



ARC/NRC-PM-011

January 6, 2026

US Nuclear Regulatory Commission ATTN: Document Control Desk
Washington, DC 20555 -0001

Subject: ARC Clean Technology, Inc. (ARC)
 Submittal of the ARC Quality Assurance Program Plan

This letter transmits the ARC-20 Project Quality Assurance Program Plan (QAPP). The QAPP sets forth the quality requirements for the ARC-20 Project. This Plan is the top tier in the hierarchy of documents that, when taken together, comprise the overall ARC-20 Project Quality Program. The Plan establishes the responsibilities and requirements for activities affecting quality and associated processes and procedures.

ARC is submitting this QAPP as a topical report, even though it presently is specifically applicable to the ARC-20 project conceptual and preliminary phase of the design, because it intends to apply it, suitably expanded, to all future phases of the project. Accordingly, ARC seeks the approval of the Nuclear Regulatory Commission for its use.

If you have any questions or need any additional information, please contact me at riotti@arc-cleantech.com or (732) 890-3602; alternatively Raymond Burski, ARC-100 Licensing Director, at rburski@arc-cleantech.com or (504) 909-6436.

Sincerely,

A handwritten signature in black ink that reads "Robert Iotti". The signature is written in a cursive style.

Robert Iotti
ARC-20 Project Manager

Enclosures:
ARC-20 Project Quality Assurance Program Plan (QAPP)

CC:
 Stephanie Devin-Gill Senior Project Manager, NRR/DANU/UAL1
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ARC Clean Technology, Inc.

ARC-20

Project Quality Assurance Program Plan (QAPP)

Topical Report - PUBLIC

QM-QA-005_Rev 2.0

Effective 08/27/2025

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Approved By: Robert Iotti
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ARC Clean Technology, Inc.

Notice

The ARC-20 Project Quality Assurance Program Plan (QAPP) sets forth the quality requirements for the ARC-20 Project. This Plan is the top tier in the hierarchy of documents that, when taken together, comprise the overall ARC-20 Project Quality Program. The Plan establishes the responsibilities and requirements for activities affecting quality and associated processes and procedures.

ARC Clean Technology, Inc. (ARC) is the organization responsible for ensuring that the ARC-20 Project Team either follows this Quality Plan or follows a Plan, the content of which meets the intent of this procedure. As such, this Plan is intended to be flexible to the extent that project team members need not modify their own quality programs, provide they are judged by ARC to meet the intent of the ARC-20 Project QAPP.

Document No. QM-QA-005 Revision 2	ARC Clean Technology, Inc. ARC-20 Project Quality Assurance Program Plan
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Revision History

Revision	Section(s) or Page(s)	Description of Change
0	All	Initial Issue
1	All	Revised from NQA-1 2008 Edition 2009 Addenda to NQA-1 2015 Edition
2	All	Revised legal name from ARC Clean Energy, LLC to ARC Clean Technology, Inc. All footers and pages 1 and 2.

ARC-20 PROJECT POLICY STATEMENT

Every individual performing quality-related nuclear work under the provisions of the ARC-20 Project shall comply with the expectations of this Policy Statement.

Commitment to Safety

- Management maintains and effectively communicates a priority commitment to safety, with clear expectations for the behaviors of all members of the organization regarding safe execution of work.
- All members of the organization embrace the commitment, understand the expectations, and are dedicated to sustaining a safety conscious work environment.
- All members of the organization act conservatively in safety-related matters by demonstrating a questioning attitude, challenging potentially unsafe conditions, and responding appropriately to safety concerns.

Problem Identification and Resolution

- All employees, including subcontractors, raise safety concerns, and conditions that are averse to quality, without fear of retaliation, through their avenue of choice, including the regulators of the countries in which the work is performed.
- Management encourages employees to raise safety concerns through their avenue of choice, including the regulators of the countries in which work is performed. Multiple avenues to raise safety concerns are provided.
- Management ensures timely and effective resolutions to safety concerns and issues consistent with the corrective action program. Management ensures resolutions are communicated to affected employees.
- Corrective actions are employed effectively to prevent recurrence.
- The organization embraces critical self-assessment for learning, growth, and improvement.
- Lessons learned from work performance and events from project work and external events are effectively used in improving future work plans and work performance.

Trust

- Commitments are met.
- Employees actively work to build an elevated level of trust within the organization.
- All project employees treat each other with dignity and respect.
- Management establishes and maintains effective communication.
- Management establishes regular face-to-face communication, with high visibility of managers and supervisors in the field.

Prevention of Retaliation

- No employees will engage in harassment, intimidation, retaliation, and discrimination (HIRD).
- Management takes timely action to prevent HIRD.
- When HIRD events occur, or are perceived to have occurred, managers take prompt and effective corrective action and mitigate any chilling effect on the organization.

Signed:



Irfan Ali, President, ARC Clean Technology, Inc.

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PURPOSE

This Project Quality Assurance Program Plan (QAPP) sets forth the quality requirements for the ARC-20 Project. This Plan is the top tier in the hierarchy of documents that, when taken together, comprise the overall ARC-20 Project Quality Program. The Plan establishes the responsibilities and requirements for activities affecting quality and associated processes and procedures. In this Plan, whenever ARC-20 is used, it denotes the specific project called the ARC-20, awarded to Advance Reactor Concept, INC. by the Department of Energy (DOE) under contract DE-NE0009223 whereas ARC-I00 is the name of the reactor, the conceptual, advanced conceptual and preliminary design of which is within the scope the ARC-20 project. In this Program Plan Document whenever ARC is used, it denotes ARC Clean Technology, INC, whereas the parent company of ARC is Advanced Reactor Concepts, INC. and is never abbreviated.

APPLICABILITY

The ARC-20 QAPP shall be applicable to all ARC-20 project personnel, who perform quality-related work activities that are governed by the requirements of this Plan. These associated work activities include but are not limited to engineering, design, research and development, and testing, to develop the deliverables defined in the contract between the DOE and ARC. While the ARC-20 Project is limited to the conceptual, advanced conceptual and preliminary design of all ARC-I00 facilities, [REDACTED]

For the ARC-20 Project related activities, conceptual and advanced conceptual design work in areas that are nuclear safety related (i.e., design documentation that is issued as Revision A, B, etc.) is expected to follow the guidelines described in this Plan. However, preliminary design work that is nuclear safety related (i.e., design documentation that is issued as Revision 0, 1, etc.) must adhere to these QAPP requirements. ARC-20 Project Team members may follow their established quality assurance programs, provided their content is judged by ARC to meet the intent of this QAPP.

This QAPP is written to comply with the ASME NQA-1 - 2015 Edition. Other standards are identified in appropriate sections of this Plan as invoked or modified. Section 21 provides a comparison between ASME NQA-1 and DOE QA requirements, so that as the ARC-20 project work proceeds, what modifications, if any, might be needed to satisfy the DOE.

1.0 ORGANIZATION

1.1 ARC-20 Project Organization

The organizational structure of the ARC-20 Project (shown in Figure 1.1-1) for activities affecting quality is identified in this section. This structure illustrates that Quality Management personnel have direct access to the ARC-20 Project Manager where appropriate action can be taken. Further, the Quality Assurance personnel within the supporting organizations will have an indirect reporting relationship with the ARC Quality Assurance Manager, should potential quality issues warrant escalation to the ARC-20 Project Manager. This reporting structure illustrates that those responsible for assuring that an appropriate quality assurance program has been established and those verifying activities affecting quality have the required authority, and organizational freedom, and access to work to perform the verification functions, including sufficient independence from cost and schedule considerations. These verification functions include: (1) identifying quality problems; (2) initiating, recommending, or providing solutions to quality problems; (3) verifying implementation of solutions; and (4) assuring that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency or unsatisfactory condition has occurred.

ARC-20 PROJECT QUALITY ASSURANCE PROGRAM PLAN

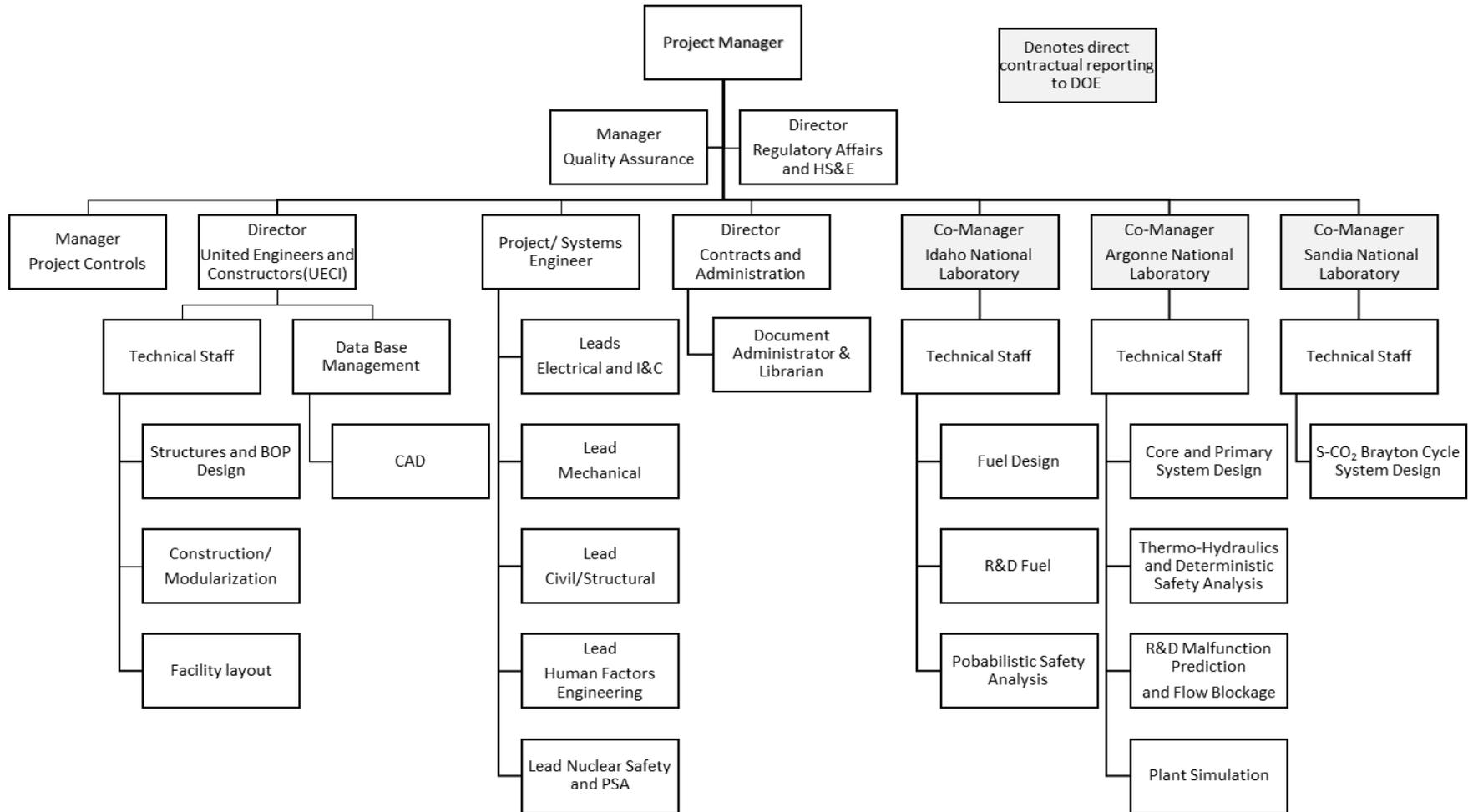


Figure 1.1-1 ARC-20 Project Organization

1.2 Responsibility

In general, at all management levels, it is the responsibility of management to create an atmosphere in the workplace where reporting and resolution of problems are encouraged at all levels.

Managers have the responsibility and authority to suspend work activities within their area of responsibility, which are not accomplished in compliance with applicable procedures and/or regulatory requirements.

Managers give full support to safety and quality, thereby assuring that all work performed under their cognizance will conform to and support the requirements of this Quality Assurance Program Plan.

1.2.1 Project Manager (PM)

The ARC-20 Project Manager (PM) provides single-point accountability for performance, compliance, and contractual matters regarding the work performed by ARC and its subcontractor/suppliers (hereinafter the ARC Project Team). The PM is responsible for the overall leadership, direction, organization, and administration of the ARC-20 project. The PM ensures that work for which the ARC Project Team is responsible for is performed effectively and efficiently, ensuring quality while protecting the safety of workers, the public, and the environment. The PM assigns responsibility and delegates authority to Co-Managers for establishing expectations for effective implementation of the quality assurance program and responsibilities for obtaining the desired result.

The PM is responsible for setting and implementing policies and priorities to ensure that the quality is achieved and maintained by those assigned responsibility for performing work, and quality achievement is verified by those not solely responsible for performing the work. In addition, the PM ensures that those responsible for verifying quality achievement have sufficient authority, direct access to management, organizational freedom, and access to the work to perform their function. Supporting the PM is a Project Team organization that is responsible for performing the work necessary to implement the contractually defined work scope, including providing related support.

1.2.2 Quality Assurance Manager

The Quality Assurance Manager has the functional authority, independence, and responsibility to ensure the effective implementation of and compliance with the quality assurance requirements. Consistent with this authority is the responsibility to document interpretations of those activities controlled by this program and the extent to which the requirements of this program apply.

The Quality Assurance Manager reports directly to the PM and is responsible to ensure that an appropriate QA program, the scope of which includes all the systems and activities that affect safety and quality, is established, and implemented in accordance with contractual requirements. The ARC-20 Project Quality Assurance Manager also has an indirect reporting relationship with the corporate Advanced Reactor Concept, INC. Director - Quality Assurance.

The Quality Assurance 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 project activities. If the Quality Assurance Manager disagrees with any actions taken by the ARC-20 organization and is unable to obtain a resolution, the Quality Assurance Manager shall inform the Advanced Reactor Concepts INC. Director, Quality Assurance who will determine the final disposition.

The Quality Assurance Manager reviews ARC-20 project activities with the goal of identifying areas where changes could lead to improvements in safety and/or quality. The Quality Assurance Manager has the authority to cross organizational lines to identify quality problems, to initiate, recommend, or provide solutions, control the disposition of non-conforming items, and to verify implementation.

The Quality Assurance Manager is responsible for the following major functions:

- Providing guidance and oversight for ARC-20 project based on applicable requirements 10 CFR 50 Appendix B, ASME NQA-1, and other contractual quality requirements.

- Supporting the conduct of independent audits and surveillance.
- Providing guidance on quality and safety to the ARC-20 project team.
- Performing evaluations and self-assessments on a planned and periodic basis to verify the QA program is being effectively implemented.
- Providing for the review and acceptance of contractor and vendor QA programs.
- Providing for the review of procedures and other quality-related documents.
- Providing a working interface and line of communication with other departments, appropriate industry representatives, and regulatory groups for quality assurance matters.
- Establishing indoctrination and training programs for QA personnel, and when appropriate Quality Control (QC) personnel.
- Providing input for quality assurance indoctrination of personnel outside of the quality assurance organization.
- Issuing periodic reports to appropriate management on the status of quality activities; and
- Notifying appropriate management of any significant conditions adverse to quality.

1.2.3 Co-Managers

The Co-Managers are the lead individuals of the National Laboratories in the ARC-20 Project Team and are responsible for the day-to-day operation of their areas of the project. More specifically for QA, the Co-Managers are responsible for:

- Implementation of the QA program in all the areas which apply to their scope of responsibility.
- Ensuring that the ARC-20 project tasks incorporate the appropriate quality assurance provisions into work processes.
- Contractual compliance.
- Developing and maintaining a comprehensive set of management controls.
- Interfacing and communicating with the other PM's direct reports, such as the Project/Systems Engineer and the Quality Assurance Manager in accomplishing facility design and R&D.
- Establishing and assuring adequate training and indoctrination for all personnel in the groups reporting to them; and
- Establishing management processes, including planning, scheduling, and providing resources for work.

1.2.4 Project/Systems Engineer

The Project/Systems Engineer is the final technical authority (design authority) and is responsible for the:

- Quality and accuracy of the engineering and design activities of ARC-20 Project.
- Any research and development programs and resulting activities; and
- Nuclear safety.

1.2.5 Managers (Discipline Managers, Project Managers, Program Managers)

[Note – This section is not applicable to the ARC-20 Project. Discipline Managers are covered under 1.2.7 Personnel, and the Program Manager is the same person as the Project Manager of 1.2.1]

1.2.6 Director Regulatory Affairs and HS&E

The Director of Regulatory Affairs is responsible for:

- Serving as the primary interface with the Nuclear Regulatory Commission.
- Establishing and implementing an effective Regulatory Engagement Plan.
- Addressing areas of potential licensing issues by causing development of topical reports to facilitate discussion of those areas with the NRC; and
- Ensuring that all submittals to the NRC achieve acceptable quality.

1.2.7 Personnel

All personnel performing work for the ARC-20 Project are responsible for:

- Achieving acceptable quality during the performance of work activities.
- Safely accomplishing work activities in accordance with instructions, procedures, and drawings or other appropriate methods.
- Stopping work activities and informing their supervisors when adherence to a procedure is not possible or may result in an unsafe condition; and
- Promptly identifying and reporting safety and quality deficiencies to their supervisors.

1.2.8 Document Administrator & Librarian

The Document Administrator and Librarian reports directly to the Director, Contracts and Administration and is responsible for overseeing document and record control operations, policies, procedures for the secure management and access of company information assets. Also, it establishes a security protocol for the access, storage, backup, maintenance, reproduction, and disposition of all documents.

1.3 Interface Control

Where ARC-20 project teams involve more than one organization or organizational unit, including subcontractors, in the execution of activities, the responsibility and authority of each organization needs to be clearly defined. The external interfaces between organizations and the internal interfaces between organizational units, and any changes, shall be documented, and interface responsibilities shall be defined and documented in accordance with Procedure SM-ENG-003, Interface Control.

1.4 Delegation of Work

The delegation of work between ARC personnel and other Project Team members/subcontractors is identified in applicable contracts, plans, work agreements, ordering agreements, subcontracts, and implementing procedures. In all cases of delegation, ARC retains overall responsibility for all work performed under its direction. All project activities affecting quality shall meet the requirements of this Quality Assurance Program Plan. Work of the other Project Team organizations may be performed under their ARC approved subcontractor QA programs.

ARC-20 Co-Managers have the authority to delegate tasks to other qualified individuals within their organization. The manager responsible retains responsibility for implementing the applicable requirements.

1.5 Authority to Stop Work

Quality assurance and inspection personnel have the authority and the responsibility to stop work in progress that is not being done in accordance with Procedure QM-QA-004, Stop Work Notice or where safety may be jeopardized.

2.0 **QUALITY ASSURANCE PROGRAM**

2.1 **Requirements**

The ARC-20 Project Team shall comply with this Plan and its implementing procedures. The implementing procedures invoked by the QAPP must also comply with specific contractual requirements. The QA Program shall be documented, implemented, and maintained as described in this QAPP, and implementing procedures and instructions. The ARC QA Program will:

- Identify the quality-affecting activities and items to which it applies.
- Provide control over activities affecting quality to an extent consistent with their importance.
- Include monitoring activities using acceptance criteria in a manner sufficient to provide assurance that the activities affecting quality are performed satisfactorily.
- Be established at the earliest time consistent with the schedule for accomplishing the activities.
- Provide for planning and accomplishment of activities affecting quality under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for a given activity are satisfied before starting work. The program shall provide any special controls, processes, test equipment, tools, and skills to attain the required quality and for verification of quality.
- Provide for indoctrination and training as necessary for personnel performing activities affecting quality to ensure that suitable proficiency is achieved and maintained; and
- Ensure that management implementing the QA program, or portions thereof, regularly assesses the adequacy and effectiveness of that part of the QA program for which they are responsible.

2.2 **Program Description**

This QAPP describes the overall content of the ARC-20 Project quality program. The Plan is implemented through ARC procedures and project specific procedures/instructions which comply with the requirements from NQA-1 2015 Edition. Not all supplementary requirements will apply to work performed by ARC. Deviations from requirements shall be specifically approved.

The QAPP describes applicable ARC procedures and project-specific instructions. The procedures and, if needed, project-specific instructions control the work to meet the ARC-20 Project Quality Program. The ARC Project Manager is responsible for developing and approving project-specific changes that might be required to this QA program, for example organization, roles, responsibilities, and applicable procedures. The QAPP also describes subcontractor control by requiring that Subcontractor QA program requirements be consistent with this QAPP.

2.3 **Quality Program Documentation**

The key documents of the QA Program are:

- *Quality Assurance Program Plan*- describes the QA program for ARC Clean Technology. It identifies the general requirements, organization, roles, responsibilities, and controls for implementing and maintaining the QA Program.
- *Procedures* – provides instructions and requirements for activities affecting quality for commonly applied processes that meet specific regulatory requirements. These procedures implement the requirements of the QAPP. These procedures are developed and owned by corporate functional management and may be directly used or modified to serve as project specific procedures.
- *Project Instructions* - provide project-specific procedural steps for project-specific activities that are not covered by the ARC procedures, or to accommodate a unique scope of work or DOE requirements not addressed by ARC procedures.

Implementation of the ARC QA Program is accomplished by application of the requirements of this manual through implementing procedures and as modified with project-specific instructions to meet contractual requirements. Collectively, those documents establish the QA program.

2.4 Qualification, Indoctrination, and Training of Personnel

2.4.1 General Requirements

This section provides requirements for the indoctrination and training of personnel performing or managing activities affecting quality.

Personnel to be indoctrinated or trained shall be identified. The extent of indoctrination and training shall be commensurate with the following:

- (a) The scope, complexity, and nature/importance of the activity; and
- (b) The education, experience, and proficiency of the person.

2.4.2 Indoctrination

Personnel performing or managing safety-related activities affecting quality shall receive indoctrination in the following subjects as they relate to a particular function:

- (a) General criteria, technical objectives, including applicable codes, standards, and company procedures.
- (b) Applicable quality assurance program elements; and
- (c) Job responsibilities and authority.

2.4.3 Training

Training shall be provided, if needed, to:

- (a) Achieve initial proficiency.
- (b) Maintain proficiency; and
- (c) Adapt to changes in technology, methods, or job responsibilities.

On-the-job training shall be used if direct, direct applications or experience is needed.

2.4.4 Training Delivery Methods

The training delivery method is determined based on the position, nature and complexity of the activity/task, frequency of performance, and the scope of change (regulatory, procedural, etc.) Delivery methods may include:

- (a) Formal instructions using approved training materials based on learning objectives and presented in an interactive setting such as classroom, on-site sessions, On-the-job (OJT), or using electronic methods (e.g., Teams Meetings, Teleconferences, Web Based or Computer Based Training; and
- (b) General instructions which use informal methods such as required reading, return-receipt brochures, briefings, seminars, or workshops.

2.4.5 Qualification Requirements:

- (a) Personnel performing audit activities are qualified in accordance with the applicable requirements, including specific provisions for education and experience. Qualification includes documenting capabilities through either written examinations or by proficiency demonstrations (or both) and documented evidence of maintenance of proficiency based on continued satisfactory performance and retraining if warranted. Personnel qualification records or certifications specifying the activities for which the individual is qualified, the basis for certification and the period for which the certification is valid shall be maintained.
- (b) ARC Technologies shall establish the qualifications and requirements for the use of technical

specialists to accomplish the auditing of quality assurance programs.

2.4.6 Qualification, Indoctrination, Training and Certification of Audit Personnel

Personnel selected for quality assurance auditing assignments shall have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited.

2.4.7 Auditors shall have, or be given, appropriate training or orientation to develop their competence for performing required audits. Competence of personnel for the performance of the various auditing functions shall be developed by one or more of the methods:

- (a) Orientation to provide a working knowledge and understanding of NQA-1, this QAPP, and the procedures for implementing audits and reporting results. The governing procedure for the ARC-20 Project audits is ARC procedure QM-QA-002, Conduct of Audits.

2.4.8 Training programs to provide general and specialized training in audit performance. General training shall include fundamentals, objectives, characteristics, organization, performance, and results of quality auditing. Specialized training shall include methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing out audit findings.

2.4.9 On-the-job training, guidance, and counseling under the direct supervision of a Lead Auditor. Such training includes planning, performing, reporting, and follow-up action involved in conducting audits.

2.4.10 Lead Auditors shall maintain their proficiency through one or more of the following:

- (a) Regular and active participation in the audit process.
- (b) Review and study of codes, standards, procedures, instructions, and other documents related to quality assurance program and program auditing; or
- (c) Participation in training program(s).

2.5 Auditor Qualification Records

Records shall be retained in accordance with ARC records requirements. Refer to Section 17.0, *Quality Assurance Records*

2.6 Records

Records of the implementation of indoctrination and training may take the form of:

- (a) Attendance sheets
- (b) Training logs
- (c) Personnel training records
- (d) Controlled document review acknowledgements

3.0 DESIGN CONTROL

3.1 General

This section establishes the control measures, requirements, and responsibilities necessary to assure that applicable design requirements including design bases, statutory or regulatory requirements, and applicable codes and standards are correctly translated into the different design activities of design input, design output, configuration and design changes, documentation and technical interfaces in a manner that is consistent with the graded approach.

3.2 Responsibilities

The Project/Systems Engineer is responsible for the implementation of design controls on the project. Project personnel are responsible for adhering to implementing procedures which address the requirements of this section.

Each project organization is responsible for reviewing design documents for inclusion of appropriate quality standards and requirements. Each responsible engineering discipline manager or designee is responsible for review of specifications, drawings, etc., to be prepared for items or for services performed to ensure inclusion of appropriate quality standards and requirements.

3.3 General Requirements

The design shall be defined, controlled, and verified. Applicable design inputs shall be appropriately specified on a timely basis and correctly translated into design documents. Design interfaces shall be identified and controlled. Design adequacy shall be verified by qualified people other than those who designed the item or computer program. Design changes shall be governed by control measures commensurate with those applied to the original design.

3.4 Design Input

Applicable design inputs, such as design bases, performance requirements, regulatory requirements, codes, and standards, shall be identified and documented, and their selection reviewed and approved by the responsible design organization.

The design input shall be specified and approved on a timely basis and to the level of detail necessary to permit the design activity to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes. Changes from approved design inputs, including the reason for the changes, shall be identified, approved, documented, and controlled.

To implement the requirements for Design Input, ARC Procedure SM-ENG-002, *Design Input*, shall be used, or equivalent procedures by the ARC-20 Project Team members.

3.5 Design Process

The discipline design organization responsible shall prescribe and document the design activities on a timely basis and to the level of detail necessary to permit the design process to be carried out in a correct manner, and to permit verification that the design meets requirements.

Design documents shall be adequate to support facility design, construction, and operation. Appropriate quality standards shall be identified and documented, and their selection reviewed and approved. Changes from specified quality standards, including the reasons for the changes, shall be identified, approved,

documented, and controlled. Design methods, materials, parts, equipment, and processes that are essential to the function of the structure, system, or component shall be selected and reviewed for suitability of application. Applicable information derived from experience, as set forth in reports or other documentation, shall be made available to cognizant design personnel.

The final design (approved design output documents and approved changes thereto) shall:

- (a) Be relatable to the design input by documentation in sufficient detail to permit design verification.
- (b) Specify required inspections and tests and include or reference appropriate acceptance criteria; and

When such an assembly or component part is a commercial grade item, the critical characteristics of the item shall be verified for acceptance and the acceptance criteria for those characteristics shall be defined. Critical characteristics to be verified are those which provide reasonable assurance that the item will perform its intended function.

If a commercial grade item that, 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.

Guidance on the design process that is employed in the ARC-20 project can be found in ARC procedure SM-ENG-AA, *Design Process Reference Document*, and the prescription for the design activities and their documentation will be done in accordance with ARC procedure SM-ENG-001, *Design Planning*, or equivalent procedures by the ARC-20 Project Team members.

3.5.1 Design Analyses

Design analyses shall be performed in accordance with Design Analysis and Calculations SM-ENG-007 in a planned, controlled, and documented manner. Design analysis documents shall be legible and, in a form, suitable for reproduction, filing, and retrieval. They shall be sufficiently detailed as to purpose, method, assumptions, design input, references, and units such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator.

Calculations shall be identifiable by subject (including the structure, system, or component to which the calculation applies), originator, reviewer, and date, or by other data such that the calculations are retrievable.

3.5.2 Use of Computer Programs

Computer programs may be utilized for design analysis without individual verification of the program for each application provided:

- (a) The computer program has been verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed; and
- (b) The encoded mathematical model has been shown to produce a valid solution to the physical problem associated with the application.

Computer software shall be controlled to ensure that changes are documented and approved by authorized personnel. Where changes to previously verified computer programs are made, verification shall be required for the change, including evaluation of the effects of these changes on (a) and (b) above.

3.5.3 Documentation of Design Analysis

Documentation of design analyses shall include:

- (a) Definition of the objective of the analyses.
- (b) Definition of design inputs and their sources.
- (c) Results of literature searches or other applicable background data.
- (d) Identification of assumptions and indication of those that must be verified as the design proceeds.
- (e) Identification of any computer calculation, including computer type, computer program (e.g.,

name), revision identification, inputs, outputs, evidence of or reference to computer program verification, and the bases (or reference to) supporting application of the computer program to the specific physical problem; and Review and approval.

ARC procedures SM-ENG-007, *Design Analyses and Calculations*, and SM-ENG-005, *Design Verification, Validation and Release*, or equivalent procedures by the ARC-20 Project Team members, shall be used for analyses, and for verification and validation of computer codes, respectively.

3.6 Design Verification

Design control measures shall be applied to verify the adequacy of design, such as by one or more of the following: the performance of design reviews, the use of alternate calculations, or the performance of qualification tests. Verification of computer programs for design work shall include appropriate testing. The design organization responsible shall identify and document the design verification method(s) used. The results of design verification shall be clearly documented with the identification of the verifier clearly indicated.

Design verification shall be performed by any competent individual(s) or group(s) other than those who performed the original design. However, the verifier may be from the same organization as the original designer(s). This verification may be performed by the originator's supervisor, provided the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design or, provided the supervisor is the only individual in the organization competent to perform the verification. cursory supervisory reviews do not satisfy the intent of this Part.

Verification shall be performed in a timely manner. Design verification, for the level of design accomplished, shall be performed prior to release for procurement, manufacture, construction, or release to another organization for use in other design activities, except in those cases where this timing cannot be met, such as when insufficient data exists. In those cases, the unverified portion of the design shall be identified and controlled. In all cases the design verification shall be completed prior to relying upon the component, system, structure, or computer program to perform its function.

If the design is modified to resolve verification findings, the modified design shall be verified prior to release or use.

Verification of design as detailed in the following subsections shall be per ARC Procedure SM-ENG-005, *Design Verification, Validation and Release*, or equivalent procedures by the ARC-20 Project Team members.

3.6.1 Extent of Design Verification

The extent of the design verification required is a function of the importance to safety, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proven designs. Where the design has been subjected to a verification process in accordance with this Part, the verification process need not be duplicated for identical designs. However, 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 standard or previously proven designs and their effects on other features shall be considered.

The original design and associated verification measures shall be adequately documented and referenced in the files of subsequent applications of the design. Where changes to previously verified designs have been made, design verification shall be required for the changes, including evaluation of the effects of those changes on the overall design and on any design analyses upon which the design is based that are affected by the change to previously verified design.

3.6.2 Methods of Design Verification

Acceptable verification methods include, but are not limited to, any one or a combination of the following: design reviews, alternate calculations, and qualification testing.

3.6.2.1 Design Reviews

Design reviews are critical reviews to provide assurance that the final design is correct and satisfactory. Where applicable, the following questions shall be addressed:

- (a) Were the design inputs correctly selected?
- (b) Are the assumptions necessary to perform the design activity adequately described and reasonable?
- (c) Where necessary, are the assumptions identified for subsequent re-verifications when the detailed design activities are completed?
- (d) Was an appropriate design method used?
- (e) Were the design inputs correctly incorporated into the design?
- (f) Is the design output reasonable compared to design inputs?
- (g) Are the necessary design input and verification requirements for interfacing organizations specified in the design documents or in supporting procedures or instructions?
- (h) Have suitable materials, parts, processes, and inspection and testing criteria been specified?

3.6.2.2 Alternate Calculations

Alternate calculations are calculations or analyses that are made with alternate methods to verify the correctness of the original calculations or analyses. Alternate calculations shall use alternate methods to verify the correctness of the original calculations or analyses. The appropriateness of assumptions; input data used; and the computer program, its associated hardware and system software; or other calculation methods used shall also be reviewed.

3.6.2.3 Qualification Tests

Where design adequacy is to be verified by qualification tests, the tests shall be identified, and the test configurations shall be clearly defined and documented. Testing shall demonstrate the adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions in which the item must perform satisfactorily shall be considered in determining the most adverse conditions. Where the test is intended to verify only specific design features, the other features of the design shall be verified by other means.

Test results shall be documented and evaluated by the responsible design organization to assure that test requirements have been met. If qualification testing indicates that modifications to the item are necessary to obtain acceptable performance, the modification shall be documented, and the item modified and retested or otherwise verified to assure satisfactory performance.

When tests are being performed on models or mockups, scaling laws shall be established and verified. The results of model test work shall be subject to error analysis, where applicable, prior to use in final design work.

3.7 Change Control

Changes to design inputs, preliminary or final designs, field changes, modifications to operating facilities, and nonconforming items dispositioned use-as-is or repair shall be justified and subject to design control measures commensurate with those applied to the original design. These measures shall include evaluation of effects of those changes on the overall design and on any analysis upon which the design is based and assurance that the design analyses for the structure, system, or component are still valid. The design shall include facility configurations that occur during operation, maintenance, test, surveillance, and inspection activities.

Changes shall be approved by the same affected groups or organizations which reviewed and approved of the original design documents, except where an organization which originally was responsible for approving a particular design document is no longer responsible. In that case, the Owner or his designee shall designate a new responsible organization, which could be the Owner's engineering organization. The designated organization shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design.

When a design change is approved other than by revision to the affected design documents, measures shall be established to incorporate the change into these documents, where such incorporation is appropriate. Where a significant design change is necessarily because of an incorrect design, the design process and verification procedure shall be reviewed and modified, as necessary.

Design changes shall be in conformance with ARC procedures SM-ENG-006, *Design Change Control*, or equivalent procedures by the ARC-20 Project Team members.

3.8 Configuration Management of Operation Facilities

Procedures implementing configuration management requirements shall be established and documented at the earliest practical time prior to facility operation. These procedures include the responsibilities and authority of organizations whose functions affect the configuration of the facility including activities such as operations, design, maintenance, construction, licensing, and procurement.

Configuration management requirements shall include measures to ensure changes that may affect the approved configuration are recognized and processed.

The configuration shall include, as applicable, characteristics derived from regulatory requirements and commitments, calculations and analyses, design inputs, installation and test requirements, supplier manuals and instructions, operating and maintenance requirements, and other applicable sources.

Interface controls shall include the integration of activities of organizations that can affect the approved configuration.

Documentation shall identify the design bases and the approved configuration for the approved modes of operation.

Measures shall be established and implemented to ensure that proposed changes to the configuration are evaluated for their conformance to the design bases.

The implementation sequence for approved configuration changes shall be reviewed to determine that the configuration conforms to the design bases.

The configuration of the facility shall be documented in drawings, specifications, procedures, and other documents that reflect the operational status of the facility. The process used to control the current revision and issuance of these documents shall consider the use of the document and the need for revision in support of operation.

3.9 Interface Control

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

Design information transmitted across interfaces shall be documented and controlled. Transmittals shall identify the status of the design information or documents provided and, where necessary, identify incomplete items which require further evaluation, review, or approval. Where it is necessary to initially transmit design information orally or by other informal means, the transmittal shall be confirmed promptly by a controlled document.

Interface control shall be in conformance with ARC procedure SM-ENG 003, *Design Interface*, or equivalent procedures by the ARC-20 Project Team members.

3.10 Design Records

ARC shall maintain records sufficiently to provide evidence that the design was properly accomplished. These records include the conceptual, preliminary, and final design output and any revisions of the preliminary and final design, as well as record of the important design steps (e.g., calculations, analyses, and computer programs) and the sources of input that support the final output.

Design records management shall be in conformance with ARC procedure QM-DM-002, *Records Management*, or equivalent procedures by the ARC-20 Project Team members.

4.0 PROCUREMENT DOCUMENT CONTROL

4.1 General

Applicable design bases and other requirements necessary to ensure adequate quality shall be included or referenced in documents for procurement of items and services. To the extent necessary, procurement documents shall require External Suppliers to have a quality assurance program consistent with the applicable industry standards.

4.2 Content of the Procurement Documents

Procurement documents issued at all tiers of procurement shall include provisions for the following, as deemed necessary by the Purchaser.

4.3 Scope of Work

Procurement documents shall include a statement of the scope of the scope of work to be performed by the supplier.

4.4 Technical Requirements

Technical requirements shall be specified in the procurement documents. These requirements shall be specified, as appropriate by reference to specific drawings, specifications, codes, standards, regulations, procedures, or instructions, including revisions thereto that describe the items or services to be furnished. The procurement documents shall identify appropriate test, inspection, and acceptance criteria for determining acceptability of the item or service.

4.5 Quality Assurance Program Requirements

Quality assurance program requirements shall be specified in the procurement documents. These requirements shall be consistent with the importance and/or complexity of the item or service being procured. The procurement documents shall require the Supplier to incorporate appropriate quality assurance program requirements in sub tier procurement documents.

4.6 Rights of Access

The procurement documents shall provide for access to the Supplier's and sub tier Supplier's facilities and records for surveillance, inspection, or audit by the Purchaser, its designated representative, and others authorized by the ARC Tech.

4.7 Documentation Requirements



4.8 Nonconformances

The procurement documents shall specify the Purchaser's requirements for the Supplier's reporting of nonconformances.

4.9 Procurement Document Review

A review of the procurement documents, and changes thereto, shall be made and documented prior to award to assure that documents transmitted to prospective Supplier(s) include appropriate provisions to assure that items or services will meet the specified requirements.

Technical or quality assurance program changes made as a result of bid evaluations or negotiations shall be incorporated into the procurement documents prior to their issuance to the Supplier.

Procurement document review shall be performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and intent of the procurement documents.

4.10 Procurement Document Changes

Procurement document changes affecting the technical or quality assurance program requirements shall be subject to the same degree of control as utilized in the preparation of the original documents.

5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

5.1 General

This section describes the requirements and responsibilities for the use of instructions, procedures, specifications, and drawings for activities affecting quality.

5.2 Responsibilities

The Project/Systems Engineer and Quality Assurance Manager are responsible for the identification of, and/or development of instructions, procedures, specifications, and drawings and for ensuring compliance with the requirements of this section for activities within their area(s) of authority.

The Quality Assurance Manager shall review project procedures and instructions governing activities affecting quality. The Quality Assurance Manager shall assure you that an independent review of specifications, drawings, etc., prepared for items, or for services performed on items, is conducted.

5.3 Requirements

Activities affecting quality and services shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings of a type appropriate to the circumstances.

These documents should include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished.

The activity shall be described to a level of detail commensurate with the complexity of the activity and the need to assure consistent and acceptable results. The need for, and level of detail in, written procedures or instructions shall be determined based upon complexity of the task, the significance of the item or activity, work environment, and worker proficiency and capability (education, training, experience).

6.0 Document Control

6.1 General

ARC documents shall be controlled to ensure that the correct documents are being employed in performance of work activities. ARC has established processes for document preparation, review, approval, issuance, and changes to documents that specify quality requirements or prescribe activities affecting quality, thereby ensuring that correct documents are being employed by personnel. These documents, including changes, are reviewed for administrative and technical adequacy, and approved for release by authorized personnel.

The implementing procedure established to provide controls over ARC generated documents, and those generated by the ARC-20 Project Team members is QM-DM-001, *Document Control*. ARC related procedures, such as SM-ENG-005, *Design Verification, Validation and Release*, and VM-SCM-002, *Control of Purchased Items and Services*, describes methods for preparing, reviewing, approving, and issuing documents, maintaining master lists of controlled documents, controlling document distribution, maintenance of record copies, correction and deletion of documents, and control and retention of supplier generated documents. Documents, including changes thereto, are reviewed for adequacy and approved for release by authorized personnel in accordance with the applicable ARC Procedures and the equivalent ones of the ARC-20 Project Team members.

6.2 Requirements

6.2.1 Types of Documents

Applicable documents shall be controlled in accordance with this section. Examples of ARC-20 documents to be controlled under the ARC QA program include project procedures, project deliverables, design requirement documents, basis of design documents, engineering specifications, drawings, calculations, procurement documents, supplier documents, etc.

6.2.2 Document Preparation, Review, Approval, and Issuance

The control system for document preparation, review, approval, and issuance shall be documented and include the following four elements.

1. Identification of documents to be controlled and their specified distributions for use at the appropriate location.
2. Identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents.
3. Review of documents for administrative and technical adequacy, completeness, and correctness prior to approval and issuance; and
4. A method to ensure the correct document is being used.

6.3 Documents Changes

6.3.1 Major Changes

Major changes to documents shall have the same review and approval as the original document. Changed documents shall be reviewed for administrative and technical adequacy, correctness, and completeness, prior to approval and issuance. Reviewing organizations shall have access to pertinent background data or information upon which to base their approval.

6.3.2 Minor Changes

Minor changes to documents, such as inconsequential editorial corrections, shall not require that the revised document receive the same review and approval as the original documents. To avoid omission of a required review, implementing procedures shall delineate the type of minor changes that do not require such a review and approval. The individuals who can authorize such a decision shall be clearly delineated.

6.4 Electronic Media and Electronic Signatures

Electronic version of controlled documents shall be maintained in a secure database (i.e., cloud, visual vault) as described below:

6.4.1 Electronic Database

An electronic database of commonly used documents will be maintained per this QAPP.

Maintenance of the electronic database is the responsibility of the Quality (Company) as follows:

- Maintain the database structure to allow secure storage and easy retrieval of specified electronic documents.
- The database will ensure a level of security to allow only approved, authorized personnel to add new documents and modify or delete existing documents.
- Require PDF or an equivalent format to reduce the chance of unauthorized changes to documents.

Authorized personnel will have access to the electronic database as appropriate for their job function.

Access is controlled by:

- o Individual security user ID & password required.
- o Access only users are not allowed to add, modify, or delete controlled documents.
- o Authorized users can add documents to the database and modify or delete controlled documents as appropriate for their level of authorization.

6.4.2 Contents of Electronic Database

Electronic documents will be in the following formats:

- Adobe PDF
- Protected Microsoft Office Documents
- Visual Vault Formats
- Other, with appropriate security

6.5 Electronic Signatures

Electronic signatures shall be either Visual Vault electronic signatures, Adobe Sign, Adobe e-signatures, or other as approved by the Directors of Engineering and Quality. Electronic signatures utilize the username/password combination that is created by the System Administrator for each employee. Electronic signatures can be used for all internal documents, including those submitted to clients.



6.7 Maintenance of Hard Copies

The signed hard copies of controlled electronic documents are not required to be maintained with exception of the QA Manual, QA implementing procedures, the Engineering Manual and other documents as determined appropriate by the Director of Quality Assurance. The signed hard copies of other documents can be maintained for convenience.

7.0 CONTROL OF PURCHASED ITEMS AND SERVICES

7.1 General

The procurement of items and services shall be controlled to ensure conformance with specified requirements. Such control shall provide for the following as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by the Supplier, source inspection, audit, and examination of items or services upon delivery or completion.

7.2 Supplier Evaluations and Selection

Prior to the award of a contract, the Purchaser shall evaluate the Supplier's capability to provide items or services in accordance with the requirements of the procurement documents. Supplier evaluation and selection and the results therefrom shall be documented and shall include one or more of the following:

- a. Supplier's history of providing an identical or similar product that performs satisfactorily in actual use. The Supplier's history shall reflect current capability.
- b. Supplier's current quality records supported by documented qualitative and quantitative information that can be objectively evaluated.
- c. Supplier's technical and quality capability as determined by a direct evaluation of the facilities, personnel, and the implementation of the Supplier's quality assurance program.

7.3 Bid Evaluations

Bids are solicited; the bid evaluation shall include a determination of the Supplier's capability to conform to the technical and quality assurance requirements. Prior to the award of the contract, the Purchaser shall resolve or obtain commitments to resolve unacceptable technical and quality assurance conditions resulting from the bid evaluation.

7.4 Control of Supplier Generated Documents

Controls shall be implemented to ensure that the submittal and evaluation of Supplier-generated documents and changes are accomplished in accordance with the procurement document requirements. These controls shall provide for the acquisition, processing, and recorded evaluation of the quality assurance, technical, inspection, and test documentation or data against acceptance criteria.

7.5 Acceptance of Items or Services

Prior to offering the item or service for acceptance, the Supplier shall verify that the item or service being furnished complies with the procurement requirements. The extent of the verification activities by the Purchaser shall be a function of the relative importance, complexity, and quantity of the item or services provided and the Supplier's quality performance. Where required by code, regulation, or contract requirement, documentary evidence that items conform to procurement requirements shall be available at the nuclear facility site prior to installation or use.

7.6 Methods of Acceptance

7.7 Certificate of Conformance

When a Certificate of Conformance is used, the minimum requirement shall be met:

- a) The certificate shall identify the purchased material or equipment, such as by the purchase order number.
- b) The certificate shall identify the specific procurement requirements met by the purchased material or

equipment, such as codes, standards, and other specifications. This may be accomplished by including a list of the specific requirements or by providing, on-site, with a copy of the purchase order and the procurement specifications or drawings, together with a suitable certificate. The procurement requirements identified shall include any approved changes, waivers, or deviations applicable to the subject material or equipment.

- c) The certificate shall identify any procurement requirements that have not been met, together with an explanation and the means for resolving the nonconformances.
- d) The certificate shall be signed or otherwise authenticated by a person who is responsible for this quality assurance function and whose function and position are described in the Purchaser's or Supplier's quality assurance program.
- e) The certification system, including the procedures to be followed in filling out a certificate and the administrative procedures for review and approval of the certificates, shall be described in the Purchaser's or Supplier's quality assurance program.
- f) Means shall be provided to verify the validity of Supplier certificates and the effectiveness of the certification system, such as during the performance of audits of the Supplier or independent inspection or test of the items. Such verification shall be conducted by the Purchaser at intervals commensurate with the Supplier's past quality performance.

7.8 Source Verification

When source verification is used, it shall be performed at intervals consistent with the importance and complexity of the item or service, and shall include monitoring, witnessing, or observing selected activities. Source verification shall be implemented in accordance with plans to perform inspections, examinations, or tests at predetermined points. Upon Purchaser acceptance of source verification, documented evidence of acceptance shall be furnished to the receiving destination of the item, to the Purchaser, and to the Supplier.

7.9 Receiving Inspection

When applicable, when receiving an inspection is used, purchased items shall be inspected as necessary to verify conformance to specified requirements, considering source verification and audit activities and the demonstrated quality performance of the Supplier. Receiving inspection shall verify by objective evidence such features as

- 1) configuration
- 2) identification
- 3) dimensional, physical, and other characteristics
- 4) freedom from shipping damage
- 5) cleanliness

Receiving inspection shall be coordinated with review of Supplier documentation when procurement documents require such documentation to be furnished prior to receiving inspection.

7.10 Post Installation Testing

When post installation testing is used, post installation test requirements and acceptance documentation shall be mutually established by the Purchaser and Supplier

7.11 Acceptance of Services Only

In cases involving procurement of services only, such as third-party inspection; engineering and consulting services; auditing; and installation, repair, overhaul, or maintenance work, ARC-20 personnel shall accept the service by any or all the following methods:

- 1) technical verification of data produced.
- 2) surveillance and/or audit of the activity.
- 3) review of objective evidence for conformance to the procurement of document requirements.

7.12 Control of Nonconformance

Methods for control and disposition of Supplier nonconformances for items and services that do not meet procurement document requirements shall include:

- a) evaluation of nonconforming items.

- b) submitting nonconformance notice to Purchaser by Supplier as directed by the Purchaser. These submittals shall include Supplier-recommended disposition (e.g., use-as-is or repair) and technical justification. Nonconformances to the procurement requirements or Purchaser-approved documents, which consist of one or more of the following, shall be submitted to the Purchaser for approval of the recommended disposition:
- 1) Technical or material requirement is violated.
 - 2) requirement in Supplier documents, which has been approved by the Purchaser, is violated.
 - 3) nonconformance cannot be corrected by continuation of the original manufacturing process or by rework.

7.13 Commercial Grade Items and Services

When commercial grade items or services are utilized, the requirements of Part II, Subpart 2.14, Quality Assurance Requirements for Commercial Grade Items and Services, shall apply and are an acceptable alternative to sections 7.3 thru 7.12, except that Supplier evaluation and selection, where determined necessary by ARC-20 personnel, shall be in accordance with section 7.2 of this Requirement.

7.14 Records

Records shall be established and maintained to indicate the performance of the following functions:

- 1) supplier evaluation and selection
- 2) acceptance of items or services
- 3) supplier nonconformances to procurement document requirements, including their evaluation and disposition.

8.0 IDENTIFICATION AND CONTROL OF ITEMS

[REDACTED]

9.0 CONTROL OF PROCESSES

[REDACTED]

10.0 INSPECTION

[REDACTED]

11.0 TEST CONTROL

11.1 General

Tests ^{Note} required to verify conformance of an item or computer program to specified requirements and to demonstrate satisfactory performance for service or continued acceptability of items in service shall be planned and executed. Characteristics to be tested and test methods to be employed shall be specified. Test results shall be documented and their conformance with acceptance criteria shall be evaluated.

Tests required to collect data, such as for siting or design input, shall be planned, executed, documented, and evaluated.

Note Except for computer programs verification and validation, as outlines below, for the ARC-20 project, it is expected that no testing will be required. However, should input data to the design justify some testing at the National Laboratories, the requirements of this section would apply.

11.2 Requirements

Test requirements and acceptance criteria shall be provided or approved by ARC-20 design personnel responsible for the design of the item to be tested unless otherwise designated.

Required tests (other than for computer programs) including, as appropriate, prototype qualification tests, production tests, proof tests prior to installation, construction tests, pre-operational tests, and operational tests shall be controlled. Computer program tests including, as appropriate, software design verification, factory acceptance tests, and in-use tests shall be controlled.

Required tests shall be controlled under appropriate environmental conditions using the tools and equipment necessary to conduct the test in a manner to fulfill test requirements and acceptance criteria. The tests performed shall obtain the necessary data with sufficient accuracy for evaluation and acceptance.

Test requirements and acceptance criteria shall be based upon specified requirements contained in applicable design or other pertinent technical documents that provide approved requirements.

If temporary changes to the approved configuration of a facility are required for testing purposes, approval by the design authority is required prior to performing the test.

Test requirements and acceptance criteria for computer programs shall be provided by the organization responsible for the use of the computer program and shall include the following, as applicable:

- (a) Software design verification testing shall demonstrate the capability of the computer program(s) to provide valid results for test problems encompassing the range of documented permitted usage.
- (b) Computer program acceptance testing shall consist of the process of exercising or evaluating a system or system component by manual or automated means to ensure that it satisfies the specified requirements and to identify differences between expected and actual results in the operating environment.
- (c) In-use computer programs testing shall demonstrate required performance over the range of operation of the controlled function or process.

11.3 Test Procedures

Tests procedures shall include or reference the test configuration and test objectives and provisions for assuring that prerequisites for the given test have been met, that adequate instrumentation is available and used, appropriate tests and equipment are used, necessary monitoring is performed, and that suitable environmental conditions are maintained.

Prerequisites shall include the following, as applicable:

- 1) calibrated instrumentation.
- 2) appropriate equipment.
- 3) trained personnel.

- 4) appropriate condition of test equipment and the item to be tested.
- 5) suitable environmental conditions.
- 6) provisions for data acquisition.

In lieu of specially prepared written test procedures, appropriate sections of related documents, such as ASTM methods, Supplier manuals, equipment maintenance instructions, or approved drawings or travelers with acceptance criteria, may be used. Such documents shall include or be supplemented with appropriate criteria to ensure adequate procedures for the test.

11.4 Test Results

Test results shall be documented and evaluated by a responsible engineer to ensure that test requirements have been satisfied.

11.5 Test Records

Test records shall be retained in accordance with ARC-20 records requirements. Refer to ARC Quality Management Procedure QM-DM-002, *Records Management*. Test records shall, as a minimum, identify the following:

- (a) Item tested.
- (b) Date of test.
- (c) Tester or data recorder.
- (d) Type of observation.
- (e) Results and acceptability.
- (f) Action taken in connection with any deviations noted; and
- (g) Person evaluating test results.

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 General

Tools, gages, instruments, and other measuring and test equipment used for activities affecting quality shall be controlled and at specified periods calibrated and adjusted to maintain accuracy within necessary limits.

When appropriate to the scope of work, this Quality Assurance Program shall incorporate by reference the requirements of ASME NQA-12015 and ANSI/IEEE Standard 498-1990, *IEEE Standard Requirements for the Calibration and Control of Measuring and Test Equipment Used in Nuclear Facilities*. When subcontractors execute control of measuring and test equipment, their procurement documents will invoke these requirements.

12.2 Requirements

12.2.1 Selection

Selection of measuring and test equipment shall be controlled to ensure that such items are of proper type, range, accuracy, and tolerance to accomplish the function of determining conformance to specified requirements.

12.3 Calibration Control

Measuring and test equipment shall be calibrated, adjusted, and maintained at prescribed intervals or prior to use and whenever the accuracy of the measuring and test equipment is suspect, against and traceable to certified equipment having known valid relationship to nationally recognized standards, or to international standards known to be equivalent to and verified against corresponding nationally recognized standards. Where no such standards exist, the bases for calibration shall be defined and documented.

Calibration procedures shall identify, or reference required accuracy and shall define methods and frequency of checking accuracy. The method and interval of calibration for each item shall be defined, based on the type of equipment stability characteristics, required accuracy, intended use, and other conditions affecting performance.

12.4 Application

Measuring and testing equipment shall be traceable to its application and use.

12.5 Corrective Action

When measuring and test equipment is lost, damaged, or found to be out of calibration the validity of previous measurement, inspection, or test results, and the acceptability of items previously inspected or tested shall be evaluated. This evaluation shall be from at least the last acceptable calibration of the M&TE. The evaluation and resulting actions shall be commensurate with the significance of the condition.

12.6 Handling and Storage

Measuring and testing equipment shall be properly handled and stored to maintain accuracy.

12.7 Environmental Controls

Measuring and testing equipment shall be properly handled and stored to maintain accuracy.

12.8 Pre-Calibration Check

Measuring and testing equipment and reference standards submitted for calibration shall be checked and the results recorded before any required adjustments or repairs are made.

12.9 Status Indication

Measuring and test equipment shall be suitably marked, tagged, labeled, or otherwise identified to indicate calibration status and establish traceability to calibration records.

12.10 Commercial Devices

Calibration and control measures are not required for commercial equipment such as rulers, tape measures, levels, etc., if such equipment provides the required accuracy.

12.11 Records

Records shall be established and maintained to indicate calibration status and the capability of measuring and test equipment to satisfactorily perform its intended function.

12.12 Reports and Certificates

Calibration reports and certificates reporting the results of calibrations shall include the information and data necessary for interpretations of the calibration results and verification of conformance to applicable requirements.

13.0 HANDLING, STORAGE, AND SHIPPING



13.1 General

Handling, storage, cleaning, packaging, shipping, and preservation of items shall be controlled to prevent damage or loss and to minimize deterioration.

13.2 Requirements

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

13.3 Special Requirements

When required for items, special equipment (such as containers, shock absorbers, and accelerometers) and special protective environments (such as inert gas atmosphere, specific moisture content levels, and temperature levels) shall be specified, provided, and their existence verified.

13.4 Procedures

When required for critical, sensitive, perishable, or high-value articles, specific procedures for handling, storage, packaging, shipping, and preservation shall be used.

Special handling tools and equipment shall be utilized and controlled as necessary to ensure safe and adequate handling.

13.5 Tools and Equipment

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

13.6 Operators

Personnel used for special handling and lifting equipment shall be experienced or trained in the use of the equipment.

13.7 Marking or Labeling

When applicable, instructions for marking and labeling for packaging, shipment, handling, and storage of items shall be established as necessary to adequately identify, maintain, and preserve the item, including indication of the presence of special environments or the need for special controls.

14.0 INSPECTION, TEST, AND OPERATING STATUS



15.0 CONTROL OF NONCONFORMING ITEMS

15.1 General

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

15.2 Identification

Nonconforming items shall be identified by legible marking, tagging, or other methods not detrimental to the item, on either the item, the container, or the package containing the item.

15.3 Segregation

Nonconforming items shall be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned.

When segregation is impractical or impossible due to physical conditions such as size, weight, or access limitations, other precautions shall be employed to preclude inadvertent use of a nonconforming item.

15.4 Disposition

Nonconforming items shall be evaluated and recommended dispositions shall be proposed. Further processing, delivery, installation, or use of a nonconforming item shall be controlled pending the evaluation and an approved disposition by authorized personnel.

15.5 Responsibility and Authority

The responsibility and authority for the evaluation and disposition of nonconforming items shall be defined. Responsibility for the control of further processing, delivery, installation, or use of nonconforming items shall be designated in writing.

15.6 Personnel

Personnel performing evaluations to determine a disposition shall have:

1. Demonstrated competence in the specific area they are evaluating.
2. Have an adequate understanding of the requirements.
3. Access to pertinent background information.

15.7 Disposition

A disposition, such as use-as-is, reject, repair, or rework of nonconforming items shall be made and documented. Technical justification for the acceptability of a nonconforming item dispositioned repair or use-as-is shall be documented. Nonconformances to design requirements dispositioned use-as-is or repair shall be subject to design control measures commensurate with those applied to the original design. Required as-built records shall reflect the use-as-is or repair condition.

15.8 Reexamination

Reworked items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria. Repaired items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria unless the disposition has established alternate acceptance criteria.

16.0 CORRECTIVE ACTION

16.1 Requirements

Conditions adverse to quality shall be identified promptly and corrected as soon as practical.

In the case of a significant condition adverse to quality, the cause of the condition shall be determined, and corrective action taken to preclude recurrence. Significant conditions adverse to quality will also require ARC-20 Senior Management (i.e., Project Manager and Co-Managers) review of cause determination and planned corrective actions.

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

Corrective action shall be governed by ARC procedure QM-CAP-001, *Corrective Action Program*, and the equivalent procedures of the ARC-20 Project Team Members.

17.0 QUALITY ASSURANCE RECORDS

11.1 General

ARC-20 project records that furnish documentary evidence of quality shall be specified, prepared, and maintained. Records shall be legible, identifiable, and retrievable. Records shall be protected against damage, deterioration, or loss. Requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition shall be established and documented. The term *records* used throughout this QAPP are to be interpreted as *Quality Assurance Records*.

11.2 Requirements

17.2.1 Records Administration

A records system(s) shall be established by the ARC-20 project organization at the earliest practicable time consistent with the schedule for accomplishing work activities and in compliance with the general requirements of this section and ARC Procedure QM-DM-002, *Records Management*, and the equivalent procedures set forth by the ARC-20 Project Team members.

The records system(s) shall be defined, implemented, and enforced in accordance with ARC-20 procedures, instructions, or other documentation.

17.2.2 Generation of Records

The applicable design specifications, procurement documents, test procedures, operational procedures, or other documents shall specify the records to be generated, supplied, or maintained. Documents that are designated to become records shall be legible, accurate, and traceable to associated items and activities and accurately reflect the work accomplished or information required.

17.2.3 Authentication of Records

17.2.4 Index

Records shall be indexed. The indexing system(s) shall include, as a minimum, record retention times and the location of the record within the record system.

17.2.5 Distribution

Records shall be distributed, handled, and controlled in accordance with written procedures.

17.2.6 Identification

Records and/or indexing system(s) shall provide sufficient information to permit identification between the record and the item(s) or activity(s) to which it applies.

17.2.7 Classification

Records shall be classified as *Lifetime* or *Nonpermanent* for the DOE, in accordance with the criteria given

below and consistent with applicable regulatory requirements.

17.2.8 Lifetime Records

Lifetime records are those that meet one or more of the following criteria:

1. those that would be of significant value in demonstrating capability for safe operation.
2. those that would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item.
3. those that would be of significant value in determining the cause of an accident or malfunction of an item.
4. those that provide required baseline data for Inservice inspections.

Lifetime records are required to be maintained for the life of the item while it is installed in the plant or stored for future use.

17.2.9 Nonpermanent Records

Nonpermanent records are those required to show evidence that an activity was performed in accordance with the applicable requirements but need not be retained for the life of the item because they do not meet the criteria for lifetime records. Nonpermanent records shall be maintained for the identified retention period.

17.2.10 Corrected Information in Records

Records may be corrected in accordance with procedures which provide for appropriate review or approval by the originating organization. The correction shall include the date, and the identification of the person authorized to issue such correction.

17.3 Record Receipt

When receiving records, the Project Manager shall provide protection from damage or loss during the time that the records are in ARC's possession.

17.4 Storage, Preservation, and Safekeeping

17.4.1 Storage

The records shall be stored in predetermined location(s) that meets the requirements of applicable standards, codes, regulatory agencies, and the DOE.

Prior to storage of records for the ARC-20 project, a project-specific storage procedure shall be prepared, and responsibility assigned for enforcing the requirements of that procedure.

17.4.2 Preservation

Records shall be stored in a manner approved by the organization or organizations responsible for storage. To preclude deterioration of the records, the following requirements shall apply:

1. Provisions shall be made in the storage arrangement to prevent damage from moisture, fire, temperature, and pressure.
2. Records shall be attached in binders or placed in folders or envelopes for storage in steel file cabinets or on shelving them in containers; and
3. Provisions shall be made for special processed records (such as radiographs, photographs, negatives, microform, and magnetic media) to prevent damage from excessive light, stacking, electromagnetic fields, temperature, and humidity.

17.4.3 Safekeeping

Measures shall be established to preclude the entry of unauthorized personnel into the storage area. These

measures shall guard against larceny and vandalism.

Measures shall be taken to provide for replacement, restoration, or substitution of lost or damaged records.

17.4.4 Storage Facilities

Records shall be stored in facilities constructed and maintained in a manner which minimizes the risk of damage or destruction from the following:

1. Natural disasters such as winds, floods, or fires.
2. Environmental conditions such as high and low temperatures and humidity.
3. Infestation of insects, mold, or rodents; and
4. Dust or airborne particles.

Access to the processing, storage, and retrieval of records shall be limited to authorized personnel.

Activities detrimental to records shall be prohibited in the storage area.

Provisions shall be made to prevent damage from harmful conditions (such as excessive light, stacking, electromagnetic fields, temperature, and humidity), as applicable to the specific media utilized for record storage.

17.4.5 Facility Types

Single storage consists of a storage facility, vault, room, or container(s) with a minimum two-hour fire rating. The design and construction of a single storage facility, vault room, or container shall be reviewed for adequacy by a person competent in fire protection or contain a certification or rating from an accredited organization.

Dual facilities: containers, or a combination thereof shall be at locations sufficiently remote from each other to eliminate the chance exposure to a simultaneous hazard.

17.4.6 Temporary Storage

The Project Manager responsible for the receipt of records shall designate a person or organization responsible for receiving the records. The designee shall be responsible for organizing and implementing a system of receipt control of records for permanent and temporary storage.

When temporary storage of records (such as for processing, review, or use) is required, the storage facility or container shall provide a one-hour fire rating, unless utilizing dual storage.

Each receipt control system shall be structured to permit a current and accurate assessment of the status of records during the receiving process.

17.4.7 Storage of Electronic Records

Storage of electronic records shall require both media and compatible processing systems. The media containing the electronic records and the compatible processing systems access should translate the records into an appropriate retrievable, legible format. The types of media utilized for electronic record storage should be identified in the records management procedure.

The selection of the storage media should consider the shelf life of the media and the manufacturer's recommended qualified life. The degradation of electronic media starts immediately after manufacturing. Electronic records should be migrated into new media before the manufacturer's recommended useful life is exceeded.

Two sets of electronic records should be maintained to ensure timely recovery in the event they are damaged or lost. These sets may be established in processing systems installed on separate servers, stand-alone computer platforms, or in a removable media format (e.g., USB, SD card etc.).

If temporary storage for electronic records is used, two sets of in-process records should be maintained, since the electronic media may be exposed to computer viruses and inadvertent alterations.

17.4.8 Retention of Records

Records shall be retained in accordance with the above classifications. The retention period for nonpermanent records shall be the duration of the ARC-20 Project.

17.4.9 Retrieval

Storage systems shall provide for the retrieval of information in accordance with planned retrieval times based upon the record type.

Records maintained by the ARC-20 Project shall be accessible to the DOE (and the eventual future ARC-100 Owner).

17.4.10 Maintenance

Records shall be protected from damage or loss.

Record controls shall provide for retrievability within planned retrieval times based upon the record type or content.

The method of record changes shall be documented.

Provisions shall be established to ensure that no unacceptable degradation of the electronic record media occurs during the established retention period.

Provisions shall be made to ensure that the records remain retrievable after hardware, software, or technology changes.

Lifetime electronic records should be reviewed periodically for legibility. This review should also confirm the accessibility and retrievability of the record, thus providing assurance that compatible software and hardware systems are available. Media intended for storage of electronic records should be evaluated prior to use to ensure that it is free of errors, defects, and corruption.

17.5 Disposition

Records accumulated at various locations, prior to transfer, shall be made accessible to the DOE directly.

The custodian shall invent the submittals, acknowledge receipt, and process these records in accordance with this QAPP.

Various regulatory agencies have requirements concerning records that are within the scope of this QAPP. The most stringent of the DOE or NRC requirements shall be used in determining the final disposition.

18.0 AUDITS

18.1 General

The ARC-20 Project activities shall be independently audited to verify compliance with applicable aspects of the QA program and to determine its effectiveness.

Audits shall be scheduled, planned, and performed to verify that performance criteria are met and to determine the effectiveness of the program. These audits shall be performed in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing the activities being audited. Audit results shall be documented and reported to, and reviewed by, responsible management. Follow-up action shall be taken where indicated.

18.2 Internal Audits

Internal quality assurance audits shall be scheduled in a manner to provide coverage and coordination with ongoing quality assurance program activities. Audits shall be scheduled at a frequency commensurate with the status and importance of the activity. The conduct of ARC-20 Project audits shall conform to ARC procedure QM-QA-002, *Conduct of Audits*, or equivalent procedures by the ARC-20 Project Team members.

18.3 External Audits

External audits (e.g., Supplier audits) shall be performed on a triennial basis and supplemented by annual evaluations of the Supplier's performance to determine if the regular schedule audit frequency shall be maintained or decreased or if other corrective action is required. A continuous or ongoing evaluation of the Supplier's performance may be conducted in lieu of the annual evaluations, provided that the results are reviewed to determine if corrective action is required.

18.4 Scheduling

The audit schedule shall be reviewed periodically by the Quality Assurance Manager and revised as necessary to ensure that coverage is maintained. Regularly scheduled audits shall be supplemented by additional audits of specific subjects when necessary to provide adequate coverage.

A grace period of 90 days may be applied to scheduled audits and annual evaluations of supplier performance. When the grace period is used, the next scheduled date for the activity shall be based on the activity schedule date and not on the date the activity was performed. If the activity is performed early, the next schedule date shall be based on the date the activity was performed.

18.5 Audit Plan

The auditing organization shall develop and document an audit plan for each audit. This plan shall identify the audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures or checklists. The auditing organization shall select and assign auditors who are independent of any direct responsibility for the performance of the activities which they will audit. Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective.

Audits shall be performed in accordance with written procedures or checklists.

Audit records shall include audit plans, audit reports, written replies, and the record of completion of corrective action.

18.6 Personnel

The audit team leader shall ensure that the audit team is prepared prior to initiation of the audit. The audit team shall have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited.

Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective.

18.7 Selection of Audit Team

An audit team shall be identified prior to the beginning of each audit. This team shall contain one or more Auditors; one being designated Lead Auditor who organizes and directs the audit. The audit team shall have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited.

18.8 Performance

Elements selected for the audit shall be evaluated against specified requirements. Objective evidence shall be examined to the depth necessary to determine if these elements are being implemented effectively. Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization.

18.9 Reporting

Management of the audited organization or activity shall investigate audit findings, schedule corrective action, including measures to prevent recurrence of significant conditions adverse to quality, and notify the appropriate organization in writing of action taken or planned. Audit responses shall be evaluated by or for the auditing organization.

18.10 Response

Management of the audited organization or activity shall investigate audit findings, schedule corrective action, including measures to prevent recurrence of significant conditions adverse to quality, and notify the appropriate organization in writing of action taken or planned. Audit responses shall be evaluated by or for the auditing organization.

18.11 Follow-up Action

Follow-up action shall be taken to verify that corrective action is accomplished as scheduled.

19.0 ADDITIONAL QUALITY REQUIREMENTS



20.0 ADDITIONAL QA REQUIREMENTS FOR COMPUTER SOFTWARE

This section provides requirements for the acquisition, development, operation, maintenance, and retirement of computer software, as applied to the design, construction, operation, modification, repair, and maintenance of nuclear facilities and more specifically to that employed in the design and R&D activities encompassed by the ARC-20 Project. The appropriate requirements of this section shall be implemented through the policies, procedures, plans, specifications, or work practices that provide the framework for software engineering activities.

20.1 General Requirements

20.1.1 Applicability

The requirements set forth in this section apply to computer software used to produce or manipulate data which is used directly in the design, analysis, and operation of structures, systems, and components. The application of specific requirements shall be prescribed in plans for software quality assurance and in written policies and procedures.

As an example, this entire section applies to the software development of the ARC-20 project R&D program for modeling flow blockage.

Software shall be approved, documented, verified, validated, and controlled in accordance with this QAPP and the ARC implementing procedure SM-ENG-005, *Design Verification, Validation and Release*.

This section includes and integrates the requirements of ASME NQA-1, 2015 Part I, Basic Requirement 3, Paragraph 800 and Part II, Subpart 2.7. Software Life Cycle and Software Engineering Method.

The subsections that follow (20.1.2 through 20.1.8) are based on a software life cycle model (like IEEE 1012) which illustrates a systematic approach to software development and maintenance.

Software development shall proceed in a traceable, planned, and orderly manner. The number of phases and relative emphasis placed on each phase of software development will depend on the nature and complexity of the software. Software development may be performed in an iterative or sequential manner.

20.2 Software Engineering

The scope of software engineering activities includes the following elements, as appropriate:

1. Software acquisition method(s) for controlling the acquisition process for software and software services.
2. Software engineering method(s) used to manage software life cycle activities.
3. Application of standards, conventions, and other work practices that support the software life cycle.
4. As appropriate, the software engineering method, software acquisition method, or both shall establish the need for standards, conventions, and other required work practices to facilitate software life-cycle activities (e.g., software design and implementation); and
5. Controls for support software used to develop, operate, and maintain computer programs.

The software engineering activities described above shall define the baseline documents that are to be maintained as records.

The software engineering activities described above shall define the control points and associated reviews. Reviews of software shall ensure compliance with the approved software design requirements.

Two reviews are required:

- (a) Requirements related to activities of preparing the computer program for acceptance testing; and
- (b) Assurance of the satisfactory completion of the software development cycle, including acceptance testing.

20.2.2 Requirements Phase

During this phase, the technical and software engineering requirements include security features (e.g., vulnerability protection and cybersecurity).³ Identify applicable reference drawings, specifications, codes, standards, regulations, procedures, or instructions that establish software design requirement test, inspection, and acceptance criteria. Security requirements shall be specified commensurate with the risk from unauthorized access or use. The software must satisfy that pertain to functionality, performance, design constraints, attributes, and external interfaces shall be specified, documented, reviewed, and approved. These requirements shall identify the operating system, function, interfaces, performance requirements, installation considerations, design inputs and any design constraints of the computer program. Software design requirements shall be traceable throughout the software life cycle. Software design requirements shall be identified and documented, and their selection reviewed and approved.

20.2.3 Design Phase

During this phase, a software design based on the requirements shall be developed, documented, and reviewed. The design shall define the computational sequence necessary to meet the software requirements. The documentation shall include, as applicable, numerical methods, mathematical models, physical models, control flow, control logic, data flow, process flow, data structures, process structures, and the applicable relationships between data structures and process structures. This documentation may be combined with the documentation of the software design requirements, or the computer program listings resulting from implementation of the software design.

The software design shall consider the computer program's operating environment. Measures to mitigate the consequences of problems, as identified through analysis, shall be an integral part of the design. These potential problems include external and internal abnormal conditions and events that can affect the computer program.

Design phase software verification and validation activities shall evaluate the technical adequacy of the design approach and consist of:

1. The generation of test plans based on the requirements and design.
2. The generation of design-based test cases; and
3. The review of the software design to ensure that the software design is traceable to the requirements being addressed.

20.2.4 Implementation Phase

Implementation phase software verification activities shall consist of the examination of source code listings to assure adherence to coding standards and conventions.

20.2.5 Testing Phase

In addition to Section 11 testing requirements, additional requirements apply. During this phase, the design as implemented in code shall be exercised by executing the test cases. Failure to successfully execute the test cases shall be reviewed to determine if modifications of the requirements, the design, the implementation, or the test plan and test cases are required. Testing phase activities shall consist of the validation of the code to assure adherence to the requirement and to ensure that the software produces correct results for the test cases. To evaluate technical adequacy, the software test case results can be compared to results from alternative methods, such as:

1. Analysis without computer assistance.
2. Other validated computer programs.
3. Experiments and tests.
4. Standard problems with known solutions; or
5. Confirmed published data and correlations.

The acceptance testing activity shall demonstrate that the computer program adequately and correctly performs all intended functions (i.e., specified software design requirements). Acceptance testing shall demonstrate, as appropriate, that the computer program:

- (a) Properly manages abnormal conditions and events as well as credible failures.
- (b) Does not perform adverse unintended functions; and
- (c) Does not degrade the system either by itself, or in combination with other functions software engineering items.

Acceptance testing shall be performed prior to approval of the computer program for use. Software engineering items shall be under configuration control prior to starting acceptance testing. Acceptance testing shall be planned and performed for all software design requirements.

Acceptance testing ranges from a single test of all software design requirements to a series of tests performed during computer program development.

Performance of a series of tests provides assurance of correct translation between activities and proper function of individual modules.

Testing shall include a comprehensive acceptance test performed in the operating environment prior to use.

Test plans, test cases, and test results shall be documented, reviewed, and approved prior to use of the computer program in accordance with the Test Control Program described in Section 11 of this QAPP.

Observations of unexpected or unintended results shall be documented and dispositioned prior to test result approval.

The acceptance testing of changes to the computer program shall be subjected to selective retesting to detect unintended adverse effects introduced during the change. Such testing shall provide assurance that the changes have not caused unintended adverse effects in the computer program, and to verify that a modified system(s) or system component(s) still meets specified software design requirements.

20.2.6 Testing Plan Procedures

The requirements of this section apply to testing computer programs and, as appropriate, the computer hardware and operating system.

Computer program test procedures shall provide for demonstrating the adherence of the computer program to documented requirements. For those computer programs used in design activities, computer program test procedures shall provide for ensuring that the computer program produces correct results. For those computer programs used for operational control, computer program test procedures shall provide for demonstrating required performance over the range of operation of the controlled function or process. The procedures shall also

provide for evaluating technical adequacy through comparison of test results from alternative methods, such as hand calculations, calculations using comparable proven programs, or empirical data and information from technical literature.

In-use test procedures shall be developed and documented to permit confirmation of the acceptable performance of the computer program in the operating system. In-use test procedures shall be performed after the computer program is installed on a different computer or when there are significant changes in the operating system. Periodic in-use manual or automatic self-check tests shall be prescribed and performed for those computer programs in which computer program errors, data errors, computer hardware failures, or instrument drift can affect required performance. The test plans, test cases, and test

results shall be documented, reviewed, and approved prior to use of the computer program. Test procedures or plans shall specify the following, as applicable:

- a) required tests and tests sequence.
- b) required ranges of input parameters.
- c) identification of the stages at which testing is required.
- d) criteria for establishing test cases.
- e) requirements for testing logic branches
- f) requirements for hardware integration
- g) anticipated output values
- h) acceptance criteria
- i) reports, records, standard formatting, and conventions

Observations of unexpected or unintended results shall be documented and dispositioned prior to test result approval. Test results shall be evaluated by the responsible authority to ensure that test requirements have been satisfied.

20.2.7 Installation and Checkout Phase

During this phase, the software becomes part of a system incorporating applicable software components, hardware, and data. The process of integrating the software with applicable components may consist of installing hardware, installing the program, reformatting, or creating databases, and verifying that all components have been included.

Installation and checkout phase in use and validation activities shall consist of:

1. The execution of tests for installation and integration; and
2. Documentation of the approval of the software for operational use.

20.2.8 Operations and Maintenance Phase

Prior to this phase the software has been approved for operational use. Further activity shall consist of maintenance of the software that includes application documentation, access control specifications, computer vulnerability protections, and in-use testing. In addition, maintenance of the software to remove latent errors (corrective maintenance), to respond to new or revised requirements (perfective maintenance), or to adapt the software to changes in the operating environment (adaptive maintenance). Software modifications shall be approved, documented, verified, validated, and controlled.

20.2.9 Retirement Phase

During the retirement phase, the support for a software product is terminated, and the routine use of the software shall be prevented.

20.3 Software Verification and Validation

Software verification and validation activities shall:

- (a) Ensure that the software adequately and correctly performs all intended functions; and
- (b) Ensure that the software does not perform any unintended function that either by itself or in combination with other functions can degrade the entire system.

Software verification and validation activities shall be planned and performed for each system configuration which may impact on the software. The results of software verification and validation activities shall be documented. Software verification and validation shall be performed by a competent individual or group(s) other than those who designed the software, but who may be from the same organization. Verification may

be performed by the originator's supervisor, provided:

- (a) The supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design; or
- (b) The supervisor is the only individual in the organization competent to perform the verification. (Cursory supervisory reviews do not satisfy the intent of this standard).

20.3.1 Software Verification

Software verification shall be performed during the software development to ensure that the products of a given life cycle phase fulfill the requirements of the previous phase or phases.

Software design verification shall evaluate the technical adequacy of the design approach and ensure internal completeness, consistency, clarity, and correctness of the software design and shall verify that software design is traceable to the software design requirements.

Software design verification shall include review of test results.

The software design verification shall be completed prior to approval of the computer program for use.

The requirements for the software design verification activity shall be documented in the software engineering method.

Software design verification shall be performed by a competent individual(s) or group(s) other than those who developed and documented the original design but who may be from the same organization. This verification may be performed by the originator's supervisor, provided.

- a) The supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design, or
- b) The supervisor is the only individual in the organization competent to perform the verification. Cursory supervisory reviews do not satisfy the intent of this section.

The results of verification shall be documented with the identification of the verifier indicated. Software verification methods shall include any one or a combination of design reviews, alternate calculations, and test performed during computer program development. The extent of verification and the methods chosen are a function of the complexity of the software, the degree of standardization, the similarity with previously proven software, and the importance to safety.

20.3.2 Software Validation

Software validation is performed at the end of the implementation phase to ensure that the code satisfies the requirements. Software validation activities, such as the development of test plans and test cases, shall be integrated into each phase of the software life cycle. The validation of modifications shall be subject to selective regression testing to detect errors introduced during the modification of systems or system components, to verify that the modifications have not caused unintended adverse effects, and to verify that a modified system or system component still meets specified requirements.

20.4 Software Configuration Management

Software configuration management includes, but is not limited to configuration identification, change control, and status control. Software shall be maintained under configuration management until the software is retired.

The appropriate software engineering elements shall identify when configuration baselines are to be established. Items to be under configuration management include:

- (a) Documentation for software design requirements, instructions for computer program use, test plans, and results.
- (b) Computer programs, including source, object, and backup files; and
- (c) Support software

20.4.1 Configuration Identification

A configuration baseline shall be defined at the completion of each major phase of software development. Approved changes created after a baseline shall be added to the baseline. A baseline shall define the most recent approved software configuration.

A labeling system for configuration items shall be implemented that:

- 1. Uniquely identify each configuration item.
- 2. Identifies changes to configuration items by revision; and
- 3. Provides the ability to uniquely identify each configuration of the revised software available for use.

20.4.2 Configuration Change Control

Changes to software shall be formally documented. This documentation shall contain a description of the change, the rationale for the change, and the identification of affected baselines.

The change shall be formally evaluated and approved by the organization responsible for the original design unless an alternate organization has been given the authority to approve the changes. Only authorized changes shall be made to the software baselines. Software verification activities shall be performed for the change as necessary to ensure the change is appropriately reflected in software documentation, and to ensure that document traceability is maintained. Software validation shall be performed as necessary for the change.

The software configuration change control process shall include:

- 1) Initiation, evaluation, and disposition of the change request.
- 2) Control and approval of changes prior to implementation; and
- 3) Requirements for retesting (e.g., regression testing) and acceptance test results.

20.4.3 Configuration Status Accounting

The information that is needed to manage a configuration shall be documented. This information shall identify the approved configuration, the status of proposed changes to the configuration, the status of approved changes, and information to support the functions of configuration identification, and configuration control.

20.5 Documentation

The following sections identify the required documentation for software.

20.5.1 Plan(s) for Software Quality Assurance



The plan for software quality assurance shall identify:

1. The software products to which it applies.
2. The organizations are responsible for performing the work and achieving software quality and their tasks and responsibilities.
3. Required documentation.
4. Standards, conventions, techniques, or methodologies which shall guide the software development, as well as methods to assure compliance to the same.
5. The required software reviews; and
6. The methods for reporting and corrective action.

20.5.2 Software Requirements Documentation

Software requirements documentation shall outline the requirements that the proposed software must satisfy. The requirements shall, as applicable, address the following:

1. Functionality - the functions the software is to perform.
2. Performance - the time-related issues of software operation such as speed, recovery time, response time, etc.
3. Design constraints imposed on implementation phase activities-any elements that will restrict design options.
4. Attributes - non-time-related issues of software operation such as portability, acceptance criteria, access control, maintainability, etc.; and
5. External interfaces - interactions with people, hardware, and other software.

An item can be called a software requirement only if its achievement can be verified and validated. Software requirements shall be traceable throughout the remaining stages of the software development cycle.

20.5.3 Software Design and Implementation Documentation

Software design and implementation documentation includes a document or series of documents that shall contain:

1. A description of the major components of software design as they relate to the software requirements.
2. A technical description of the software with respect to the theoretical basis, mathematical model, control flow, data flow, control logic, and data structure.
3. A description of the allowable or prescribed ranges for inputs and outputs; and
4. The design described in a manner that can be translated into code.

20.5.4 Software Verification and Validation Documentation

Software verification and validation documentation shall describe the tasks and criteria for accomplishing the verification of the software in each phase, and the validation of the software at the end of the development cycle. The documentation shall also specify the hardware and software configurations pertinent to the software verification and validation. The documentation shall be organized in a manner that allows traceability to both the software requirements and the software design. This documentation shall also contain the results of the execution of the software verification and validation activities, and shall include the results of reviews and tests, and a summary of the status of the software, e.g., incomplete design performance and application requirements.

20.5.5 User Documentation

[REDACTED]

20.6 Verification Reviews

Verification reviews shall identify the participants and their specific responsibilities during the review and in the preparation and distribution of the review documentation. The reviewed documents shall be updated and placed under configuration control.

Documentation of review comments and their disposition shall be retained until they are incorporated into the updated software. Comments and their disposition not incorporated shall be retained in accordance with the established procedures.

20.6.1 Software Requirements Review

The review of software requirements shall be performed at the completion of the software requirements documentation. This review shall ensure that the requirements are complete, verifiable, consistent, and technically feasible. The review shall also ensure that the requirements will result in feasible and usable code.

20.6.2 Software Design Review

The software design review shall be held at the completion of the software design documentation. This review shall meet the design verification requirements of ASME NQA-1, 2015 Edition, part II, subpart 2.7 (or equivalent standards in countries other than the U.S.). This review shall evaluate the technical adequacy of the design approach, and assure internal completeness, consistency, clarity, and correctness of the software design, and shall verify that the software design is traceable to the requirements.

20.6.3 Development Documentation Review

Upon completion of the testing phase (and the installation phase if necessary) the development cycle documentation shall be reviewed and approved to ensure completion and acceptability.

20.1 Problem Reporting and Corrective Action

A formal procedure for software problems and corrective action shall be established for software errors and failures. This problem reporting system shall ensure that problems are promptly reported to affected organizations to ensure formal processing of problem resolutions. This problem reporting and corrective action process shall address and align with the requirements of Section 16 of this Plan.

Method(s) for documenting, evaluating, and correcting software problems shall:

- (a) Describe the evaluation process for determining whether a reported problem is an error or other type of problem (e.g., user mistake); and
- (b) Define the responsibilities for disposition of the problem reports, including notification to the originator of the results of the evaluation.

When the problem is determined to be an error, the method shall provide for:

- (a) How the error relates to appropriate software engineering elements.
- (b) How the error impacts past and present use of the computer program.
- (c) How the corrective action impacts previous development activities.
- (d) How the users are notified of the identified error and its impact; and
- (e) How to avoid errors, pending implementation of corrective actions.

Problems with software may be classified by the organization responsible for the evaluation. Any classification system shall have defined criteria based on the impact of the software output.

Corrective action by the responsible organization shall ensure that:

- (a) Problems are identified, evaluated, documented, and corrected, if required.
- (b) Problems are assessed for impact on past and present applications of the software by the responsible organization.
- (c) Corrections or changes shall be controlled in accordance with Section 6, Document Control; and
- (d) Preventive actions and corrective actions results are provided to affected organizations.

20.8 Access Control

To the extent appropriate, controls shall be established to permit authorization and prevent unauthorized access to a computer system.

20.9 Software Procurement

20.9.1 Contracted Software

Individuals or organizations developing and supplying software under contract shall be required to have policies and procedures that meet the applicable requirements of this Section as specified in procurement documents. The documentation that is required by this Section and Section 4.0 shall be delivered or made available by the supplier to the purchaser. The applicable requirements of this Section shall become the responsibility of the purchaser upon receipt of software. Typically, this software enters the purchaser's organization at the start of the installation and checkout phase. Procurement documents shall identify requirements for Supplier's reporting of software errors to the Purchaser, and the Purchaser's reporting of errors to the Supplier. The supplier shall report software errors, or failures, to the purchaser, and the purchaser shall report software errors to the supplier.

20.9.2 Otherwise Acquired Software

Acquired or pre-existing software that has not been previously approved under a program consistent with NQA-1 (or equivalent standards in countries other than the U.S.) for use in its intended application is considered "otherwise acquired software". Quality assurance requirements for commercial grade item and service dedication process shall be applied to this type of acquired or pre-existing software. This software shall be identified and controlled during the dedication process.

Otherwise acquired computer programs whose results are verified with the design analysis for each application as specified in section 3.5.1 are excluded from the requirements of this section. Otherwise acquired computer programs shall be identified and controlled during the dedication process. The dedication process shall be documented and include the following:

- a) identification of the capabilities and limitations for intended use as critical characteristics
- b) utilization of test plans and test cases as the method of acceptance to demonstrate the capabilities within the limitations.
- c) instructions for use (e.g., user manual) within the limits of the dedicated capabilities

20.9.3

The dedication process of documentation and associated computer program(s) shall establish the current baseline. Subsequent revisions of the software shall be dedicated in accordance with this section.

20.9.4 Procured Software Services

In case the ARC-20 Project were to acquire software services (not presently planned), the organization providing software services shall have a plan(s) for software quality assurance that meets the requirements of this Section. The user organization shall determine the adequacy of this plan.

20.10 Support Software

Support software includes software tools and system software.

As appropriate, the software engineering method, software acquisition method, or both shall establish the need for software tools.

20.10.1 Software Tools

Software tools shall be evaluated, reviewed, tested, and accepted for use, and placed under configuration control as a part of the software development cycle of a new or revised software product.

Software tools that do not affect the performance of the software need not be placed under configuration control.

In cases involving modifications of software products using the software tools, the configuration of the support software associated with that modification shall be managed.

Changes to the software tool shall be evaluated for impact on the software product to determine the level of reviews and retesting that will be required.

20.10.2 System Software

System software consists of on-line computer programs used to provide basic or general functionality and facilitate the operation and maintenance of the application computer program. Examples include lower-level software layers, assemblers, interpreters, diagnostics, and utilities.

System software shall be evaluated, reviewed, tested, and accepted for use as a part of the software development cycle of a new or revised software product.

System software shall be placed under configuration change control.

Changes to the system software shall be evaluated for impact on the software product to determine the level of reviews and retesting that will be required.

20.11 Records

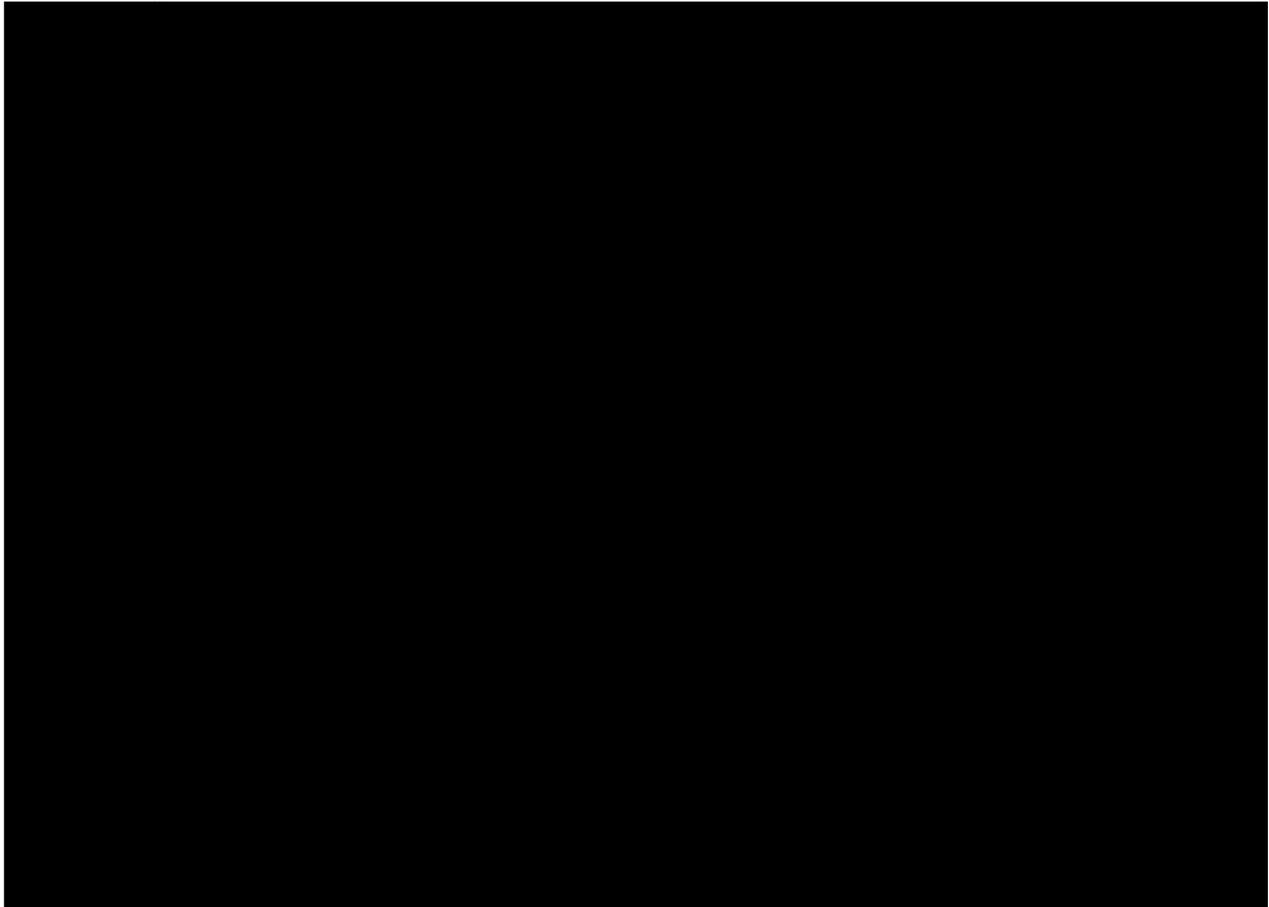
Record copies of required documentation shall be retained with other project records as required by codes, standards, specifications, plans or procedures.

21.0 U.S. DEPARTMENT OF ENERGY

For Quality Assurance, DOE Order, DOE Order 414.1D, *Quality Assurance*, applies to nuclear facilities and activities, while Title 10, Code of Federal Regulations, Part 830, Subpart A, *Quality Assurance Requirements*, codifies these regulatory requirements. 10 CFR 830.121 requires that a Quality Assurance Program based on the criteria of 10 CFR 830.122 and a voluntary consensus standard, in this case ASME NQA-1-2015, be developed by nuclear contractors and applied to nuclear-related items and activities licensed and regulated by the DOE.

This ARC-20 Quality Assurance Program Plan consists of controls necessary to comply with 10 CFR 830 Appendix B regulatory requirements and is designed to meet the requirements of ASME NQA-1-2015. It establishes requirements, assigns responsibilities, and describes the management systems established to assure the quality of ARC-20 nuclear activities and products. The ARC-100 facility is planned to be licensed and regulated by the NRC.

Table 21-1 depicts the integration of NQA-1, 10 CFR 830.120 Subpart A, and DOE Order 414.1"X" (applicable version) requirements into the corresponding sections of this Quality Manual and their associated topics.



22.0 REFERENCES

1. American National Standards Institute/ American Society for Quality Control Standard E-4, Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs (ANSI/ASQC E4, 1994).
2. American Society of Mechanical Engineers (ASME), NQA-1-2015 Edition, Quality Assurance Requirements for Nuclear Facility Applications (ASME NQA-1-2015 Edition).
3. The American Society of Nondestructive Testing, Recommended Practice No. ASNT TC 1 A, 2006.
4. Institute of Electrical and Electronics Engineers, IEEE Standard Requirements for the Calibration and Control of Measuring and Test Equipment Used in Nuclear Facilities, ANSI/IEEE Standard 498-1990.
5. Institute of Electrical and Electronics Engineers, IEEE Standard for Software Verification and Validation, IEEE Std. 1012-1998.
6. National Fire Protection Association, NFPA Standard 232, Standard for the Protection of Records, 2007.
7. Title 10, Code of Federal Regulations, Part 21, Reporting of Defects and Noncompliance, Current Issue.
8. Title 10, Code of Federal Regulations, Part 50, Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants, Current Issue.
9. Title 10, Code of Federal Regulations, Part 830, Subpart A, Quality Assurance Requirements, Current Issue.
10. U.S. Nuclear Regulatory Commission, Regulatory Guide 1.28, Quality Assurance Program Requirements - Design and Construction, Revision 4, June 2010.

23.0 DEFINITIONS AND TERMS

The following definitions are provided to ensure a uniform understanding of select terms as they are used in this QA Program.

Acceptance criteria – specified limits placed on the performance, results, or other characteristics of an item, process, or service defined in codes, standards, or other requirement documents.

Acceptance testing – the process of exercising or evaluating a system or system component by manual or automated means to ensure that it satisfies the specified requirements and to identify differences between expected and actual results in the operating environment.

Audit – a planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence, the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.

Baseline – A specification or product that has been formally reviewed and agreed upon, that thereafter serves as the basis for use and further development, and that can be changed only by using an approved change control process.

Basic component –

(1) When applied to nuclear power plants licensed under 10 CFR part 50 or part 52 (or the equivalent regulations in countries other than the U.S.), basic component means a structure, system, or component, or part thereof that affects its safety function necessary to assure:

- (A) The integrity of the reactor coolant pressure boundary.
- (B) The capability to shut down the reactor and maintain it in a safe shutdown condition; or
- (C) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in § 50.34(a)(1), § 50.67(b)(2), or § 100.11, (or the equivalent regulations in countries other than the U.S.), as applicable.

Basic components are items designed and manufactured under a quality assurance program complying with appendix B to part 50 (or the equivalent regulations in countries other than the U.S.), or commercial grade items which have successfully completed the dedication process.

(2) In the US, when applied to standard design certifications under subpart C of part 52, and standard design approvals under part 52, basic component means the design or procurement information approved or to be approved within the scope of the design certification or approval for a structure, system, or component, or part thereof, that affects its safety function necessary to assure:

- (i) The integrity of the reactor coolant pressure boundary.
- (ii) The capability to shut down the reactor and maintain it in a safe shutdown condition; or
- (iii) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in §§ 50.34(a)(1), 50.67(b)(2), or 100.11 of this chapter, as applicable.

(3) When applied to other facilities and other activities licensed under 10 CFR parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72 (or the equivalent regulations in countries other than the U.S.), basic component means a structure, system, or component, or part thereof, that affects their safety?

function, that is directly procured by the licensee of a facility or activity subject to the regulations in this part and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard.

(4) In all cases, basic component includes safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware, design certification, design approval, or information in support of an early site permit application under part 52 (or the equivalent regulations in countries other than the U.S.), whether these services are performed by the component supplier or others.

Certificate of Conformance – a document signed or otherwise authenticated by an authorized individual certifying the degree to which items or services meet specified requirements.

Certification – the act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements.

Characteristic – any property or attribute of an item, process, or service that is distinct, desirable, and measurable.

Code – one or more computer programs, or part of a computer program.

Commercial grade item (CGI) – an item satisfying the following:

(1) When applied to nuclear power plants and activities licensed pursuant to 10 CFR Part 30, 40, 50, 52, or 60 (or the equivalent regulations in countries other than the U.S.), commercial grade item means a structure, system, or component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified).

(2) When applied to facilities and activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72 (or the equivalent regulations in countries other than the U.S.), commercial grade item means an item that is:

- (a) Not subject to design or specification requirements that are unique to those facilities or activities.
- (b) Used in applications other than those facilities or activities.
- (c) Is to be ordered from the manufacturer or supplier based on specifications set forth in a manufacturer-published product description (e.g., a catalog)

(3) When applied to Department of Energy nuclear facilities and activities regulated under 10 CFR 830, Nuclear Safety Management, commercial grade items are a structure, system, or component, or part thereof, that affects its safety function, that was not designed and manufactured in accordance with the requirements of NQA-1.

Computer program – a defined set of instructions which are fixed (compiled into an executable file) such that the computational algorithms are not within the control of the user.

Condition adverse to quality – an all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances. A significant condition adverse to quality is one which, if uncorrected, could have a serious effect on safety or operability.

Configuration item – a collection of hardware or software elements treated as a unit for the purpose of configuration control.

Configuration management (software) – the process of identifying and defining the configuration items in a system (i.e., software and hardware), controlling the release and change of these items throughout the system's life cycle, and recording and reporting the status of configuration items and change requests.

Corrective action – measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition.

Critical characteristics - When applied to nuclear power plants licensed pursuant to 10 CFR Part 50 (or the equivalent regulations in countries other than the U.S.), critical characteristics are those important design, material, and performance characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended safety function.

Dedication - An acceptance process performed in accordance with NQA-1 (or the equivalent standards in countries other than the U.S.), requirements to provide reasonable assurance that a commercial grade item or service will perform its intended safety function and, in this respect, is deemed equivalent to an item or service designed and manufactured or provided under the requirements of NQA-1 (or the equivalent regulations in countries other than the U.S.).

(1) When applied to nuclear power plants licensed pursuant to 10 CFR Part 30, 40, 50, 60 (or the equivalent regulations in countries other than the U.S.), dedication is an acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR 50, appendix B, quality assurance program (or the equivalent regulations in countries other than the U.S.). This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at hold points at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance with the applicable provisions of 10 CFR 50, Appendix B (or the equivalent regulations in countries other than the U.S.). The process is considered complete when the item is designated for use as a basic component.

(2) When applied to facilities and activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72 (or the equivalent regulations in countries other than the U.S.), dedication occurs after receipt when that item is designated for use as a basic component.

Design authority – the organization having the responsibility and authority for approving design bases, design configuration, and design changes.

Design bases – that information which identifies the specific functions to be performed by a structure, system, or component of a facility and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. These values may be:

- (a) Restraints derived from accepted state-of-the-art practices for achieving functional goals; or
- (b) Requirements derived from analysis based on calculations or experiments of the effects of a postulated accident for which a structure, system, or component must meet its functional goals.

Design change – any revision or alteration of the technical requirements defined by approved and issued design output documents and approved and issued changes.

Design, final – approved design output documents and approved changes.

Design input – those criteria, parameters, performance requirements, codes and standards, design bases, regulatory requirements, or other design requirements upon which detailed final design is based.

Design output – drawings, specifications, and other documents used to define technical requirements of structures, systems, components, and computer programs.

Design process – technical and management processes that commence with identification of design input and that lead to and include the issuance of design output documents.

Deviation – a departure from specified requirements (including technical requirements included in a procurement document, or specified in early site permit information, a standard design certification or standard design approval).

Document – any hardcopy or electronic information, in either text or graphic format, describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. A document is not considered to be a QA Record until it satisfies the definition of a QA Record as defined in this QA Program.

Electronic document – a document stored in a form (e.g., magnetic, or optical media) that is typically accessible only by a computer.

Error – a discrepancy between a computed, observed, or measured value or condition and the true, specified, or theoretically correct value or condition.

Finding - A result of an assessment, audit, or investigation. A written conclusion that includes: The citation of the regulation/requirement, and a description of the quantitative and/or qualitative data supporting a decision of compliance or noncompliance with that regulation/requirement.

Guideline – a suggested practice that is not mandatory in programs intended to comply with this QA program. The word “should” denote guidance while the word “shall” denote a requirement.

Graded Approach - The process of ensuring that the level of rigor and detail applied to ARC program/project processes and implementing documents are commensurate with:

- Relative importance to safety, health, environment, and security.
- Magnitude of any hazard involved.
- Complexity of the facility, systems, and/or equipment being relied on to maintain an acceptable level of risk.
- Life-cycle stage of a project, facility, or activity.
- Programmatic mission of a project, facility, or activity; and
- Regulatory framework of a project, facility, or activity.

Inspection – examination or measurement to verify whether an item or activity conforms to specified requirements.

Inspector – a person who performs inspection activities to verify conformance to specific requirements.

Item – an all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, or unit. Note to the extent that a computer program is a physical part of plant systems (e.g., digital reactor protection systems, digital instrumentation, etc.) it is included in the term item.

Measuring and test equipment (M&TE) – devices or systems used to calibrate, measure, gauge, test, or inspect to control or acquire data to verify conformance to specified requirements.

Nonconformance – a deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.

Objective evidence – any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests which can be verified.

Observation - A condition that complies with specific requirements but has the potential through inattention or credible circumstances to give rise to a deficiency.

Owner – the organization legally responsible for the construction or operation of a nuclear facility, including but not limited to one who has applied for or who has been granted a construction permit or operating license by the regulatory authority having lawful jurisdiction.

Portability – the ease with which software can be transferred from one computer system or environment to another.

Procedure – a document that specifies or describes how an activity is to be performed.

Procurement document – purchase requisitions, purchase orders, drawings, contracts, specifications, or instructions used to define requirements for purchase.

Purchaser – the organization responsible for establishment of procurement requirements and for issuance or administration or both of procurement documents.

QA record – a completed document that furnishes evidence of the quality of items or activities affecting quality. In addition to paper, records may include electronic documents and specially processed records such as radiographs, photographs, negatives, and microforms.

Qualification, personnel – the characteristics or abilities gained through education, training, or experience as measured against established requirements such as standards or tests that qualify an individual to perform a required function.

Qualified procedure - an approved procedure that has been demonstrated to meet the specified requirements for its intended purpose.

Quality assurance (QA) – all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service.

Quality Level (QL) – a risk-based categorization scheme for applying a graded implementation of quality requirements:

Receiving – taking delivery of an item at a designated location.

Recommendation - A non-mandatory proposal intended to improve or enhance program compliance or program execution.

Repair – the process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired even though that item still does not conform to the original requirement.

Rework – the process by which an item is made to conform to original requirements by completion or correction.

Right of access – the right of a purchaser or designated representative to enter the premises of a supplier for the purposes of inspection, surveillance, or QA audit.

Service – the performance of activities such as design, fabrication, inspection, nondestructive examination, repair, or installation.

Shall – see definition of the term *guidance*.

Should – see definition of the term *guidance*.

Software – computer programs, procedures, rules, and associated documentation and data pertaining to the operation of a computer system.

Software life cycle – the period that begins when a software product is conceived and ends when the software product is no longer available for routine use. The software life cycle typically includes a concept phase, requirements phase, a design phase, implementation phase, test phase, installation, and checkout phase, operation, and maintenance phase, and sometimes retirement phase. These phases may overlap or be performed iteratively, depending on the software development approach used.

Software quality assurance plan – a plan for the development of software products necessary to provide adequate confidence that the software conforms to established requirements.

Software validation – See acceptance testing.

Software design verification – the process of determining if the product of the software design activity fulfills the software design requirements.

Special process – a process, the results of which are highly dependent on the control of the process or the skill of the operators, and in which the specified quality cannot be readily determined by inspection or test of the product.

Supplier – any individual or organization who furnishes items or services in accordance with a procurement document. An all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, and their sub-tier levels.

Surveillance – the act of monitoring or observing to verify whether an item or activity conforms to specified requirements.

System software – software designed to enable the operation and maintenance of the computer system and associated programs (e.g., operating systems, compilers, utilities).

Test case – a set of test inputs, execution conditions, and expected results developed for a particular objective, such as to exercise a particular program path or to verify compliance with a specific requirement.

Test plan – a document that describes the approach to be followed for testing a system or component. Typical contents identify the items to be tested, the testing to be performed, and responsibilities for testing activities.

Testing – an element of verification for the determination of the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions.

Traceability – the ability to trace the history, application, or location of an item and like items or activities by means of recorded identification.

Use-as-is – a disposition permitted for a nonconforming item when it can be established that the item is satisfactory for its intended use.

Verification – the act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements.

Waiver – documented authorization to depart from specified requirements.

24.0 ACRONYMS

ANSI – American National Standards Institute

ARC – ARC Clean Technology Inc. The group is set up by ARC to do nuclear work (projects) in various countries.

ASME – American Society of Mechanical Engineers

ASTM – ASTM International

CFR – Code of Federal Regulations

DOE – U.S. Department of Energy

IEEE – Institute of Electrical and Electronics Engineers

ISO – International Organization for Standardization

M&TE – Measuring and test equipment.

NQA – ASME Nuclear Quality Assurance

NRC – U.S. Nuclear Regulatory Commission

PM – Program/Project Manager

QA – Quality Assurance

QAPP – ARC-20 Project Quality Assurance Project Plan

QA/QC – Quality Assurance/Quality Control

S/CI - Suspect Counterfeit Items