

Eden Isotope Production Complex Construction Permit Application

Enclosure 6: Quality Assurance Program Description




Eden Radioisotopes, LLC

Quality Assurance Program Description for Design, Licensing and Construction of the Eden Isotope Production Complex

Document No. PG-NQ-02-01

Revision 2

Effective Date 12/19/2025

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Revision	Effective Date	Description of Revision
0	10/28/2020	Initial Issue
1	10/8/2021	<ul style="list-style-type: none"> Added a Policy Statement Document numbering change to align with Eden numbering Editorial and formatting changes Updated to read to ANSI 15.8 Updated language pointing to EUF, EPF, and EFTA to Radionuclide Processing Area as necessary Updated TOC to show 2nd level steps Changed Enclosures to Exhibits Added EPRI audit/assessment direction for pandemics Removed details in Section 4 as that will be part of operating license submittal.
2	12/19/2025	<ul style="list-style-type: none"> Updated title of document Updated Organization Chart and Position Descriptions Miscellaneous editorial and format changes

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POLICY STATEMENT

Eden Radioisotopes, LLC (Eden) shall design, procure, construct, operate and decommission the Eden Isotope Production Complex (Eden facility) in a manner that shall ensure the health and safety of the public and workers. These activities shall be performed in compliance with the requirements of the Code of Federal Regulations (CFR), the applicable U.S. Nuclear Regulatory Commission (NRC) Construction Permit and Facility Operating License, and applicable laws and regulations of the state of New Mexico and local governments.

The Eden Quality Assurance Program (QAP) consists of this Quality Assurance Program Description (QAPD) and the associated implementing documents. Together they provide for control of Eden activities that affect the quality of safety-related nuclear facility structures, systems, and components (SSCs) and include all planned and systematic activities necessary to provide adequate confidence that such SSCs shall perform satisfactorily in service. The QAPD may also be applied to certain equipment and activities that are not safety-related, but support safe facility operations, or where other NRC guidance references program requirements.

The QAPD is the top-level policy document that establishes the manner in which quality is to be achieved and presents Eden’s overall philosophy regarding achievement and assurance of quality. Implementing documents assign more detailed responsibilities and requirements and define the organizational interfaces involved in conducting activities within the scope of the QAP. Eden applies a graded approach to quality consistent with importance to safety and reliability. Eden management establishes overall expectations for obtaining the desired end result and remains accountable to ensure that the requirements of this QAPD are met. Compliance with the QAPD and implementing documents is mandatory for personnel directly or indirectly associated with the implementation of this QAPD.

Signed: 
 Carrie Freeman
 Chief Executive Officer

Date: 12/19/2025



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1.0 PURPOSE


Eden Radioisotopes, LLC (Eden) intends to submit applications to the U.S. Nuclear Regulatory Commission (NRC) seeking approval of licenses to construct and operate a facility for the sole purpose of producing urgently needed medical isotopes, which are in short supply around the globe and produced primarily in foreign countries. As a domestic medical isotope production facility, the Eden facility will enhance both national security and public health. The facility will produce Molybdenum-99 (Mo-99) through fission of uranium and separation of the Mo-99 from the uranium and other fission products (fission process). In addition to the production of Mo-99, the Eden facility shall have the capability of producing Iodine-131 and Xenon-133 through the fission process and will also produce other isotopes such as Lutetium-177 through neutron activation. The Eden facility will enable reliable, concurrent access to Mo-99 and Lu-177, which are essential for cancer diagnosis and treatment.

The Eden facility consists of a small, non-power, open pool reactor utilization facility, a separation processing hot cell production facility, a target fabrication facility, and a waste packaging, handling, and storage facility in addition to administrative and storage areas. The reactor utilization facility, the hot cell production facility and the waste packaging, handling and storage facility shall be licensed under Title 10 of the Code of Federal Regulations (10 CFR) Part 50 and the target fabrication facility shall be licensed at the operating license stage under 10 CFR Part 70.

2.0 INTRODUCTION

2.1 Overview

This Quality Assurance Program Description (QAPD) addresses the program requirements in 10 CFR 50.34(a)(7) for establishing and executing a Quality Assurance Program (QAP) specific to Eden. NRC Regulatory Guide 2.5, Revision 1, "Quality Assurance Program Requirements for Research and Test Reactors," and American National Standards Institute/American Nuclear Society standard (ANSI/ANS) 15.8-1995 (R2005;R2013), "Quality Assurance Program Requirements for Research Reactors," provide an acceptable method of complying with the quality assurance program requirements of 10 CFR 50.34(a)(7) for the 10 CFR Part 50 utilization facility.

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2.2 Scope

The QAPD describes the administrative and engineered controls for ensuring compliance with ANSI/ANS 15.8-1995 (R2005;R2013) requirements. These QAPD requirements are to be applied as applicable to siting, designing, purchasing, fabrication, handling, shipping, receiving, storing, cleaning, erecting, installing, repairing, maintaining, modifying, inspecting, construction and testing of the Eden facility. The QAPD shall be amended when appropriate as the facility proceeds to pre-operational activities, including training, operation, and decommissioning.

2.3 Application

The QAP applied by Eden to its activities shall be consistent with the importance of the activities to safety and reliability. Activities included in this QAP shall be, as a minimum, those affecting the quality and performance of safety-related Structures, Systems and Components (SSCs).


Eden shall apply a graded approach to those items and activities that could affect the quality of SSCs, and other components not specifically designated as safety-related. A Quality Level (QL) description (Exhibit A) is used to ensure quality requirements are understood and specified for each SSC. Applicable activities shall be performed in accordance with the graded approach.

Eden shall develop and implement the QAP beginning with the design, siting, and construction phase of the facility. This QAP shall focus on the development of appropriate controls to ensure the facility is properly designed and fabricated to meet Eden requirements. Most of these controls shall provide documentation that attests that the facility quality supports an operating license.

Following facility construction and commissioning, the focus of this quality program shifts to establishing those controls that ensure proper and reliable facility operations. 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 design, construction, and modifications would be implemented only as necessary. Quality assurance requirements for operations will be addressed in the facility operating license application. The QAP implementation strategy shall support the graded approach by considering the tangible and intangible attributes of replacement costs and schedule delays.


2.4 Definitions

Definitions are listed to provide uniform interpretation of terms and phrases used in this document. Definitions from ANSI/ANS 15.8-1995 (R2005;R2013) not applicable

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to Eden are not used in the QAPD. Additional definitions applicable to Eden activities are added to the QAPD.

Term	Definition
Commissioning	The process during which constructed reactor SSCs are made operational and verified to meet design requirements.
Corrective Action	Measures taken to rectify conditions adverse to quality, and where necessary, to prevent repetition.
Document	Any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results.
Engineered Safety Features (ESFs)	ESFs are active or passive features designed to mitigate the consequences of accidents and to keep radiological exposures to the public, the facility staff and the environment within acceptable values. ESFs are managed at the same level as Safety-Related Items.
Experiment	Any operation, hardware, or target (excluding devices such as detectors, foils, etc.), that is designed to investigate non-routine reactor characteristics or that is intended for irradiation within the pool, on or in a beamport or irradiation facility, and that is not rigidly secured to a core or shield structure so as to be a part of their design.
Licensed Operator	An individual licensed by the NRC to carry out the duties and responsibilities associated with the position of reactor operator or senior reactor operator.
Maintenance	Those activities necessary to maintain operability or restore systems to within specified design limits. Maintenance consists of repair, rework, replacement, adjustment, cleaning, or other actions necessary to maintain an item in or restore an item to an acceptable condition.
Management	Management means those persons within the Eden organization whose responsibility and authority includes the QAP. The levels of management are as described in American National Standard for Development of Technical Specifications for Research Reactors, ANSI/ANS-15.1-2007 (R2018).
Modification	A change in the physical design or functional characteristics of an SSC.

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Term	Definition
Non-power Reactor	See "research reactor".
Procedure	A document that specifies or describes how an activity is to be performed.
Quality	The degree to which an item or process meets or exceeds the user's requirements and expectations.
Quality Assurance	Those planned and systematic actions necessary to provide adequate confidence that the SSCs will perform satisfactorily in service.
Research Reactor	A device designed to support a self-sustaining neutron chain reaction for research, development, educational, training, or experimental purposes, and that may have provisions for the production of radioisotopes.
Safety-related Items	Those physical SSCs whose intended functions are to prevent accidents that could cause undue risk to the health and safety of workers and the public, or to the research reactor's programs; and to control or mitigate the consequences of such accidents.
Shall, should and may	The word "shall" is used to denote a requirement; the word "should" to denote a recommendation; and the word "may" to denote permission, neither a requirement nor a recommendation.

3.0 DESIGN, CONSTRUCTION, AND MODIFICATIONS

Eden provides requirements for establishing, managing, conducting, and assessing the program of controls over the design, construction, and modification of the Eden facility. This QAPD recognizes that described controls are integral to the management of the licensed activity and do not necessitate the establishment of a separate program. The QAP is established administratively by this QAPD and implemented by a series of implementing quality procedures, that are applicable to the specific sections of the QAPD and the scope of work activities.

3.1 Organization

Eden has established an organizational structure, functional responsibilities, levels of authority, and interfaces for establishing, executing, and verifying QAP implementation. The organizational structure includes internal and external functions for Eden, including interface responsibilities for multiple organizations that perform quality-related functions. Implementing documents assign more specific responsibilities and duties and define the organizational interfaces involved in

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conducting activities and duties within the scope of the QAP. Management considers the timing, extent, and effects of organizational structure changes. The Eden functional organization chart is provided in Exhibit B. Organization control measures, including a detailed organization chart, are provided in implementing procedures.

Eden’s organization shall evolve during the design, construction, and operation of the facility. Organization changes made as the project evolves from construction to operation shall be provided in future revisions to this QAPD.

The organizational structure and assignment of responsibilities shall be defined and documented such that:

- a) quality is achieved and maintained by those who have been assigned responsibility for performing work; and
- b) quality achievement is verified by persons not directly performing the work.

Eden staff responsible for ensuring that appropriate controls have been established, and for verifying that activities have been correctly performed, will have sufficient authority, access to work areas, and freedom to:

- a) identify problems;
- b) initiate, recommend, or provide corrective action; and
- c) ensure corrective action implementation.


All employees have the right and responsibility to stop work when they encounter an unsafe condition. Additionally, quality assurance and inspection personnel have the authority and the responsibility to stop work in process which is not being done in accordance with approved procedures or where safety-related SSCs quality may be jeopardized. This extends to off-site work performed by suppliers that furnish materials and services.

Independence shall be maintained between the organizations performing the work or service and oversight performed by the quality organization (i.e., quality assurance and quality control).

The Eden organizational structure includes the following:

Chief Executive Officer (CEO)

The CEO is responsible for the overall management and leadership of the company. The CEO is also responsible for all technical and administrative support activities provided by Eden and suppliers. The CEO provides direction to the Chief Operating Officer (COO) to fulfill the organization’s responsibilities. The CEO reports to the Board of Directors. The CEO has overall responsibility for the Eden QAP and delegates the necessary responsibility and authority to direct reports to ensure

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quality is achieved and maintained by those who have been assigned the responsibility for performing the work and quality achievement is verified by persons not directly performing work.

Chief Operating Officer (COO)

The COO reports to the CEO and is responsible for all operational aspects of the company including safety, quality, environmental stewardship, regulatory affairs, security, facility management, information technology, supply chain management and all engineering support activities, including design engineering and construction. The COO is responsible for all external operations of Eden, including supplier organizations. The COO is responsible for integrating all quality requirements as defined in the QAP across the internal and external organizations and reports to the CEO on all matters concerning quality.

The COO delegates sufficient responsibility and authority to his direct reports to ensure that appropriate controls have been established and for verifying that activities have been correctly performed. Authority is also provided to access necessary work areas and encourages managers and employees to identify problems, initiate, recommend, or provide corrective action and ensure corrective action implementation.

Chief Technology Officer (CTO)


The CTO is the design authority for the facility and reports to the COO. The CTO has functional areas of responsibility that include authority for engineering support activities, design engineering, engineering configuration management, engineering administration, modifications and their implementation, facility design configuration control, facility engineering, system engineering, system testing, construction and technical support. The CTO may establish subordinate Engineering Director roles as needed and delegate duties and responsibilities among them as deemed necessary to execute the CTO functions. The responsibilities and authority of such directors shall be specified in implementing procedures under the Eden QAP.

Licensing Director

The Licensing Director reports to the COO and is responsible for all nuclear related licensing and is also responsible for maintaining the safety analysis. The Licensing Director is responsible for the planning and execution of the licensing process for the design, construction, and operation of the facility. The Licensing Director is responsible for ensuring clear lines of communication between Eden and the NRC.

Quality Assurance Director (QAD)

The QAD reports to the COO for day-to-day functions and to the CEO for any quality issues which cannot be resolved at the COO level. The QAD is responsible for the

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development and independent verification of implementation of the Eden QAP. Responsibilities include assuring compliance to regulatory requirements and procedures through independent assessments and technical reviews; monitoring organizational processes to ensure conformance to commitments and licensing document requirements; ensuring that suppliers implement quality assurance programs that meet the Eden QAP; and that procured items and services meet the applicable quality and technical requirements defined in the applicable procurement documents. The QAD has sufficient independence from other priorities to bring forward issues affecting safety, quality, and makes judgements regarding quality in all areas necessary regarding Eden’s activities.

Procurement Director

The Procurement Director reports to the COO and is the primary point of contact between Eden and its suppliers. The Procurement Director is responsible for systematically planning and conducting procurement of items and services to conform with applicable quality and technical requirements. Responsibilities include soliciting and evaluating bids, supplier selection, preparation and approval of procurement documents that include appropriate acceptance criteria, receipt and acceptance of items and services, and supplier interface control.


Supplier organizations are responsible for their portion of the execution of the design, fabrication, procurement, construction, and testing of quality related SSCs for the facility as specified in Eden procurement documents. Such supplier organizations are responsible for identifying, implementing, and verifying flow-down of quality requirements as applicable. They participate in necessary assessments and inspections as specified in procurement documents.

Support Director

The Support Director reports to the COO and is responsible for planning and administering controlled documents and quality records. The Support Director prepares and implements procedures that provide for preparation, identification, approval, distribution, access, use, and revision of controlled documents and records, including their secure storage and retrieval.

Nuclear Engineering Director

The Nuclear Engineering Director reports to the CTO and is responsible for executing the Eden design control processes and procedures to establish the design, design criteria, design basis and functional and technical specifications for the Reactor and Hot Cell Facility SSCs. The Nuclear Engineering Director interfaces with the Licensing Director and Facility Engineering Director to ensure SSC designs incorporate applicable licensing and facility interface requirements.

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Facility Engineering Director

The Facility Engineering Director reports to the CTO and is responsible for all facility design and construction activities and is also responsible for establishing and maintaining the facilities configuration management system. The Facility Engineering Director is responsible for the planning and execution of the processes for the design, construction, and pre-operational testing of the facility.

3.2 Quality Assurance Program

As documented in this QAPD, Eden shall follow the requirements of ANSI/ANS-15.8-1995 (R2005;R2013) for establishing, implementing, and managing the QAP. The QAPD shall provide the requirements for establishing a QAP at the earliest time consistent with the project schedule for accomplishing quality-affecting activities. This shall include the managerial and administrative aspects of internal and external activities that affect quality of the Eden facility and programs.

The program shall provide for the appropriate and necessary indoctrination and training of personnel who perform activities that affect quality, to ensure that suitable proficiency is achieved and maintained.

3.3 Design Control

Eden shall prescribe, develop, document, and preserve the design of the SSCs of the Eden facility.

3.3.1 Design Requirements


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

3.3.2 Design Process

Design interfaces shall be identified and controlled, and the design efforts shall be coordinated among the participating organizations. 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 final design shall:

- a) be relatable to design input by documentation in sufficient detail to permit design traceability and verification; and

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- b) identify assemblies and/or components 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.

3.3.3 Design Verification

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


- a) the performance design reviews,
- b) the use of alternate calculations,
- c) the performance of qualification tests, or
- d) comparison of similar proven systems.

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

The need for or the use of qualification tests shall 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 shall be documented and evaluated by the responsible design organization to assure that test requirements have been met.

3.3.4 Design Documents and Records

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

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3.3.5 Commercial Grade Items

The use of commercial grade equipment in safety-related applications shall be reviewed to assure that this equipment can adequately perform its intended function. When a commercial grade item, prior to its installation, is modified or selected by special inspection and/or testing to requirements that are more restrictive than the supplier's published product description, the component part shall be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.

3.3.6 Change Control


Modifications to facility SCCs, 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. These measures shall include assurance that the design analyses for the SSCs, or computer code are still valid. Where a significant design change is necessary because of an incorrect design, the design process and verification procedure should be reviewed and modified as necessary.

3.4 Procurement Document Control

Procurement documents shall contain sufficient technical and quality requirements to ensure that the items or services satisfy the needs of the procurement document or specification. The procurement documents at all procurement levels shall identify the documentation required to be submitted for information, review, or approval by the purchaser. At each level of a procurement, the procurement documents shall provide for access to the supplier's plant facilities and records, for inspection or audit by the purchaser, the designated representative, or other parties authorized by the purchaser. The procurement documents shall include purchaser's requirements for reporting and approving disposition of supplier nonconformances associated with the items or services being procured. The procurement documents for safety-related items should prohibit the supply of substandard or counterfeit parts and materials.

3.5 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

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acceptance criteria for determining that activities have been satisfactorily accomplished.

3.6 Document Control

The preparation, issue, and change of documents which specify requirements that affect quality, or prescribe activities affecting quality, shall be controlled to assure 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; and
- c) review of documents for adequacy, completeness, and correctness prior to approval and issuance.

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.

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

3.7.1 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.

3.7.2 Work Control

Eden shall establish measures to control the supplier's performance as appropriate.

3.7.3 Verification Activities

The supplier shall be responsible for the quality of its 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, Eden shall consider independently

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verifying the quality of a supplier’s product through source surveillances, inspections, audits, or review of the supplier’s nonconformances, dispositions, waivers, and corrective actions.

3.7.4 Item or Service Acceptance


Eden shall establish a system to provide assurances that purchased items and services conform to procurement specifications. Eden’s 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 inspections shall be performed in accordance with established procedures and instructions, to verify by objective evidence such features as proper configuration, identification, and cleanliness, and to determine any shipping damage, fraud, or counterfeit.

3.8 Identification and Control of Items

When specified by codes, standards, or specifications that include specific 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. 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 has expired.

3.9 Control of Special Processes

Special processes include any in which the results are highly dependent on the control of the process or the skill of the personnel. These are also those processes in which the specified quality cannot be readily determined by inspection or non-destructive testing of the product. Special processes shall be controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means. It is the responsibility of the organization performing the special process to adhere to the approved procedures and processes. The requirements of applicable

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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.


3.10 Inspections

Inspections to verify conformance of an item or activity to requirements shall be planned, documented, and performed. The inspection program shall apply to procurement, construction, modification, maintenance, and experiment fabrication. 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 they 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 inspections. Records of inspection personnel's qualification shall be established and maintained by the Eden Support Director.

3.11 Test Control

Formal testing shall be required to verify conformance of designated SSCs to specified requirements, and demonstrate satisfactory performance for service, or to collect data in support of design or fabrication. 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 assure that test requirements have been satisfied. Computer programs used for operational control

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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.

3.12 Control of Measuring and Test Equipment

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.

3.13 Handling, Storage, and Shipping

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


3.14 Inspection, Test, and Operating Status

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

3.15 Control of Nonconforming Items and Services

Items that do not conform to requirements shall be controlled to prevent inadvertent installation or use. 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.

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 dispositioned "repair" or "use as-is" shall be documented. Nonconformance to design requirements of items dispositioned "use as-is" or

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“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 reexamined in accordance with applicable procedures and with the original acceptance criteria, unless the nonconforming item disposition has established alternate acceptance criteria.

3.16 Corrective Actions

Conditions adverse to quality shall be identified promptly and corrected as soon as practical. The corrective actions shall be in accordance with the design requirements unless those requirements were faulty. In the case of a significant condition adverse to quality, the cause of the condition shall be investigated and corrective action taken to preclude recurrence.


3.17 Quality Records

A records system or systems shall be established at the earliest practicable 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: inspection and test results, results of quality assurance reviews, quality assurance procedures, and engineering reviews and analyses in support of designs or changes and modifications.

Some records shall be maintained by or for Eden for the life of the particular item while it is installed in the plant 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 safety-related item;
- d) those which provide required baseline data for in-service inspections; or
- e) those which would be of value in planning for facility decommissioning.

Other records shall be retained for a shorter period as determined by Eden. The records shall be stored in a location or locations that prevent damage from moisture, temperature, and pestilence. Additional provisions shall be made for special processed records such as radiographs, photographs, negatives, microfilm,

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and magnetic media, to prevent damage from excessive light, stacking, electromagnetic fields, temperature, and humidity. Records maintained by a supplier shall be accessible to Eden.

3.18 Assessments

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

3.19 Experimental Equipment


The QAP shall provide controls over the design, fabrication, installation, and modification of experimental equipment to the extent that these impact safety-related items.

4.0 FACILITY OPERATIONS

The regulations in 10 CFR 50.34(b) requires that each applicant for a license to operate a facility include, in its final safety analysis report, a description of the managerial and administrative controls to be used to assure safe operation. How Eden intends to comply with this requirement shall be described in the operating license submittal.

5.0 APPLICABILITY TO EXISTING FACILITIES

The Eden facility shall be a newly constructed facility and this section does not apply.

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6.0 DECOMMISSIONING

Quality assurance provisions in compliance with 10 CFR 50.82(b) shall be submitted as a part of the decommissioning plan submittal.

7.0 REFERENCES

7.1	ANSI/ANS 15.8-1995 (R2005;R2013)	1995, American National Standards Institute/American Nuclear Society, ANSI/ANS 15.8-1995, "Quality Assurance Program Requirements for Research Reactors".
7.2	ANSI/ANS 15.4-2016 (R2021)	2016, American National Standards Institute/American Nuclear Society, ANSI/ANS 15.4-2016, "Selection and Training of Personnel for Research Reactors."
7.3	ANSI/ANS 15.1-2007 (R2018)	2007, American National Standards Institute/American Nuclear Society, ANSI/ANS 15.1-2007, "Development of Technical Specifications for Research Reactors".
7.6	NRC, NUREG 1537, 1996	1996, Nuclear Regulatory Commission, "NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content."
7.7	NRC, ISG NUREG-1537, 2012	2012, Nuclear Regulatory Commission, "Final Interim Staff Guidance Augmenting NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content."
7.8	NRC, RG 2.5, Rev. 1, 2010	2010, Regulatory Guide 2.5, Rev. 1, Nuclear Regulatory Commission, "Quality Assurance Program Requirements for Research and Test Reactors."

8.0 EXHIBITS

Exhibit A - Graded Approach to Quality

Exhibit B - Eden Functional Organizational Chart

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Exhibit A – Graded Approach to Quality

The graded approach to quality is a process by which the level of analysis, documentation, and actions necessary to comply with a requirement is commensurate with the safety significance. The graded approach permits the implementing organization to focus resources on those activities that are deemed, by qualitative analysis, to reduce the associated risks and hazards.

The activities and tasks are performed in accordance with approved implementing procedures.

QL-1 shall implement the full measure of this QAPD and shall be applied to safety-related SSCs, and safety-related activities.

QL-2 is applied to selected SSCs and activities intended to support or protect the safety-related activities.

QL-3 is applied to nonsafety-related SSCs and activities and does not support or protect the safety function of safety-related SSCs, or activities. However, the performance of QL-3 SSCs, and activities may be important to ensuring customer requirements are met, or operational or mission-related goals such as throughput, cost, or schedule are achieved. Controls, appropriate for the application, are applied to SSCs, and activities using elements of the Eden QAP for efficiency to avoid the creation and use of a separate or redundant management system. The controls on these SSCs and activities do not impact QL-1 or QL-2 SSCs and activities or the regulatory basis of the facility.

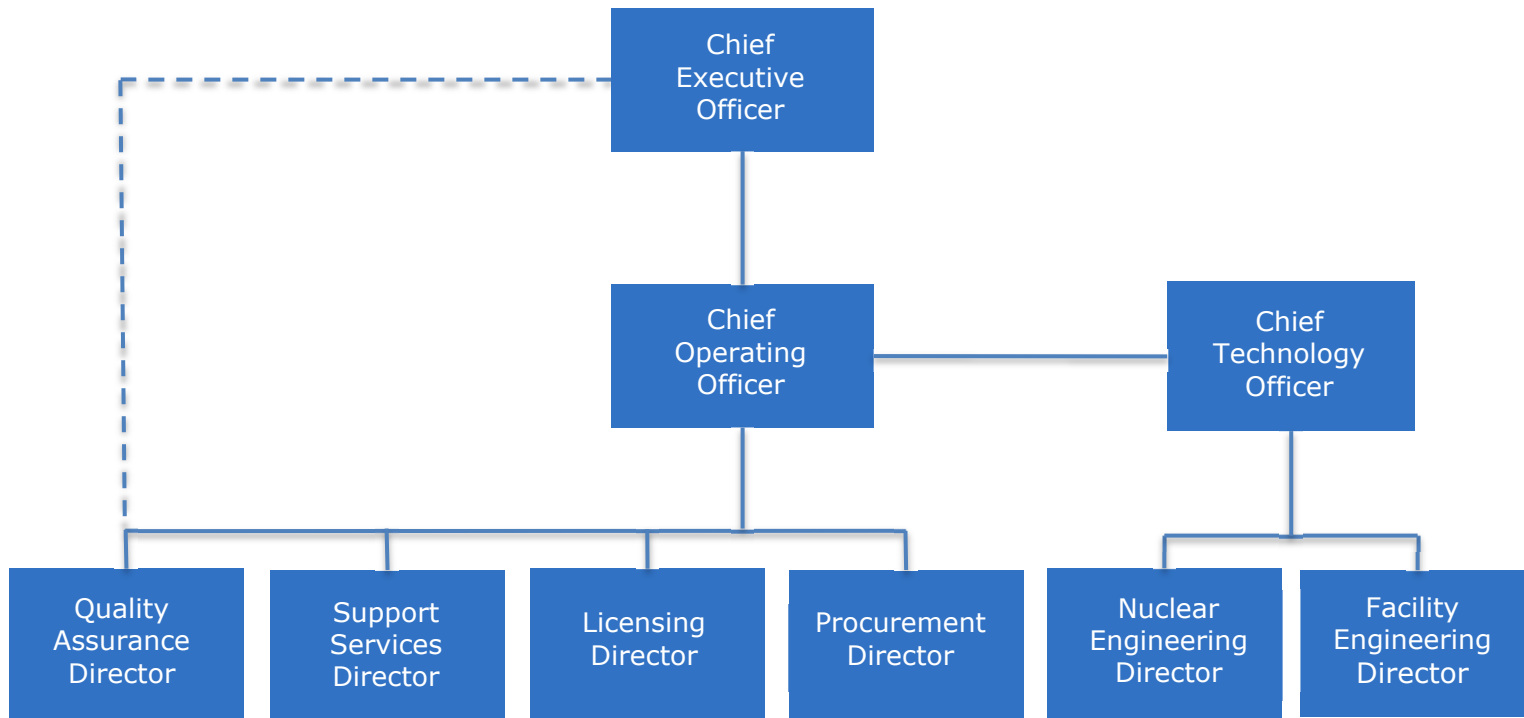


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Exhibit B – Eden Functional Organization Chart



Quality Assurance function has direct access to levels of management necessary to assure effective execution of the Quality Assurance Program irrespective of the organizational structure