMENTS AND IMPLEMENTATION

The following sections are organized to reflect the 15 subsections in Section 3, “Facility Operations,” of ANSI-15.8. While this Conduct of Operations portion of the QAP is not required until submittal of the FSAR for the Meitner-1 facility, AAI has developed it for submittal with the PSAR for Meitner-1, to replace the previously NRC-approved version (AAO-VIPR-20-QAPD(NP), Rev. 0-A) that was submitted as a topical report to the NRC.

This internally approved QAP is being implemented for AAI Meitner-1 preliminary design and other related administrative activities and may be used for other AAI projects or activities. It is intended to replace the previously NRC-approved QAP description upon NRC approval of the Meitner-1 PSAR.

3.1 ORGANIZATION

The organization described in Section **Error! Reference source not found.** describes the structure of the organization, along with the responsibilities and authorities for the key roles included in the organization.

3.2 QA PROGRAM

The QAP described in Section 2.2 shall be implemented where applicable during the operational phase for AAI facilities, in addition to these Conduct of Operations requirements in Section 3.

3.3 PERFORMANCE MONITORING

AAI shall establish key performance indicators (KPIs) for its planned operations to measure performance and update performance improvement goals. The KPIs shall be identified, controlled, and tracked, and results shall be routinely reported to staff and others as deemed appropriate by the CEO or COO.

Operations shall be routinely assessed by AAI management, either separately or as a group, with an emphasis on operations that influence the KPIs—these planned assessments shall be included in AAI's master assessment schedule. Each assessment shall be planned, conducted, and documented per AAI's assessment procedure. As necessary, remedial and preventive corrective actions shall be identified, assigned, completed, and verified. Effectiveness of preventive actions shall be evaluated in subsequent assessments. These processes are further described in Sections 2.16 and 2.18.

3.4 OPERATOR EXPERIENCE

AAI's Training and Qualification Program, based on ANSI-15.4, shall describe how operating experience is documented and tracked. Operators are responsible for maintaining experience in operating the reactor, which will be achieved by routine operation of the reactor and documentation of such operations. The operator training and qualification processes provide for keeping operators apprised of important current information, including lessons learned, that is related to facility operations and individual job assignments. Operator training and qualification activities are described in Sections 12.1.4 and 12.10 of the Meitner-1 PSAR.

3.5 OPERATING CONDITIONS

AAI shall utilize pre-operational checklists and pre-job briefings to verify readiness for operations. Logs of operations and equipment use, maintenance, and status shall be maintained. Applicable operating and maintenance information shall also be updated in the Master Equipment List. General instructions for checklists and log entries, including observation of abnormal situations, are included in each checklist or log. Creation and use of checklists and logs are directed in operating procedures.

3.6 OPERATIONAL AUTHORITY

AAI shall utilize formal shift turnover walk-throughs and checklists, as applicable, to ensure that incoming new shift personnel are cognizant of the prior shift operations and current facility and equipment status, including any abnormal conditions or events that occurred which might warrant increased observation. Turnover instructions for specific operations shall be addressed in the respective operating procedures.

3.7 CONTROL AREA

Operators shall be alert and attentive to the control console's indications, alarms, and other activities within the control area. Only persons specifically authorized or certified to operate the reactor or isotope manufacturing processing equipment shall operate control area equipment. Trainees may operate equipment only when they are directly supervised by certified operators. Control area activities and access should be limited to ensure that the operators are attentive to control responsibilities. Procedures shall be in place for quick placement of the reactor or process equipment in a safe configuration if evacuation of the control area or site is necessary.

3.8 ANCILLARY DUTIES

AAI addresses the key provisions of this element, i.e., that personnel shall not be assigned ancillary duties that could interfere with their ability to perform their primary duties to monitor and control their respective equipment and areas assigned, in respective operational procedures. This is a fundamental expectation for all personnel involved in operations, which is stressed in training topics as well.

3.9 EMERGENCY COMMUNICATIONS

AAI facilities and areas shall have capability for personnel to promptly notify other facility personnel and to reach AAI management, and emergency response personnel, when necessary, in the case of an abnormal event or condition. Additional details and instructions are provided in Section 12.7 and Appendix 12B of the PSAR for Meitner-1.

3.10 CONFIGURATION CONTROL

Configuration control of Q-Level items shall be maintained from acceptance for operations through retirement or final disposition of the items. The AAI Master Equipment List includes key configuration parameters for each item, when applicable. Pre-operational checklists shall be used to ensure the proper configuration of items prior to use, including necessary calibrations, other checks, completion of maintenance and proper post-maintenance configuration, and the use of current procedures and other documents, as applicable. Changes and modifications to, plus new Q-Level items and activities after the respective facility licenses are issued, shall be reviewed prior to implementation of changes or modifications to, or new items and activities.

3.11 LOCKOUTS AND TAGOUTS

Locks and tags shall be placed on equipment when, for safety or other special administrative reasons, controls are required. If there is potential for equipment damage or personnel injury during equipment

operation, maintenance, inspection, or modification activities, or from inadvertent activation of equipment, a documented facility lockout/tagout process shall be utilized. Personnel that work with equipment which requires lockout/tagout shall be trained accordingly.

AAI will assign a system engineer to each system or piece of equipment that requires lockout/tagout who shall be responsible for specifying the appropriate means for lockout/tagout of their respective assigned systems and equipment.

3.12 TEST AND INSPECTION

Tests and inspections shall be planned, performed, and documented for Q-Level system maintenance, design changes, or activities that involve dismantlement of components or systems to demonstrate that the component or system can perform its intended function. Individuals that conduct inspections and tests shall be trained accordingly. The Technical Authority is responsible for specifying appropriate maintenance, test, and inspection requirements, and overseeing design changes. Test and inspections schedules are documented and coordinated with affected parties.

3.13 OPERATING PROCEDURES

Approved, controlled administrative and operational procedures and other controlled documents shall be used to provide operating instructions for Q-Level items and activities.

Paper copies of all controlled documents pertaining to each AAI facility and its operations shall be maintained at the facility for reference use in the event the electronic document management system is unavailable during operations. Prior to the start of any Q-Level operation, the supervisor of the operation shall verify that the correct revision of the procedure(s) and any other documents to be used as called out by the specific operating procedure are available for use at the facility.

3.14 OPERATOR AID POSTINGS

Information that aids personnel in performing their duties may be developed, approved, and posted in operational facilities. Such postings shall be reviewed by the Technical Authority for the item or activity to ensure they are necessary and correct before approving their posting. Postings shall be checked periodically for continued applicability as part of routine facility inspections.

3.15 EQUIPMENT LABELING

Equipment shall be labeled to help facility personnel positively identify equipment they operate and maintain. Information on labels shall be consistent with the appropriate source material which may include facility procedures, valve lineup sheets, piping and instrument diagrams, or other applicable documents. Labels should be permanent, securely attached, readable, and have appropriate information. Equipment labeling shall be checked periodically as part of routine facility assessments and inspections.

4 APPLICABILITY TO EXISTING FACILITIES

Existing facilities shall not be required to prepare QA documentation for the as-built facility. However, all available as-built records should be collected and stored in accordance with the provision of Section 2.17.

All replacements, modifications, and changes to important-to-safety items shall meet the applicable QA requirements of this QA Program. The replacement, modification, or change to the facility shall meet or exceed the requirements of the original system or component. The replacement, modification, or change shall be documented and maintained to establish the current configuration of important-to-safety items at the facility.

5 DECOMMISSIONING

This section of the QAP will be updated for submission with the FSAR.

6 REFERENCES

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ANSI/ANS-15.4-2016. Reaffirmed 2021 "Selection and Training of Personnel for Research Reactors." Approved 4/19/2016, ANS.

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IAEA 05-00411: IAEA Safety Standards Series No. RS-G-1.9, "Categorization of Radioactive Sources," 2005. STI/PUB/1227, ISBN 92–0–103905–0, Vienna, Austria.

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NRC 2012: Final Interim Staff Guidance (ISG) Augmenting NUREG-1537 Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content," and NUREG-1537 Part 2, "…. Non-Power Reactors: Standard Review Plan and Acceptance Criteria," Chapter 19, Environmental Report. (2012)

NRC 2022: Letter, 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, NRC, to Thomas Eiden, AAI Chief Executive Officer, "Atomic Alchemy– Final Safety Evaluation for AAI Topical Report AAO-VIPR-20-QAPD-NP, Revision 0, "Versatile Isotope Production Reactor Quality Assurance Program Description (EIPD L-2022-LLL-0025)," dated 8/10/22.

NUREG-1537 Part 1: "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," 1996, NRC.

7 APPENDICES

Appendix A: Additional Requirements and Implementation for Activities Subject to 10 CFR Part 71

APPENDIX A: ADDITIONAL REQUIREMENTS AND IMPLEMENTATION FOR ACTIVITIES SUBJECT TO 10 CFR PART 71

Specific requirements are imposed in 10 CFR Part 71, "Packaging and Transportation of Radioactive Material," for licensees that package, prepare for shipment, and transport licensed material. They apply to any licensee authorized by specific or general license issued by the NRC to receive, possess, use, or transfer licensed material, if the licensee delivers that material to a carrier for transport, transports the material outside the site of usage as specified in the NRC license, or transports that material on public highways.

Per 10 CFR 71.17, "General license: NRC-approved package:"

> *(a) A general license is issued to any licensee of the Commission to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, certificate of compliance (CoC), or other approval has been issued by the NRC.*
>
> *(b) This general license applies only to a licensee who has a quality assurance program approved by the Commission as satisfying the provisions of subpart H of this part.*
>
> > *(c) Each licensee issued a general license under paragraph (a) of this section shall—*
> >
> > *(1) Maintain a copy of the Certificate of Compliance, or other approval of the package, and the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken before shipment;*
> >
> > *(2) Comply with the terms and conditions of the license, certificate, or other approval, as applicable, and the applicable requirements of subparts A, G, and H of this part; and*
> >
> > *(3) Submit in writing before the first use of the package to: ATTN: Document Control Desk, Director, Division of Fuel Management, Office of Nuclear Material Safety and Safeguards, using an appropriate method listed in 10 CFR 71.1(a), the licensee's name and license number and the package identification number specified in the package approval.*
>
> *(d) This general license applies only when the package approval authorizes use of the package under this general license.*

Certain exemptions from these requirements are allowed under 10 CFR 71.4, "Exemptions for low-level materials." Individuals performing activities within the scope of 10 CFR Part 71 shall review the scope and exemptions to determine applicability of the supplemental requirements specified herein.

The QA requirements of 10 CFR 71, Subpart H, establish a more rigorous and comprehensive framework compared to ANSI/ANS-15.8. While ANSI/ANS-15.8 outlines QA practices suitable for research reactor operations, 10 CFR 71, Subpart H, introduces enhanced regulatory requirements that strengthen independence, documentation, verification, and oversight of important-to-safety activities.

Key differences include:

- Independence of QA functions with authority to stop work when safety is at risk
- More prescriptive requirements for procurement, supplier oversight, and document control.
- Stricter controls on design verification, testing, inspection, and qualification of personnel.
- Formal processes for corrective action, root cause analysis, and recurrence prevention.
- Expanded requirements for QA records retention, audits, and management review.

In summary, 10 CFR 71, Subpart H, builds upon the ANSI/ANS-15.8 framework by mandating a regulatory-grade QA program aligned with NRC expectations, ensuring greater traceability, accountability, and compliance in activities affecting public health and safety.

The QA requirements of 10 CFR 71, Subpart H apply to design, procurement, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important-to-safety. Each licensee is responsible for satisfying the QA requirements that apply to its use of a packaging for the shipment of licensed material subject to this subpart.

Table 1 presents a comparison of the QA program elements required by 10 CFR 71, Subpart H, against those outlined in ANSI/ANS-15.8. The table highlights additional requirements imposed by 10 CFR 71, Subpart H, beyond the ANSI/ANS-15.8 standard, and describes how AAI implements the additional requirements for activities subject to 10 CFR Part 71. Elements with additional requirements for packaging and transportation items and activities are noted in **bold font** in the AAI Implementation column.

If AAI contracts work subject to these supplemental requirements, these requirements shall be flowed down to the contractor via procurement documents, and AAI shall verify that the contractor has an NRC-approved QA Program that includes the scope of the contracted work.

Table 1: AAI Implementation of 10 CFR 71, Subpart H

QA Program Element	ANSI/ANS-15.8 Requirement	Additional Requirements (10 CFR 71, Subpart H)	AAI Implementation
1. Organization	Defines responsibilities and authority for QA functions.	Explicit requirements for independence of QA functions from cost and schedule; clear authority to stop work affecting safety.	Adequately addressed in Section 2.1 b) and c) ii.

QA Program Element	ANSI/ANS-15.8 Requirement	Additional Requirements (10 CFR 71, Subpart H)	AAI Implementation
2. QA Program	Requires documented QA program for research reactor operations.	Program shall be approved, established, and maintained; requires periodic review and updates for compliance with NRC regulations.	Adequately addressed in Sections 1.3, 2.2, and 2.17. **This AAI QAP shall be approved by NRC prior to AAI's performance of activities subject to 10 CFR 71. If packaging and transportation services are contracted, then the supplier shall perform the work per their NRC-approved QAP that meets applicable requirements for the scope of work.**
3. Design Control	Design changes subject to QA review for safety implications.	Requires measures for verifying design adequacy (independent checks, design reviews, qualification tests).	AAI will not typically design its own packaging or components thereof. **If needed, AAI's design control procedures shall be assessed against the specific requirements in 10 CFR 71.108 to determine applicability and implementation. The applicable specific additional controls shall be imposed via inclusion in design documentation.**
4. Procurement Document Control	Purchases of materials, services, and components require specifications and QA requirements.	Explicitly requires inclusion of regulatory and technical requirements in procurement documents.	Adequately addressed in Section 2.4.
5. Instructions, Procedures, and Drawings	Operational activities conducted per approved procedures.	Requires detailed, documented procedures, including quantitative acceptance criteria.	Adequately addressed in Section 2.5.

QA Program Element	ANSI/ANS-15.8 Requirement	Additional Requirements (10 CFR 71, Subpart H)	AAI Implementation
6. Document Control	Procedures for controlling QA documents.	Stricter controls on review, approval, distribution, and revision to prevent use of obsolete documents.	Adequately addressed in Section 2.6.
7. Control of Purchased Material, Equipment, and Services	Receipt inspection required to verify conformance.	Adds supplier audits, source inspections, and verification activities beyond simple receipt checks.	Adequately addressed in Section 2.7.
8. Identification and Control of Materials, Parts, and Components	Requires traceability to ensure correct installation and use.	Emphasizes maintaining identification throughout fabrication, installation, and use.	Adequately addressed in Section 2.8.
9. Control of Special Processes	Special processes such as welding, NDE, and heat treating require qualified personnel.	Requires qualification of procedures and personnel to applicable codes and standards.	Adequately addressed in Section 2.9.
10. Inspection	Requires inspections to verify compliance with procedures.	Mandates independent inspection, inspector qualification, and inspection hold points.	Adequately addressed in Section 2.10.
11. Test Control	Testing of research reactor systems shall follow procedures.	Adds test program planning, documented results, and acceptance criteria before use in important-to-safety service.	Adequately addressed in Section 2.11.
12. Control of Measuring and Test Equipment	Calibration of instruments and test equipment required.	Requires periodic calibration traceable to national standards and documented status indication.	Adequately addressed in Section 2.12.

QA Program Element	ANSI/ANS-15.8 Requirement	Additional Requirements (10 CFR 71, Subpart H)	AAI Implementation
13. Handling, Storage, and Shipping	Requires measures to prevent damage or deterioration.	Adds more prescriptive requirements for packaging, shipping, and maintenance during storage.	Adequately addressed in Section 2.13.
14. Inspection, Test, and Operating Status	Requires indication of inspection, test completion on equipment.	More rigorous controls to ensure only accepted items are used; requires physical status indicators.	Adequately addressed in Section 2.14. **Additionally, for packaging, AAI shall establish measures to identify the operating status of components of the packaging, such as tagging valves and switches, to prevent inadvertent operation.**
15. Nonconforming Materials, Parts, or Components	Requires identification and segregation of nonconforming items.	Adds documented evaluation, disposition process, and notification requirements.	Adequately addressed in Section 2.15.
16. Corrective Action	Deficiencies shall be corrected.	Formal corrective action program with root cause analysis, recurrence prevention, and documentation.	Adequately addressed in Section 2.16.

QA Program Element	ANSI/ANS-15.8 Requirement	Additional Requirements (10 CFR 71, Subpart H)	AAI Implementation
17. QA Records	QA records maintained for essential activities.	Requires retention, classification, and retrievability of records; prescribes minimum retention times.	Adequately addressed in Section 2.17. **Additionally, packaging and transportation records subject to 10 CFR 71 shall include changes to the QAP as required by 10 CFR 71.106, the instructions, procedures, and drawings required by 10 CFR 71.111 to prescribe QA activities, and closely related specifications such as required qualifications of personnel, procedures, and equipment.**
18. Audits	Periodic audits of QA program elements required.	Requires scheduling, performance by qualified auditors, management review of results, and corrective actions.	Adequately addressed in Section 2.18.