QUALITY ASSURANCE PROGRAM DESCRIPTION
BLUE ENERGY GLOBAL, INC.

REVISION *2*

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Blue Energy Quality Assurance Program Description

RECORD OF REVISION PAGE

Revision	Approval Date	Change Description	Page(s)	Effective Date
2		***1.1.2 b) - added statement ensuring resources; 2.0 - Scope-clarified applicability to Phase 1; 2.0 - Scope-added SSC classification list, removed Texas and South Korea mfg. locations from table; 2.1 - added notification of NRC of changes; 2.6 - Moved 2.6.1 to Section 7.10 "Exceptions" & 2.6.2 to Section 18 "Exceptions"; 3.0,1 - "based" & "base" to "basis" and throughout QAPD; 3.5.4 - deleted entire section, "Config. of Oper. Plants"; 3.9 - added SP 2.20; 4.1.4 - added App B/Part 21 to procurement docs.; 7.7 - added NEI guidance related to CGD of laboratories; 7.7 - added Part 21 applicability to CGD items; 10.6 - deleted entire section "Inspected During Operations"; 10.7 - added ref SP 2.5; 15.3.3 - added req. for Part 21 evaluation; 16.0 - added CR reporting responsibilities & significant conditions reported to management; 16.1 - added req. for Part 21 evaluation and trending/evaluation; 17.0 - added NIRMA TG references; 17.0 - added training requirement, added NIRMA TGs; 17.2.3. - added electronic records indexing information; 17.4 - added transfer of authentication; 17.6.4 - added electronic record maintenance requirements; 18.1.3 - removed, "Suppliers and"; 20.0 - a & c. added revisions for RGs 1.189 & 1.155; 21.0 - corrected revision for RGs 1.164, 1.234, 1.26 & 1.29.***	***8, 12, 13, 14, 19, 20, 27,28 30, 41-43, 44, 51, 63, 65, 67, 68, 70, 71, 77-79, 84, 85***	
1	05/08/2025	Updated introduction to clarify applicability of QAPD to design and construction activities. Update roles and responsibilities to add additional details. Updated Figure 1-	4,7-11, 39, 41-42, 79-80	06/01/2025

		1 to indicate all engineering sites report to the Senior Vice-President of Engineering. Added statement related suspect and counterfeit items. Added a new Section 21 related to regulatory commitments.		
0	03/28/2025	Initial Release 10 CFR Part 50, Appendix B, and NQA-1-2022 Quality Assurance Program Description	ALL	06/01/2025

Current revision changes to this document are bold and italicized.

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INTRODUCTION

Blue Energy Global, Inc., referred to as Blue Energy, is introducing its modular nuclear power plant that can be centrally fabricated in existing fabrication yards and shipyards. The activities include design engineering, fabrication, and transport of a fully prefabricated, unfueled modular plant. Activities will be performed in two phases. ***The first phase focuses on design and pre-construction.*** The second phase will focus on construction and operations. This QAPD topical report is applicable in the first phase to support an application for a construction permit under 10 CFR Part 50. For the second phase, Blue Energy will update and revise this QAPD as necessary.

POLICY STATEMENT

Blue Energy has established a Quality Assurance Program (QAP) that complies with 10 CFR Part 50, Appendix B, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants”; 10 CFR Part 21, “Reporting of Defects and Noncompliance”; ASME NQA-1-2022, “Quality Assurance Requirements for Nuclear Facility Applications”; and Regulatory Guide (RG) 1.28, Revision 6, “Quality Assurance Program Criteria (Design And Construction”), for all nuclear safety related work, and in a graded manner to all other Blue Energy work, when applicable. The Blue Energy Chief Executive Officer is responsible for the implementation and execution of this program. The Corporate Quality Assurance Manager is responsible for development, maintenance, and independent oversight of the QAP.

The program is planned, implemented and maintained in accordance with the aforementioned law and industry standards, and provides control over activities affecting quality to an extent consistent with their importance to safety.

The program identifies the activities covered by the Quality Assurance Program Description (QAPD), along with the major organizations and their designated functions. The program takes into account the need for special controls, processes, test equipment, tools, and personnel skills necessary to attain the required quality, plus the need for independent verification of quality by audit, surveillance, inspection, test, or other appropriate means.

Activities important to quality shall be performed in accordance with the quality assurance practices described in the Blue Energy QAP. The program consists of the QAPD and implementing procedures. The implementing procedures are known as Quality System Procedures or Standard Operating Procedures. Implementing procedures are actionable instructions, which downflow additional responsibilities and provide more detail. Together they provide planned and systematic activities necessary to achieve quality.

It is the policy of Blue Energy:

- That clients and other appropriate outside agencies shall be provided reasonable access to Blue Energy facilities and documents, as necessary, for the accomplishment of their review and monitoring of work activities. Confidentiality of clients' proprietary or safeguarded information shall be maintained and may only be released to others with the expressed written permission of its owner.
- That activities prescribed in this QAPD be performed, documented, and verified in accordance with the requirements of the QAPD and its supporting implementing procedures.
- That every employee has the responsibility and freedom to identify quality problems (i.e., conditions adverse to quality) without fear of repercussion.
- That management will provide procedures, processes, tools, and commit to continually improve the quality assurance program.

Jake Jurewicz, CEO

SECTION 1 - ORGANIZATION

1.0 GENERAL

Senior management establishes the overall expectations for the effective implementation of the Program and is responsible for obtaining the desired results.

1.1 STRUCTURE AND RESPONSIBILITY

1.1.1 Organizational Structure

a) Blue Energy documents and maintains the organizational structure, functional responsibilities, levels of authority, and lines of communication for activities affecting quality through the use of implementing procedures. The organizational structure and responsibility assignments are such that:

1. Quality is achieved and maintained by those who have been assigned responsibility for performing work.
2. Quality achievement is verified by persons or organizations not directly responsible for performing the work.

b) Functions may be performed by a superior or delegated to qualified individual(s) within the organization.

1.1.2 Independence of Persons Performing Quality Assurance Functions

a) The Corporate Quality Assurance Manager (CQAM) reports directly to the Chief Executive Officer (CEO) and has the responsibility for establishing the QAP and verifying that activities affecting quality are performed in accordance with the QAP. This reporting relationship assures that the CQAM is sufficiently independent from cost and schedule when opposed to quality and that sufficient authority, direct access to responsible levels of management, access to work to perform this function, and organizational freedom are assured when opposed to safety function considerations. In

addition, if the CQAM disagrees with actions taken by the organization and is unable to obtain resolution, the CQAM shall refer the matter to the CEO/President, who shall render a final determination. These verification functions include:

1. identifying quality problems
2. initiating, recommending, or providing solutions to quality problems through designated channels
3. verifying the implementation of solutions
4. assuring that further processing, delivery, installation, manufacturing, or use of products or procedures is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred
5. ***Issuing*** "Stop Work" order to curtail Blue Energy work or supplier work, as deemed necessary in response to quality problems

b) The CEO and Corporate QA Manager shall ensure that adequate QA resources are applied commensurate with the duties and responsibilities of the QA organization.

c) The Executive Team consists of the CEO, the Senior Vice President of Engineering, the Chief Commercial Officer, the Senior Vice President of Commercial and Business Development, and the Vice President of Regulatory Affairs. The Executive Team is responsible for establishing, maintaining, and controlling department work instructions and/or procedures to control the work and to satisfy the requirements of this QAPD. The Executive team also:

1. reviews and approves procurement documents in accordance with Blue Energy policies and procedures

2. ensures that all department personnel are aware of and that they comply with applicable procedures
3. interfaces with QA Management in implementing changes affecting the quality system
4. provides support for internal and external audits and access to QA personnel as needed and as required
5. assesses adequacy and effectiveness of implementation of the quality program annually

d) Engineering consists of staff in the United States and the United Kingdom. The Engineering organization is responsible for designating project leads who hold accountability for the quality of all safety-related activities and for ensuring effective coordination with external entities to uphold quality standards. This is accomplished by:

1. independent checking of completed design documents
2. independent design reviews
3. identification of approved bidders
4. performance of technical bid reviews and selection of suppliers
5. review of procurement documents, in conjunction with QA, to establish the necessary level of supplier surveillance and to identify supplier submittal requirements
6. review of supplier-furnished design documents
7. ensure appropriate manufacturing and supplier contract oversight, qualifications, and execution

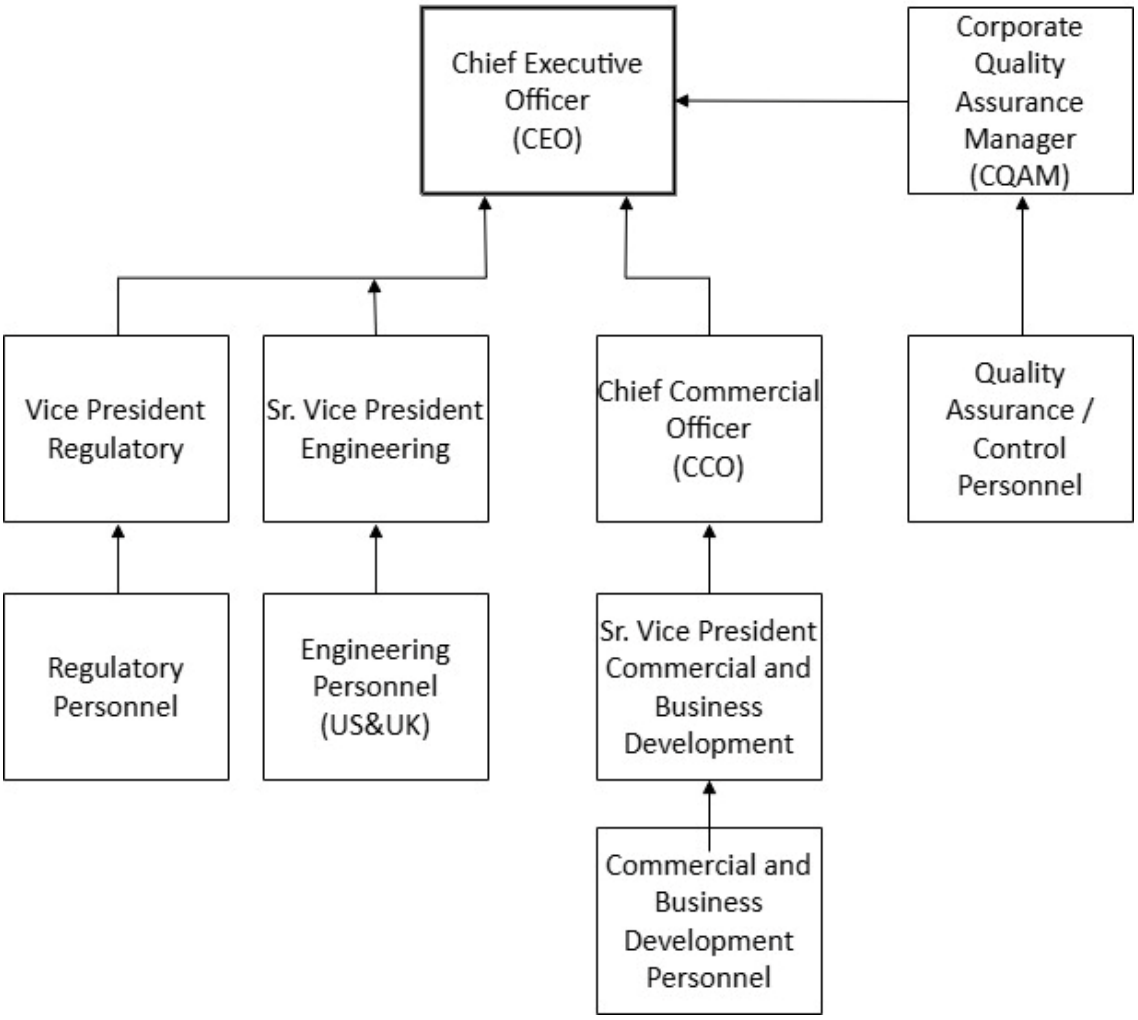
e) Any Blue Energy employee who has an issue with quality is encouraged to bring it to the attention of their Lead, Supervisor, or

Manager. If the issue is not resolved to their satisfaction, the employee has access to the CQAM or the CEO.

f) Any Blue Energy employee has the authority to stop work until the proper resolution and disposition have been made.

g) The organization chart is identified in Figure 1-1.

Figure 1-1: Blue Energy Organization



1.1.1 Delegation

The individual(s) or organization(s) responsible for establishing and executing a quality assurance program may delegate any, or all, work to others, but shall retain responsibility thereof.

1.2 INTERFACE CONTROL

When more than one organization, internal or external, is involved in the execution of activities covered by the QAP, the responsibilities, interfaces, authority, and changes thereto of each organization is defined and documented. Responsibilities and interfaces between organizations shall be defined in contracts, purchase orders, implementing procedures and associated project documents.

1.3 NQA-1 COMMITMENT

In establishing its organizational structure, Blue Energy commits to compliance with NQA-1-2022, Part I, Requirement 1, “Organization”.

SECTION 2 - QUALITY ASSURANCE PROGRAM

2.0 GENERAL

Scope

The Blue Energy quality assurance program, also referred to as the "QAP" in this document, is comprised of the Quality Assurance Program Description (QAPD) and the associated implementing procedures. ***Blue Energy activities will be performed in two phases. This QAPD applies to the first phase (Phase 1) which is for design and pre-construction.***

The QAPD is the top-level policy that establishes the way Blue Energy is to assure and achieve quality. The QAPD focuses employee attention on regulatory requirements while requiring the identification of concerns and non-conforming conditions. Quality System Procedures (QSPs) and Standard Operating Procedures (SOPs) are the primary implementing procedures for the requirements of the QAPD and provide, in detail, how key activities are to be performed while achieving the QAP commitments. Activities affecting quality are controlled to the extent necessary and consistent with their importance.

The QAP provides for any special controls, processes, test equipment, tools, and skills or training to attain the required quality and for verification of quality, as applicable. Implementation of the QAP, or portions thereof, shall be regularly assessed by management for adequacy and effective implementation.

The QAP meets the following regulations and guidance:

- 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants" and 10 CFR Part 21, "Reporting of Defects and Noncompliance"
- NQA-1-2022, "Quality Assurance Requirements for Nuclear Facility Applications"

- Regulatory Guide 1.28, Revision 6, “Quality Assurance Program Criteria (Design and Construction)”

Blue Energy shall establish and maintain a plant-level SSC classification listing of all Safety-Related SSCs. A list or system that identifies SSCs and activities this program applies shall be maintained at a Blue Energy facility.

The QAP also applies, in a graded manner (referred to as Augmented Quality (AQ)) to certain areas and activities that are not clearly identified as safety-related but are required to meet unique requirements specified in other nuclear specific documents, including but not limited to Regulatory Guides, American Society of Mechanical Engineers (ASME) Codes, etc. Section 19 of this QAPD may be referred to for nonsafety-related quality controls.

Applicability of the QAP

The QAP is applicable to the following facility locations:

Location	Functions
Edinburgh, Scotland	Senior Leadership Team, Engineering
Rockville, Maryland (USA)	Licensing, Engineering
TBD	Construction and Operations

2.1 *CHANGES TO THIS QAPD*

When changes are made to this QAPD, a copy of the revised document shall be submitted to the NRC's Document Control Desk. If the communication is on paper, the signed original must be sent.”

Current revision changes to this document are bold and italicized.

2.2 INDOCTRINATION AND TRAINING

The QAP provides for indoctrination and training, as necessary, of personnel performing activities affecting quality to ensure that suitable proficiency is achieved and maintained. Blue Energy maintains documented procedures for indoctrination and training of personnel performing or managing activities affecting quality. The extent of indoctrination and training shall be commensurate with the scope, complexity, and nature of the activity, as well as the education, experience, and proficiency of the individuals performing the work.

2.2.1 Personnel shall receive indoctrination training to ensure they can perform the activities they are assigned to perform. Personnel shall be indoctrinated in quality assurance subjects as they relate to a particular function. The intent of indoctrination is to provide an awareness of the governing QA regulations (10 CFR Part 21 and 10 CFR Part 50, Appendix B, etc.), the Program, the individual's responsibility for complying with the Program, and QA's responsibility to audit and verify program implementation. Indoctrination includes, as applicable:

a) general criteria, including regulatory guides, applicable codes, standards, and company procedures

b) applicable Program elements

c) job responsibilities and authority

Training shall be provided, as needed, to:

a) achieve initial proficiency

b) maintain proficiency

c) adapt to changes in technology, methods, or job responsibilities

2.2.2 On-the-job training shall be used if direct hands-on applications or experience is needed to achieve and maintain proficiency.

2.3 QUALIFICATION REQUIREMENTS

2.3.1 Nondestructive Examination (NDE)

Personnel who perform radiographic (RT), magnetic particle (MP), ultrasonic (UT), liquid penetrant (PT), electromagnetic (ET), neutron radiographic (NR), leak testing (LT), acoustic emission (AE), and visual testing (VT) shall be qualified in accordance with the American Society for Nondestructive Testing (ASNT) Recommended Practices or Standards. Applicable codes, standards, or design criteria shall be utilized to establish the applicable ASNT qualification requirement and edition or to specify an equivalent alternative requirement. Qualifications for NDE personnel are prescribed in implementing procedures.

2.3.2 Inspection and Test

Initial capabilities are determined by an evaluation of the candidate's education, experience, training and either test results or capability demonstration. Job performance of Inspection or Test personnel shall be reevaluated at periodic intervals not exceeding three years. Any personnel who have not performed inspection or testing activities in the qualified area for a period of one year are reevaluated to begin a new triennial cycle.

If during any evaluation activity of an inspector or tester it is determined the capabilities of the individual is not in accordance with qualification requirements specified for the activity, the inspector or tester shall be removed from that activity until such time the required capability is demonstrated. Qualifications for inspectors or test personnel are prescribed in the implementing procedure.

2.3.3 Lead Auditors

Lead Auditors organize and direct audits, report audit findings, and evaluate corrective actions. Lead auditors shall be qualified to perform lead auditing responsibilities by the Corporate Quality Assurance Manager and shall meet the requirements of NQA-1-2022 in the following areas:

a) communication Skills

b) training

c) audit participation

d) examination

e) maintenance of proficiency

f) requalification

If the Lead Auditor is the CQAM, the qualification shall include the above and be performed by the CEO. Qualifications for Lead Auditors are prescribed in the implementing procedure.

2.3.4 Auditors

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

a) orientation to provide a working knowledge and understanding of the regulatory or governing standards and the auditing organization's procedures for implementing audits and reporting results

b) general and specialized training in audit performance where the general training shall include fundamentals, objectives, characteristics, organization, performance, and results of quality auditing and the specialized training shall include methods of

examining, questioning, evaluating, and documenting specific audit items and methods of closing out audit findings

c) 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.

Qualifications for auditors are prescribed in the implementing procedure.

2.3.5 Technical Specialists

The responsible auditing organization shall establish the qualifications and requirements for technical specialists for use in quality related activities that include, but are not limited to, inspections, tests, or quality assurance program audits. Qualification for Technical Specialists are prescribed in the implementing procedure.

2.4 RECORDS OF QUALIFICATION

2.4.1 The qualification of Inspection, Test and Lead Auditor personnel shall be certified in writing and include the following information:

- employer's name
- identification of person being certified
- activities certified to perform
- signature of employer's designated representative

2.4.2 In addition to 2.3.1, Inspection and Test personnel shall include:

- education and / or work experience
- training
- demonstration of capabilities
- date of certification / recertification

- any special physical requirements needed in the performance of each activity, including the need for initial and subsequent physical examination
- certification expiration

2.4.3 In addition to 2.3.1, the Lead Auditor personnel records shall include:

- basis of qualification, including education, work experience, professional accomplishments, and other management justifications
- audit communication skills evaluation results
- audit training courses, where applicable
- documentation of on-the-job training, where applicable
- audit participation
- Lead Auditor examination results and date, where applicable
- date of certification / recertification
- annual assessment of proficiency maintenance

2.5 RECORDS

Qualification, requalification, and training records shall be maintained for indoctrination, Auditor, Lead Auditor, and Inspector and Test personnel. As applicable, records shall include objectives of the training, content of the program, and one or more of:

- attendance sheets
- training logs
- personnel training records

Records shall be maintained by the responsible organization.

2.6 NQA-1 COMMITMENT

In establishing its QAP, including qualification and training, Blue Energy commits to compliance with NQA-1-2022, Part I, Requirement 2, “Quality Assurance Program”.

SECTION 3 - DESIGN CONTROL

3.0 GENERAL

Designs shall be defined, controlled, and verified. Design inputs shall be specified on a timely basis and translated into design documents. Design interfaces shall be identified and controlled. Design adequacy shall be verified by individuals 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.

Design control measure ensure:

1. applicable regulatory requirements, codes and standards, and design ***basis*** for safety-related structures, systems, and components are correctly translated into specification, drawings, procedure, and instructions;
2. appropriate quality standards are specified in design documents; and
3. deviations from standards are controlled.

3.1 DESIGN INPUT

Applicable design inputs for use in performing design activities shall be identified and documented, and their selection reviewed and approved. The design input shall be specified to the level of detail necessary to permit the design activities 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.

3.2 DESIGN PROCESS

3.2.1 The responsible design organization shall prescribe and document the design activities 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 applicable requirements. The design documents shall support the

facility design, construction and operation. The appropriate quality standards shall be identified and documented and their selection reviewed and approved.

3.2.2 Key design elements – such as methods, materials, parts, equipment, and processes – shall be chosen and reviewed to ensure they are appropriate for their intended function. Additionally, lessons learned from past experiences shall be documented and shared with design personnel to support informed decision-making.

3.2.3 Final design(s) 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

c) identify assemblies and / or components that are part of the item being designed, as applicable

3.3 DESIGN ANALYSES

Design analyses shall be sufficiently detailed, clear, legible, and concise such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without extensive research and without recourse to the originator.

3.3.1 Use of Computer Programs

Computer programs used for design analysis shall be verified for use by applying the applicable requirements of NQA-1-2022, Parts I and II prior to use or the computer program's results shall be independently verified with the design analysis for each application. Any acceptance of controlled

computer programs for design analysis and / or the verification methods applied to the results of unproven programs shall meet:

a) The computer program, or the verification method applied to the computer results, shall be shown to produce correct solutions for the applied mathematical model within defined limits for each parameter employed.

b) The applied mathematical model shall be shown to produce a valid solution to the physical problem associated with the particular application.

3.3.2 Documentation of Design Analyses

Documentation of design analyses shall include:

a) the objective of the analyses

b) the design inputs and their sources

c) the results of literature searches or other applicable background data

d) assumptions and indication of those assumptions that must be verified as the design proceeds

e) the identification of any computer calculation, including the identification of the computer type, computer program name and revision / version, inputs, outputs, evidence of or reference to computer program verification, and the ***basis*** (or reference thereto) supporting application of the computer program to the specific physical problem

f) review and approval

3.4 DESIGN VERIFICATION

3.4.1 The responsible design organization shall identify and document the particular design verification method(s) used. The results of design verification shall be 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 but who may be from the same organization. Cursory supervisor / manager reviews do not satisfy the intent of design verification.

Design verification may be performed by the originator's supervisor or manager based on either of the following:

a) The supervisor or manager did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design.

b) The supervisor or manager is the only individual in the organization competent to perform the verification.

3.4.2 Design verification shall be performed prior to releasing the design for procurement, manufacture, construction, or for use by another design organization, except where this timing cannot be met, such as when insufficient data exists. In those cases, any unverified portions 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, component, or computer program to perform its function.

3.4.3 Designs that are modified as a result of verification findings shall be re-verified prior to releasing the final design for use.

3.4.4 The extent of design verification shall be 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 proved designs. The verification process need not be duplicated for identical designs; however, the use of

standardized or previously approved designs with respect to meeting pertinent design inputs shall be verified for each application. Known problems affecting the standard or previously approved designs and their effect on other features shall be considered. The original design and associated verification documentation shall be referenced in records of subsequent application of the design.

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

a) Design Reviews

Design reviews shall provide assurance that the final design is correct and satisfactory by addressing, where applicable:

1. Were the design inputs correctly selected?
2. Are any assumptions necessary to perform the design activity adequately described and reasonable? Where necessary, are the assumptions identified for subsequent reverifications when the detailed design activities are completed?
3. Were appropriate design methods and computer programs used?
4. Were the design inputs correctly incorporated into the design?
5. Is the design output reasonable compared to the design inputs?
6. Are the necessary design inputs for interfacing organizations specified in the design documents or in supporting procedures or instructions?
7. Have suitable materials, parts, processes, and inspection and testing criteria been specified?

b) Alternate Calculations

Alternate calculations shall use alternate methods to verify correctness of the original calculations or analyses. The appropriateness of

assumptions; input data used; the computer program, its associated computer hardware and system software; or other calculation method used shall be reviewed.

c) Qualification Tests

Qualification testing shall demonstrate adequacy of performance under conditions that simulate the most adverse design conditions. The operating modes and environmental conditions are considered when determining the most adverse condition. Where the test is intended to verify only a specific design feature, the other features shall be verified by other means. Scaling laws shall be established and verified for tests being performed on models or mockups. The results of model test work shall be subject to error analysis, where applicable, prior to use in the final design.

3.5 DESIGN CHANGE CONTROL

3.5.1 Changes to design inputs, final designs, field designs, field changes, and temporary or permanent modifications to operating facilities 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 any analysis upon which the design is based. The evaluation shall include facility configurations that occur during operation, maintenance, test, surveillance, and inspection activities. Changes shall be approved by the same groups or organizations that reviewed and approved the original design documents. Where an organization that was originally responsible for approving a particular design document is no longer responsible, then a new responsible organization shall be designated. 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.

3.5.2 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.

3.5.3 Where a significant design change is necessary because of an incorrect design, the design and verification process shall be reviewed and modified as necessary.

3.6 INTERFACE CONTROL

3.6.1 Interface controls shall include assignment of responsibility and establishment of procedures among participating design organizations for review, approval, release, distribution, and revision of documents involving design interfaces.

3.6.2 Design information transmitted across interfaces shall identify the status of the design information or document provided, and identify incomplete items that 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.

3.7 SOFTWARE DESIGN CONTROL

Software design control shall incorporate the applicable requirements found in NQA-1-2022, Part II, Subpart 2.7, Quality Assurance Requirements for Computer Software for Nuclear Facility Applications.

3.8 DOCUMENTATION AND RECORDS

Design documentation and records shall include not only final design documents, such as drawings and specifications, and revisions to those documents, but also documentation that identifies the important steps in the design process, including sources of design inputs that support the final design.

3.9 NQA-1 COMMITMENT

In establishing its QAP, Blue Energy commits to compliance with NQA-1-2022, Part I, Requirement 3, Design Control and Part II, Subpart 2.7, Quality Assurance Requirements for Computer Software for Nuclear Facility Applications ***and Subpart 2.20 "Quality Assurance Requirements for Subsurface Investigations for Nuclear Facilities".***

SECTION 4 - PROCUREMENT DOCUMENT CONTROL

4.0 GENERAL

Applicable design ***basis*** 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 Suppliers to have a QAP consistent with the applicable requirements of this QAPD.

4.1 CONTENT OF PROCUREMENT DOCUMENTS

Procurement documents issued at all tiers of procurement shall include provisions for the following, as deemed necessary by Blue Energy:

4.1.2 Scope of Work

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

4.1.3 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 as applicable.

4.1.4 Quality Assurance Program Requirements

QAP 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 QAP requirements in subtier procurement documents.

When requirements, 10 CFR 50, Appendix B and 10 CFR, Part 21 apply to the procured item or service, these requirements shall be included in the procurement documents and flowed down as compliance requirements to the prime supplier and be applicable to any of the prime's subtier suppliers.

4.1.5 Right of Access

The procurement documents shall provide for access to the Supplier's and subtier Supplier's facilities and records for surveillance, inspection, or audit by Blue Energy, its designated representative, and others authorized by Blue Energy.

4.1.6 Documentation Requirements

The procurement documents shall identify the documentation required to be submitted for information, review, or approval by Blue Energy. The time of submittal shall also be established. When Blue Energy requires the Supplier to maintain specific records, the retention times and disposition requirements shall be prescribed.

4.1.7 Nonconformances

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

4.1.8 Spare and Replacement Parts

If applicable, the procurement documents shall specify the Supplier's requirements to identify spare and replacement parts or assemblies, and the related data required for ordering these parts or assemblies.

4.2 PROCUREMENT DOCUMENT REVIEW

4.2.1 A review of 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.

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

4.2.3 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.

4.3 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.

4.4 NQA-1 COMMITMENT

In establishing its QAP, Blue Energy commits to compliance with NQA-1-2022, Part I, Requirement 4, Procurement Document Control.

SECTION 5 - INSTRUCTIONS, PROCEDURES, AND DRAWINGS

5.0 GENERAL

Activities affecting quality and services shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings that 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 (i.e., education, training, and experience).

5.1 NQA-1 COMMITMENT

In establishing its QAP, Blue Energy commits to compliance with NQA-1-2022, Part I, Requirement 5, Instructions, Procedures and Drawings.

SECTION 6 - DOCUMENT CONTROL

6.0 GENERAL

The preparation, issuance, and changes to documents that specify quality requirements or prescribe activities affecting quality, such as instructions, procedures, purchase orders, engineering calculations, or drawings, shall be controlled to ensure that correct documents are being employed. Such documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel.

6.1 DOCUMENT CONTROL

The following controls shall be applied to documents, and changes thereto:

a) the unique identification of controlled documents, including revision control identification

b) the specified distribution of controlled documents for use at the appropriate location

c) the identification of individual roles responsible for the preparation, review, approval and distribution of controlled documents

d) a review of controlled documents for adequacy and completeness prior to approval, distribution, or processing

e) a method to ensure that correct documents and revisions are being used

6.2 DOCUMENT CHANGES

6.2.1 Major Changes

Changes to documents, other than those defined as minor changes, are considered major changes and shall be reviewed and approved by the same organizations that performed the original review and approval, unless other organizations are specifically designated. The reviewing organization

shall have access to pertinent background data or information upon which to base their approval.

6.2.2 Minor Changes

Minor changes to documents are changes that do not alter their applicability, meaning, intent, or technical content. Minor errors are inconsequential editorial corrections (e.g., typos or spelling errors) and do not require the same review and approval as the original documents. To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval and the persons who can authorize such a decision shall be clearly delineated. Program implementing procedures contain the specific requirements for minor changes.

6.3 NQA-1 COMMITMENT

In establishing its QAP, Blue Energy commits to compliance with NQA-1-2022, Part I, Requirement 6, ***Document Control***.

SECTION 7 - CONTROL OF PURCHASED ITEMS AND SERVICES

7.0 GENERAL

The procurement of items and services are controlled to ensure conformance with specified requirements. The controls, as appropriate, are established for 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.

7.1 SUPPLIER EVALUATION AND SELECTION

7.1.1 Prior to awarding a contractual agreement, (e.g., a Purchase Order), Blue Energy shall evaluate a supplier's capability to provide items or services in accordance with the requirements of the procurement document. The type and depth of the evaluation shall be commensurate with the significance of the item and service being procured. Evaluation methods shall include at least one of:

a) Supplier's history of providing identical or similar items that perform satisfactorily in use shall reflect current capability.

b) Supplier's current quality records are supported by documented qualitative and quantitative information that can be objectively evaluated and may include third-party certificates that recognize the Supplier's quality assurance program or other technical certifications.

c) Supplier's technical and quality capability are determined by a direct evaluation of the facilities, personnel, and the implementation of the supplier's quality assurance program (i.e., audits). Audits are performed IAW section 18.0 of the QAPD.

7.2 BID EVALUATION

When 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 a contract, Blue Energy shall resolve or obtain commitments to resolve unacceptable technical or quality conditions resulting from the bid evaluation.

7.3 CONTROL OF SUPPLIER-GENERATED DOCUMENTS

Controls are implemented to ensure the submittal and evaluation of Supplier-generated documents and changes are accomplished in accordance with procurement document requirements. The controls include acquisition, processing and recorded evaluation of the quality assurance, technical, inspection and test documentation or data against the acceptance criteria. Supplier-generated documents to be submitted to Blue Energy shall be identified in the Purchase Order.

7.4 ANNUAL SUPPLIER EVALUATIONS

In accordance with NRC Regulatory Guide 1.28, Revision 6 (ML23177A002), Blue Energy should perform or arrange for annual evaluations of suppliers. The evaluations should be documented and take into account the following, where applicable:

a) the review of supplier-furnished documents and records such as certificates of conformance, nonconformance notices and corrective actions, results of previous source verifications, audits, and receipt inspections

b) operating experience of identical or similar products furnished by the same supplier and result of audits from other sources (e.g., Nuclear Procurement Issues Corporation (NUPIC) audit reports or NRC inspection reports)

7.5 ACCEPTANCE OF ITEM OR SERVICE

7.5.1 General

Prior to offering an item or service for acceptance, the Supplier shall verify the item or service being furnished complies with the procurement requirements. The extent of the verification activities by Blue Energy is a function of relative importance, complexity, and quantity of the item or services procured and the Supplier's quality performance. As determined 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.

7.5.2 Methods of Acceptance

Methods used to accept an item or service from a Supplier include at least one of:

7.5.2.1 Supplier Certificate of Conformance

The following minimum criteria shall be met:

- The certificate shall identify the purchased material or equipment (e.g., the purchase order number).
- The certificate shall identify the specific procurement requirements met by the purchased material or equipment such as codes, standard and other specifications. The procurement requirements identified shall include any approved changes, waivers, or deviations applicable to the material or equipment.
- The certificate shall identify any procurement requirements that have not been met, together with an explanation and the means for resolving the nonconformances.
- The certificate shall be signed or otherwise authenticated by a person who is responsible for the quality assurance

function and whose function and position are described in the Blue Energy or Supplier's QAP.

- The certification system, including 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 QAP.
- Means shall be provided to verify the validity of the Supplier certificates and the effectiveness of the certification system, such as during the performance of an audit of the Supplier or independent inspection or test of the items. The verification shall be conducted by Blue Energy at intervals commensurate with the Supplier's past quality performance.

7.5.2.2 Source Verification

If 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. The source verification shall be implemented in accordance with plans to perform inspections, examination, or tests at predetermined points. The Blue Energy acceptance of source verification shall include documented evidence and shall be furnished to the receiving destination of the item and to the Supplier.

7.5.2.3 Receiving Inspection

If receiving inspection is used, the purchased items shall be inspected, as necessary, to very conformance to specified requirements, taking into account source verification and audit activities and the demonstrated quality performance of the

Supplier. Receipt inspect shall verify by objective evidence such features as:

- configuration
- identification
- dimensional, physical, and other characteristics
- freedom from shipping damage
- cleanliness
- evaluation of counterfeit, fraudulent, and suspect items (CFSI) characteristics

The receipt inspection is coordinated with a review of Supplier documentation when procurement documents require such documentation to be furnished prior to receiving inspection.

7.5.2.4 Post-Installation Testing

When used, post-installation and test requirements shall be mutually established by Blue Energy and the Supplier.

7.5.2.5 Acceptance of Services Only

When the procurement involves services only, such as third-party inspection; engineering and consulting services; auditing; and installation, repair, overhaul, or maintenance work, Blue Energy will accept by any of the following methods:

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

7.6 CONTROL OF SUPPLIER NONCONFORMANCES

Purchase orders or service agreements require notification to Blue Energy by the supplier for items and services that do not meet specified requirements.

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

a) evaluation of nonconforming items inclusive of the supplier recommended disposition (e.g., use-as-is or repair) and any technical justifications

b) submittal of nonconformance notice to Blue Energy by the supplier as directed by the procurement document. Nonconformances to the procurement requirements of Blue Energy approved documents, which consist of one or more of the following, shall be submitted to Blue Energy for approval of the recommended disposition:

- technical or material requirement is violated
- requirement in a Supplier document, which has been approved by Blue Energy is violated
- nonconformance cannot be corrected by continuation of the original manufacturing process or by rework
- the item does not conform to the original requirements even though the item can be restored to a condition such that the capability of the item to function is unimpaired

c) Blue Energy disposition of Supplier's recommendation

d) verification of implementation of the disposition

e) maintenance of records of Supplier-submitted nonconformances

7.7 COMMERCIAL GRADE ITEMS AND SERVICES

Blue Energy establishes procedures for the dedication and / or acceptance of commercial grade items and services. The requirements of NQA-1-2022, Part II, Subpart 2.14, *Quality Assurance Requirements for Commercial Grade Items and Services*, shall apply.

Commercial Grade Calibration and Testing services may be accepted and used utilizing the industry guidance found in NEI 14-05A, Revision 1, September 2020, "**Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services"** (ML20135H229). ***When using this method, the following criteria shall apply:***

The following are the actions and steps that are necessary for a licensee and/or a supplier of basic components to accept accreditation of domestic and international calibration and test laboratory services by ILAC MRA signatories in lieu of performing a commercial-grade survey as part of the commercial-grade dedication process:

1) ***The method to use accreditation by an ILAC MRA signatory in lieu of a commercial-grade survey (alternative method) is documented in the licensee and/or supplier of basic components' QA program.***

2) ***The method the licensee and/or supplier of basic components needs to follow, and document in their QA program, consists of:***

   A. ***A documented review of the laboratory's accreditation is performed and includes a verification of the following:***

      I. ***The calibration or test laboratory holds accreditation by an accrediting body recognized by the ILAC MRA. The accreditation encompasses ISO/IEC-17025:2017, "General Requirements for the Competence of Testing and Calibration Laboratories."***

II. ***For procurement of calibration services, the published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.***

III. ***For procurement of testing services, the published scope of accreditation for the test laboratory covers the needed testing services including test methodology and tolerances/uncertainty.***

IV. ***The laboratory has achieved accreditation based on an on-site accreditation assessment by the selected AB within the past 48 months. The laboratory's accreditation cannot be based on two consecutive remote accreditation assessments.***

B. The purchase documents require that:

I. ***The service must be provided in accordance with their accredited ISO/IEC-17025:2017 program and scope of accreditation.***

II. ***As-found calibration data must be reported in the certificate of calibration when calibrated items are found to be out-of-tolerance (for calibration services only). c. The equipment/standards used to perform the calibration must be identified in the certificate of calibration (for calibration services only).***

III. ***Subcontracting of these accredited services is prohibited.***

IV. ***The customer must be notified of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation.***

V. ***Performance of the services listed on this order is contingent on the laboratory's accreditation having been achieved through an on-site accreditation assessment by the AB within the past 48 months. g. Any additional technical and quality requirements, as necessary, based upon a review of the procured scope of***

services, which may include, but are not necessarily limited to, tolerances, accuracies, ranges, and industry standards.

C. It is validated, at receipt inspection, that the laboratory's documentation certifies that:

I. The contracted calibration or test service has been performed in accordance with their ISO/IEC-17025:2017 program, and has been performed within their scope of accreditation, and

II. The purchase order's requirements are met.

Program implementing procedures shall contain the requirements of NQA-1-2022, Part II, Subpart 2.14 and ***the appropriate requirements from*** NEI 14-05A, ***Revision 1 listed above.***

The requirements of 10 CFR Part 21 will apply, upon completion of dedicated items and services.

7.8 RECORDS

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

a) supplier evaluation and selection

b) acceptance of items or services

c) supplier nonconformances to procurement document requirements, including their evaluation and disposition

7.9 NQA-1 COMMITMENT

In establishing its QAP, Blue Energy commits to compliance with NQA-1-2022, Part I, Requirement 7, Control of Purchased Items and Services, with the following exceptions:

- Blue Energy considers 10 CFR Part 50 licensees, Authorized Nuclear Inspection Agencies, National Institute of Standards and Technology, or other State and Federal agencies, which may provide items or services to Blue Energy, as not requiring evaluation or audit.
- When purchasing commercial grade calibration or testing services from a laboratory holding accreditation by an accrediting body recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement, Blue Energy will implement the requirements of Revision 1 of NEI 14-05A as endorsed by NRC Final Safety Evaluation (ML20322A019).

7.10 *QA PROGRAM EXCEPTIONS*

7.10.1 *The following exception to NQA-1-2022, Requirement 7, Control of Purchased Items and Services is being taken:*

Blue Energy considers other 10 CFR Part 50 licensees, Authorized Nuclear Inspection Agencies, National Institute of Standards and Technology, and other state and Federal agencies that provide items and services to Blue Energy, are not required to be evaluated or audited (consistent with NRC Safety Evaluation (SE) ML23254A050). This exception does not include procurements from manufacturing licensees for which quality can only be verified during the fabrication or manufacturing process.

SECTION 8 - IDENTIFICATION AND CONTROL OF ITEMS

8.0 GENERAL

Controls shall be established to ensure that only correct and accepted items are used or installed. Identification shall be maintained on the items or in documents traceable to the items, or in a manner that ensures that identification is established and maintained.

8.1 IDENTIFICATION METHODS

8.1.1 Item Identification

Items of production (e.g., batch, lot, component, part) shall be identified from the initial receipts and fabrication of items up to and including installation and use. This identification shall relate an item to an applicable design or other pertinent specifying document.

8.1.2 Physical Identification

Physical identification shall be used to the maximum extent possible. The types of acceptable physical identification methods include but are not limited to written markings, etching, affixing stickers with bar or quick response (QR) codes, stamping, and tags. The identification markings shall be applied using materials and methods that provide clear and legible identification and do not degrade the function or service life of the item.

Identification markings shall be transferred to each part of an identified item when subdivided. Surface treatment and coatings shall not obliterate or hide the identification marking unless other means of identification are substituted.

8.1.3 If physical identification on the item is impractical or insufficient, physical separation, procedural control, or other appropriate means shall be employed.

8.2 SPECIFIC REQUIREMENTS

8.2.1 Identification and Traceability of Items

Blue Energy shall ensure specific identification and traceability controls required by codes, standards, or specifications (such as identification or traceability of the item to applicable specification and grade of material; heat; batch, lot, part, or serial number; etc.) are maintained.

8.2.2 Limited Life Items

Items with a limited calendar or operating life or cycles shall be identified and controlled to preclude use of the items whose calendar, shelf or operating life has expired.

8.3 Maintaining Identification of Stored Items

Provisions are provided to control item identification consistent with the planned duration and conditions of storage, such as:

- provisions for maintenance or replacement of markings and identification records due to damage during handling or aging
- protection of identification on items subject to excessive deterioration due to environmental exposure
- provisions for updating existing facility records

8.4 NQA-1 COMMITMENT

In establishing its QAP, Blue Energy commits to compliance with NQA-1-2022, Part I, Requirement 8, **Identification and Control of Items.**

SECTION 9 - CONTROL OF SPECIAL PROCESSES

9.0 GENERAL

Special processes that control or verify quality (e.g., welding, heat treating, and nondestructive examination) shall be performed using qualified personnel and procedures in accordance with specified requirements. Any special processes not performed by Blue Energy shall be conducted in accordance with Sections 4, *Procurement Document Control* and 7, *Control of Purchased Items and Services* of this manual.

9.1 PROCESS CONTROL

9.1.1 Special Processes

Blue Energy shall control any special processes by using appropriate means (e.g., procedures drawings, travelers, etc.). The documentation for special processes shall provide the necessary instruction and, as applicable, include:

- applicable codes and standards including acceptance criteria
- personnel and equipment qualification requirements
- conditions necessary for the accomplishment of the process (i.e., proper equipment, control parameters of the process, environment and calibration requirements)

9.1.2 Special Requirements

For special processes not covered by existing codes and standards, or where quality requirements specified exceed those of existing codes or standards, the necessary requirement for qualification of personnel, procedures, or equipment shall be documented or referenced in procedures or instructions.

9.2 RESPONSIBILTY

All Blue Energy personnel are responsible for performing special processes in accordance with the approved procedures and processes.

9.3 RECORDS

Records shall be maintained for the currently qualified personnel, processes and equipment of each special process.

9.4 NQA-1 COMMITMENT

In establishing its QAP, Blue Energy commits to compliance with NQA-1-2022, Part I, Requirement 9, Special Processes.

SECTION 10 - INSPECTION

10.0 GENERAL

Inspections required to verify conformance of an item or activity to specified requirements, or continued acceptability of items in service, shall be planned and executed. Blue Energy identifies characteristics subject to inspection and the inspection method shall be specified. Inspection results shall be documented. Inspection for acceptance shall be performed by qualified personnel other than those who performed or directly supervised the work being inspected. Any inspection activity not performed by Blue Energy shall be conducted in accordance with Sections 4, **Procurement Document Control** and 7, **Control of Purchased Items and Services** of this manual.

10.1 INSPECTION REQUIREMENTS

Inspection requirements and acceptance criteria shall include specified requirements contained in the applicable design documents or other pertinent technical documents approved by the responsible design organization (e.g., drawings, specifications, etc.).

10.2 INSPECTION HOLD POINTS

If applicable mandatory inspection hold points are required beyond which work shall not proceed without the specific consent of the designated representative, the specific hold points shall be indicated in appropriate documents. Consent to waive specified hold points shall be recorded prior to continuation of work beyond the designated hold point.

10.3 INSPECTION PLANNING

10.3.1 Characteristics to be inspected, methods of inspection and acceptance criteria shall be identified during the planning process.

10.3.2 Sampling of items to be inspected shall be performed in accordance with an engineering-approved standard statistical method.

10.4 IN-PROCESS INSPECTION

10.4.1 Inspection shall be conducted for items under construction or otherwise in process as necessary to verify the quality of the item.

10.4.2 For any inspection process that is impossible or disadvantageous, indirect control by monitoring of the processing methods, equipment, and personnel shall be performed by personnel who are independent from the personnel performing the process controls or by qualified automated means. Both inspection and process monitoring shall be provided when quality verification is inadequate without both.

10.5 FINAL INSPECTIONS

10.5.1 Resolution of Nonconformances

Final inspection shall include a records review of the results and resolution of nonconformances identified by prior inspections.

10.5.2 Inspection Requirements

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

10.5.3 Modifications, Repairs, or Replacements

Any modification, repairs, or replacement of items performed subsequent to final inspection shall require reinspection or retest, as appropriate, to verify acceptability.

10.5.4 Acceptance

The acceptance of items shall be approved by authorized personnel.

10.6 RECORDS

Records shall be established, maintained and as a minimum identify:

a) item inspected

b) date of inspection

c) inspector

d) type of observation

e) results or acceptability

f) reference to information on action taken in connection with nonconformances.

10.7 NQA-1 COMMITMENT

In establishing its QAP, Blue Energy commits to compliance with NQA-1-2022, Part I, Requirement 10, Inspection ***and Subpart 2.5 "Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete, Structural Steel, Soils, and Foundations for Nuclear Facilities".***

SECTION 11 - TEST CONTROL

11.0 GENERAL

Tests required to collect data such as for siting or design input, to verify conformance of an item or computer program to specified requirements or to demonstrate satisfactory performance for 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 test requirements and acceptance criteria shall be evaluated. Any testing activity which is not performed by Blue Energy shall be conducted in accordance with Sections 4, *Procurement Document Control* and 7, *Control of Purchased Items and Services* of this manual.

11.1 TEST REQUIREMENTS

Test requirements and acceptance criteria shall be provided or approved by the responsible design organization. Required tests (other than for computer programs) including as appropriate, prototype, qualification tests, production tests, proof tests prior to installation, construction tests, preoperational tests, and operational tests shall be controlled. Computer program tests including, as appropriate, software design verification, factory acceptance tests, site 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 the 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 documents, 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.

11.2 TEST PROCEDURES (OTHER THAN FOR COMPUTER PROGRAMS)

11.2.1 Test procedures shall include or reference the test configuration and test objectives. Test procedures shall also include provisions for assuring the prerequisites and suitable environmental conditions are met, adequate instrumentation is available and used, appropriate tests and equipment are used, and necessary monitoring is performed. Prerequisites shall include, as applicable:

- calibrated instrumentation
- appropriate equipment
- trained personnel
- condition of test equipment and the item to be tested
- suitable environmental conditions
- provisions for data acquisition

11.2.2 As an alternative to 11.2.1, appropriate sections of related documents, (e.g., ASTM methods, Supplier manuals, equipment maintenance instruction, or approved drawings or travelers with acceptance criteria) may be used. Such documents shall include, or be supplemented with, applicable prerequisites to ***ensure*** adequate procedures for the test are used.

11.3 COMPUTER PROGRAM TEST PROCEDURES

11.3.1 Testing and development of required documentation (e.g., test plans, cases reports, etc.) shall be performed in accordance with NQA-1-2022, Part II, Subpart 2.7, "**Quality Assurance Requirements for Computer Software for Nuclear Facility Operations"** to verify that the computer program adequately and correctly implements the approved software requirements. The testing shall demonstrate, as appropriate, that the computer program:

a) properly handles abnormal conditions and events as well as credible failures

b) does not perform adverse unintended functions

c) does not degrade the system either by itself or in combination with other functions of configuration items

d) provides valid results for test problems encompassing the range of documented permitted usage

11.3.2 In-use test procedures shall be developed and documented to permit confirmation of acceptable performance of the computer program in the operating environment. 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 in-use 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. In-use computer program testing shall demonstrate required performance over the range of operation of the controlled function or process.

11.4 TEST RESULTS

Test results shall be documented and maintained. Test results shall be evaluated by the responsible authority to ensure that test requirements have been satisfied.

11.5 TEST RECORDS

Test records shall be established and maintained to indicate the ability of the item or computer program to satisfactorily perform its intended function or to meet its documented requirements.

Test records include:

1. item tested
2. date of test
3. tester of data recorder
4. type of observation
5. results and acceptability
6. action taken in connection with any deviations
7. person evaluating test results

11.6 COMPUTER PROGRAM TEST RECORDS

NQA-1-2022 Part II, Subpart 2.7 shall be adhered to for computer program test records.

11.7 NQA-1 COMMITMENT

In establishing its QAP, Blue Energy commits to compliance with NQA-1-2022, Part I, Requirement 11, *Test Control* and Part II, Subpart 2.7 "**Quality Assurance Requirements for Computer Software for Nuclear Facility Operations"**.

SECTION 12 - CONTROL OF MEASURING AND TEST EQUIPMENT

12.0 GENERAL

Tools, gages, instruments, and other measuring and test equipment (M&TE) used for activities affecting quality shall be controlled, calibrated at specific periods, adjusted, and maintained to required accuracy limits. Any calibration activity not performed by Blue Energy shall be conducted in accordance with Sections 4, "**Procurement Document Control"** and 7, ***Control of Purchased Items and Services"*** of this manual.

12.1 SELECTION

The selection of M&TE is based on the type, range, and accuracy needed to accomplish the required measurements for determining conformance to specified requirements.

12.2 CALIBRATION AND CONTROL

12.2.1 Calibration

M&TE shall be calibrated at prescribed times or intervals and whenever the accuracy of the results obtained using the M&TE is suspect. Calibration shall be against and traceable to certified equipment or reference standards having known valid relationship to nationally recognized standard, or to international standards known to be equivalent to and verified against corresponding nationally recognized standards. If no standards exist, the basis for calibration shall be defined.

12.2.2 Reference Standards

The reference standards used to calibrate M&TE shall have a minimum accuracy of four times greater than that of the M&TE being calibrated. Where the 4:1 ratio cannot be maintained, the basis for selection of standard in question shall be technically justified.

12.2.3 Control

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

M&TE, which is overdue for calibration or found to be out-of-calibration, shall be tagged and / or segregated, or removed from service, and shall not be used until it has been recalibrated. Measuring or test equipment consistently found to be out-of-calibration shall be repaired or replaced.

12.2.4 Application

M&TE shall be traceable to its application and use.

12.2.5 Corrective Action

When M&TE 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.

12.2.6 Handling and Storage

M&TE shall be properly handled and stored to maintain accuracy.

12.2.7 Environmental Controls

M&TE shall be used and calibrated in environments that are controlled to the extent necessary to ensure that the required accuracy and precision are maintained.

12.2.8 Precalibration Checks

M&TE and reference standards submitted for calibration shall be checked and the results recorded before any required adjustments or repairs made.

12.2.9 Status Indicator

M&TE shall be suitably marked, tagged, labeled, or otherwise identified to indicate calibration status and establish traceability to calibration records.

12.3 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.

12.4 RECORDS

Records shall be established and maintained to indicate calibration status and the capability of M&TE to satisfactorily perform its intended function.

12.5 REPORTS AND CERTIFICATES

Calibration reports and certificates reporting the results of calibration shall include the information and data necessary for interpretation of the calibration results and verification of conformance to applicable requirements. The calibration record report shall include as found calibration data when calibrated items are found to be out of tolerance.

12.6 NQA-1 COMMITMENT

In establishing its QAP, Blue Energy commits to compliance with NQA-1-2022, Part I, Requirement 12, *Control of Measuring and Test Equipment.*

SECTION 13 - HANDLING, STORAGE AND SHIPPING

13.0 GENERAL

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

13.1 SPECIAL REQUIREMENTS

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

13.2 PROCEDURES

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

13.3 TOOLS AND EQUIPMENT

Special handling tools and equipment shall be utilized and controlled where necessary to ensure safe and adequate handling. The special handling tools and equipment shall be inspected and tested in accordance with procedure at specified time intervals or prior to use.

13.4 OPERATORS

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

13.5 MARKING OR LABELING

13.5.1 Marking or labeling shall be utilized as necessary to adequately maintain and preserve the item, including indication of the presence of special environments or the need for special controls.

13.5.2 Per NRC Regulatory Guide 1.28, Revision 6 (ML23177A002), etching should not be used on nickel alloys, weld areas, or sensitized areas of stainless steel.

13.6 NQA-1 COMMITMENT

In establishing its QAP, Blue Energy commits to compliance with NQA-1-2022, Part I, Requirement 13, "**Handling, Storage, and Shipping"** and Part II, Subpart 2.2, Quality Assurance **"Requirements for Packaging, Shipping, Receiving, Storage and Handling of Items for Nuclear Facilities".**

SECTION 14 - INSPECTION, TEST AND OPERATING STATUS

14.0 GENERAL

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

The operating status of nuclear facility structures, systems, and components shall be identified to prevent inadvertent operation.

14.1 AUTHORITY

The authority for application and removal of status indicators shall be specified in implementing procedures.

14.2 STATUS INDICATION

Status indication shall be maintained through physical means such as tags, marking, labels, stamps, or other suitable methods to prevent inadvertent installation, use, or operation.

14.3 NQA-1 COMMITMENT

In establishing its QAP, Blue Energy commits to compliance with NQA-1-2022, Part I, Requirement 14, **“Inspection, Test, and Operating Status”**.

SECTION 15 - CONTROL OF NONCONFORMING ITEMS

15.0 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, disposition of nonconforming items, and notification to affected organizations.

15.1 IDENTIFICATION

Nonconforming items shall be identified with legible marking, tagging, or other methods, such as identifying and controlling the item as nonconforming in an electronic system. If identification of each nonconforming item is not practical the container or the package containing the item shall be identified. The identification method shall not be detrimental to the item.

15.2 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 prevent inadvertent use of a nonconforming item.

15.3 DISPOSITION

15.3.1 Control

Nonconforming items shall be evaluated and recommended dispositions shall be proposed. Further processing, delivery, installation, or use shall be prevented until an evaluation and approved disposition by authorized personnel has occurred.

15.3.2 Responsibility and Authority

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

15.3.3 ***10 CFR, Part 21***

As part of the defect evaluation and disposition process, an evaluation shall be conducted to determine the applicability of 10 CFR, Part 21. The evaluation shall identify the existence of a noncompliance or potential noncompliance that may result in safety critical condition. A safety critical defect or noncompliance is defined as a deviation from contract requirements that may cause the product (items, components, services, software, etc.) to not perform its intended task or output and that this could contribute to exceeding a safety limit, resulting in the loss of safety function, or otherwise cause a hazardous condition.

If it is determined that 10 CFR Part 21 does not apply, no further notification is regarding actions required in 10 CFR Part 21.

If it is determined that 10 CFR Part 21 is applicable, a Condition Report shall be initiated as in accordance with Section 16 of this QAPD. Notification requirements, time limits and details shall be performed in accordance with the requirements of 10 CFR, Part 21 and Blue Energy procedures.

15.3.4 Personnel

Personnel performing evaluations to determine disposition shall have:

a) demonstrated competence in the specific area they are evaluating; and

b) an adequate understanding of the requirements; and

c) access to pertinent background information.

15.3.5 Disposition

A disposition, such as use-as-is, reject, repair, or rework of nonconforming items shall be made and documented including a technical justification for the acceptability of a nonconforming items dispositioned as repair or use-as-is. Nonconformances to design requirements dispositioned as repair and use-as-is shall be subjected 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.

15.3.6 Reexamination

15.3.6.1 Reworked items shall be reexamined in accordance with the applicable procedures and with the original acceptance criteria.

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

15.4 NQA-1 COMMITMENT

In establishing its QAP, Blue Energy commits to compliance with NQA-1-2022, Part I, Requirement 15, “Control of Nonconforming Items”.

SECTION 16 - CORRECTIVE ACTION

16.0 GENERAL

Conditions adverse to quality shall be identified promptly, documented, and corrected as soon as practicable. ***Reporting conditions adverse to quality is the responsibility of all Blue Energy employees.*** The type of causal analysis utilized, and the corrective actions taken, shall be commensurate with the significance of the item and / or service impacted by the adverse condition.

The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management.

The corrective action process shall also provide for a review of the potential for reporting a deviation or a failure to comply in accordance with the requirements of 10 CFR 21, *Reporting of Defects and Noncompliance*.

16.1 *10 CFR, Part 21*

As part of the evaluation of the condition adverse to quality, an evaluation shall be conducted to determine the applicability of 10 CFR, Part 21.

If it is determined that 10 CFR Part 21 does not apply, no further notification is required regarding actions required in 10 CFR Part 21.

If it is determined that 10 CFR Part 21 is applicable, notification requirements, time limits and details shall be performed in accordance with the requirements of 10 CFR, Part 21 and Blue Energy procedures.

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. ***Conditions adverse to quality shall be analyzed to identify trends in quality performance***. The identification, cause, and corrective action for significant conditions adverse to quality ***and trends adverse to quality*** shall be documented

and reported to appropriate levels of management. Completion of corrective actions shall be verified.

For a condition adverse to quality created by suppliers working on safety-related activities under the Blue Energy QAP, Blue Energy may delegate specific responsibilities of the Corrective Action Program; however, Blue Energy maintains responsibility for the Corrective Action process.

16.2 NQA-1 COMMITMENT

In establishing its QAP, Blue Energy commits to compliance with NQA-1-2022, Part I, Requirement 16, “Corrective Action*”.*

SECTION 17 - QUALITY ASSURANCE RECORDS

17.0 GENERAL

The control of quality assurance records shall be established with the schedule for accomplishing work activities. Quality assurance records shall furnish documentary evidence that items or activities meet specified quality requirements. Quality assurance records shall be identified, generated, authenticated, and maintained and their final disposition specified. Record control requirements and responsibilities for these activities shall be documented. Records may be identified, generated, authenticated, and maintained in either a hard copy or electronic format***. Blue Energy personnel organizing and managing non-electronic records, electronic records, data/media storage, implementation of security measures, migration/regeneration, and recovery shall be trained to requirements to ensure adequate records control.***

For electronic records storage and retrieval systems, Blue Energy will manage the storage of Quality Assurance Records in electronic media consistent with:

- NRC Generic Letter 88-18, "Plant Record Storage on Optical Disks”
- NQA-1-2022, Part II, Subpart 2.17 *Quality Assurance Requirements for Electronic Quality Assurance Records Systems*
- Regulatory Guide 1.28 Revision 6, *Quality Assurance Program Criteria (Design and Construction)*, Section 3
- ***NIRMA Technical Guide TG 11-2011, “Authentication of Records and Media”***
- ***NIRMA Technical Guide TG 15-2011, “Management of Electronic Records”***
- ***NIRMA Technical Guide TG 16-2011, “Software Quality Assurance Documentation and Records”***

- ***NIRMA Technical Guide TG 21-2011, "Required Records Protection, Disaster Recover and Business Continuation"***

17.1 GENERATION OF RECORDS

17.1.1 Records shall meet the following requirements:

a) Records shall be legible.

b) Records shall be traceable to the associated items and activities and accurately reflect the work accomplished or information required.

c) Records to be generated, supplied, or maintained shall be specified in applicable documents, such as design specification documents, procurement documents and operational procedures.

17.2 AUTHENTICATION OF RECORDS

17.2.1 Documents shall be considered valid records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated. Corrections to documents shall be reviewed and approved by the responsible individual from the originating or authorized organization.

17.2.2 Electronic documents shall be authenticated with comparable information as found in 17.2.1 above, as appropriate and with:

a) identification on the media or

b) authentication information contained within or linked to the document itself

17.2.3 ***For electronic records, in addition to the minimum indexing information requirements, the software name, version, and equipment (hardware) used to produce and maintain the electronic media must be provided***

17.3 CLASSIFICATION

17.3.1 Records shall be classified as *lifetime* or *nonpermanent* and maintained by the Owner, or authorized agent, in accordance with the criteria in Sections 17.3.1 and 17.3.2 of this QAPD and shall be consistent with applicable regulatory requirements. Lifetime Records

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

a) those that are of significant value in demonstrating capability for safe operation

b) those that would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item

c) those that would be of significant value in determining the cause of an accident or malfunction of an item

d) those that provide required baseline data for in-service inspections

Lifetime records are required to be maintained by the Owner or an authorized agent for the life of the item while it is installed in the facility or stored for future use.

17.3.2 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.

17.4 RECEIPT CONTROL OF RECORDS

Each organization 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 receipt controls for permanent and

temporary storage. Receipt controls shall provide a method for identifying the records received, receipt and inspection of incoming records and submittal of records to storage. ***Transfer of authentication authority shall be documented and controlled in accordance with Blue Energy procedures***.

17.5 STORAGE

17.5.1 General

a) Records shall be stored at a predetermined location(s) in facilities, containers, or a combination thereof, constructed and maintained in a manner that minimizes the risk of loss, damage, or destruction from:

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
4. dust or airborne particles

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

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

d) 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.

e) Electronic record storage shall meet the requirements consistent with the intent specified in section 17.0, *General* of this manual.

17.5.2 Facility Types

There are two equally satisfactory methods of providing storage of hard copy records, single or dual.

a) 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.

b) 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. Facilities used for dual storage are not required to satisfy the requirements of Section 17.5.2.a) but shall meet the requirements of Section 17.5.1.

17.5.3 Temporary Storage

When temporary storage of hard copy records (such as for processing, review, or use) is required, the storage facility or container shall provide a one-hour fire rating unless one of the storage requirements of Section 17.5.2 are met.

17.6 RETENTION

17.6.2 Record retention periods shall be documented.

17.6.3 Records shall be maintained for their retention periods.

17.6.4 ***When retaining records electronically, the identify and maintenance of the information system (software/hardware), the documentation that describes the information system operation and use, and the record standard it produces shall be identified***.

17.7 MAINTENANCE OF RECORDS

17.7.2 Records shall be protected from damage or loss.

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

17.7.4 The methods for record changes shall be documented.

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

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

17.7.7 Provisions shall be established to ensure the following when records are duplicated or transferred to the same media or to a different media for the purposes of maintenance or storage:

a) Duplication or transfer is appropriately authorized.

b) Record content, legibility, and retrievability are maintained.

17.8 NQA-1 COMMITMENT

In establishing its QAP, Blue Energy commits to compliance with NQA-1-2022, Part I, Requirement 17, **"Quality Assurance Records"** and Part II, Subpart 2.17 **"Quality Assurance Requirements for Electronic Quality Assurance Records Systems"**.

SECTION 18 - AUDITS

18.0 GENERAL

Audits shall be performed to verify compliance to the QAP requirements; to verify that performance criteria are met; and to determine the effectiveness of the QAP. 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, reported to, and reviewed by responsible management. Follow-up action shall be taken where indicated.

Blue Energy may utilize audits conducted by outside organizations for supplier qualifications provided that the scope and adequacy of the audits meet Blue Energy requirements.

18.1 SCHEDULING

18.1.1 Audits shall be scheduled in a manner that provides coverage and coordination with ongoing activities and at a frequency commensurate with the status and importance of the activity. Scheduled audits shall be supplemented by additional audits of specific subjects when necessary to provide adequate coverage.

18.1.2 A grace period of 90 days, with documented justification, may be applied to scheduled audits and annual evaluations of supplier performance. The grace period shall not reset the "clock" for an activity forward. The original due date shall be maintained even though the activity was completed after the scheduled date.

However, in the event of early accomplishment of a specified activity, the clock for the activity is reset backwards by the amount the activity is performed early. For example (based on a triennial audit timeframe), if an audit was scheduled to be performed June 1st, 2025 but the audit is

performed April 2nd, 2025 the next scheduled due date then becomes April 2nd, 2028.

18.1.3 Internal Audits

Except where specific regulatory guidance exists or Code restrictions apply, organizations shall audit internal activities at the following intervals:

1. Nuclear Facilities Prior to Placing the Facility into Operation

   All applicable quality assurance program elements shall be audited at least once a year or at least once during the life of the activity, whichever is shorter.

2. Nuclear Facilities After Placing the Facility into Operation

   All applicable quality assurance program elements for each functional area shall be audited within a period of two years. For well-established activities, the period may be extended one year beyond the two-year interval based on results of an annual evaluation of the applicable functional area and objective evidence that the functional area activities are being satisfactorily accomplished. The internal audit interval shall not exceed a maximum of four years. Functional areas include, and may not be limited to engineering, construction, procurement, operations, maintenance, radiological protection chemistry, and security.

3. Other Nuclear Support Organizations

   All applicable quality assurance program elements shall be audited at least once each year or at least once during the life of the activity, whichever is shorter. This interval may be extended to 2 years based on the results of an annual evaluation and objective evidence that the activities are being satisfactorily accomplished in accordance with the applicable quality assurance program elements.

18.1.4 External (Supplier) Audits

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

18.1.4.2 NRC Regulatory Guide 1.28, Revision 6 (ML23177A002).

If more than one purchaser buys from a single supplier, a purchaser may either perform or arrange for an audit of the supplier on behalf of itself and other purchasers to reduce the number of external audits of the supplier. The scope of this audit should satisfy the needs of all the purchasers, and all the purchasers for whom the audit was conducted should receive the audit report. Each of the purchasers relying on the results of an audit performed on behalf of several purchasers remains individually responsible for the adequacy of the audit. Blue Energy's requirements for accepting third party audits are contained in the QAP's implementing procedures.

18.2 PREPARATION

18.2.1 Audit Plan

The auditing organization shall develop 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 to be utilized during the audit.

18.2.2 Audit Personnel

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

18.2.3 Audit Team Selection

Audit teams shall be identified prior to the beginning of each audit. This team shall contain one or more Auditors, one being designated as a 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.

18.3 PERFORMANCE

Elements selected for audit shall be evaluated against the specified codes and requirements. During audit performance, 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 to the management of the audited organization as soon as practicable.

18.4 REPORTING

An audit report shall be generated for each audit. The audit report shall be signed or otherwise endorsed by the Lead Auditor and issued to the audited organization. The audit report shall include:

a) a description of the audit scope

b) the identification of the auditors and the people contacted during the audit

c) a summary of the audit results, including a statement on the effectiveness of the elements audited

d) a description of each reported audit finding

18.5 RESPONSE

Management of the audited organization or activity shall investigate adverse 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.

18.6 FOLLOW-UP ACTION

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

18.7 RECORDS

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

18.8 NQA-1 COMMITMENT

In establishing its QAP, Blue Energy commits to compliance with NQA-1-2022, Part I, Requirement 18, *Audits.*

18.9 *NQA-1 Exception*

18.9.1 *The following exception to NQA-1-2022, Requirement 18, Audits is being taken:*

Under exigent conditions, the audit and / or survey interval may be extended up to 25 percent by the CQAM during periods where performance of such activities is not feasible as a result of extenuating circumstances. Examples of extenuating circumstances would include, but are not limited to:

1) declaration of a national emergency;

2) *severe localized or national weather conditions or damage to licensee or supplier infrastructure;*

3) *localized outbreak of a severe health concern to the public and licensee.*

Continued use of suppliers that have exceeded the maximum allowed audit or survey time due to extenuating circumstances is allowed if the following conditions are met:

a) ***A documented evaluation must be performed to summarize why the audit or survey could not be performed prior to the end of the 90-day grace period and to provide the basis for maintaining the supplier as an approved supplier during the 25% (9-month) grace period. While implementing procedures must describe elements to be included in the documented evaluation, the following items should be considered as applicable:***

- ***For 10 CFR 50, Appendix B suppliers, verification that the supplier's quality assurance program is still committed to meeting the requirements of 10 CFR 50, Appendix B.***
- ***For commercial suppliers who are approved based on commercial grade survey, verification the supplier has maintained adequate documented programmatic controls in place for the activities affecting the critical characteristics of the item/services being procured.***
- ***Evaluation of any significant open issues with the NRC, 10 CFR Part 21 Notifications, and any open findings since the previous triennial audits describing impact on the items/services being procured from that supplier.***
- ***Review of procurement history since last triennial audit/survey including receipt inspection results to identify any potential issues. The results of the performance history must be included in the evaluation.***

- ***The degree of standardization of the items being procured. For instance, suppliers of catalog items which are used across multiple industry with widely accepted good performance histories would be considered good candidates for a 25% (9-month) grace period.***

b) If concerns are identified based on the above evaluation, the following mitigating actions may be considered:

- ***Enhanced receiving inspections beyond visual inspections and quality checks.***
- ***Identification of any additional requirements/restrictions to be placed on the supplier.***

c) For audits/surveys performed during the 25% grace period, the audit/survey shall include a review of activities performed by the supplier since the 36month audit/survey expiration date.

d) d. The allowance would only apply to existing suppliers on the Qualified Supplier's List.

e) The 25% grace period discussed above is applicable to domestic and international suppliers.

f) For audits/surveys performed during the 25% grace period, the audit/survey "clock" does not have to reset backwards to the original expiration date for which the audit/survey should have been performed. The end of the audit or survey would determine the date of the next triennial audit/survey.

Exercising this extension is described in the implementing procedure and is consistent with precedent in NRC SER (ML20132A017). This extension may be applied to domestic or international suppliers.

SECTION 19 - NONSAFETY-RELATED SSC QUALITY CONTROLS

19.0 General

Specific program controls are applied to nonsafety-related portions of nuclear reactor projects, and for non-reactor work. The specific program controls consistent with applicable sections of the QAPD are applied to those items in a selective manner and targeted at those characteristics or critical attributes that render the structure, system, or component (SSC) a significant contributor to plant safety.

19.1 Quality Requirements for Nonsafety-Related Work Scopes

The following establish the applicability of the QAP to nonsafety portions of nuclear reactor projects except when it is determined that compliance with sections 1 – 18 above are required.

I. Organization

The verification activities described in this section may be performed by the line organization. Independent verification may be, but is not required to be, performed by QA / QC.

II. Quality Assurance Program

Procedures describe the appropriate quality controls to be applied to the subject equipment. A new or separate QA program is not required.

III. Design Control

Measures are established to ensure that the contractually established design requirements are included in the design. Applicable design inputs are included or correctly translated into design documents, and deviations therefrom are controlled. Normal supervisory review of the designer's work is an adequate control measure.

IV. Procurement Document Control

Applicable design ***basis*** and other requirements necessary to ensure component performance, including design requirements, are included or referenced in documents for procurement of items and services, and deviations therefrom are controlled.

V. Instructions, Procedures, and Drawing

Activities affecting quality shall be performed in accordance with documented instructions, procedures, or drawings of a type appropriate to the circumstances. This may include such things as written instructions, plant procedures, cautionary notes on drawings, and special instructions on work orders. Any methodology which provides the appropriate degree of guidance to personnel performing activities important to the component functional performance is acceptable.

VI. Document Control

The issuance and change of documents that specify quality requirements or prescribe activities affecting quality are controlled to ensure that correct documents are used.

VII. Control of Purchased Items and Services

Measures are established that ensure that all purchased items and services conform to appropriate procurement documents.

VIII. Identification and Control of Purchased Items

Measures are established where necessary, to identify purchased items and preserve their functional performance capability. Examples of circumstances requiring such control include the storage of environmentally sensitive equipment or material, and the storage of equipment or material that has a limited shelf life.

IX. Control of Special Processes

Measures are established to control special process including welding, heat treating, and nondestructive testing. Applicable codes, standards, specification, criteria, and other special requirements may serve as the basis of these controls.

X. Inspection

Inspections are performed where necessary to verify conformance of an item or activity to specified requirements or to verify that activities are satisfactorily accomplished. Inspections need not be performed by personnel who are independent of the line organization. However, personnel that perform inspections must be knowledgeable.

XI. Test Control

Measures are established that demonstrate that equipment conforms with design requirements. Tests are performed in accordance with test procedures. Test results are recorded and evaluated to ensure that test requirements are met.

XII. Control of Measuring and Test Equipment.

Measures are established to control, calibrate, and adjust M&TE at specific intervals.

XIII. Handling, Storage, and Shipping

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

XIV. Inspection, Test, and Operating Status

Measures are established to identify items that have satisfactorily passed required tests and inspection and to indicate the status of inspection, test, and operability as appropriate.

XV. Control of Nonconforming Items

Items that do not conform to specified requirements are identified and controlled to prevent inadvertent installation or use.

XVI. Corrective Action

Measures are established to ensure that failures, malfunctions, deficiencies, deviations, defective components, and non-conformances are properly identified, reported, and corrected.

XVII. Records

Records are prepared and maintained to furnish evidence that the above requirements for design, procurement, document control, and inspection and test activities have been met.

XVIII. Audits

Audit independent of line management are not required, if line management periodically reviews and documents the adequacy of the process and takes any necessary corrective action. Line management is responsible for determining whether reviews conducted by line management or audits conducted by the organization independent of line management are appropriate. If performed, audits are conducted and documented to verify compliance with design and procurement documents, instructions, procedures, drawings and inspection test activities.

SECTION 20 - NONSAFETY-RELATED SSC CREDITED FOR REGULATED EVENTS

20.0 GENERAL

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

a. Blue Energy commits to implement quality requirements to the fire protection system in accordance with Regulatory Position 1.7, “Quality Assurance,” in RG 1.189, ***Rev. 5, October 2023,*** “Fire Protection for Operating Nuclear Power Plants.”

b. Blue Energy commits to implement the quality requirements to ATWS equipment in accordance with GL 85-06, “Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related.”

c. Blue Energy commits to implement quality requirements to SBO equipment in accordance with Regulatory Position 3.5 “Quality Assurance and Specific Guidance for SBO Equipment that Is Not Safety Related,” and Appendix A, “Quality Assurance Guidance for Non-Safety Systems and Equipment,” in RG 1.155 ***(Original) August 1988***, “Station Blackout.”

SECTION 21 - REGULATORY GUIDES AND QUALITY ASSURANCE STANDARDS COMMITMENTS

21.0 GENERAL

Blue Energy commits to compliance with RG 1.28, Revision 6, Quality Assurance Program Criteria (Design and Construction) which describes a method acceptable to the NRC staff for complying with the provisions of Appendix B with regard to establishing and implementing the requisite quality assurance program for the design and construction of nuclear power plants.

Blue Energy commits to compliance to other RG and Generic Letters supplementing the Blue Energy QAPD within the applicable license application documents, including but not limited to:

- Generic Letter 89-02, Actions to Improve the Detection of Counterfeit and Fraudulently Marked Products.
- Generic Letter 91-05, Licensee Commercial-Grade Dedication Programs.
- Regulatory Guide 1.164 Dedication of Commercial-Grade Items for Use in Nuclear Power Plants, Rev ***1***, ***April 2024***.
- Regulatory Guide 1.231, Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Safety-Related Applications for Nuclear Power Plants, Rev 0, January 2017.
- Regulatory Guide 1.234, Evaluating Deviations and Reporting Defects and Noncompliance Under 10 CFR Part 21, Rev ***1, March 2024***.
- Regulatory Guide 1.26, Quality Group Classifications and Standards for Water-, Steam-, And Radioactive-Waste-Containing Components of Nuclear Power Plants, ***Rev. 6, December 2021***.
- Regulatory Guide 1.29, Seismic Design Classifications for Nuclear Power Plants, ***Rev. 6, July 2021***.

Commitment to a particular RG or standard does not constitute a commitment to other RGs or standards that may be referenced therein.