TerraPower

May 28, 2021

TP-LIC-LET-0004
Project Number 99902087

U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
ATTN: Document Control Desk

**Subject:** Response to Request for Additional Information on NRC's Assessment of the Quality Assurance Program Description for TerraPower, LLC's Quality Assurance Topical Report

**References:**

1. TerraPower, LLC Quality Assurance Topical Report, TP-REG-LET-0004, February 26, 2021 (ML21057A084)

2. U.S. Nuclear Regulatory Commission, "Request for Additional Information on NRC's Assessment of the Quality Assurance Program Description for TerraPower, LLC's Quality [Assurance] Topical Report Revision 1," dated April 13, 2021 (ML2109A046)

By letter dated February 26, 2021 (Reference 1), TerraPower, LLC (TerraPower) submitted a revision of the Quality Assurance Topical Report. The letter dated April 13, 2021 (Reference 2), included a request for additional information (RAI) from the U.S. Nuclear Regulatory Commission (NRC) to support the NRC staff's review.

The Enclosures to this letter provides the TerraPower response to the RAI and a revised Quality Assurance Topical Report.

This letter and enclosed responses make no new or revised regulatory commitments.

If you have any questions regarding this submittal, please contact Ryan Sprengel at rsprengel@terrapower.com or (425) 324-2888.

Sincerely,

Ryan Sprengel
License Application Development Manager
TerraPower, LLC

Enclosures:
1. TerraPower Response to Request for Additional Information
2. TerraPower, LLC Quality Assurance Topical Report, TP-QA-PD-0001, Revision 11, *TerraPower QA Program Description*

cc: Ben Beasley, NRC
Mallecia Sutton, NRC

**ENCLOSURE 1**

**TerraPower Response to Request for Additional Information**

ENCLOSURE 1

TerraPower Response to Request for Additional Information

RAI Application Title: TerraPower Quality Assurance Topical Report
Date of RAI Issuance: 4/13/2021

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**RAI 1**

Request for additional information (RAI) 1 asked TerraPower, LLC (TerraPower) to clarify whether TerraPower is committed to NQA-1-2015 for each of the 18 criteria of Appendix B to Title 10 of the Code of Federal Regulations (10 CFR) Part 50. In its response, TerraPower stated that they would review each of the criteria and specify clarifications or exceptions as applicable.

The NRC staff confirmed that the Quality Assurance Program Description (QAPD) was updated with a statement committing to NQA-1-2015; however, for Criterion 2, and 7, a statement committing to Regulatory Guide (RG) 1.28 was not included. Further, a statement committing to RG 1.28 was included under Criterion 17, but it did not include the revision number.

Clarify if TerraPower is committed to Revision 5 of RG 1.28 for Criterion 2, 7 and 17 to ensure the NRC's regulatory positions will be adequately implemented.

**TerraPower Response to RAI 1**

TerraPower is committed to Regulatory Guide 1.28, "Quality Assurance Program Criteria (Design and Construction)," Revision 5, October 2017, for Criterion 2, 7, and 17 in the Quality Assurance Program Description (QAPD).

The following updates were made to the TerraPower QAPD, see Enclosure 2:

- Added Revision 5 to previously included RG 1.28 in Section 2.4
- Added Revision 5 to previously included RG 1.28 in Section 2.8
- Added RG 1.28, Revision 5 to Section 2.10
- Added Revision 5 to previously included RG 1.28 in Section 4
- Added RG 1.28, Revision 5 to Section 7.8.2
- Added Revision 5 to previously included RG 1.28 in Section 17.8
- Added Revision 5 to previously included RG 1.28 in Section 18.8
- Added Revision 5 to previously included RG 1.28 in Section 20

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ENCLOSURE 1

TerraPower Response to Request for Additional Information

**RAI 2**

In RAI 6 the NRC asked TerraPower if they were committed to Revision 3 of RG 1.189 since Revision 3 is the latest revision and the QAPD stated they were committed to Revision 2. In RAI 7 the NRC asked TerraPower to document the regulatory guides, generic letters (GLs), and other quality assurance (QA) standards that are applicable and provide justification for guidance that may not be applicable due to unique design considerations.

In its response, TerraPower stated that they would revise the QAPD to commit to Revision 3 of RG 1.189 and that an evaluation will be done to determine which RGs, GLs, and QA standards are applicable and then develop a list of commitments and a justification for inclusion or not will be provided in the QAPD.

Section 20, "Regulatory Guides and Quality Assurance Standards Requirements," in Revision 1 of the QAPD, states, in part:

"TerraPower commits to identifying the extent of conformance, including justifications for exclusion or modifications based on the specific characteristics of TerraPower's non-LWR technology, to other Regulatory Guides (RGs), Generic Letters (GLs) and Quality Assurance (QA) standards supplementing the TerraPower QAPD within the applicable license application documents, including but not limited to:

- RG 1.26 (no revision provided)
- RG 1.29 (no revision provided)
- RG 1.37, Revision 1
- Regulatory Position (RP) 3.5 and Appendix A in RG 1.155 (no revision provided)
- GL 85-06
- GL 89-02
- GL 89-05
- RP 1.7 in RG 1.189 (no revision provided)"

a. The statement "…within the applicable license application documents…" seems to suggest that TerraPower's QAPD may be applicable to any type of application and not specific to a Construction Permit (CP) as previously discussed. The NRC staff's review of a QAPD is dependent on the type of application that will be submitted due to the different quality assurance requirements for the different types of applications. Clarify if TerraPower's QAPD is based on the QA requirements for a CP.

b. The NRC understands that because of the substantial differences between TerraPower's plant design and a light-water reactor, direct commitment to RGs, GLs and QA standards may not be appropriate at this time. However, Section 20 of the QAPD did not include a comprehensive list of RGs, GLs, and QA standards that are applicable and did not include justification for guidance that may not be applicable due to unique design considerations. Further, TerraPower is not consistent in providing the applicable revision number for the guidance listed.

Explain TerraPower's plans to review the applicable guidance and include justification for that guidance that may not be applicable due to unique design considerations.

**TerraPower Response to RAI 2**

The TerraPower QAPD is for complying with the provisions of 10 CFR 50 Appendix B with regard to establishing and implementing the requisite quality assurance program for the design and construction of nuclear power plants.

The following update has been made to the TerraPower QAPD, see Enclosure 2:

- Added a clarifying statement in Section 2 for the applicability of the QAPD regarding design and construction, with specific reference to construction permit application process
- Section 20 previously included discussion on the scope of the quality assurance program for design and construction of nuclear power plants, no change made to those statements other than a clarification to Regulatory Guide 1.28 Revision 5 identified in the response to RAI 1

TerraPower has made the following commitments to standards and regulatory guides in the QAPD, see Enclosure 2:

- 10 CFR Part 50 Appendix B Criterion
- ANSI/ASME NQA-1-2015, Quality Assurance Requirements for Nuclear Facility Applications, Parts I, II, and III only sections as described in sections of this document. (listed in Regulatory Guide 1.28)
- Revision 1 of Nuclear Energy Institute14-05A, Guidelines for the use of accreditation in lieu of commercial grade surveys for procurement of laboratory calibration and test services Revision 1
- Regulatory Guides (Section 20):
    - Regulatory Guide 1.164 Dedication of Commercial-Grade Items for Use in Nuclear Power Plants, Revision 0 June 2017

TerraPower identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in the design control documentation.

- Regulatory Guide 1.189, "Fire Protection for Nuclear Power Plants.". Revision 3, February 2018
  TerraPower identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in the design control documentation.
- Regulatory Guide 1.231, Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Safety-Related Applications for Nuclear Power Plants, Revision 0, January 2017
  TerraPower identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in the design control documentation.
- Regulatory Guide 1.234, Evaluating Deviations and Reporting Defects and Noncompliance Under 10 CFR Part 21. Revision 0, April 2018
- Regulatory Guide 1.26, Quality Group Classifications and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants, Revision 5, February 2017
  The Natrium reactor design is a Fast Sodium Cooled Reactor and is significantly different from the design of light water reactors. So, the conventional quality group classifications may not be directly applicable. TerraPower identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in the design control documentation.
- Regulatory Guide 1.28, Quality Assurance Program Criteria (Design and Construction), Revision 5, October 2017
- Regulatory Guide 1.29, Seismic Design Classifications for Nuclear Power Plants Revision 5, July 2016
  TerraPower identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in the design control documentation.

- Regulatory Guide 1.54, - Service Level I, II, and III Protective Coatings Applied to Nuclear Power Plants, Revision 3, April 2017
  TerraPower identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in the design control documentation.

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**RAI 3**

Section 7.8, "Commitment," was created to list the exceptions taken for Criterion VII. One of the exceptions listed is the use of the International Laboratory Accreditation Cooperation (ILAC) accreditation process.

a. The exception contains the following statement: "…commercial-grade surveys and source verifications need not be performed…" The NRC's approval of the ILAC accreditation process is only acceptable to use in lieu of commercial-grade surveys, and can't be used in lieu of performing source verifications. In addition, the current write-up references both the 2005 and 2017 editions of International Standards Organization 17025. The 2005 edition of ISO 17025 is only acceptable until June 1, 2021.

b. Clarify if TerraPower plans to implement Revision 1 of Nuclear Energy Institute14-05A, which the NRC staff recently endorsed in a safety evaluation report dated November 23, 2020 (Agencywide Documents Access and Management System Accession No. ML20322A019).

**TerraPower Response to RAI 3**

TerraPower has made a clarification in the QAPD that the ILAC accreditation process is only applicable to commercial grade surveys. A clarification was also made for the end date of June 1, 2021 for NEI 14-05A Revision 0 and start date for NEI 14-05A Revision 1 on June 2, 2021.

The following updates were made to the TerraPower QAPD, see Enclosure 2:

- Removed 'and source verifications' in Section 7.8.1
- Clarified the timing for use of Revision 0 and Revision 1 of NEI 14-05A in Section 7.8.1

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**RAI 4**

Section 18.2, "Exigent Conditions," was created to include guidance on the 25 percent extension for supplier audits/surveys during exigent conditions.

a. This section is included under Criterion XVIII; however, it should be included under Criterion VII. Criterion VII addresses the requirements for supplier oversight, which includes external audits, while Criterion XVIII addresses the requirements for internal audits.

b. The following condition is missing from the current write-up in Section 18.2: "Receipt inspection and industry operating experience are reviewed on an ongoing basis as the information becomes available and documented. The results of the review are promptly considered for the effects on a supplier's continued qualification and adjustments made as necessary, including corrective actions."

**TerraPower Response to RAI 4**

The exigent condition section has been moved from criterion XVIII to criterion VII in the TerraPower QAPD, see Enclosure 2.

The following text has been added to the TerraPower QAPD Section 7.2, "Receipt inspection and industry operating experience are reviewed on an ongoing basis as information becomes available and documented. The results of the review are promptly considered for the effects on a supplier's continued qualification and adjustments are made as necessary, including corrective actions."

The following updates have been made to the TerraPower QAPD, see Enclosure 2:

- Added exception for Exigent Conditions to Section 7.2
- Added Exigent Conditions as Section 7.2.1, Removed from Section 18
- Added text noted above to Section 7.2.1

**ENCLOSURE 2**

**TerraPower, LLC Quality Assurance Topical Report, TP-QA-PD-0001, Revision 11,**
***TerraPower QA Program Description***

# PROGRAM DESCRIPTION

| | | | | |
|---|---|---|---|---|
| **Document Number:** | TP-QA-PD-0001 | Topical Report | **Revision:** | 11 |
| **Document Title:** | TerraPower QA Program Description | | | |
| **Issuing Organization:** | Quality Assurance/Quality Control | | | |
| **Effective Date:** | 5/26/2021 | **Released Date:** | 5/26/2021 | |
| | | | **Page:** | 1 of 46 |

**Approval**

| Title | Name | Signature | Date |
|---|---|---|---|
| Approver, Director, Environmental, Safety, Health, and Quality (ESH&Q) | James Nikola | Electronically Signed in Agile | 5/25/2021 |
| Approver, President | Chris Levesque | Electronically Signed in Agile | 5/26/2021 |

| | | |
|---|---|---|
| **Export Controlled Content:** | **Yes** ☐ | **No** ☒ |
| **QA Related:** | **Yes** ☒ | **No** ☐ |
| **QA Criterion:** | 2 - Quality Assurance Program | |

# REVISION HISTORY

| Revision No. | Effective Date | Affected Section(s) | Description of Change(s) |
|---|---|---|---|
| 11 | 5/26/2021 | 2.0, 2.1, 2.4, 2.8, 2.10, 4.0, 7.2, 7.2.1, 7.8.1, 7.8.2, 17.8, 18.2, 18.8, 20.0 | Extensive changes to address RAI responses throughout. Updates to Section 20 to update regulatory guides and quality assurance standards commitments. Update to section 2 and 18 to remove exigent conditions from section 18 to section 2. Updated revision to Reg guide 1.28 throughout. |
| 10 | 2/25/2021 | Various | Extensive changes to address RAI responses. Revised Quality Level designations in section 2.8. Added guidance on use of additional 25% grace period for supplier audits/surveys during exigent conditions in section 18.2. |
| 9**A** | 8/4/2020 | Footers | **Minor Change to** replace Confidentiality marking with dated Copyright marking for submission to NRC |
| 9 | 7/27/2020 | Quality Program Policy, Section 1.3 2.0, 2.8, 15 and 16. | Added references to 10 CFR Part 21, and corrected acronym for Director, Environment, Safety, Health & Quality. Also removed “receipt inspection” from table in section 2.8 QL-2. |
| 8B | 10/10/2019 | 1.6 | **Minor Change** to insert the position of VP Commercial Operations in lieu of Director Contracts & Supply Management Section 1.6 |
| 8**A** | 10/7/2019 | Page 8, Section 2, and Section 3.9 | **Minor Change** to remove parenthetical references to NQA-1-2008/09. |
| 8 | 3/18/2019 | 2.8 | Added new Section 2.8, *Application of QAPD Based on Quality Level* |
| 7 | 02/25/2019 | 1.4<br>17 | Updated to reflect centralization of Engineering and other technical functions.<br>Clarified RG 1.28 applicability for Records<br>Other changes throughout, indicated by revision bars, to clarify intent and correct errors. |
| 6 | 07/16/2018 | Various | NQA-1-2015 and RG 1.28 Rev. 5 revisions. Updated NQA-1 and RG references throughout. Section 3: Editorial corrections and shuffling of paragraphs to align with NQA-1. Added sentence to section 7 related to calibration and test labs. |
| 5 | 05/04/2018 | All Sections | Many changes to allow flexibility of individual TerraPower projects to adapt all or parts of the NQA-1 quality program where full compliance is not required. This revision allows designation of a technical authority and a quality authority for each project and points to a Project Quality Plan for |

# REVISION HISTORY

| Revision No. | Effective Date | Affected Section(s) | Description of Change(s) |
|---|---|---|---|
| | | | organizational responsibility details. Requirements for contract review and continuous improvement are added. |
| 4 | 11/27/2017 | Numerous | Extensive Revisions throughout the document to include requirements from NUREG-0800 Standard Review Plan, Section 17.5 Due to the extensive amount of revisions, no revision bars are present. |
| 3 | 2/27/2017 | Page 8, 21 | Removed paragraph that describes the safety classification process and relies on the statement that implementing procedures describe that and other safety and quality level topics (page 8). Corrected typo page 21, 7.7. |
| 2**A** | 11/30/2016 | Page 6 | **Minor Change** to add TerraPower President wet signature to Page 6, *Quality Program Policy*. |
| 2 | 11/142016 | 16 and 18 | Cited Audit schedule to be consistent with TP procedures |
| 1**B** | 3/23/2016 | 7.7 | **Minor Change** to correct cited references in second paragraph of Section 7.7. |
| 1**A** | 3/21/2016 | Cover Page; 18.7 | **Minor Change** to correct (a) Department typo and QA Criterion typo on Cover Page, and (b) editorial error in the first sentence of paragraph 18.7 Audit Records. |
| 1 | 3/16/2016 | All pages | Modified Design Change Control requirements, changed QA records to Lifetime, changed QA Manager to Director, Quality, Safety & Information Systems (QSIS), changed agreements to procurement documents. |
| 0 | 5/22/2015 | All pages | • Supersedes TP-QA-PLAN-0001<br>• Based on TP-IM-PROC-0001, “Record and Document Numbering Procedure for TerraPower”, this document reverts to Revision 0<br>• Change back to corporate applicability. Add in new role of President<br>• Add intent to dedicate calibration and test labs per NEI 14-05, Rev. 1 |

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## QUALITY PROGRAM POLICY

TerraPower (TP) has established a Quality Assurance Program that complies with 10 CFR 50 Appendix B, 10 CFR Part 21, ASME NQA-1-2015, and Regulatory Guide (RG) 1.28, Revision 5 for all nuclear safety related work (nuclear reactor projects), and in a graded manner to all other TP work, when applicable. The TP President is responsible for implementation and execution of this program. The Director, Environment, Safety, Health & Quality (ESH&Q) is responsible for development, maintenance, and independent oversight of the Quality Assurance Program.

The quality assurance program is described in this Quality Assurance Program Description (QAPD). 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 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.

It is the policy of TP:

- That clients and other appropriate outside agencies shall be provided reasonable access to TP 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 management system.

Chris Levesque
CEO/President
TerraPower, LLC

# 1 ORGANIZATION

Organizational structure and lines of communication are depicted in Corporate and Project Organization Charts (where applicable). Roles and responsibilities of managers and employees are also described in implementing procedures. Functional responsibilities and levels of authority related to quality are described throughout this QAPD and in implementing procedures. Descriptions of interfacing organizations are provided in applicable implementing procedures. Organizational structure and implementing procedures ensure quality is achieved and maintained by those assigned responsibility for performing the work, and that quality achievement is verified by those not directly responsible for performing the work.

## 1.1 Program Management

The President provides top-level leadership for TP and is responsible for implementation and execution of this QAPD and all its subordinate documents.

## 1.2 Management Responsibility for Quality

TP Managers responsible for executing any part of this QAPD may delegate any or all of the work to others but shall retain responsibility thereof. Quality is administered as a Line Organization function, such that all TP personnel are responsible for meeting QA requirements. Line Organization is defined as any department or organization within TP that implements any portion of the quality program and includes, but is not necessarily limited to Procurement, Engineering, Laboratory/Testing, and Records Management & Document Control (RMDC). The management structure for each TP project is depicted in project-specific organization charts and/or a Project Quality Plan (PQP) and/or procedures for each TP project.

## 1.3 Quality Assurance

The Director, ESH&Q is assigned primary responsibility for verifying that the QAPD is in place and is effective. The Quality Assurance function (QA) is responsible for verifying that activities affecting quality have been performed in accordance with this QAPD and applicable implementing procedures. The President and Director, ESH&Q ensure that adequate QA resources are applied to this oversight function. The Director ESH&Q may delegate QA program administration and verification to a senior QA person assigned to a TP project but shall maintain overall responsibility for those delegated duties.

QA personnel have sufficient authority, access to work areas and organizational freedom to:

- Review item characteristics, process implementation, and other quality related information, and to identify items, services, and processes to confirm compliance with requirements and effectiveness.
- Identify quality problems.
- Initiate, recommend or provide solutions to quality problems.
- Verify implementation of solutions to problems.
- Ensure that further processing, delivery, installation or use is controlled until proper disposition of a non-conformance or other unsatisfactory condition has occurred.

QA Management (and specifically delegated QA project personnel) is responsible for:

- Review of customer contract documentation to identify quality requirements for the project.
- Ensuring that TP procedures, QAPD and any necessary PQPs adequately address all customer requirements.
- Preparation and issuance of PQPs and QA procedures.
- Review of procurement documents to suppliers and subcontractors to ensure specification of appropriate quality requirements.
- Review of supplier and subcontractor quality submittals.
- Performance of audits and surveillance of supplier and subcontractor activities.
- Scheduling, participating in, and documenting the annual management review of the quality program to ensure its suitability and effectiveness. This may also be performed at the TP project level if specified in a PQP.
- Representing TP for quality evaluations conducted by external assessors and/or customers on TP's quality system.
- Providing adequate resources and/or trained personnel to satisfy the contractual requirements of projects executed by TP.
- Verifying that the quality system is adequately and effectively implemented and maintained through the performance of audits, surveillance and reviews of engineering, design, procurement, and fabrication documents.
- Coordinating project responses to external audits and/or reviews.

The Director, ESH&Q reports directly to the President, who ensures that required authority and organizational freedom are provided to meet the above stated responsibilities. QA is at the same organizational level as the highest line function directly responsible for performing activities affecting quality. QA is sufficiently free from cost and schedule considerations associated with fulfilling the assigned responsibilities. QA is the owner of this QAPD.

If QA disagrees with any actions by the organization and is unable to obtain resolution, QA shall bring the matter to the attention of President/CEO, who will determine the final disposition.

QA has "Stop Work" authority to curtail TP work at TP facilities or at Supplier locations, as deemed necessary in response to quality problems. Resumption of work after the quality problems have been appropriately addressed will be authorized by the President, (and may be delegated to QA).

1.4 Engineering and Technical Authority

Each TP project will have an individual designated as Project Engineer who has responsibility for ensuring that equipment and facilities are engineered and designed in compliance with the project and customer requirements and in accordance with the requirements of this QAPD. This is accomplished by:

- Independent checking of completed design documents.
- Independent design reviews.
- Support of Procurement in the identification of approved bidders.
- Performance of technical bid reviews and support of Procurement in selection of suppliers.
- Support of Procurement in the review of procurement documents, in conjunction with QA, to establish the necessary level of supplier surveillance and to identify supplier submittal requirements.
- Review of supplier-furnished design documents.
- Supports and participates in customer contract reviews as required to ensure TP capabilities to meet the technical requirements specified in the contract.

Engineering is a centralized organization that provides design support and/or engineering personnel to individual projects. This organization is responsible for ensuring adequacy and consistency of qualification and training of engineers and other technical personnel; staffing projects as necessary with engineering and/or technical personnel; plant licensing and regulatory affairs; analytical software control; and for the technical adequacy of design for all TP projects. The PQP, if applicable, identifies roles and responsibilities for design on a particular project.

1.5 Project Management, Project Development

This function is responsible for Project Management (cost, schedule, and budget) and Project Development. Project Management supports and participates in customer contract reviews to ensure that appropriate project planning and scheduling is accomplished as required.

1.6 Contracts & Supply Management

This function is responsible for contracting and procurement functions and reports directly to the Executive Vice President and CFO. This function is responsible for activities and interfaces related to external contracts and agreements, supplier technical management and procurement; and assists line organizations implement contracts, including flow down of client QA requirements.

This function is responsible for assuring that subcontracted services are in full compliance with project, customer, and procurement document requirements by:

- Coordinating development of approved bidders' lists, as applicable.
- Commercial evaluation/validation of the bid/pricing data received.
- Coordination of bid reviews and subcontractor selection with QA and Engineering.
- Participation in subcontractor qualification.

- Review of procurement documents with Engineering and QA to establish the necessary level of supplier surveillance and to identify supplier quality control and document submittal requirements.

Customer requirements are evaluated during contract reviews. Contracts & Supply Management is responsible for:

- Coordinating contract reviews that shall include, as a minimum, Contracts & Supply Management, Engineering, Project Management, Legal, and QA.
- Negotiating, executing, and distributing contract changes and amendments. All contract changes shall be reviewed by each affected discipline to ensure compliance in contract performance.

1.7 Line Organization Managers

- Establish, maintain, and control department work instructions and/or procedures to control the work and to satisfy the requirements of this QAPD.
- Ensure that all department personnel are aware of and that they comply with applicable procedures.
- Identify, evaluate, and record actual and potential quality problems with the department or at the interface with other departments. The CR/CAR process should be used to manage this process.
- Control further processing, delivery, or installation of nonconforming product or service until the deficiency or unsatisfactory condition has been corrected. The NCR and/or the CR/CAR process should be used to manage this process.
- Interface with QA Management in implementing changes affecting the quality system.
- Provide support and access to QA for internal audits and/or surveillances of the quality system.
- Provide support and access, when required, for external audits of the TP quality system.

1.8 Individuals

All TP personnel shall be responsible for the quality of their own work and for the self-checking of this work prior to any intra-departmental or inter-departmental checks that are required. All personnel also have the right and the responsibility to stop unsafe or non-compliant work or work that cannot be performed correctly due to inadequate procedures. QA or safety will evaluate the condition to authorize re-start or additional actions.

Supervisors shall ensure that those reporting to them are aware of the QAPD requirements and the procedures governing their current activities.

1.9 Commitment

For section 1-Organization, TP commits to compliance with 10 CFR Part 50 Appendix B, Criteria I, and NQA-1-2015 Edition, Requirement 1.

## 2 QUALITY ASSURANCE PROGRAM

The quality management system described herein is intended to facilitate and ensure the effectiveness of all TP activities affecting quality. This QAPD is applicable for the design and construction permitting application process only. Should TP decide at a later date to pursue an operating license, the TP QAPD will be updated to reflect the additional regulatory commitments. The QAPD is a living document, which may be revised as various TP programs progress. The QAPD will be periodically reviewed by the President and the Director, ESH&Q to evaluate the need for its revision. This is typically accomplished as part of the annual management review of the quality program.

Included in the TP quality management system is a series of implementing procedures, describing in detail the methods used in managing, performing, and evaluating the quality and adequacy of work. This quality management system applies to each organizational element and individual performing work at TP.

The QAPD implements the applicable requirements of ASME NQA-1-2015, 10 CFR 50 Appendix B, 10 CFR Part 21, and RG 1.28, Revision 5 for nuclear safety related work (reactor projects) and applies in a graded manner to all other TP work. This QAPD is based on the requirements and of ASME NQA-1-2015, "Quality Assurance Requirements for Nuclear Facility Applications," Parts I and II, with specific reference to selected parts III and IV guidance, as identified in this document. TerraPower established and maintains a plant-level SSC classification listing of all Safety-Related (SR) and Non-Safety Related with Special Treatment (NSRT) SSCs. A list or system that identifies SSCs and activities to which this program applies is maintained at TerraPower facilities.

The QAPD provides for the planning and accomplishment of activities affecting quality under suitably controlled conditions. Controlled conditions include the use of appropriate analytical tools, suitable environmental conditions for accomplishing the activity and assurance that prerequisites for the given activity have been satisfied. The QAPD provides for any special controls, processes, test equipment, tools and skills to attain the required quality and for verification of that quality.

TP management shall implement client specific QA requirements as established in external contracts and agreements. These requirements may be identified in a PQP or procedures to ensure that client QA requirements are met, consistent with this QAPD.

Management shall regularly assess the adequacy and effective implementation of the quality program. This is accomplished on a minimum annual basis where the TP President, Director ESH&Q and line management assess information related to results of both internal and external audits, corrective and preventive actions, non-conformances, design revisions due to errors, Nuclear Regulatory Commission (NRC) and other regulatory or customer oversight results, and other information as applicable. This information is assessed to determine if the program and procedure controls in place provide an adequate level of guidance, if those controls are being implemented in an effective manner, and if TP is achieving desired outcomes. TP also has a Self-Assessment program in place where line managers and individual contributors perform assessments of activities for which they are responsible. These assessments will identify any process or performance improvements that might be needed in order to support the TP commitment to compliance, customer satisfaction, and continuous improvement.

A general grace period of 90 days may be applied to provisions that are required to be performed on a periodic basis unless otherwise noted. Annual supplier evaluations and triennial supplier audits are examples in which the 90-day general grace period could be applied. The grace period does not allow the “clock” for a particular activity to be reset forward. The “clock” for an activity is reset backwards by performing the activity early.

2.1 Exigent Conditions

During periods of exigent conditions affecting TP facilities or its suppliers, and where performance of audit or survey activities for domestic and international suppliers is not feasible, an additional 25% extension of the triennial audit period may be exercised. Personnel Indoctrination, Training and Qualification

TP personnel, contractors, consultants, and others performing or managing activities affecting quality in accordance with this QAPD or its implementing procedures, shall be appropriately indoctrinated, trained and qualified. Procedures are in place that prescribe specific requirements for the qualification of personnel to perform specific job functions. The extent of indoctrination and training shall be commensurate with the scope, complexity and nature of the activity to be performed, and the education, experience and proficiency of the individual.

Personnel shall be indoctrinated in the following subjects as they relate to a particular function:

- General criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, and implementing procedures.
- Applicable QA requirements.
- Job responsibilities and authority.

Training shall be provided, if needed, to achieve initial proficiency, maintain proficiency and adapt to changes in technology, procedures, or job responsibilities. On-the-job training shall be used if direct hands-on applications or experience is needed to achieve and maintain proficiency. Indoctrination and training shall be documented using attendance sheets, training logs or other comparable documentation.

2.2 Qualification of Inspection and Test Personnel

Personnel performing inspections or test activities shall be qualified in accordance with NQA-1-2015 Requirement 2, Section 302 for nuclear reactor project work. Specific requirements for the qualification of inspection and test personnel shall be provided in an implementing procedure. Contracts for services requiring inspection and testing will incorporate appropriate quality requirements, including requirements for qualification of Inspection and Test Personnel.

2.3 Qualification of Nondestructive Examination Personnel

Personnel performing Nondestructive Examination (NDE) activities are required to be qualified in accordance with NQA-1-2015 Requirement 2, Section 301 for nuclear reactor project work. Specific requirements for NDE personnel qualification shall be provided in an implementing procedure prior to the time TP personnel perform this function. Procurement Documents for services requiring NDE services will incorporate appropriate quality requirements, including requirements for qualification of NDE personnel.

2.4 Qualification of Quality Assurance Audit Personnel

Lead Auditors organize and direct audits, report audit findings, and evaluate corrective action. Lead Auditors shall be qualified in accordance with the requirements of NQA-1 2015 Requirement 2, Section 303, as modified by RG 1.28, Revision 5. Orientation, training and qualification processes for Lead Auditors, Auditors, and Technical Specialists are described in an implementing procedure and shall meet the requirements specified in NQA-1 2015 Requirement 2, Sections 304 and 305.

2.5 Records of Qualification

The qualification of inspection, test, and NDE personnel, and Lead Auditors shall be certified in writing and shall include the information required by NQA-1 2015 Requirement 2, Section 400. These requirements are described in an implementing procedure.

2.6 PQPs for Nuclear Reactor Projects

Occasionally, there may be a need to establish a PQP, or similar, to ensure the appropriate quality requirements for a specific scope of work are implemented. PQPs will address all applicable requirements for the work and shall describe the measures taken to comply. PQPs must be approved by the technical person responsible for the work and by QA. PQPs to bridge compliance gaps or exceptions could apply to TP suppliers, or to work that TP may perform for others.

2.7 PQPs for Non-Reactor Projects

Non-Reactor project work shall be performed in accordance with the requirements of this QAPD (Section 19, as a minimum). Those requirements listed in Section 19 should be augmented or revised as necessary to comply with applicable industry standards specific to the project, and any customer or regulatory requirements.

2.8 Application of QAPD Based on Quality Level

TP uses a Quality Level system to establish the compliance basis and associated work controls used to complete work. Completed work is considered to be that which has been reviewed and approved by qualified personnel as required by applicable procedures. This includes documents prepared by Design, Testing, QA/QC, Procurement, etc. that affect quality.

The table below describes Quality Levels.

| **Quality Level** | A designation that indicates the compliance basis for completed work. Quality Level considers regulatory and customer requirements and may consider business risk. |
|---|---|
| **QL-1** | Work that is performed that impacts a nuclear safety related Structure, System or Component (SSC). QL1 is also applied to work if the results are to be used as a safety related SSC for licensing support and/or design input. Full NQA-1/ RG 1.28, Revision 5 compliance (accomplished by implementation of the QAPD) is required for QL1 work. QL1 also meets DOE Safety Class SSCs. |
| **QL-2** | QL2 meets one of the following:<br>1. **Nuclear** work that is performed that impacts non-QL1 SSCs but whose preventive or mitigative function is a major contributor to defense-in-depth and/or worker safety as determined from safety analyses. This is used for DOE “Safety-Significant” class.<br>**-or-**<br>2. **Nuclear** work that is performed that impacts a non-safety related with Special Treatment SSC. QL2 is also applied to work if the results are to be used as a non-safety related with Special Treatment design input.<br>**NOTE:** Any work performed at a QL2 level could not be used as a safety related design input without further validation that meets the requirements of NQA-1. |
| **QL-3** | Work that does not meet the requirements of QL1 or QL2. |

Engineering assigns quality levels to work based on safety classification of nuclear project SSCs, regulatory requirements, industry codes or standards, level of QA/QC verification required and business risk.

QA/QC plans and performs oversight, qualification and verification activities (audits, surveillances, source verification, inspection, receipt inspection, etc.) based on the quality level associated with the work.

Procurement ensures that supplier selection is appropriate based on assigned quality level and other technical and QA/QC requirements.

Determination of Quality Levels and their impact on work processes is described in implementing procedures.

2.9 Measurement, Analysis and Improvement

TP has established a “low threshold” corrective action system to allow any employee to enter a concern or process improvement recommendation that will be evaluated and, where applicable, action taken. The corrective action system will also account for issue or deficiency trends in order to provide actionable information to management to correct adverse trends.

The effectiveness of the quality program will be measured by results of the internal audit program, external audits, management self-assessments, quality surveillances, annual management review of the quality program, and the corrective action process.

The annual management review of the quality program should include:

- Results of audits, surveillance and self-assessment
- Customer feedback (if applicable)
- Nonconformances (if applicable)
- Corrective Actions
- Follow-up actions from previous annual reviews
- Changes that could affect the quality system (if applicable)

Outputs from the management reviews should include any decisions and actions related to:

- Improvement of the effectiveness of the quality management system and its processes
- Resource needs

2.10 Commitment

For section 2-Quality Assurance Program, TP commits to compliance with 10 CFR Part 50 Appendix B, Criteria II and NQA-1-2015 Edition, Requirement 2 and RG 1.28, Revision 5.

## 3 DESIGN CONTROL

The design shall be defined, controlled and verified. Design inputs shall be specified in a timely manner and correctly translated into design documents. Designed items and processes must conform to sound engineering / scientific principles and appropriate standards. 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 controls commensurate with those applied to the original design. Specifications are reviewed by QA to ensure that appropriate quality requirements are addressed. Quality requirements for non-safety design are established by responsible engineering management as described in implementing procedures. Design requirements for nuclear reactor project work designated as non-safety, or non-reactor project work shall, as a minimum, comply with the requirements of Section 19 of this QAPD.

### 3.1 Design Input

Design inputs such as performance requirements, regulatory requirements, codes and standards shall be identified and documented, and their selection reviewed and approved by the design organization. Design inputs 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 and evaluating design changes. Changes to design inputs shall be identified, documented and controlled.

### 3.2 Design Process

TP shall develop procedures for design activities to the level of detail necessary to permit the design process to be performed correctly and to permit verification that the design meets requirements. Implementing procedures describe the organizational responsibilities and interfaces for preparing, reviewing, approving and verifying design documents such as system descriptions, design input and criteria, design drawings, design analyses, computer programs, specifications, other types of design output documents, and procedures. Appropriate quality standards shall be identified and documented, and their selection reviewed and approved. The final design shall:

- Be relatable to the design input by documentation in sufficient detail to permit design verification.
- Specify any required inspections and tests and include or reference appropriate acceptance criteria.
- Identify assemblies and / or components that are part of the item being designed.

NOTE: When the assembly or component part is a Commercial Grade Item (CGI), the characteristics of the item to be verified for acceptance and applicable acceptance criteria shall be specified. Commercial grade dedication is further described in QAPD, Section 7, and in implementing procedures. Commercial Grade dedication shall be performed in accordance with the requirements of NQA-1-2015, Part II, and Subpart 2.14.

### 3.3 Design Analyses

Design analysis shall be sufficiently detailed such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without input from the originator.

3.4 Use of Computer Programs

Each computer program used for design analysis shall be accepted for use and controlled as described in the TP Software Management Plan which commits with the requirements of NQA-1-2015, Part II, Subpart 2.7, prior to use, or the computer program's results shall be independently verified with the design analysis for each application.

The acceptance of controlled computer programs used for design analysis, and verification methods applied to the results of unproven programs, shall meet the following requirements:

a) The computer program, or the verification method applied to the computer program 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.

3.5 Documentation of Design Analyses

Documentation of design analyses shall include the following:

a) The objective of the analyses

b) Design inputs and their sources

c) 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) Identification of any computer calculation, including identification of the computer type, computer program name, and revision, inputs, outputs, evidence of or reference to computer program verification, and the bases supporting application of the computer program to the specific physical problem

f) Review and approval

3.6 Design Verification

The TP organization responsible for the design shall identify and document the 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. This verification may be performed by the originator's supervisor, provided the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design; and the supervisor is the only individual in the organization competent to perform the verification.

Design verification shall be performed prior to releasing the design for procurement, manufacture, construction, or use by another design organization, except where this timing cannot be met, such as when insufficient data exist. In those cases, the unverified portion of the design shall be identified and controlled. In all cases the design verification shall be completed prior to relying upon the component, system, structure, or computer program to perform its function.

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

The extent of the 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. Where the design has been subjected to a verification process in accordance with this QAPD, the verification process need not be duplicated for identical designs. However, the applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, shall be verified for each application. Known problems affecting the standard or previously proved designs and their effects on other features shall be considered. The original design and associated verification documentation shall be referenced in records of subsequent application of the design.

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

a) Design reviews

b) Alternate calculations

c) Qualification testing

Design reviews, when used, shall provide assurance that the final design is correct and satisfactory by determining that design inputs were correctly selected; assumptions necessary to perform the design activity are adequately described and reasonable; appropriate design methods and computer programs were used; the design inputs were correctly incorporated into the design; the design outputs were reasonable compared to the design inputs; the necessary design inputs for interfacing organizations were specified in the design documents or in supporting procedures or instructions; and suitable materials, parts, processes, and inspection and testing criteria have been specified.

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

Qualification testing, when used, shall identify the tests and shall clearly define and document the test configuration. Testing shall demonstrate adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions shall be considered in determining the most adverse conditions. Where the test is intended to verify only specific design features, the other features of the design shall be verified by other means. Test results are documented and evaluated by the responsible design organization to ensure that test requirements have been met. If qualification testing indicates that modifications to the item are necessary to obtain acceptable performance, the modification is documented, and the item modified and retested or otherwise verified to ensure satisfactory performance. When tests are being performed on models or mockups, scaling laws shall be established and verified. The results of model test work shall be subject to error analysis, where applicable, prior to use in the final design.

## 3.7 Design Change Control

Changes to design inputs, final designs, and field drawings shall be justified and subject to proceduralized design control and change measures commensurate with those applied to the original design. These measures shall include evaluation of effects of those changes on the overall design and on any analysis upon which the design is based. The evaluation shall include facility configurations that occur during operation, maintenance, test, surveillance, and inspection activities. Changes shall be approved by the same affected groups or organizations which reviewed and approved the original design documents.

When a design change is approved other than by revision to the affected design documents, measures shall be established to incorporate the change into these documents, where such incorporation is appropriate.

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

3.8 Interface Control

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

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.

3.9 Software Design Control

The requirements of ASME NQA-1-2015, Part I Requirement 3, Section 400 and 800 as well as Part II Subpart 2.7 apply to computer software design control and shall be implemented in accordance with a TP implementing procedure.

3.10 Important to Safety

For nuclear safety related design activities all of the requirements of this section shall apply. For Important to safety and non-safety design activities, a graded application of this section will be used as described in implementing procedures or, as a minimum, as described in Section 19 of this QAPD.

3.11 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 step in the design process, including sources of design inputs that support the final design.

3.12 Commitment

For section 3 - Design Control TP commits to compliance with 10 CFR Part 50 Appendix B, Criterial III and NQA-1-2015, Requirement 3. In establishing requirements for computer program design control, TP also commits to compliance with NQA-12015, Subpart 2.7 for computer software.

## 4 PROCUREMENT DOCUMENT CONTROL

Procurement planning is accomplished by coordination between the organization acquiring items or services and the procurement organization. Procurement documents are prepared, reviewed and approved by personnel in the organization acquiring items or services and by the procurement organization. QA requirements for non-reactor project work shall, at a minimum, meet the requirements of Section 19 of this QAPD.

Quality assurance personnel review and approve purchases of safety related items and services to ensure that the appropriate quality requirements are specified; that proposed or selected suppliers have been or will be appropriately qualified prior to starting work; and that appropriate acceptance criteria are specified, where applicable.

Supplier selection is performed by the procurement organization based on applicable commercial considerations and as approved by Quality Assurance for safety related procurements. Where required, bid evaluation is coordinated by the procurement organization with participation by appropriate technical and quality assurance personnel.

Applicable design documents and other requirements necessary to ensure adequate quality shall be included or referenced in documents for procurement of items or services. Processes to ensure that approved suppliers continue to provide acceptable items and services shall be implemented. Procurement documents for safety related items or services for nuclear reactor project work shall require suppliers to have a QA program consistent with applicable requirements of ASME NQA-1-2015 and RG 1.28, Revision 5.

### 4.1 Content of Procurement Documents

Procurement documents shall include provisions for the following as applicable to the procurement:

- A statement of work to be performed by the supplier.
- A detailed description of items, services, or other deliverables to be provided.
- References to appropriate technical requirements such as drawings, specifications, standards, etc., and identification of appropriate test, inspection, and acceptance criteria for determining acceptability of the item or service.
- QA programmatic requirements with which the supplier's QA program must comply, including the requirement to flow requirements down to sub-tier suppliers.
- The right of access to supplier's and sub-tier suppliers' facilities and records by TP personnel, designated representatives, and other personnel as authorized by TP.
- Documentation submittal requirements, including identification of records, the required time for submittal, their retention times, and disposition requirements for those records that TP requires the supplier to maintain.
- Requirements to be met when reporting non-conformances and obtaining disposition approval where original design requirements cannot be met such as for use-as-is and repair dispositions.
- Requirements for the supplier to identify spare and replacement parts and related data required for ordering these parts.
- Requirement that the supplier have measures in place to prevent suspect/counterfeit items or documents from being included in delivered items or services.

4.2 Procurement Document Review

A review of procurement documents shall be made and documented prior to award, to ensure documents transmitted to prospective suppliers include provisions that ensure items or services will meet the specified requirements. Technical or QA program changes resulting from bid evaluations or negotiations shall be incorporated into procurement documents prior to issuance to the supplier. Procurement documents shall be reviewed by personnel with 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 shall be subject to the same degree of control and approval as utilized in the preparation of the original documents.

4.4 Commitment

For section 4-Procurement Document Control, TP commits to compliance with 10 CFR Part 50 Appendix B, Criteria IV and NQA-1-2015 Edition, Requirement 4.

## 5 INSTRUCTIONS, PROCEDURES AND DRAWINGS

Activities affecting quality shall be prescribed by and performed in accordance with documented procedures or instructions, which include or reference appropriate acceptance criteria for ensuring prescribed results have been satisfactorily attained. The level of detail in written procedures or instructions shall be determined based upon complexity of the task, significance of the item or activity, work environment, and worker proficiency and capability. Quality assurance personnel shall review and approve procedures and instructions for performance of safety related work to ensure that quality requirements for the work are appropriately described.

5.1 Commitment

For section 5-Instructions, Procedures and Drawings, TP commits to compliance with 10 CFR Part 50 Appendix B, Criteria V and NQA-1-2015 Edition, Requirement 5.

## 6 DOCUMENT CONTROL

The preparation, issue, and revision of documents that specify quality requirements or prescribe activities affecting quality, such as procedures, instructions, specifications and drawings shall be controlled to ensure that correct documents are being employed. Such documents and their revisions shall be reviewed for adequacy and approved for release by authorized personnel.

### 6.1 Document Preparation, Review, Approval and Issuance

The following controls shall be applied to documents and changes thereto. These controls shall be described in the appropriate implementing procedure:

- Documents to be controlled shall be identified.
- An Electronic Document Management System (EDMS) shall be established for all controlled documents to maintain current revisions where only authorized personnel have access to the documents.
- The identification of individuals responsible for the preparation, review, and approval of controlled documents shall be specified. This includes QA review of documents to ensure that necessary QA requirements have been addressed.
- Document Control personnel responsibilities for the review and control of documents is specified in supporting procedures.

### 6.2 Document Changes

Revisions to documents shall be reviewed and approved according to supporting procedures. Changes to documents shall be reviewed and approved by the same organization(s) that performed the original review and approval unless another responsible organization is designated in writing. The reviewing personnel shall have access to pertinent background data upon which to base their approval.

Minor changes to documents, such as inconsequential editorial corrections, shall not require that the revised documents receive the same review and approval as the original documents. Requirements for review and approval of minor changes shall be specified in an implementing procedure.

### 6.3 Quality Assurance Plan Revisions

Revisions to this QAPD shall be accomplished by revising Sections of this plan as the need arises. Each revision shall include a new electronically signed Title Page, a revised Table of Contents and all QAPD Sections in their entirety.

### 6.4 Commitment

For section 6-Document Control, TP commits to compliance with 10 CFR Part 50 Appendix B, Criteria VI and NQA-1-2015 Edition, Requirement 6.

## 7 CONTROL OF PURCHASED ITEMS AND SERVICES

The purchase of items and services shall be controlled to ensure conformance with specified requirements. Procurement controls shall provide for the following as appropriate:

- Supplier evaluation and selection.
- Evaluation of objective evidence of quality furnished by the supplier.
- Audit (minimum triennial) and annual evaluation of the supplier.
- Source surveillance or inspection.
- Examination of items or services upon delivery or completion to verify quality.
- Specific measures to be taken to ensure no suspect / counterfeit items or documents are included in the items or services being purchased.
- Product certifications.

### 7.1 Procurement Planning

Procurement planning shall provide for the integration of the activities described below. These activities shall be described procedurally, as applicable:

- Procurement document preparation, review, approval, and change control.
- Selection of procurement sources.
- Bid evaluation and procurement document award.
- Purchaser verification of supplier performance.
- Surveillance, inspection or audit activities to confirm compliance with requirements.
- Control of supplier's non-conformances.
- Corrective action.
- Acceptance of the item or service.
- Submittal of QA records and product certifications.

### 7.2 Supplier Evaluation and Selection

Prior to performance of safety related work by a supplier, the Director, ESH&Q or designee shall evaluate the potential supplier's capability to provide items or services in accordance with the quality requirements of the procurement documents. The results of the supplier evaluation shall be documented. Supplier evaluation shall be by:

- Review of the supplier's current quality records supported by documented qualitative and quantitative information that can be objectively evaluated (such as a documented quality assurance program and procedures), and
- Supplier's technical and quality capability as determined by a direct evaluation at the supplier's facility (qualification audit or survey). Supplier audits shall be performed at least triennially, with the exception identified in 7.2.1 for Exigent Conditions. The triennial period begins when a satisfactory audit is completed (report issued). A documented

supplier performance evaluation shall be performed as described below in section 7.3, for any year in which a full scope audit has not been performed.

NOTE: Audits are not required for U.S. government agencies such as National Institute of Standards and Technology (NIST).

If 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, the Purchaser shall resolve unacceptable technical and quality assurance conditions resulting from the bid evaluation.

7.2.1 Exigent Conditions

Exigent conditions affecting TP facilities or TP suppliers, and where performance of audit or survey activities for domestic and international suppliers is not feasible, a 25% extension of the triennial audit period may be exercised.

A documented evaluation shall be performed identifying the conditions inhibiting performance of the audit or survey and providing a basis for maintaining the supplier as an approved supplier during the exigent conditions 25% extension period.

For audits performed during the 25% extension period for exigent conditions, the audit "clock" does not reset backwards to the original date the audit or survey should have been performed. Rather, the date that the audit or survey is actually performed would be the start of the new triennial audit or survey frequency.

If the contract or a contract modification that significantly changes scope or changes the methods or controls for activities performed by the same supplier, the supplier is to provide documented justification that the changes are adequately addressed by its quality assurance program controls.

Examples of exigent conditions include, but are not limited to:

- Outbreak of a severe health concern to the public impacting TP facilities or supplier infrastructure
- Declaration of a national emergency or state of emergency impacting TP facilities or supplier infrastructure
- Natural disaster, weather emergency, or other severe localized or national weather even or resulting damage to or impacting TP facilities or supplier infrastructure

Continued use of suppliers who have exceeded the time period for audits due to exigent conditions is allowable, if the following conditions are met:

- Audits are completed on affected suppliers in order of the expiration of the triennial audit period and completed as soon as practical and shall also include a review of supplier activities performed since the triennial audit expiration date.
- TP shall verify that the supplier is still implementing a quality assurance program that meets contractual requirements and maintained adequate documented programmatic controls for activities affecting quality.
- Receipt inspection and industry operating experience are reviewed on an ongoing basis as information becomes available and documented. The results of the review

are promptly considered for the effects on a supplier's continued qualification and adjustments are made as necessary, including corrective actions.

If there is no ongoing receipt inspection or operating experience for a period of 12 months since the last audit or survey, an annual documented evaluation shall be performed and include the following:

- Review of supplier-furnished documents and records (e.g., certificates of conformance, nonconformance notices, and corrective actions).
- Previous source verifications, audits, receiving inspection activities results.
- Operating experience/ identical or similar products furnished by the same supplier.
- Results of audits from other sources.

7.3 Supplier Performance Evaluation

TP shall establish measures to interface with the supplier and to verify the supplier's performance. The extent of verification activities shall be a function of the relative importance, complexity and quality of the item or services procured and the supplier's past quality performance.

Activities performed to verify conformance to requirements of procurement documents shall be recorded. The Director, ESH&Q shall ensure that supplier quality performance is evaluated at least annually for all active suppliers of safety related items or services. This evaluation shall be performed and documented by QA. A formal supplier quality performance evaluation is not required for any year in which a full scope audit has been performed. Supplier quality performance evaluations shall address the following, as applicable:

The review of supplier-furnished documents and records such as Certificates of Conformance, nonconformance notices, or other documents as may be requested by QA;

- Results of previous source verifications, audits, and receiving inspections;
- Operating experience of identical or similar products furnished by the same supplier; and
- Results of audits from other sources, if applicable/available, such as those performed by the Nuclear Regulatory Commission.

7.4 Control of Supplier Generated Documents

Supplier generated submittals required by procurement documents shall be evaluated to verify compliance with contract requirements. Implementing procedures shall describe the acquisition, processing and evaluation of these submittals.

7.5 Acceptance of Items or Services

Prior to providing an item or service to TP, the supplier shall verify that the item or service being furnished complies with the procurement requirements. The extent of the verification activities performed by TP personnel for acceptance shall be a function of the relative importance, complexity, and quantity of the item or services procured and the supplier's quality performance.

7.5.1 Methods used to accept items or services shall be one or a combination of the following:

- Technical verification of data produced.

- Surveillance and / or audit of the activity.
- Review of objective evidence for conformance to the procurement document requirements.

7.5.2 Acceptance of items or services shall be by one or more of the following:

- Supplier's Certificate of Conformance – The certificate shall identify the purchased material or equipment, such as by the purchase order number. The certificate shall identify the specific procurement requirements met by the purchased material or equipment, such as codes, standards, and other specifications. This may be accomplished by including a list of the specific requirements or by providing, on-site, a copy of the purchase order and the procurement specifications or drawings, together with a suitable certificate. The procurement requirements identified shall include any approved changes, waivers, or deviations applicable to the subject material or equipment. The certificate shall identify any procurement requirements that have not been met, together with an explanation and the means for resolving the nonconformance. The certificate shall be signed or otherwise authenticated by a person who is responsible for this quality assurance function and whose function and position are described in the supplier's quality assurance program. The certification system, including the procedures to be followed in filling out a certificate and the administrative procedures for review and approval of the certificates, shall be described in the supplier's quality assurance program. Means shall be provided to verify the validity of supplier certificates and the effectiveness of the certification system, such as during the performance of audits of the supplier or independent inspection or test of the items.

- Source verification – When used, source verification shall be performed at intervals consistent with the importance and complexity of the item or service, and shall include monitoring, witnessing, or observing selected activities. Source verification shall be implemented in accordance with plans to perform inspections, examinations, or tests at predetermined points. Upon TP acceptance of source verification, documented evidence of acceptance shall be furnished to the receiver of the item, to responsible TP personnel, and to the supplier.

- Receiving inspection – Purchased items shall be inspected by qualified personnel as necessary to verify conformance to specified requirements. Receiving inspection shall verify by objective evidence such features as configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage; and cleanliness. Receiving inspection shall be coordinated with review of supplier documentation when procurement documents require such documentation to be furnished prior to receiving inspection.

- Post-installation testing – When used, post installation test requirements and acceptance documentation shall be mutually established by appropriate TP personnel and the supplier.

- Acceptance of Services – In cases involving procurement of services only, such as third-party inspection, engineering and consulting services; auditing, installation, repair, overhaul, or maintenance work, TP shall accept the service by any or all of the following methods: Technical verification of data produced; surveillance and/or audit of the activity; or review of objective evidence for conformance to the procurement document requirements.

7.6 Control of Supplier Nonconformance

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

- Evaluation of nonconforming items.
- Submittal of nonconformance notice to TP by supplier as directed in the procurement documents.
    - These submittals shall include supplier-recommended disposition (e.g., use-as-is or repair) and technical justification. Nonconformance to the procurement requirements of TP-approved documents, which consist of one or more of the following, shall be submitted to TP for approval of the recommended disposition: Technical or material requirement is violated; requirement in supplier documents, which has been approved by TP, is violated; nonconformance cannot be corrected by continuation of the original manufacturing process or by rework; the item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired.
- TP disposition of supplier recommendations.
- Maintenance of records of supplier-submitted nonconformance.

7.7 Dedication of Commercial Grade Items and Services for use in Safety Related Applications

When Commercial Grade Items (CGI) or Commercial Grade Services (CGS) are intended to be used, the applicable requirements of NQA-1-2015, Part II, Subpart 2.14, Quality Assurance Requirements for Commercial Grade Items and Services, shall apply. Details are provided in implementing procedures.

7.8 Commitment

7.8.1 In establishing a program for the control of items and services, TP commits to compliance with 10 CFR Part 50 Appendix B, Criteria VII and NQA-1-2015 Edition, Requirement 7 with the following exceptions:

- TP 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 TP, 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, commercial grade surveys need not be performed provided each of the following conditions are met:
    - A documented review of supplier's accreditation will be performed and will include a verification of each of the following:
        - Ending on June 1, 2021, the NRC endorsement of NEI 14-05A revision 0, utilizing either the 2005 and the 2017 editions of ISO/IEC 17025 will no longer be valid. Starting on June 2, 2021Revision0 of NEI 14-05A will become superseded by Revision 1 of NEI 14-05A. Licensees and suppliers of basic components using the ILAC accreditation process in lieu of performing a commercial-grade survey for calibration and testing services will have to start implementing Revision 1 of NEI 14-05A.

7.8.2 In establishing a program for dedication of commercial-grade items TP commits to compliance with NQA-1-2015, Subpart 2.14 and RG 1.28, Revision 5.

## 8 IDENTIFICATION AND CONTROL OF ITEMS

Controls shall be established in implementing procedures and process control documents to ensure that only the correct and accepted items are used or installed. Identification shall be maintained on the items or in documents traceable to the items in a manner which ensures that identification is established and maintained. TP shall convey marking or identification requirements to suppliers.

### 8.1 Identification Methods

Items of production shall be identified from the initial receipt and fabrication of items up to and including installation or use. This identification shall relate an item to an applicable design or other pertinent specifying document.

Physical identification shall be used to the maximum extent possible. Where physical identification is impractical or insufficient, other appropriate means shall be employed. Identification markings shall be applied which provide a clear and legible identification and do not degrade the function or service life of the item. Markings shall be transferred to each part of an identified item when subdivided and shall not be obliterated by surface treatment or coating unless other means of identification are substituted.

If at any time, an item cannot be physically identified (traceability is lost), that item shall be considered non-conforming requiring preparation of a nonconformance report. The nonconformance report will document disposition of the item (scrap, segregation, retest or other reverification of traceability).

### 8.2 Additional Requirements When Specified

When codes, standards or specifications include specific identification or traceability requirements, such as traceability of an item to a material test report by its heat number, process control documentation shall impose these requirements on those performing the work.

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

Provisions shall be made for the preservation of item identification consistent with the planned duration and conditions of storage.

### 8.3 Commitment

For section 8-Identification and Control of Items, TP commits to compliance with 10 CFR Part 50 Appendix B, Criteria VIII and NQA-1-2015 Edition, Requirement 8.

## 9 CONTROL OF SPECIAL PROCESSES

Processes affecting the quality of items or services shall be controlled. Special processes that control or verify quality, such as those used in welding, heat treating and NDE, shall be performed by qualified personnel using qualified procedures in accordance with specified requirements.

### 9.1 Process Control

Processes shall be controlled by instructions, procedures, drawings, checklists, travelers, or other process control documentation. This documentation shall ensure that process parameters are controlled and that specified environmental conditions are maintained.

9.2 Special Processes

Special processes shall be performed in accordance with procedures, which include or reference procedure, personnel and equipment qualification requirements. Qualification of personnel, procedures and equipment shall comply with specified requirements. Records shall be maintained documenting the currently qualified personnel, methods and equipment for each special process. Conditions necessary for accomplishment of the process shall be included in procedures. These conditions shall specify required equipment, parameters of the process, and calibration requirements. Requirements of applicable codes and standards, including acceptance criteria for the process, shall be specified or referenced in the procedures.

9.3 Commitment

For section 9-Control of Special Processes, TP commits to compliance with 10 CFR Part 50 Appendix B, Criteria IX and NQA-1-2015 Edition, Requirement 9.

## 10 INSPECTION

Inspections required to verify conformance of an item or activity to specified requirements shall be planned and performed. Characteristics to be inspected and inspection methods to be employed shall be specified in process control documentation and resulting outcomes shall be documented. Inspection for acceptance shall be performed by persons other than those who performed or directly supervised the work being inspected.

10.1 Inspection Requirements

Inspection requirements and acceptance criteria shall be specified or referenced in design documents that are approved by the responsible design organization. These requirements and acceptance criteria are incorporated into process control documentation to convey the information to personnel performing the work. Inspection activities shall be documented and controlled by instructions, procedures, drawings, checklists, travelers or other process control documentation. Appropriate criteria to prevent the use of counterfeit parts in items or equipment being inspected shall also be established.

10.2 Inspection Personnel

Inspection personnel shall not report directly to the immediate supervisors who are responsible for performing the work being inspected. Personnel who verify conformance of work activities or items for acceptance shall be qualified in accordance with Section 2 of this QAPD and the applicable implementing procedure.

10.3 Inspection Hold Points

If mandatory inspection hold points are required, they shall be indicated in process control documentation. Work may not proceed past the hold point until required actions have been completed or the hold has been formally waived. The technical authority responsible for the work or QA may waive hold points. The technical authority and QA shall review the impact of waived hold points prior to releasing the work for further production or use. Consent to waive specified hold points shall be recorded prior to continuation of work beyond the designated hold point.

10.4 Inspection Planning

Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process. Sampling procedures, when used, shall be based upon standard statistical methods and shall receive engineering approval.

10.5 In-Process Inspection

Inspection of items under construction or otherwise in process shall be performed as necessary to verify quality. If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment, and personnel shall be provided. Process monitoring shall be performed by qualified personnel or qualified automated means. Both inspection and process monitoring shall be provided when control is inadequate without both.

10.6 Final Inspections

Final inspections shall include a records review of the results and resolution of nonconformances identified by prior inspections. Completed items shall be inspected for completeness, markings, calibration, adjustments, protection from damage, or other characteristics as required to verify the quality and conformance of the item to specified requirements.

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

The acceptance of the item shall be approved by authorized personnel.

10.7 In-Service Inspection

Required in-service inspections or surveillances of structures, systems, and components (SSCs) shall be planned and performed by or for the organization responsible for operation.

10.8 Records

Appropriate records shall be developed and maintained. Inspection documentation shall contain as a minimum:

- Item inspected.
- Date of inspection.
- Inspector.
- M&TE used for verification, if applicable.
- Type of observation.
- Results of inspection or item acceptability.
- Reference to action taken in connection with nonconformance.

10.9 Commitment

For section 10-Inspection, TP commits to compliance with 10 CFR Part 50 Appendix B, Criteria X and NQA-1-2015 Edition, Requirement 10.

## 11 TEST CONTROL

Tests required to collect data such as for siting or design input, to verify conformance of an item of 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.

Each computer program used for design analysis shall be accepted for use and controlled as described in the TP Software Management Plan which commits with the requirements of NQA-1-2015, Part II, Subpart 2.7, prior to use, or the computer program's results shall be independently verified with the design analysis for each application.

### 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) such as prototype qualification tests, production tests, proof tests prior to installation, construction tests, preoperational tests, and operational tests shall be controlled. Computer program tests such as 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 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.

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

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

### 11.2 Test Procedures (other than for computer programs)

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

- Calibrated instrumentation.

- Appropriate equipment.
- Trained personnel.
- Acceptable condition of test equipment and the item to be tested.
- Suitable environmental conditions.
- Provisions for data acquisition.

As an alternative to these requirements, appropriate sections of related documents such as ASTM methods, supplier manuals, equipment maintenance instructions, or approved process control documents with acceptance criteria can be used. Such documents shall include or be supplemented with appropriate criteria shown above to assure adequate procedures for the test.

11.3 Computer Program Test Procedures

Computer program test procedures shall provide for demonstrating the adherence of the computer program to documented requirements. For those computer programs used in design activities, computer program test procedures shall provide for assuring that the computer program produces correct results. For those computer programs used for operational control, computer program test procedures shall provide for demonstrating required performance over the range of operation of the controlled function or process. The procedures shall also provide for evaluating technical adequacy through comparison of test results from alternative methods such as hand calculations, calculations using comparable proven programs, or empirical data and information from technical literature. In-use test procedures shall be developed and documented to permit confirmation of acceptable performance of the computer program in the operating system. In-use test procedures shall be performed after the computer program is installed on a different computer, or when there are significant changes in the operating system. Periodic in-use manual or automatic self-check 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.

Test procedures or plans shall specify the following, as applicable:

- Required tests and test sequence.
- Required ranges of input parameters.
- Identification of the stages at which testing is required.
- Criteria for establishing test cases.
- Requirements for testing logic branches.
- Anticipated output values.
- Acceptance criteria.
- Reports, records, standard formatting, and conventions.

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 (other than computer program test records)
Test records shall include the following as a minimum:

- Item tested.
- Date of test.
- Tester or data recorder.
- Type of observation.
- Results and acceptability.
- Action taken in connection with any deviations noted.
- Person evaluating test results.

11.6 Computer Program Test Records
Computer program test records shall contain the following as a minimum:

- Computer program tested including system software used.
- Computer hardware used.
- Test equipment and calibrations, where applicable.
- Date of test.
- Tester or data recorder.
- Simulation models used, where applicable.
- Test problems.
- Results and applicability.
- Action taken in connection with any deviations noted.
- Person evaluating test results.
- Acceptability.

11.7 Commitment
For section 11-Test Control TP, commits to compliance with 10 CFR Part 50 Appendix B, Criteria XI and NQA-1-2015 Edition, Requirement 11 for establishing test control requirements. For establishing requirements for computer program test procedure and test records, TP commits to compliance with NQA-1-2015 Subpart 2.7.

## 12 CONTROL OF MEASURING AND TEST EQUIPMENT

Tools, gauges, instruments, and other Measuring and Test Equipment (M&TE) used for activities affecting quality shall be controlled, calibrated at specified intervals, adjusted and maintained to required accuracy limits. M&TE used for acceptance of safety related SSCs or processes shall be calibrated by a qualified TP individual or by a calibration laboratory that has been qualified either by QA audit or via the Commercial Grade Dedication process.

### 12.1 Selection

Selection of M&TE shall be based on the type, range, accuracy, and tolerance needed to accomplish the required measurements for determining conformance to specified requirements.

### 12.2 Labeling and Tagging

M&TE shall be labeled, tagged, or otherwise controlled to indicate its calibration and to ensure its traceability to calibration test data.

### 12.3 Calibration and Control

M&TE shall be calibrated at prescribed times or intervals and whenever the accuracy of the equipment is suspect. Calibration shall be against, and traceable to, certified equipment or reference standards having known, valid relationships to nationally recognized standards. If no nationally recognized standards exist, the basis for calibration shall be documented.

Reference standards shall have a minimum accuracy four times greater than that of the M&TE being calibrated to ensure that the reference standards contribute no more than one-fourth of the allowable calibration tolerance. Where this 4:1 ratio cannot be maintained, the basis for selection of the standard in question shall be technically justified.

Calibration procedures shall identify, or reference required accuracy and shall define methods and frequency of checking accuracy. The calibration method and interval 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 not used until it has been recalibrated. M&TE consistently found to be out of calibration shall be repaired or replaced.

- M&TE shall be traceable to its application and use.
- 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.
- M&TE shall be properly handled and stored to maintain accuracy.
- 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.
- M&TE and reference standards submitted for calibration shall be checked and the results recorded before any required adjustments or repairs are made.
- 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 the M&TE to satisfactorily perform their intended functions. 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.

12.5 Commitment

For section 12-Control of Measuring and Test Equipment, TP commits to compliance with 10 CFR Part 50 Appendix B, Criteria XII and NQA-1-2015 Edition, Requirement 12.

## 13 HANDLING, STORAGE, AND SHIPPING

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 performed in accordance with established work procedures, process control documentation, specifications, shipment instructions, manufacturer's recommendations, or other pertinent documentation.

13.1 Requirements

When required, special equipment and special protective environments shall be specified, provided and their existence verified.

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

Special handling tools and equipment shall be utilized as necessary to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested periodically or prior to use to verify that they are adequately maintained.

Operators of special handling and lifting equipment shall be experienced and trained in the use of the equipment if necessary.

13.2 Marking or Labeling

Instructions for marking and labeling for packaging, shipment and storage of items shall be established as necessary to adequately identify, maintain and preserve the item.

13.3 Commitment

For section 13-Handling, Storage, and Shipping, TP commits to compliance with 10 CFR Part 50 Appendix B, Criteria XIII and NQA-1-2015 Edition, Requirement 13.

## 14 INSPECTION, TEST, AND OPERATING STATUS

The status of inspection and test activities shall be identified either on the items or in documents traceable to the items. Indicating the status of items is important when it is necessary to ensure that required inspections and tests have been performed and to ensure that items which have not passed required inspections and tests are not inadvertently used, installed, or operated. Status shall be maintained through indicators such as physical location, tags, markings, process control documents, stamps or other suitable means. Status indicators shall also provide for indicating the operating status of systems and components such as by tagging valves and switches to prevent inadvertent operation. The authority for application and removal of tags, markings, labels, and stamps shall be specified in implementing procedures.

### 14.1 Commitment

For section 14-Inspection, Test, and Operating Status, TP commits to compliance with 10 CFR Part 50 Appendix B, Criteria XIV and NQA-1-2015 Edition, Requirement 14.

## 15 CONTROL OF NONCONFORMING ITEMS

Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use. Controls shall provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items. Additionally, controls shall be in place to ensure that identified nonconformance's are screened to determine if the condition needs to be evaluated for potential reportability pursuant to 10 CFR Part 21. TP has a procedure in place to accomplish these administrative evaluations and reporting where applicable. Affected organizations shall be notified of the nonconforming item.

### 15.1 Identification and Segregation

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

When practical, nonconforming items shall be placed in a clearly identified hold area until properly dispositioned. When segregation is impractical or impossible due to size, weight or access limitations, other precautions shall be employed to preclude inadvertent use of the nonconforming item.

### 15.2 Disposition

Nonconformance shall be documented on a nonconformance report in accordance with applicable implementing procedures. Personnel performing evaluations to determine a disposition shall have demonstrated competence in the specific area they are evaluating; an adequate understanding of the requirements; and access to pertinent background information.

The responsibility and authority for the evaluation and disposition of nonconforming items is identified in implementing procedures. The Director, ESH&Q or designee is responsible for the control of further processing, delivery, installation, or use of nonconforming items.

A disposition such as use-as-is, reject, repair, or rework shall be identified and documented. Technical justification for the acceptability of a nonconforming item dispositioned repair or use-as-is shall be documented. Nonconformance to design requirements dispositioned use-as-is or repair shall be subject to design control measures commensurate with those applied to the original design. The as-built records, if such records are required, shall reflect the accepted "use as is" or "repair" condition.

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

15.3 Commitment

For section 15-Control of Non-Conforming Items, TP commits to compliance with 10 CFR Part 50 Appendix B, Criteria XV and NQA-1-2015 Edition, Requirement 15.

## 16 CORRECTIVE ACTION

Conditions adverse to quality shall be identified promptly and corrected as soon as practical. In the case of a significant condition adverse to quality, the cause of the condition shall be determined and both corrective action and action to preclude recurrence shall be identified and completed. Controls shall be in place to ensure that identified conditions adverse to quality are screened to determine if the condition needs to be evaluated for potential reportability pursuant to 10 CFR Part 21. TP has a procedure in place to accomplish these administrative evaluations and reporting where applicable. The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management. Completion of corrective action shall be verified.

Findings documented during external audits will not be documented on a TP Condition Report (CR) / Corrective Action Report (CAR). They will be tracked in the supplier's own corrective action system, with notification to the audit team leader upon completion of the corrective action. These Findings should be included for evaluation in subsequent audits to determine if preventive measures have been successful, depending on the severity of the findings.

Adverse conditions are trended to determine whether additional analysis, management action, and/or corrective action is needed.

CRs/CARs may be used for other (non-quality related) deficiencies as described in implementing procedures.

16.1 Commitment

For section 16-Corrective Action, TP commits to compliance with 10 CFR Part 50 Appendix B, Criteria XVI and NQA-1-2015 Edition, Requirement 16.

## 17 QUALITY ASSURANCE (QA) RECORDS

The control of QA records for safety related work shall be established consistent with the schedule for accomplishing work activities. QA records furnish documentary evidence that items or activities meet specified quality requirements. QA records are identified, generated, authenticated, and maintained, controlled, and their final disposition specified in implementing procedures.

### 17.1 Generation of Records

QA records shall be legible. Records shall be traceable to associated items, activities, and accurately reflect the work accomplished or information required. Records to be generated, supplied, or maintained shall be specified in applicable documents such as design specifications, procurement documents, test procedures, and operational procedures.

### 17.2 Authentication of Records

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 accomplished in accordance with procedural requirements that include identification of the individual making the correction and the date the correction was made. Corrections to documents shall be reviewed and approved by a responsible individual from the originating or authorized organization, unless another individual or organization is designated in writing to perform the review and approval. Once a document has been authenticated as a QA record, no further changes are allowed. If clarification or correction of a record is determined to be necessary, the record may be amended or supplemented in accordance with an approved procedure, but no original information may be changed.

Electronic documents shall be authenticated with comparable information shown above, as appropriate, with identification on the media, or with authentication information contained within or linked to the document itself.

### 17.3 Classification

Records for safety related work shall be classified as lifetime or nonpermanent and maintained by TP, or authorized agent.

#### 17.3.1 Lifetime records

Lifetime records are those that meet one or more of the following criteria: Those that would be of significant value in demonstrating capability for safe operation; those that would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item; those that would be of significant value in determining the cause of an accident or malfunction of an item; and those that provide required baseline data for in-service inspection. Lifetime records are required to be maintained by or for TP for the life of the particular item while it is installed in the plant or stored for future use.

#### 17.3.2 Nonpermanent records

Nonpermanent records are those that show evidence that an activity was performed in accordance with the applicable requirements. TP or the authorized agent does not need to retain these records 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 lifetime 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.

17.5 Storage

Records shall be stored at a predetermined location or locations in facilities, containers, or a combination thereof, constructed and maintained in a manner that minimizes the risk of loss, damage, or destruction from natural disasters such as winds, floods, or fires; environmental conditions such as high and low temperatures and humidity; infestation of insects, mold, or rodents; and dust or airborne particles.

- Activities detrimental to the records shall be prohibited in the storage area.
- Access to the processing, storage, and retrieval of records shall be limited to authorized personnel.
- 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.
- TP uses a dual storage process so the requirements for single-facility storage are not addressed herein.
- 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.
- Records retention periods are identified in implementing procedures. Records are maintained for their retention periods.

17.6 Maintenance of Records

Records shall be protected from damage or loss. Record controls shall provide for retrievability within planned retrieval times based upon the record type or content.

- The methods for record changes are described in implementing procedures.
- Provisions shall be established to ensure that no unacceptable degradation of electronic record media occurs during the established retention period.
- Provisions shall be established to ensure that the records remain retrievable after hardware, software, or technology changes.

17.7 Managing Quality Assurance Records in Electronic Media

For the management of electronic records, appropriate control on quality assurance include the following:

- No deletion or modification of records unless authorized pursuant to the record retention rule.
- Redundancy (system backup, dual storage, etc.) is provided.
- Legibility is required of each record.
- Records media are properly maintained.
- Inspections to ensure no degradation of records.
- Records are acceptably converted into any new system before the old system is taken out of service.

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: Duplication or transfer is appropriately authorized; record content, legibility, and retrievability are maintained.

17.8 Commitment

For section 17-Quality Assurance (QA) Records TP commits to compliance with 10 CFR Part 50 Appendix B, Criteria XVII and NQA-1-2015 Edition, Requirement 17, and RG 1.28, Revision 5.

## 18 AUDITS

Planned and scheduled audits shall be performed to verify compliance with this QAPD and associated implementing procedures. Audits shall evaluate the effectiveness of the implementation of this QAPD. Audits shall be performed in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing the activities being audited. Audit results shall be documented and reported to and reviewed by responsible management. Follow-up action shall be taken to verify resolution of identified discrepancies.

18.1 Scheduling

An annual internal audit schedule shall be prepared by the QA department with input from other TP organizations. The internal audit schedule may be modified to respond to emerging audit needs or direction from senior management. The audit schedule shall ensure that all elements of the quality program are audited annually, or at least once during the lifetime of the activity, whichever is shorter.

For activities expected to last less than one year, the schedule for audit of those activities should be based on the optimal time for audit, such as when there has been sufficient work performed to determine satisfactory performance. Shorter duration activities may also be monitored via the quality surveillance process as described in procedure TP-QA-PROC-0006, “QA Surveillance”.

External audits (e.g., Supplier audits) shall be performed on a triennial basis and supplemented by annual evaluations of the Supplier's performance. External or supplier audits may be tracked on the audit schedule and / or the Evaluated Supplier List (ESL). If a subsequent contract or contract modification significantly enlarges the scope of or changes the supplier's methods or controls, an audit of the modified methods or controls shall be conducted, thereby starting a new triennial period.

A grace period of 90 days may be applied to extending the schedule of an audit, but this does not allow the "clock" for the original audit schedule to be reset forward.

18.2 Audit Preparation

The audit team shall prepare a written audit plan for each audit. The plan shall identify the audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, and schedule.

Personnel having direct responsibility for performing the activities being audited shall not be involved in the selection of the audit team. Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective. Auditors shall have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited.

The audit team shall be identified prior to each audit and shall contain one or more auditors. This team shall have a Lead Auditor who meets the requirements of a Lead Auditor as described in ASME NQA-1-2015 Requirement 2, Section 303. The Lead Auditor organizes and directs the audit and coordinates the preparation and issuance of the audit report.

18.3 Audit Performance

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

Adverse internal audit findings shall be identified on a Condition Report.

18.4 Audit Reporting

An audit report shall be generated, signed by the audit team leader, and issued to the audited organization. The contents of the audit report shall:

- Describe the audit scope.
- Identify the audit team.
- Identify personnel contacted during the audit.
- Summarize the audit results including a statement on the effectiveness of the elements audited.
- Describe each adverse audit finding.

18.5 Response

Management of the audited organization or activity shall investigate adverse audit findings, identify and schedule corrective action and notify the audit team leader in writing of action taken or planned. Completion dates for Corrective Action and action to prevent recurrence shall also be provided. The adequacy of the responses shall be evaluated by the audit team leader.

18.6 Follow-Up Action

Follow-up action shall be taken to verify that the Corrective Action was completed satisfactorily as scheduled. This shall be done prior to completing the closeout section of the Corrective Action Report.

18.7 Audit Records

Audit records are non-permanent records. Audit records include the audit plan, audit checklist, audit report including audit findings, responses to findings, and record of completion of Corrective Action.

18.8 Commitment

For section 18-Audits TP commits to compliance with 10 CFR Part 50 Appendix B, Criteria XVIII and NQA-1-2015 Edition, Requirement 18, and RG 1.28, Revision 5.

## 19 QUALITY REQUIREMENTS FOR NON-SAFETY WORK FOR REACTOR PROJECTS AND FOR NON-REACTOR PROJECTS

Specific program controls are applied to non-safety related portions of nuclear reactor projects, and for non-reactor project 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.

The following establish the applicability of the QA Program to non-safety portions of nuclear reactor projects and non-reactor projects except where TP management has determined that compliance with requirements 1 through 18 above shall be required.

19.1 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.

19.2 Quality Assurance Program

QA requirements for non-safety related portions of nuclear reactor projects and non-reactor projects are established in appropriate procedures and/or a PQP. Suppliers of non-safety related SSCs or services shall describe the quality controls applied in appropriate procedures. A PQP may be required if there are gaps between the supplier procedures and TP product or service quality requirements.

19.3 Design Control

Design control measures shall ensure that the established design requirements are included in the design. These measures ensure that applicable design inputs are included or correctly translated into the design documents and deviations from those requirements are controlled. Design verification is provided through the normal supervisory review of the designer's work.

19.4 Procurement Document Control

Procurement documents for items and services include or reference documents describing applicable design bases, design requirements, and other requirements necessary to ensure component performance. These procurement documents are controlled.

19.5 Instructions, Procedures, and Drawings

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

19.6 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. These controls include review and approval of documents, identification of the appropriate revision for use, and measures to preclude the use of superseded or obsolete documents.

19.7 Control of Purchased Items and Services

Measures, such as inspection of items or documents upon receipt or acceptance testing, ensure that all purchased items and services conform to appropriate procurement documents.

19.8 Identification and Control of Purchased Items

Where necessary, measures are employed to identify purchased items and preserve their functional performance capability. Storage controls take into account appropriate environmental, maintenance, or shelf-life restrictions for the items.

19.9 Control of Special Processes

Process and procedure controls are used for special processes, including welding, heat treating, and nondestructive testing. These controls are based on applicable codes, standards, specifications, criteria, or other special requirements for the special process.

19.10 Inspection

Use of documented instructions shall be used to ensure necessary inspections are performed to verify conformance of an item or activity to specified requirements or to verify that activities are satisfactorily accomplished. These inspections may be performed by knowledgeable personnel in the line organization. Knowledgeable personnel can be from the same discipline and have experience related to the work being inspected.

19.11 Test Control

Measures shall be employed to identify required testing that demonstrates that equipment conforms to design requirements. These tests are performed in accordance with test instructions or procedures. The test results are recorded, and authorized individuals evaluate the results to ensure that test requirements are met.

19.12 Control of Measuring and Test Equipment

Measures shall be employed to control M&TE use, calibration, and adjustment at specific intervals or prior to use.

19.13 Handling, Storage, and Shipping

Measures shall be employed to control the handling, storage, cleaning, packaging, shipping, and preservation of items to prevent damage or loss and to minimize deterioration. These measures include appropriate marking or labels, and identification of any special storage or handling requirements.

19.14 Inspection, Test, and Operating Status

Measures shall be employed to identify items that have satisfactorily passed required tests and inspections and to indicate the status of inspection, test, and operability as appropriate.

19.15 Control of Nonconforming Items

Measures shall be employed to identify and control items that do not conform to specified requirements to prevent their inadvertent installation or use.

19.16 Corrective Action

Measures shall be employed to ensure that failures, malfunctions, deficiencies, deviations, and non-compliances are properly identified, reported, and corrected.

19.17 Records

Measures shall be employed to ensure records are prepared and maintained to furnish evidence that the above requirements for design, procurement, document control, inspection, and test activities have been met.

19.18 Audits

Measures shall provide that line management periodically review and document the adequacy of processes, including taking any necessary corrective action. Audits 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 any 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 and test activities.

## 20 REGULATORY GUIDES AND QUALITY ASSURANCE STANDARDS COMMITMENTS

TerraPower commits to compliance with RG 1.28, Revision 5, 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.

TerraPower commits to identifying the extent of conformance, including justifications for exclusion or modifications based on the specific characteristics of TerraPower's non-LWR technology, to other RG, Generic Letters and standards supplementing the TerraPower 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 0, June 2017.

  TerraPower identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in the design control documentation.

- Regulatory Guide 1.189, Fire Protection for Nuclear Power Plants, Rev 3, February 2018.

  TerraPower identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in the design control documentation.

- 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.

  TerraPower identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in the design control documentation.

- Regulatory Guide 1.234, Evaluating Deviations and Reporting Defects and Noncompliance Under 10 CFR Part 21, Rev 0, April 2018.

- Regulatory Guide 1.26, Quality Group Classifications and Standards For Water-, Steam-, And Radioactive-Waste-Containing Components Of Nuclear Power Plants, Rev 5, February 2017.

  The Natrium reactor design is a Fast Sodium Cooled Reactor and is significantly different from the design of light water reactors. So, the conventional quality group classifications may not be directly applicable. TerraPower identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in the design control documentation.

- Regulatory Guide 1.28, Quality Assurance Program Criteria (Design and Construction), Rev 5, October 2017.

- Regulatory Guide 1.29, Seismic Design Classifications for Nuclear Power Plants, Rev 5, July 2016.

  TerraPower identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in the design control documentation.

- Regulatory Guide 1.54, - Service Level I, II, and III Protective Coatings Applied to Nuclear Power Plants, Rev 3, April 2017.

  TerraPower identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in the design control documentation.

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

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