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18-Aug-2022

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U.S. Nuclear Regulatory Commission
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Submission of X Energy, LLC (X-energy) Topical Report Quality Assurance Program Description, Revision 4

REFERENCES:

- 1) Letter from H. Bowers to U.S. Nuclear Regulatory Commission (NRC) dated 31 July 2019, "Submittal of X Energy, LLC (X-energy) Quality Assurance Program Description (QAPD) for Design Certification of the X-energy Xe-100 Reactor - Non-Proprietary" (ML19213A059)
- 2) Letter from U.S. Nuclear Regulatory Commission to X Energy, LLC, "Request for Additional Information on the NRC Assessment of the Quality Assurance Program Description for the X-Energy XE-100 Nuclear Reactor X-Energy, LLC (EPID L-2019-TOP-0020)" (ML20013G253)
- 3) Letter from H. Bowers to U.S. Nuclear Regulatory Commission dated 3 February 2020, "Submittal of X Energy, LLC (X-energy) Response to NRC Requests for Additional Information Letter (ML20013G253) for the Review of Topical Report Quality Assurance Program Description (XEQAPD 1.0, Revision 0) for Design Certification of the X-energy Xe-100 Reactor - Non-Proprietary" (ML20035E617).
- 4) Letter from H. Bowers to U.S. Nuclear Regulatory Commission dated 8 April 2020, "Submittal of Revision 2 to X Energy, LLC (X-energy) Quality Assurance Program Description (QAPD) for Design Certification of the X-energy Xe-100 Reactor - Non-Proprietary" (ML20104C134).
- 5) Letter from U.S. Nuclear Regulatory Commission to X Energy, LLC, dated 13 July 2020, "Draft Safety Evaluation Report Regarding the Review of X Energy's Topical Report XEQAPD, "Quality Assurance Program Description" Revision 2 (EPID NO. L-2019-TOP-0020)" (ML20140A333)
- 6) Letter from U.S. Nuclear Regulatory Commission to X Energy, LLC, dated 4 September 2020, "U.S. NUCLEAR REGULATORY COMMISSION FINAL SAFETY EVALUATION FOR X-ENERGY'S TOPICAL REPORT XEQAPD-NP, "QUALITY ASSURANCE PROGRAM DESCRIPTION," REVISION 3 (EPID NO. L-2019-TOP-0020)" (ML20233A910)
- 7) Letter from M. van Staden to U.S. Nuclear Regulatory Commission dated 4 December 2020, "X Energy, LLC (X-energy) Topical Report Submittal Revision 3-A to X Energy, LLC (X-energy), Quality Assurance Program Description (QAPD) - Non-Proprietary" (ML20343A088)

The purpose of this letter is to submit Revision 4 of the subject topical report to the U.S Nuclear Regulatory Commission (NRC) on behalf of X Energy, LLC ("X-energy"). The enclosed revision is intended to supersede other revisions. It is provided for NRC review and approval as indicated in the report and is expected to

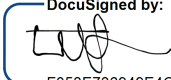


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be referenced in future Xe-100 licensing applications. The specific review schedule will continue to be developed with X-energy's NRC project manager.

This letter contains no commitments. If you have any questions or require additional information, please contact Brandon Norris at jnorris@x-energy.com or Ingrid Nordby at inordby@x-energy.com.

Sincerely,

DocuSigned by:

F053E736949E4C3...

Travis A. Chapman
Manager, U.S. Licensing, Xe-100 Program
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Enclosure: X Energy, LLC Topical Report, Quality Assurance Program Description (Non-Proprietary)



X Energy, LLC Topical Report Quality Assurance Program Description

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E-SIGNATURES: DOCUMENT APPROVAL



EXECUTIVE SUMMARY

This Quality Assurance Program Description (QAPD) identifies the basis of the X Energy, LLC (X-energy) Quality Assurance Program (QAP) and its application to the design, construction, manufacturing, and operation of the X-energy Reactor Plant. The QAPD describes methods and establishes Quality Assurance (QA) and administrative control requirements that meet 10 CFR 50 Appendix B, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants” and ASME NQA-1-2015, “Quality Assurance Requirements for Nuclear Facility Applications,” as endorsed by Regulatory Guide 1.28 Revision 5, “Quality Assurance Requirements (Design and Construction).” NUREG-0800 Section 17.5, “Quality Assurance Program Description – Design Certification Early Site Permit and New License Applicants” and the guidance in Nuclear Energy Institute (NEI) 11-04A Rev 0, “Nuclear Generation Quality Assurance Program Description” template were used to prepare the QAPD.

The QAPD is divided into five parts: I – Introduction; II – Quality Assurance Program Description Details; III – Non-Safety-Related SSC Quality Control; IV– Regulatory Commitments; and V – Additional Quality Assurance and Administrative Controls for the Plant Operational Phase.

CONFIGURATION CONTROL

Document Change History

Rev.	Date	Section or Page Affected	Changes
0	31-Jul-2019		Original document
1	12-Feb-2020	Title page	Revised revision number and revised issue date
		All pages	Revised revision number
		Document Approvals, page 6	Revised Reviewer
		Part II, Section 1, page 15	Revised per RAI-1, implementing measures to ensure the size of the QA organization is commensurate with its duties and responsibilities assigned
		Part II, Section 1, page 16	Added a role for the Analysis & Testing Manager
		Part II, Section 1, page 17	Added a role for the Engineering Manager
		Part II, Section 1, page 20	Revised organization structure in Figure 2 for Program Manager Reactor Development
		Part II, Section 2.4, page 22	Revised per RAI-2, replaced 10 CFR Part 50.55(f) with 10 CFR 50.4(b)(7)(ii)
		Part II, Section 2.5, page 23	Revised as per RAI-3, addressed the training and qualification requirements for inspection and test personnel
		Part II, Section 7.1, page 30	Revised as per RAI-4, clarified the type of outside organization and industry programs X-Energy will use as the basis for qualifying suppliers
		Part II, Section 16.1, page 37	Revised as per RAI-5, removed the reference to 10 CFR 50.55



Rev.	Date	Section or Page Affected	Changes
		Part II, Section 8, page 31	Revised as per RAI-6, clarified the applicability of SRP Section 17.5, Subsection II.H, and X-Energy's QAPD Section8, "Identification and Control of Materials, Parts, and Components," to the DC application
		Part II, Section 9, Pages 31-32	Revised as per RAI-7, clarified the applicability of SRP Section 17.5, Subsection II.I, and X-Energy's QAPD Section9, "Control of Special Processes," to the DC application
		Part II, Section 10, page 32	Revised as per RAI-8, clarified the applicability of SRP Section 17.5, Subsection II.J, and X-Energy's QAPD Section10, "Inspection," to the DC application
		Part II, Section 11, page 33	Revised as per RAI-9, clarified how the criteria of performing the test under suitable environmental conditions is being met in X-Energy's proposed QAPD
		Part II, Section 12, page 34	Revised as per RAI-10, clarified how specific Control of Measuring and Test Equipment items are being controlled in X-Energy's proposed QAPD
		Part II, Section 13, page 35	Revised as per RAI-11, clarified the applicability of SRP Section 17.5, Subsection II.M, and X-Energy's QAPD Section 13, "Handling, Storage, and Shipping," to the DC application
		Part II, Section 14, page 35	Revised as per RAI-12, clarified the applicability of SRP Section 17.5, Subsection II.N, and X-Energy's QAPD Section14, "Inspection, Test, and Operating Status," to the DC Application
		Part II, Section 15, page 36	Revised as per RAI-13, clarified how specific Nonconforming Materials, Parts, or Components items are being met in X-Energy's proposed QAPD
		Part IV, Section 1.1, page 44	Revised as per RAI-14, removed RG 1.8
		Part IV, Section 1.1, page 44	Revised as per RAI-14, confirm commitment to meeting the latest revision of RG 1.29 [Rev 5]
		Part IV, Section 1.1, page 45	Revised as per RAI-14, updated the Regulatory Guides to include the following: <ul style="list-style-type: none"> a. RG 1.231 [Rev. 0, January 2017] b. RG 1.164 [Rev. 0, June 2017] c. RG 1.234 [Rev. 0, April 2018]
2	08-Apr-2020	Part IV, Section 1.1, page 44	Revised as per NRC "Clarification call regarding X-Energy's commitments to the Regulatory Guides listed in Part IV of the QAPD" on Tuesday, 07-Apr-2020: Removed the wording for Regulatory Guide 1.28 "and exceptions" in the sentence "X-energy identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in the DCD."
3	04-Aug-2020	Document Approvals, page 6	Revised Reviewer



Rev.	Date	Section or Page Affected	Changes
		Part II, Section 7, Subsection 7.2, page 30	“NQA-1 Commitments and Exceptions,” states, in part, that “X-Energy considers that other 10 CFR Parts 50 and 52 licensees...” removed the word “other” as directed by the draft Safety Evaluation (ML20142A333) as the word “other” seems to imply that X-energy is a licensee.
		Part IV, Section 1, Subsection 1.1, page 44	Revised Regulatory Guide RG 1.54 [Rev 2], confirm commitment to meeting the latest revision of RG 1.54 [Rev3] as directed by the draft Safety Evaluation (ML20142A333).
4	27-Jul-2022	Title Page	Revised revision number and revised issue date
		All Pages	Revised Revision Number
		ABBREVIATIONS	Revised to reflect changes resulting from organization changes and addition of the construction and operations phases.
		Part I, Section 1, General	Revised to remove discussions addressing QAP application of a graded approach and integration with X-energy management systems.
		Part I, Section 1.1, Scope/Applicability	Revised to include applicability of expanded construction and operations phase activities.
		Part II, Section 1, Organization	Revised and renumbered position and organization descriptions consistent with expanded phase applicability.
		Part II, Section 1, Organization	Revised, Figure 1: X-energy Organization, consistent with revised position descriptions. Deleted, Figure 2: Reactor Development Organization.
		Part II, Section 2, Quality Assurance Program	Revised discussions to include expanded phase applicability. Removed reference to Regulatory Guide 1.26 for developing SSC list.
		Part II, Section 2.3, Site-Specific Safety-Related Design Basis Activities	Added discussion of Site-Specific Safety-Related Design Basis Activities resulting from expanded scope. Renumbered following Sections.
		Part II, Section 2.5, Issuance and Revision to Quality Assurance Program	Revised to reflect application of regulatory requirement resulting from expanded scope. Included applicable requirements of 10 CFR 50.54 as noted.
		Part II, Section 2.6, Personnel Training and Qualifications	Revised to reflect application of regulatory requirement resulting from additional plant and support staff scope.



Rev.	Date	Section or Page Affected	Changes
		Part II, Section 2.7, NQA-1 Commitment / Exceptions	Revised NQA-1-2015 Commitments/Exceptions to identify additional clarifications and exceptions regarding qualification of non-destructive examination personnel, and date of certification expiration.
		Part II, Section 3, Design Control	Revised to include discussions of temporary modifications due to expanded scope.
		Part II, Section 3.4, Setpoint Control	Added to establish minimum requirements for control of instrument and equipment setpoints that could affect nuclear safety.
		Part II, Section 3.5, NQA-1 Commitment	Added NQA-1-2015 Subpart 2.20 for subsurface investigation requirements.
		Part II, Section 6, Document Control	Added types of documents associated with expanded construction and operations phases to be controlled.
		Part II, Section 6.1, Review and Approval of Documents	Added additional document controls associated with operations phases.
		Part II, Section 6.2, Changes to Documents	Added discussion for temporary procedure changes during operational phase.
		Part II, Section 7.1, Acceptance of Item or Service	Expanded identification of established outside industry programs that may be applied during construction or operation phases. Add grace period for exigent conditions.
		Part II, Section 7.2, NQA-1 Commitment /Exceptions	Added 7.2.c, to address conditions to be met when purchasing commercial grade calibration or testing services from an accredited laboratory.
		Part II, Section 9, CONTROL OF SPECIAL PROCESSES	Revised to remove discussions of personnel qualification requirements and records identified in other Parts of this QAPD.
		Part II, Section 10, INSPECTION	Revised to include applicability of requirements in construction and operation phases.
		Part II, Section 10.1, Inspection Program	Revised to include applicability of requirements in construction, initial start-up test program and operation phases.
		Part II, Section 11, TEST CONTROL	Revised to include additional tests associated with new installation and operations.
		Part II, Section 12, CONTROL OF MEASURING AND TEST EQUIPMENT	Revised to include control of commercial grade calibration services.
		Part II, Section 12.1, Installed Instrumentation and Control Devices	Added Section 12.1, to address operational phase procedures for calibration and adjustment of facility installed instrumentation and control devices. Renumbered following sections.



Rev.	Date	Section or Page Affected	Changes
		Part II, Section 13, HANDLING, STORAGE, AND SHIPPING	Deleted discussion of suppliers testing and irradiation for test purposes. Added discussion of additional hoisting, rigging, and transport activities controls implemented during operational phase.
		Part II, Section 13.2, NQA-1 Commitment / Exceptions	Revised to include discussion of NQA-1-2015, Subpart 2.1, Subpart 2.2, Subpart 2.3, and Subpart 3.2-2.1, commitments and exceptions associated with the expanded construction and operations phases
		Part II, Section 14, INSPECTION, TEST, AND OPERATING STATUS	Deleted discussion of suppliers testing and irradiation for test purposes.
		Part II, Section 15, NONCONFORMING MATERIALS, PARTS, OR COMPONENTS	Deleted discussion of suppliers testing and irradiation for test purposes.
		Part II, Section 15.1, Interface with the Reporting Program	Revised to include 10 CFR 50.55 and/or 10 CFR 21 during ESP/CP/COL design and construction, and 10 CFR 21 during operations
		Part II, Section 16.1	Revised to include 10 CFR 50.55 and/or 10 CFR 21 during ESP/CP/COL design and construction, and 10 CFR 21 during operations
		Part II, Section 17.1, Record Retention	Revised to address additional records resulting from expanded construction and operations phases.
		Part II, Section 18.1, Performance of Audits	Revised to address additional audit requirements resulting from expanded construction and operations activities.
		Part II, Section 18.2, Internal Audits	Revised to address additional internal audit performance requirements resulting from expanded operations phase activities.
		Part II, Section 18.3, Exigent Conditions	Added to provide extended grace period under exigent conditions.



Rev.	Date	Section or Page Affected	Changes
		Part III, Section 2, NONSAFETY-RELATED SSCS CREDITED FOR REGULATORY EVENTS	<p>Revised criteria application to include, fire protection (10 CFR 50.48), Regulatory Position 1.7, "Quality Assurance," in Regulatory Guide 1.189, "Fire Protection for Nuclear Power Plants," Revision 34.</p> <p>Deleted reference to Generic Letter 85-06, "Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related " and Regulatory Position 3.5, "Quality Assurance and Specific Guidance for SBO Equipment That Is Not Safety Related," and Appendix A, "Quality Assurance Guidance for Non-Safety Systems and Equipment," in Regulatory Guide 1.155 Revision 0 August 1988, "Station Blackout. "</p> <p>Deleted discussion on questionable applicability of criteria listed due to Xe-100 unique features.</p>
		Part IV, Section 1, NRC REGULATORY GUIDES AND QUALITY ASSURANCE STANDARDS	Revised to include discussion of conformance of standards to license applications in accordance with 10 CFR 50 and 10 CFR 52 as applicable.
		Part IV, Section 1.1, Regulatory Guides	<p>Added:</p> <p>Regulatory Guide 1.8, Rev. 4, June 2019, Qualification and Training of Personnel for Nuclear Power Plants</p> <p>Regulatory Guide 1.33, Rev. 3, June 2013, Quality Assurance Program Requirements (Operations)</p> <p>Deleted:</p> <p>Regulatory Guide 1.26, [Revision 5, February 2017] - Quality Group Classifications and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants</p>
		Part IV, Section 1.2, Standards	Deleted: NEI 14-05 Revision 1, Guidelines for the use of accreditation in lieu of commercial grade surveys for procurement of laboratory calibration and test services NEI 14-05
		Part V, ADDITIONAL QUALITY ASSURANCE AND ADMINISTRATIVE CONTROLS FOR THE PLANT OPERATIONAL PHASE	<p>Added Part V; to establish the necessary measures and governing procedures for the operational phase of the plant including:</p> <p>SECTION 1: DEFINITIONS</p> <p>SECTION 2: REVIEW OF ACTIVITIES AFFECTING SAFE PLANT OPERATION</p> <p>SECTION 3: OPERATIONAL PHASE PROCEDURES</p> <p>SECTION 4: CONTROL OF SYSTEMS AND EQUIPMENT IN THE OPERATIONAL PHASE</p> <p>SECTION 5: PLANT MAINTENANCE</p>



Document Approval

Action	Designation	Name	Signature	Date
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Reviewer	Licensing Engineer	W Massie	DocuSigned by: <i>Wayne Massie</i> 65D1523E699F440...	August 5, 2022 12:06 PM EDT
Reviewer	VP, Quality and ES&H	D Bannister	DocuSigned by: <i>David Bannister</i> B989AA2E6609446...	August 5, 2022 12:42 PM EDT
Reviewer	President, TRISO-X	P Pappano	DocuSigned by: <i>Peter Pappano</i> 2C099EEC6E0244A...	August 5, 2022 12:46 PM EDT
Reviewer	CNO, X-energy	G Vanderheyden	DocuSigned by: <i>G Vanderheyden</i> D96D83880417401...	August 6, 2022 9:59 AM PDT
Reviewer	COO, X-energy	H Bowers	DocuSigned by: <i>Harlan Bowers</i> 6F6AFB82BE734BE...	August 8, 2022 7:29 AM PDT
Approver	CEO, X-energy	J Clay Sell	DocuSigned by: <i>J Clay Sell</i> 4B5C862AE06D4B4...	August 8, 2022 10:31 AM EDT



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ABBREVIATIONS

This list contains the abbreviations used in this document.

Abbreviation or Acronym	Definition
ASME	American Society of Mechanical Engineers
ATWS	Anticipated Transients Without Scram
CEO	Chief Executive Officer
CFR	Code of Federal Regulations
CNO	Chief Nuclear Officer
COL	Combined License
COO	Chief Operating Officer
CP	Construction Permit
DC	Design Certification
DCD	Design Control Document
EPRI	Electric Power Research Institute
ESP	Early Site Permit
FSAR	Final Safety Analysis Report
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
IRG	Independent Review Group
ISCE	Integrity, Safety, Customers, and Employees
ISO	International Organization for Standardization
ITAAC	Inspections, Tests, Analyses, and Acceptance Criteria
LWA	Limited Work Authorization
M&TE	Measuring and Test Equipment
MRA	Mutual Recognition Arrangement
NEI	Nuclear Energy Institute
NIRMA	Nuclear Information and Records Management Association, Inc.
NQA	Nuclear Quality Assurance
NRC	U.S. Nuclear Regulatory Commission
OL	Operating License
QA	Quality Assurance
QAP	Quality Assurance Program
QAPD	Quality Assurance Program Description
QC	Quality Control



Abbreviation or Acronym	Definition
RG	Regulatory Guide
RIS	Regulatory Issue Summary
SAR	Safety Analysis Report
SBO	Station Blackout
SDA	Standard Design Approval
SSC	Structures, Systems, and Components
SSE	Safe Shutdown Earthquake
X-energy	X Energy, LLC



QUALITY POLICY

X Energy, LLC (X-energy) is a nuclear technology design, engineering, and project delivery organization. We are principally focused upon developing proprietary Generation IV high-temperature gas cooled nuclear reactors for terrestrial applications; applying our knowledge and expertise in the development of space nuclear applications; and designing and manufacturing the fuel to power our proprietary designs and other reactor technologies. Our vision is to improve the global quality of life by providing transformational energy solutions that are clean, safe, secure, and affordable.

As an organization, we promote and implement a company culture for quality built upon our core values of Integrity, Safety, Customers, and Employees (ISCE). We will always act and communicate with integrity. Ensuring the safety of our employees, customers, and community of stakeholders will always be our most important requirement. All of our actions are driven by what is best for our customers and our employees. Together, these attributes help define our overall quality culture and must not be compromised in our day-to-day operations. This means company leadership, our Quality Management System (QMS), with associated policies and procedures must all work in concert to ensure that all participants in our enterprise are supported, equipped, empowered, encouraged, and held accountable to provide the highest-quality work products. Our QMS has been defined and implemented to produce solutions that comply with the letter and intent of all applicable local, state, federal, and country laws, policies, codes, and standards that are relevant to our customers and our business.

Our ISCE culture demands that the needs, requirements, and expectations of our customers and stakeholders are met and, when possible, exceeded. We accomplish this through our way of doing business: applying best practices as the foundation of our quality management program, and each employee being responsible for building quality into everything we do. At X-energy, quality assurance is not merely a program but part of who we are and what we do. Our QMS articulates and reflects the importance of senior management commitment, beyond compliance, to ensure quality and safety are fully integrated in all aspects of our enterprise. Fully embracing the QMS at X-energy ensures established quality objectives are continually reviewed and measured, and shortcomings addressed if they arise. We continually evaluate and review our QMS to ensure its effectiveness and that the program yields the intended results.

Our ISCE culture, along with our QMS, also recognizes the critical role and importance of our employees. We believe workforce training and development is the cornerstone of our company's success. Through training, continuing education, mentoring, and management oversight, X-energy ensures that every employee will be prepared to excel at the work they are assigned.

J. Clay Sell
Chief Executive Officer



PART I INTRODUCTION

1. GENERAL

The X-energy Quality Assurance Program Description (QAPD) is the top-level policy document that establishes the Quality Assurance (QA) policy and assigns major functional responsibilities for quality related activities conducted by or for X-energy. The QAPD describes the methods and establishes quality assurance and administrative control requirements that meet 10 CFR 50, Appendix B, 10 CFR 52, 10 CFR 71 (Subpart H) and the requirements and guidance of ASME NQA-1-2015, "Quality Assurance Requirements for Nuclear Facility Applications," Parts I and II, with specific reference to selected Part III sections, as identified in this document.

The QA Program (QAP) is defined by the U.S. Nuclear Regulatory Commission (NRC) approved regulatory document that describes the QA elements (i.e., the QAPD), along with the associated implementing documents. Procedures and instructions that control X-energy quality related activities will be developed prior to commencement of those activities. Policies establish high-level responsibilities and authority for carrying out important administrative functions which are outside the scope of the QAPD. Procedures establish practices for certain activities which are common to all X-energy organizations performing those activities, so that the activity is controlled and carried out in a manner that meets QAPD requirements. Procedures specific to a site, organization, or group establish detailed implementation requirements and methods, and may be used to implement policies or be unique to particular functions or work activities.

1.1. SCOPE/APPLICABILITY

The QAPD applies to the design-phase, construction-phase, and operations-phase activities, including those in support of Standard Design Approval (SDA), Design Certification (DC), Early Site Permit (ESP), Limited Work Authorization (LWA), Construction Permit (CP), Operating License (OL), and/or Combined License (COL) activities affecting the quality and performance of safety-related structures, systems, and components (SSCs), including, but not limited to:

- Designing
- Storing
- Operating
- Siting
- Constructing
- Maintaining
- Procuring
- Erecting
- Repairing
- Software
- Installing
- Modifying
- Cleaning
- Inspecting
- Refueling
- Handling
- Testing
- Training
- Shipping
- Start-up
- Decommissioning
- Receiving
- Safety-related analysis and evaluation
- Pre-operational activities (including ITAAC)

Safety-related SSCs, under the control of the QAPD, are identified by design documents. The technical aspects of these items are considered when determining program applicability, including, as appropriate, the item's design safety function. The QAPD may be applied to certain activities where regulations other than 10 CFR 50 and 10 CFR 52 establish QA requirements for activities within their scope.



X-energy's policy is to assure a high degree of availability and reliability of the nuclear plant(s) while ensuring the health and safety of the public and of its workers. To this end, selected elements of the QAPD are also applied to certain equipment and activities that are not safety-related, but support safe, economic, and reliable plant operation, or where other U.S. Nuclear Regulatory Commission (NRC) guidance establishes quality assurance requirements. Implementing documents establish program element applicability.

The X-energy QAPD may be applied to certain activities where regulations other than 10 CFR 50 and 10 CFR 52 establish Quality Assurance Program requirements for activities within their scope. Thus, selected elements of the X-energy QAPD are applied to the "safety-significant" activities of radioactive material transportation packages, as defined by 10 CFR 71 Subpart H and allowed by 10 CFR 71.101(f).

The definitions provided in ASME NQA-1-2015, Part I, Section 400, apply to select terms as used in this document.



PART II QUALITY ASSURANCE PROGRAM DESCRIPTION DETAILS

1. ORGANIZATION

This section describes the X-energy organizational structure, functional responsibilities, levels of authority, and interfaces for establishing, executing, and verifying QAPD implementation during the design, construction, and operations phases. The organizational structure includes corporate/support/off-site, and on-site functions required to support the performance of X-energy quality-related activities, including interface responsibilities for multiple organizations that perform quality-related functions. Implementing documents assign more specific responsibilities and duties, and define the organizational interfaces involved in conducting activities and duties within the scope of the QAPD. Management gives careful consideration to the timing, extent, and effects of organizational structure changes based upon project phase requirements.

During design, Quality and Environmental, Safety & Health management is responsible to size the Quality Assurance staff commensurate with the duties and responsibilities assigned. During construction and plant operations, this responsibility transitions to the Site Executive.

The responsibility for quality-related activities during design, construction, and operations phases shown below include, but are not limited to, the following:

Table 1: Responsibility for Quality-Related Activities

Design Phase	Construction Phase	Operations Phase
Technology Development	Construction	Operations
Engineering	Engineering	Engineering
Procurement and Supply Chain	Procurement and Supply Chain	Procurement and Supply Chain
QA/QC	QA/QC	QA/QC
	Construction Testing	Start-up/Pre-op Testing
		Maintenance
		Technical Services
		Site Services

Design, engineering, environmental, and construction services may be provided to the X-energy organization by subcontractors in accordance with their respective QAPDs.

The following sections describe the reporting relationships, functional responsibilities, and authorities for functional organizations implementing and supporting the X-energy QA Program. The X-energy organization is shown in **Figure 1** X-energy Organization.

The roles of Chief Executive Officer, President, and Chief Nuclear Officer are defined as ‘top management.’



1.1. CHIEF EXECUTIVE OFFICER

The Chief Executive Officer (CEO) is responsible for all aspects of design, construction, and operation of X-energy's nuclear facilities. The CEO is also responsible for all technical and administrative support activities provided by X-energy and contractors. The CEO directs the President and Chief Operating Officer, the Senior Vice President and Chief Nuclear Officer, and senior management of: Quality and Environmental, Safety & Health; Human Capital and Training; TRISO-X Fuels and Infrastructure; and on-site organizations in fulfillment of their responsibilities. The CEO reports to the X-energy Board of Directors with respect to all matters.

During all phases, QA management has access to the CEO as the most senior executive with overall responsibility for Quality Assurance. QA management shall have the freedom and authority to raise issues that cannot be resolved at lower levels to the CEO for final decision.

1.2. PRESIDENT AND CHIEF OPERATING OFFICER

The President and Chief Operating Officer (COO) reports to the CEO and is responsible for the corporate success of X-energy. The COO establishes the company's goals and strategies and presides over the execution/implementation of the work required to accomplish all aspects of business development, design, construction, and operation of X-energy's reactor, fuel plants, and services. The COO establishes and implements the X-energy QAPD and directs the planning and development of X-energy staff and organization resources.

1.3. SENIOR VICE PRESIDENT AND CHIEF NUCLEAR OFFICER

The Senior Vice President and Chief Nuclear Officer (CNO) reports to the CEO/COO and is responsible for ensuring X-energy programs, products, and processes deliver the highest technical quality and nuclear safety for the safe, reliable, and efficient operation of nuclear plants. The CNO directs Technology Development, Engineering, Procurement, and Supply Chain in fulfillment of their responsibilities during the design phase; and the Site Executive during construction and operations phases. The CNO is responsible for the administration of reactor development, nuclear licensing, and support activities for X-energy under the QAPD.

1.4. QUALITY AND ENVIRONMENTAL, SAFETY & HEALTH

Quality and Environmental, Safety & Health, reports to the CEO/COO and is responsible for nuclear safety assurance, quality, and the establishment and implementation of the X-energy QAPD.

The Quality Assurance (QA) organization reports to the CEO/COO and is responsible for planning and performing activities to verify the development and effective implementation of quality activities. Effective implementation includes, but is not limited to, developing and maintaining the QAPD, evaluating compliance to Quality Assurance Program (QAP) requirements through audits and technical reviews, providing independent oversight of the implementation of quality activities, and ensuring that vendors providing quality services, parts, and materials to X-energy are meeting the requirements of 10 CFR 50, Appendix B through X-energy vendor audits, and managing Quality Assurance organization resources.



Quality Assurance (QA) has sufficient authority, direct access to responsible levels of management, organizational freedom, and access to work to perform the quality assurance function, including sufficient independence from cost and schedule when opposed to safety function considerations. QA has sufficient independence from other X-energy design and testing priorities to bring forward issues affecting safety and quality and makes judgments regarding quality in all areas regarding X-energy design activities as appropriate. QA may make recommendations to management regarding improving the quality of work processes. If QA disagrees with any actions taken by the organization and is unable to obtain resolution, QA shall inform quality management and bring the matter to the attention of top management, who will determine the final disposition.

1.5. HUMAN CAPITAL AND TRAINING

The Human Capital and Training organization reports to the CEO/COO and is responsible for all aspects of human resources, recruiting, training and development, and personnel security.

1.6. TRISO-X FUELS

The TRISO-X Fuels organization reports to the CEO/COO and is responsible for design, development, fabrication, and licensing of X-energy fuels.

1.7. DESIGN PHASE AND CORPORATE SUPPORT

The following functions report to the CNO during the design phase and during corporate/off-site support of construction and operations.

1.7.1. TECHNOLOGY DEVELOPMENT

Technology Development reports to the CNO and is responsible for associated design analysis, including modeling of: coolant; materials qualification and testing; and engineering design and support services (including document control and records management).

1.7.2. PROCUREMENT AND SUPPLY CHAIN

Procurement and Supply Chain reports to the CNO and is responsible for supply chain management (including supplier evaluation) and procurement.

1.8. SITE EXECUTIVE

During construction and operations phases, the Site Executive reports to the CNO and is responsible for site-related construction and operation activities. Transition from design phase to construction and operations phases occurs such that those positions required to support quality-related activities will retain their applicable responsibilities until it is deemed that they are no longer necessary.



1.8.1. CONSTRUCTION PHASE MANAGEMENT

Construction Phase Management reports to the Site Executive and is responsible for construction activities, including construction, engineering, supply chain, construction testing, and Quality Assurance/Quality Control (QA/QC).

Construction Phase Management is staffed and has the appropriate authority required to perform quality-related construction activities. Interfaces between site/construction phase management and corporate support is defined in implementing procedures.

The X-energy Quality Assurance organization is responsible for independent oversight of the implementation of activities including, but not limited to, construction; engineering; procurement; and construction testing. QA is responsible for assuring compliance with regulatory requirements and procedures through audits and technical reviews; monitoring organizational processes to ensure conformance to commitments and licensing document requirements; and ensuring that vendors providing quality services, parts, and materials to X-energy are meeting the requirements of 10 CFR 50, Appendix B through X-energy supplier evaluations, surveillances, and audits.

QA has sufficient independence from other X-energy construction priorities to bring forward issues affecting safety and quality and makes judgments regarding quality in areas regarding X-energy construction activities. QA may make recommendations to management regarding improving the quality of work processes. If QA disagrees with any actions taken by the organization and is unable to obtain resolution, QA shall inform Construction Phase Management and bring the matter to the attention of top management, who will determine the final disposition.

1.8.2. OPERATIONS PHASE MANAGEMENT

Operations Phase Management reports to the Site Executive and is responsible for plant operation activities, including operations, maintenance, site services, technical services, engineering, supply chain, start-up/pre-op testing, and QA/QC.

Operations Phase Management is staffed and has the appropriate authority required to perform quality-related operations activities. It is anticipated that even after fuel load, construction activities will be ongoing. Those positions required to support these activities will retain their applicable construction/pre-operation responsibilities until it is deemed that they are no longer necessary. As the construction of systems (or portions thereof) is completed, control and authority (including oversight, configuration, and operations) are transferred from Construction Phase Management to the cognizant departments in the operational phase. During the transition, responsibilities will be clearly defined in instructions and procedures to ensure appropriate authority is maintained for each SSC.

No later than six months prior to fuel load of the unit, those positions which are identified for Operations will be staffed and have the appropriate authority required to perform operations activities.

The Quality Assurance organization is responsible for independent oversight of the implementation of activities including, but not limited to, operations; maintenance; site services; engineering; start-up/pre-op testing; and procurement.

QA is responsible for assuring compliance with regulatory requirements and procedures through audits and technical reviews; monitoring organizational processes to ensure conformance to commitments and licensing document requirements; and ensuring that vendors providing quality services, parts, and



materials to X-energy are meeting the requirements of 10 CFR 50, Appendix B through supplier evaluations, surveillance, and audits.

QA has sufficient independence from other X-energy operation priorities to bring forward issues affecting safety and quality and makes judgments regarding quality in all areas regarding X-energy operations activities. QA may make recommendations to management regarding improving the quality of work processes. If QA disagrees with any actions taken by the organization and is unable to obtain resolution, QA shall inform Operations Phase Management and bring the matter to the attention of top management, who will determine the final disposition.

1.9. AUTHORITY TO STOP WORK

Quality Assurance and Quality Control Inspection personnel have the authority and responsibility to stop work in progress which is not being done in accordance with approved procedures or where safety or SSC integrity may be jeopardized. This authority extends to off-site work performed by suppliers that furnish safety-related materials and services to X-energy.

1.10. QUALITY ASSURANCE ORGANIZATIONAL INDEPENDENCE

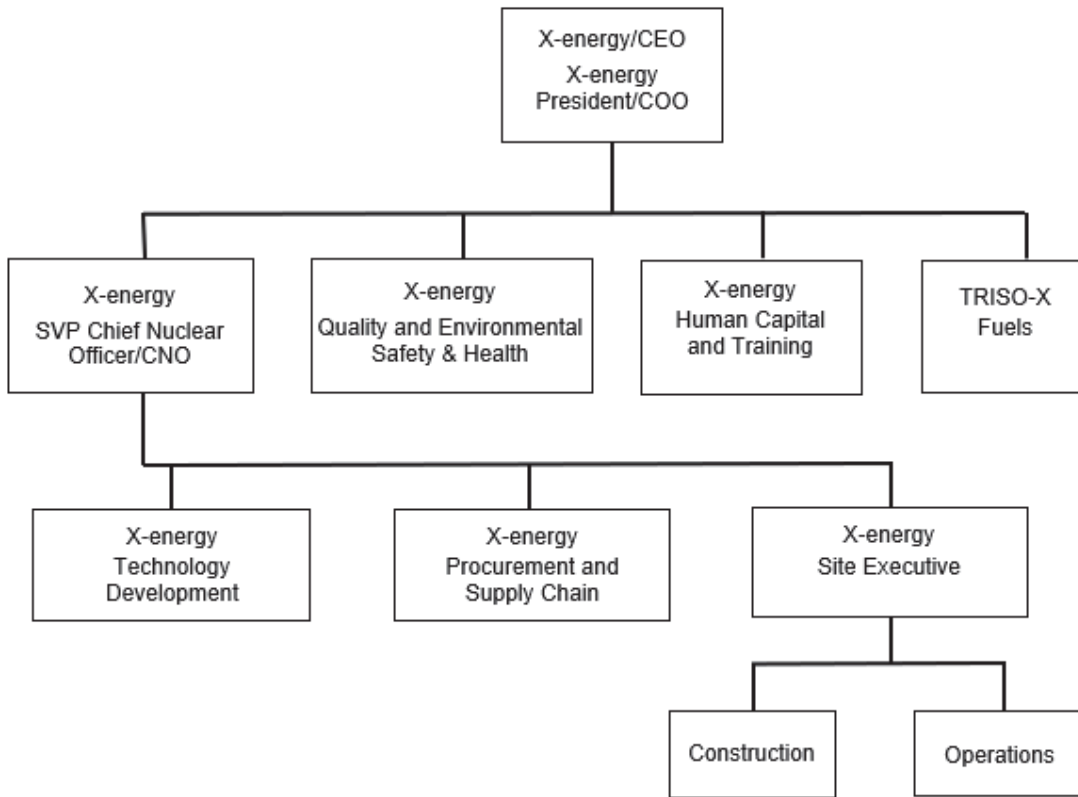
Independence shall be maintained between the organization(s) performing the checking (quality assurance and control) functions and the organizations performing the functions. This provision is not applicable to design review/verification.

1.11. NQA-1 COMMITMENT

In establishing its organizational structure, X-energy commits to compliance with NQA-1-2015, Requirement 1.



Figure 1: X-energy Organization





2. QUALITY ASSURANCE PROGRAM

X-energy has established the necessary measures and governing procedures to implement the Quality Assurance Program (QAP) as described in this QAPD for design phase activities and will establish necessary measures and governing procedures for construction and operations phase activities prior to commencement of those activities. X-energy is committed to implementing the QAP in all aspects of work that apply to the safety of the nuclear facilities as described, and to the extent delineated in this QAPD. The QAP shall include monitoring activities against acceptance criteria in a manner sufficient to provide assurance that the activities important to safety are performed satisfactorily. Further, X-energy ensures through the systematic process described herein that its suppliers of safety-related equipment or services meet the applicable requirements of 10 CFR 50, Appendix B. Senior management is regularly apprised of the adequacy of implementation of the QAP through the audit functions described in Part II, Section 18.

The objective of the QAP is to ensure that X-energy's nuclear facilities are designed, constructed, and operated in accordance with governing regulations and license requirements. The program is based on the requirements of ASME NQA-1-2015, "Quality Assurance Requirements for Nuclear Facility Applications," as further described in this document. The QAP applies to those quality-related activities that involve the functions of safety-related SSCs associated with the design, fabrication, construction, and testing of the SSCs of the facility, and to the managerial and administrative controls used to ensure safe operation. Examples of Early Site Permit (ESP), Construction Permit/Operating License (CP/OL), or Combined License (COL) program safety-related activities include, but are not limited to, site-specific engineering related to safety-related SSCs, site geotechnical investigations, site engineering analysis, seismic analysis, and meteorological analysis. A list or system that identifies SSCs and activities to which this program applies is maintained at the appropriate facility. Design documents are used as guidance for this list or system. Cost and scheduling challenges must be addressed; however, they do not prevent proper implementation of the QAP.

As described in Part III of this QAPD, specific program controls are applied to non-safety-related SSCs that are significant contributors to plant safety, for which 10 CFR 50, Appendix B, is not applicable. The specific program controls consistent with applicable sections of the QAPD are applied to those items in a select manner, targeted at those characteristics or critical attributes that qualify the SSC as a significant contributor to plant safety.

Delegated responsibilities may be performed under a supplier's or principal contractor's QAP, provided that the supplier or principal contractor has been approved as a supplier in accordance with the X-energy QAP. Periodic audits and assessments of supplier QA programs are performed to ensure compliance with the supplier's or principal contractor's QAPD and implementing procedures. In addition, routine interfaces with the supplier's personnel provide added assurance that quality expectations are met.

For the ESP, CP/OL, and/or COL applications, the QAPD applies to those activities that can affect either directly or indirectly the safety-related site characteristics or analysis of those characteristics. In addition, the QAPD applies to engineering activities that are used to characterize the site or analyze that characterization.

Nuclear plant construction will be the responsibility of the X-energy's construction organization. Detailed engineering specifications and construction procedures will be developed to implement the QAPD prior to commencement of preconstruction (ESP) and/or construction (CP/COL) activities.

Examples of Limited Work Authorization (LWA) activities that could impact safety-related SSCs include impacts of construction to existing facilities and, for construction of a new plant, the interface between non-safety-related and safety-related SSCs and the placement of seismically designed backfill.



In general, the program requirements specified herein are detailed in implementing procedures that are either X-energy implementing procedures or supplier implementing procedures governed by a supplier quality assurance program.

A grace period of 90 days may be applied to provisions that are required to be performed on a periodic basis, unless otherwise noted. When the grace period is used, the next scheduled date for the activity is based on the activity schedule date and not on the date that the activity was performed. If the activity is performed early, the next schedule date is based on the date the activity was actually performed. Annual evaluations and audits that must be performed on a triennial basis are examples where the 90-day general 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. Audit schedules are based on the month in which the audit starts.

X-energy maintains and updates the QAP as necessary to support ongoing X-energy activities. Prior to manufacturing and construction, the QAP will be revised as necessary to identify the QA controls applicable for manufacturing and construction activities.

2.1. RESPONSIBILITIES

Personnel who work directly or indirectly for X-energy are responsible for achieving acceptable quality in the work covered by the QAPD. This includes the activities delineated in Part I, Section 1.1. X-energy personnel performing verification activities are responsible for verifying the achievement of acceptable quality requirements. Activities governed by the QAPD are performed as directed by documented instructions, procedures, and drawings that are of a detail appropriate for the activity's complexity and effect on safety. Instructions, procedures, and drawings specify quantitative or qualitative acceptance criteria as applicable or appropriate for the activity, and verification is against these criteria. Provisions are established to designate or identify the proper documents to be used in an activity and to ascertain that such documents are being used. Quality Assurance is responsible to verify that processes and procedures comply with the QAPD and other applicable requirements, that such processes or procedures are implemented, and that management appropriately ensures compliance.

2.2. DELEGATION OF WORK

X-energy retains and exercises the responsibility for the scope and implementation of an effective QAP. Positions identified in Part II, Section 1 may delegate all or part of the activities of planning, establishing, and implementing the program for which they are responsible to others, but retain the responsibility for the program's effectiveness. Decisions affecting safety are made at the level appropriate based upon their nature and effect, with any necessary technical advice or review as appropriate.

2.3. SITE-SPECIFIC SAFETY-RELATED DESIGN BASIS ACTIVITIES

Site-specific safety-related design basis activities are defined as those activities, including sampling, testing, data collection, and supporting engineering calculations and reports, that will be used to determine the bounding physical parameters of the site. Appropriate quality assurance measures are applied.



2.4. PERIODIC REVIEW OF THE QUALITY ASSURANCE PROGRAM

Management of those organizations implementing the QA program, or portions thereof, shall assess the adequacy of that part of the program for which they are responsible, to assure its effective implementation at least once each year or at least once during the life of the activity, whichever is shorter.

However, the period for assessing QA programs during the plant operational phase may be extended to once every two years.

2.5. ISSUANCE AND REVISION TO QUALITY ASSURANCE PROGRAM

Administrative control of the QAPD will be in accordance with 10 CFR 50.4(b)(7)(ii). Proposed changes to the QAPD are evaluated by Quality Assurance to ensure that such changes do not degrade safety for previously approved quality assurance controls specified in the QAPD. New revisions to the document will be reviewed, at a minimum, by Quality Assurance and approved by the CEO.

Regulations require that the Final Safety Analysis Report (FSAR) include, among other things, the managerial and administrative controls to be used to ensure safe plant operation, including a discussion of how the applicable requirements of 10 CFR 50, Appendix B will be satisfied. In order to comply with this requirement, the FSAR references the QAPD and, as a result, the requirements of 10 CFR 50.54(a) are satisfied by and apply to the QAPD.

2.6. PERSONNEL TRAINING AND QUALIFICATIONS

Personnel assigned to implement elements of the QAPD shall be capable of performing their assigned tasks. To this end, X-energy establishes and maintains formal indoctrination, training, and qualification as necessary for personnel performing, verifying, or managing activities within the scope of the QAPD to achieve initial proficiency, maintain proficiency, and adapt to technology changes, method, or job responsibilities. The indoctrination, training, and qualification programs are commensurate with scope, complexity, and importance of the activities, and include or address the following:

- Education, skills, experience, and proficiency of the personnel receiving training,
- General criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements,
- On-the-job training if direct hands-on applications or experience is needed to achieve and maintain proficiency, and
- Ensure compliance of the training and qualification requirements for inspection and test personnel.

Plant and support staff minimum qualification requirements are as delineated in the unit Technical Specifications. Other qualification requirements may be established but will not reduce those required by Technical Specifications.

Sufficient managerial depth is provided to cover absences of incumbents. When required by code, regulation, or standard, specific qualification and selection of personnel is conducted in accordance with those requirements as established in the applicable X-energy procedures. Indoctrination includes the administrative and technical objectives, requirements of the applicable codes and standards, and the QAPD elements to be employed. Training for positions identified in 10 CFR 50.120 is accomplished according to programs developed to be in compliance with the facility license, including all technical specifications and applicable regulations.

Records of personnel training and qualification are maintained.



The minimum qualifications of the Quality Assurance management are an engineering or related science degree and a minimum of four years of related experience including two years of nuclear power plant experience; one year of supervisory or management experience; and one year of the experience is in performing quality verification activities. Special requirements shall include management and supervisory skills and experience or training in leadership, interpersonal communication, management responsibilities, motivation of personnel, problem analysis and decision making, and administrative policies and procedures. Individuals who do not possess these formal education and minimum experience requirements should not be eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a case-by-case basis and approved and documented by senior management.

The minimum qualifications for the individuals responsible for supervising QA or Quality Control (QC) personnel is that each has a high school diploma or equivalent and has a minimum of one year of experience performing quality verification activities. Individuals who do not possess these formal education and experience requirements should not be eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a case-by-case basis and approved and documented by senior management.

The minimum qualifications of individuals that are part of the Quality Assurance organization responsible for planning, implementing, and maintaining the programs for the QAPD are that each has a high school diploma or equivalent and has a minimum of one year of related experience. Individuals who do not possess these formal education and minimum experience requirements should not be eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a case-by-case basis and approved and documented by senior management.

2.7. NQA-1 COMMITMENT / EXCEPTIONS

In establishing qualification and training programs, X-energy commits to compliance with NQA-1-2015, Requirement 2 with the following clarifications and exceptions, and regulatory positions stated in Regulatory Guide 1.28, Rev 5.

- For Section 302, Inspection and Test, X-energy commits to the use of Subpart 3.1-2.3 guidance.
- X-energy follows Section 301 for qualification of non-destructive examination personnel, except that X-energy will follow the applicable standard cited in the version(s) of Section III and Section XI of the ASME Boiler and Pressure Vessel Code approved by the NRC for use at X-energy sites for the scope of activities governed by these cited standards.
- Sections 401 (e) and (g) require the date of certification expiration be included on the qualification record. X-energy considers the certification expiration date to be the date from the certification or recertification date plus the certification interval time, and its inclusion on the qualification record is optional.



3. DESIGN CONTROL

X-energy has established and implements a process to control the design, design changes, and temporary modifications (e.g., temporary bypass lines, electrical jumpers and lifted wires, and temporary setpoints) of items that are subject to the provisions of the QAPD. The design process includes provisions to control design inputs, outputs, changes, interfaces, records, and organizational interfaces within X-energy and with suppliers. These provisions assure that design inputs (such as design bases and the performance, regulatory, quality, and quality verification requirements) are correctly translated into design outputs (such as analyses, specifications, drawings, procedures, and instructions) so that the final design output contains or references appropriate acceptance criteria that can be related to the design input in sufficient detail to permit verification by inspection and test, as required. Design change processes and the division of responsibilities for design-related activities are detailed in X-energy and supplier procedures. Changes to design inputs, final designs, field changes, and temporary and permanent modifications to operating facilities are justified and subject to design control measures commensurate with those applied to the original design. The design control program includes interface controls necessary to control the development, verification, approval, release, status, distribution, and revision of design inputs and outputs. Design changes and disposition of nonconforming items as "use as is" or "repair" are reviewed and approved by the X-energy design organization or by other organizations so authorized by X-energy.

Design documents are reviewed by individuals knowledgeable in QA to ensure the documents contain the necessary QA requirements.

3.1. DESIGN VERIFICATION

X-energy design processes provide for design verification to ensure that items, computer programs, and activities subject to the provisions of the QAPD are suitable for their intended application, consistent with their effect on safety. Design changes are subjected to these controls, which include verification measures commensurate with those applied to original plant design.

Design verifications are performed by competent individuals or groups other than those who performed the original design but who may be from the same organization. The verifier shall not have taken part in the selection of design inputs, the selection of design considerations, or the selection of a singular design approach. This verification may be performed by the originator's supervisor provided the supervisor did not specify a singular design approach, rule out certain design considerations, and did not establish the design inputs used in the design, or if the supervisor is the only individual in the organization competent to perform the verification. If the verification is performed by the originator's supervisor, the justification of the need is documented and approved in advance by management.

The extent of the design verification required is a function of the importance to safety of the item or computer program under consideration, the complexity of the design, the degree of standardization, the state-of-the-art, and the similarity with previously proven designs. This includes design inputs, design outputs, and design changes. Design verification procedures are established and implemented to ensure that an appropriate verification method is used, the appropriate design parameters to be verified are chosen, the acceptance criteria are identified, and the verification is satisfactorily accomplished and documented. Verification methods may include, but are not limited to, design reviews, alternative calculations, and qualification testing. Testing used to verify the acceptability of a specific design feature demonstrates acceptable performance under conditions that simulate the most adverse design conditions expected for the item's intended use.



X-energy normally completes design verification activities before the design outputs are used by other organizations for design work, and before they are used to support other activities such as procurement, manufacture, or construction. When such timing cannot be achieved, the design verification is completed before relying on the item to perform its intended design or safety function.

3.2. DESIGN RECORDS

X-energy maintains records sufficient to provide evidence that the design was properly accomplished. These records include the final design output and any revisions thereto, as well as record of the important design steps (e.g., calculations, analyses, and computer programs) and the sources of input that support the final output.

Plant design drawings reflect the properly reviewed and approved configuration of the plant.

3.3. COMPUTER APPLICATION AND DIGITAL EQUIPMENT SOFTWARE

The QAPD governs the development, procurement, testing, maintenance, control, and use of computer applications and digital equipment software when used in safety-related applications and designated non-safety-related applications. Each computer program used for design analysis is accepted for use and controlled by applying the applicable requirements of Parts I and II prior to use, or the computer program's results are independently verified with the design analysis for each application. Pre-verified computer programs are controlled using a software configuration management process. X-energy and suppliers are responsible for developing, approving, and issuing procedures, as necessary, to control the use of such computer application and digital equipment software. The procedures require that the application software be assigned a proper quality classification and that the associated quality requirements be consistent with this classification. Each application software and revision thereto are documented and approved by authorized personnel. The QAPD is also applicable to the administrative functions associated with the maintenance and security of computer hardware, where such functions are considered essential in order to comply with other QAPD requirements such as QA records.

3.4. SETPOINT CONTROL

Instrument and equipment setpoints that could affect nuclear safety shall be controlled in accordance with written instructions. As a minimum, these written instructions shall:

- Identify responsibilities and processes for reviewing, approving, and revising setpoints and setpoint changes.
- Ensure that setpoints and setpoint changes are consistent with design and accident analysis requirements and assumptions.
- Provide for documentation of setpoints, including those determined operationally.
- Provide for access to necessary setpoint information for personnel who write or revise plant procedures, operate or maintain plant equipment, develop or revise design documents, or develop or revise accident analyses.



3.5. NQA-1 COMMITMENT

In establishing its program for design control and verification, X-energy commits to compliance with NQA-1-2015, Requirement 3, and Subpart 2.7 for computer software and Subpart 2.14 for Quality Assurance requirements for commercial grade items and services, and Subpart 2.20 for subsurface investigation requirements.



4. SECTION 4 PROCUREMENT DOCUMENT CONTROL

X-energy has established the necessary measures and governing procedures to assure that purchased items, computer programs, and services are subject to appropriate quality and technical requirements. Procurement document changes shall be subject to the same degree of control as utilized in the preparation of the original documents. These controls include provisions such that:

- Where original technical or quality assurance requirements cannot be determined, an engineering evaluation is conducted and documented by qualified staff to establish appropriate requirements and controls to ensure that interfaces, interchangeability, safety, fit, and function, are not adversely affected or contrary to applicable regulatory requirements.
- Applicable technical, regulatory, administrative, quality, and reporting requirements (such as specifications, codes, standards, tests, inspections, special processes, and 10 CFR 21) are invoked for procurement of items and services. 10 CFR 21 requirements for posting, evaluating, and reporting will be followed and imposed on suppliers when applicable. Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in documents for procurement of items and services. To the extent necessary, procurement documents shall require suppliers to have a documented QA program that is determined to meet the applicable requirements of 10 CFR 50, Appendix B, as appropriate to the circumstances of procurements (or the supplier may work under the X-energy approved QA program).

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

4.1. NQA-1 COMMITMENT / EXCEPTIONS

In establishing controls for procurement, X-energy commits to compliance with NQA-1-2015, Requirement 4, with the following clarifications and exceptions:

- With regard to service performed by a supplier, X-energy procurement documents may allow the supplier to work under the X-energy QAP, including implementing procedures, in lieu of the supplier having its own QAP.
- Sections 300 and 400 of Requirement 4 require the review of technical and Quality Assurance Program requirements of procurement documents prior to award of a contract and for procurement document changes. X-energy may satisfy this requirement through the review of the procurement specification when the specification contains the technical and quality assurance requirements of the procurement.

Procurement documents for Commercial Grade Items that will be procured by X-energy for use as safety-related items shall contain technical and quality requirements such that the procured item can be appropriately dedicated in accordance with the X-energy QAPD, Part II Section 7, "Control of Purchased Material, Equipment and Services."



5. INSTRUCTIONS, PROCEDURES, AND DRAWINGS

X-energy has established the necessary measures and governing procedures to ensure that activities affecting quality are prescribed by and performed in accordance with instructions, procedures, or drawings, of a type appropriate to the circumstances and which, where applicable, include quantitative or qualitative acceptance criteria to implement the QAP as described in the QAPD. Such documents are prepared and controlled according to Part II, Section 6. In addition, means are provided to disseminate to the staff instructions of both general and continuing applicability, as well as those of short-term applicability. Provisions are included for reviewing, updating, and canceling such procedures.

5.1. PROCEDURE ADHERENCE

X-energy policy is that procedures are followed, and the requirements for use of procedures have been established in administrative procedures. Where procedures cannot be followed as written, provisions are established for making changes in accordance with Part II, Section 6 of the QAPD. Requirements are established to identify the manner in which procedures are to be implemented, including identification of those tasks that require:

- The written procedure to be present and followed step-by-step while the task is being performed,
- The user to have committed the procedure steps to memory, and/or
- Verification of completion of significant steps, by initials or signatures or use of check-off lists.

Procedures that are required to be present and referred to directly are those developed for extensive or complex jobs where reliance on memory cannot be trusted, tasks that are infrequently performed, and tasks where steps must be performed in a specified sequence.

In cases of emergency, personnel are authorized to depart from approved procedures when necessary to prevent injury to personnel or damage to the plant. Such departures are recorded describing the prevailing conditions and reasons for the action taken.

5.2. PROCEDURE CONTENT

The established measures address the applicable content of procedures as described in the Introduction to Part II of NQA-1-2015. In addition, procedures governing tests, inspections, operational activities, and maintenance will include initial conditions and prerequisites for the performance of the activity.

5.3. NQA-1 COMMITMENT

In establishing procedural controls, X-energy commits to compliance with NQA-1-2015, Requirement 5.



6. DOCUMENT CONTROL

X-energy has established the necessary measures and governing procedures to control the preparation, issuance, and revision of documents that specify quality requirements or prescribe how activities affecting quality, including organizational interfaces, to ensure that correct documents are employed. The following controls, including electronic systems used to make documents available, are applied to documents and changes thereto:

- Identification of controlled documents,
- Specified distribution of controlled documents for use at the appropriate location,
- A method to identify the correct document (including revision) to be used and control of superseded documents,
- Identification of individuals responsible for controlled document preparation, review, approval, and distribution,
- Review of controlled documents for adequacy, completeness, and approval prior to distribution,
- A method to ensure the correct documents are being used,
- A method to provide feedback from users to improve procedures and work instructions, and
- Coordinating and controlling interface documents and procedures.

The types of documents to be controlled include:

- Drawings, such as design, fabrication, construction, installation, and as-built drawings,
- Engineering calculations,
- Design specifications,
- Purchase orders and related documents,
- Supplier-supplied documents,
- Audit, surveillance, and quality verification/inspection procedures,
- Inspection and test reports,
- Instructions and procedures for activities covered by the QAPD including design, construction, installation, operating (including normal and emergency operations), maintenance, calibration, and routine testing,
- Technical specifications, and
- Nonconformance reports and corrective action reports.

During the operational phase, where temporary procedures are used, they shall include a designation of the period of time during which it is acceptable to use them.

6.1. REVIEW AND APPROVAL OF DOCUMENTS

Documents are reviewed for adequacy by qualified persons other than the preparer. During the design, ESP, or construction phase, procedures for design, construction, and installation are also reviewed by the organization responsible for quality to ensure quality assurance measures have been appropriately applied. The documented review signifies concurrence.

During the operational phase, documents affecting the configuration or operation of the station as described in the FSAR are screened to identify those that require review by an Independent Review Group, prior to implementation as described in Part V, Section 2.2.



To ensure effective and accurate procedures during the operational phase, applicable procedures are reviewed and updated as necessary based on the following conditions:

- Following any modification to an affected system,
- Following an unusual incident, such as an accident, significant operator error, or equipment malfunction,
- When procedure discrepancies are found,
- Prior to use, if not used in the previous two years, and
- Results of QA audits conducted in accordance with Part II, Section 18.1.

Prior to issuance or use, documents (including revisions thereto) are approved by the designated authority. A listing of all controlled documents identifying the current approved revision, or date, is maintained so personnel can readily determine the appropriate document for use.

6.2. CHANGES TO DOCUMENTS

Changes to documents, other than those defined in implementing procedures as minor changes, are reviewed and approved by the same organizations that performed the original review and approval, unless other organizations are specifically designated. The reviewing organization has access to pertinent background data or information upon which to base their approval.

Where temporary procedure changes are necessary during the operational phase, changes that clearly do not change the intent of the approved procedure may be implemented provided they are approved by two members of the staff knowledgeable in the areas affected by the procedures.

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

6.3. NQA-1 COMMITMENT

In establishing provisions for document control, X-energy commits to compliance with NQA-1-2015, Requirement 6.



7. CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

X-energy has established the necessary measures and governing procedures to control purchased items and services to ensure conformance with specified requirements. Such control provides for the following: supplier evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, source verification and inspection, audit, and examination of items or services.

7.1. ACCEPTANCE OF ITEM OR SERVICE

X-energy establishes and implements measures to assess the quality of purchased items and services, whether purchased directly or through contractors, at intervals and to a depth consistent with the item or service importance to safety, complexity, quantity, and the frequency of procurement. Verification actions include inspection and testing during design, fabrication construction, and operation activities. Verifications occur at the appropriate phases of the procurement process, including verification of activities of suppliers below the first tier.

Measures to assure the quality of purchased items and services include the following:

- Items are inspected, identified, and stored to protect against damage, deterioration, or misuse.
- Prospective safety-related items and service suppliers are evaluated to assure only qualified suppliers are used per X-energy requirements. Qualified suppliers are audited on a triennial basis. In addition, if a subsequent contract or a contract modification significantly changes the scope, methods, or controls performed by a supplier, an audit of the changes is performed, thus starting a new triennial period.
- X-energy may utilize audits conducted by outside organizations for supplier qualification provided that the scope and adequacy of the audits meet X-energy requirements. Industry programs applied as input or the basis for supplier qualification may include ASME NQA-1 and ISO/IEC 17025. By way of example, irradiation testing will be performed by X-energy suppliers. Irrespective of what QA program a supplier is using, X-energy will review and supplement a supplier's programs where required to make them compliant with 10CFR 50 Appendix B, in addition to ASME NQA-1 requirements. Furthermore, 10 CFR 21 requirements will be included as well. Documented annual evaluations are performed for qualified suppliers to ensure they continue to provide acceptable products and services. Industry programs, such as those applied by ASME during construction or operation phases, or other established utility groups, are used as input or the basis for supplier qualification whenever appropriate. The results of the reviews are promptly considered for effect on a supplier's continued qualification and adjustments made as necessary (including corrective actions, adjustments of supplier audit plans, and input to third-party auditing entities). In addition, results are reviewed periodically to determine if, as a whole, they constitute a significant condition adverse to quality requiring additional action.
- Controls (subjected to quality and technical requirements, such as the X-energy QA program requirements) are imposed for the selection, determination of suitability for intended use (critical characteristics), evaluation, receipt, and acceptance of commercial-grade services or items to ensure they will perform satisfactorily in service in safety-related applications.
- If there is insufficient evidence of implementation of a QA program, the initial evaluation is of the existence of a QA program addressing the scope of services to be provided. The initial audit is performed after the supplier has completed sufficient work to demonstrate that its organization is implementing a QA program.



- Provisions are made for accepting purchased items and services, such as source verification, receipt inspection, pre- and post-installation tests, certificates of conformance, and document reviews (including Certified Material Test Report/Certificate). Acceptance actions/documents should be established by the Purchaser with appropriate input from the Supplier and be completed to ensure that procurement, inspection, and test requirements, have been satisfied before relying on the item to perform its intended safety function.
- Fully remote source verification may be conducted during exigent conditions due to restricted access or travel to the supplier providing the source verification is conducted in accordance with EPRI TR 3002019436-A and a screening process is used to determine if a remote source verification can be applied effectively to adequately observe the performance of the applicable activities.

7.2. NQA-1 COMMITMENT/EXCEPTIONS

In establishing controls for purchased items and services, X-energy commits to compliance with NQA-1-2015, Requirement 7, and regulatory positions stated in Regulatory Guide 1.28, Rev 5 with the following clarifications and exceptions:

- a. X-energy considers that 10 CFR Parts 50 and 52 licensees, Authorized Nuclear Inspection Agencies, National Institute of Standards and Technology, or other State and Federal agencies which may provide items or services to the X-energy plant(s) are not required to be evaluated or audited.
- b. X-energy will implement the NRC endorsed guidance from NEI 14-05A, Rev. 1-A, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys in Procurement of Laboratory Calibration and Test Services."
- c. For Section 501, X-energy considers documents that may be stored in approved electronic media under X-energy or supplier control, not physically located on the plant site, but accessible from the respective nuclear facility site as meeting the NQA-1 requirement for documents to be available at the site. Following completion of the construction period, sufficient as-built documentation will be turned over to X-energy to support operations. The X-energy records management system will provide for timely retrieval of necessary records.
- d. In establishing commercial-grade item requirements, X-energy commits to compliance with NQA-1-2015, Section 700, Subpart 2.14, with the following clarification:
 - For commercial-grade items, quality verification requirements are established and described in X-energy documents to provide the necessary assurance an item will perform satisfactorily in service. The X-energy documents address determining the critical characteristics that ensure an item is suitable for its intended use, technical evaluation of the item, receipt requirements, and quality evaluation of the item.
 - X-energy will assume 10 CFR 21 reporting responsibility for items that X-energy dedicates as safety-related.
- e. 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 (MRA), procurement source evaluation and selection measures need not be performed, provided each of the following conditions are met:
 - The purchase documents impose any additional technical and administrative requirements to comply with the X-energy QA program and technical provisions. The purchase documents require:



- ◆ The laboratory must provide the service in accordance with their accredited ISO/IEC-17025 program and scope of accreditation.
 - ◆ Reporting as-found calibration data when calibrated items are found to be out-of-tolerance (for calibration services only).
 - ◆ Identifying in the certificate of calibration, the equipment/standards used to perform the calibration (for calibration services only).
 - ◆ The testing or calibration service supplier shall not subcontract the service to any other supplier.
 - ◆ Notifying the customer of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation.
 - ◆ Additional technical and quality requirements based upon a review of the procured scope of services, which may include, but are not necessarily limited to, tolerances, accuracies, ranges, and industry standards.
- A documented review of the supplier's accreditation will be performed and will include a verification of the following:
 - ◆ The calibration or test laboratory holds accreditation by an accrediting body recognized by the ILAC MRA. The accreditation encompasses ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories."
 - ◆ For procurement of calibration services, the published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.

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



8. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

X-energy has established the necessary measures and governing procedures to identify and control items to prevent the use of incorrect or defective items. This includes controls for consumable materials and items with limited shelf life. The identification of items is maintained throughout fabrication, erection, installation, and use so that the item can be traced to its documentation, consistent with the item's effect on safety. Identification locations and methods are selected so as not to affect the function or quality of the item.

8.1. NQA-1 COMMITMENT

In establishing provisions for identification and control of items, X-energy commits to compliance with NQA-1-2015, Requirement 8.



9. CONTROL OF SPECIAL PROCESSES

X-energy has established the necessary measures and governing procedures to ensure that special processes that require interim process controls to assure quality, such as welding, heat treating, and non-destructive examination, are controlled. These provisions include ensuring that special processes are accomplished by qualified personnel using qualified procedures and equipment. Personnel are qualified and special processes are performed in accordance with applicable codes, standards, specifications, criteria or other specially established requirements. Special processes are those where the results are highly dependent on the control of the process or the skill of the operator, or both, and for which the specified quality cannot be fully and readily determined by inspection or test of the final product.

9.1. NQA-1 COMMITMENT

In establishing measures for the control of special processes, X-energy commits to compliance with NQA- 1-2015, Requirement 9.



10. INSPECTION

X-energy has established the necessary measures and governing procedures to implement inspections that ensure items, services, and activities affecting safety meet established requirements and conform to applicable documented specifications, instructions, procedures, and design documents. X-energy will be performing inspection on destructive and non-destructive testing for test purposes (includes fuel and graphite irradiation testing that will be performed by X-energy suppliers). Inspection may also be applied to items, services, and activities affecting plant reliability and integrity. Types of inspections may include those verifications related to procurement, such as source, in-process, final, and receipt inspection, as well as construction, installation, maintenance, modification, in-service, and operations activities. Inspections are carried out by properly qualified persons independent of those who performed or directly supervised the work. Inspection results are documented.

10.1. INSPECTION PROGRAM

The inspection program establishes inspections (including surveillance of processes), as necessary to verify quality:

- At the source of supplied items or services,
- In-process during fabrication at a supplier's facility or at a X-energy facility,
- For final acceptance of fabricated and/or installed items during construction,
- Upon receipt of items for a facility, and
- During maintenance, modification, in-service, and operating activities.

The inspection program establishes requirements for planning inspections, such as the group or discipline responsible for performing the inspection, where inspection hold points are to be applied, determining applicable acceptance criteria, the frequency of inspection to be applied, and identification of special tools needed to perform the inspection. Inspection planning is performed by personnel qualified in the discipline related to the inspection and includes qualified inspectors or engineers. Inspection plans are based on, at a minimum, the importance of the item to the safety of the facility, the complexity of the item, technical requirements to be met, and design specifications. Where significant changes in inspection activities for the facilities are to occur, management responsible for the inspection programs evaluate the resource and planning requirements to ensure effective implementation of the inspection program.

Inspection program documents establish requirements for performing the planned inspections, and documenting required inspection information such as rejection, acceptance, and re-inspection results, and the person(s) performing the inspection.

Inspection results are documented by the inspector, reviewed by authorized personnel qualified to evaluate the technical adequacy of the inspection results, and controlled by instructions, procedures, and drawings.

10.2. INSPECTOR QUALIFICATION

X-energy has established a qualification program for personnel performing quality inspections. The qualification program requirements are described in Part II, Section 2. These qualification programs are applied to individuals performing quality inspections regardless of the functional group where they are assigned.



10.3. NQA-1 COMMITMENT/EXCEPTIONS

In establishing inspection requirements, X-energy commits to comply with NQA-1-2015, Requirement 10 and Subparts 2.5, and 2.8 for establishing appropriate inspection requirements.



11. TEST CONTROL

X-energy has established the necessary measures and governing procedures to demonstrate that items subject to the provisions of the QAPD will perform satisfactorily in service, that the plant can be operated safely and as designed, and that the coordinated operation of the plant as a whole is satisfactory. These programs include criteria for determining when testing is required, such as proof tests before installation, pre-operational tests, post-maintenance tests, post-modification tests, in-service tests, and operational tests (such as surveillance tests required by plant Technical Specifications) to demonstrate that performance of plant systems is in accordance with design. Programs also include provisions to establish and adjust test schedules, and to maintain status for periodic or recurring tests. Tests are performed according to applicable procedures that include the following, consistent with the effect on safety:

- Instructions and prerequisites to perform the tests,
- Use of proper test equipment,
- Acceptance criteria,
- Mandatory verification points as necessary to confirm satisfactory test completion, and
- Suitable environmental conditions.

Test results are documented and evaluated by the organization performing the test and reviewed by a responsible authority to assure that the test requirements have been satisfied. If acceptance criteria are not met, re-testing is performed as needed to confirm acceptability following correction of the system or equipment deficiencies that caused the failure.

The initial start-up test program is planned and scheduled to permit safe fuel loading and start-up; to increase power in safe increments; and to perform major testing at specified power levels. If tests require the variation of operating parameters outside of their normal range, the limits within which such variation is permitted will be prescribed. The scope of the testing demonstrates, insofar as practicable, that the plant is capable of withstanding the design transients and accidents. For new facility construction, the suitability of facility operating procedures is checked to the maximum extent possible during the pre-operational and initial start-up test programs.

Except for computer program testing, which is addressed in Part II, Section 11.1, tests are performed and results documented in accordance with applicable technical and regulatory requirements, including those described in the Technical Specifications and Final Safety Analysis Report (FSAR). Test programs ensure appropriate retention of test data in accordance with the records requirements of the QAPD. Personnel that perform or evaluate tests are qualified in accordance with the requirements established in Part II, Section 2.

11.1. NQA-1 COMMITMENT FOR COMPUTER PROGRAM TESTING

X-energy establishes and implements provisions to ensure that computer software used in applications affecting safety is prepared, documented, verified and tested, and used such that the expected output is obtained, and configuration control maintained. To this end X-energy commits to compliance with the requirements of NQA-1-2015, Requirement 11 Section 400 and Subpart 2.7 to establish the appropriate provisions, in addition to the commitment to NQA-1-2015, Requirement 3.

11.2. NQA-1 COMMITMENT

In establishing provisions for testing, X-energy commits to compliance with NQA-1-2015, Requirement 11.



12. CONTROL OF MEASURING AND TEST EQUIPMENT

X-energy has established the necessary measures and governing procedures to control the calibration, maintenance, and use of measuring and test equipment (M&TE) that provides data to verify acceptance criteria are met for information important to safe plant operation. X-energy suppliers will be performing destructive and non-destructive testing for test purposes (includes fuel and graphite irradiation testing). The provisions of such procedures cover equipment such as indicating and actuating instruments and gauges, tools, reference and transfer standards, and non-destructive examination equipment. The suppliers of commercial-grade calibration services are controlled as described in Part II, Section 7. X-energy applies the following controls with regard to measuring and test equipment:

- The types of equipment covered by the program (e.g., instruments, tools, gauges, reference and transfer standards, and non-destructive examination equipment) are defined.
- M&TE is labeled, tagged, or otherwise controlled to indicate its calibration status and to ensure its traceability to calibration test data.
- M&TE is calibrated, adjusted, and maintained at prescribed intervals, or prior to use, against certified equipment having known valid relationships to nationally recognized standards. If no nationally recognized standards exist, the bases for calibration are documented.
- M&TE found to be out of calibration is tagged or segregated and not used until it is recalibrated. When measuring and test equipment is found to be out of calibration, an evaluation is made and documented of the validity of previous inspection or test results and of the acceptability of items previously inspected or tested. If any measuring or test equipment is consistently found to be out of calibration, it is repaired or replaced. A calibration is performed when the accuracy of the equipment is suspect.

12.1. INSTALLED INSTRUMENTATION AND CONTROL DEVICES

For the operational phase of the facilities, X-energy has established and implements procedures for the calibration and adjustment of instrumentation and control devices installed in the facility. The calibration and adjustment of these devices is accomplished through the facility maintenance programs to ensure that the facility is operated within design and technical requirements. Appropriate documentation will be maintained for these devices to indicate the control status, when the next calibration is due, and identify any limitations on use of the device.

12.2. NQA-1 COMMITMENT/EXCEPTIONS

In establishing provisions for control of measuring and test equipment, X-energy commits to compliance with NQA-1-2015, Requirement 12.



13. HANDLING, STORAGE, AND SHIPPING

X-energy has established the necessary measures and governing procedures to control the handling, storage, packaging, shipping, cleaning, and preservation of items, to prevent inadvertent damage or loss, and to minimize deterioration. These provisions include specific procedures, when required to maintain acceptable quality of the items important to the safe operations of the plant. Items are appropriately marked and labeled during packaging, shipping, handling, and storage, to identify, maintain, and preserve the item's integrity and indicate the need for special controls. Special controls (such as containers, shock absorbers, accelerometers, inert gas atmospheres, specific moisture content levels, and temperature levels) are provided when required to maintain acceptable quality.

Special or additional handling, storage, shipping, cleaning, and preservation requirements are identified and implemented as specified in procurement documents and applicable procedures. Where special requirements are specified, the items and containers (where used) are suitably marked.

Special handling tools and equipment are used and controlled as necessary to ensure safe and adequate handling. Special handling tools and equipment are inspected and tested in accordance with procedures at specified time intervals or prior to use.

Operators of special handling and lifting equipment are experienced or trained in the use the equipment.

During the operational phase, X-energy establishes and implements controls over hoisting, rigging, and transport activities to the extent necessary to protect the integrity of the items involved, as well as potentially affected nearby structures and components. Where required, X-energy complies with applicable hoisting, rigging, and transportation regulations and codes.

13.1. HOUSEKEEPING

Housekeeping practices are established to account for conditions or environments that could affect the quality of structures, systems, and components within the plant. This includes control of cleanliness of facilities and materials, fire prevention and protection, disposal of combustible material and debris, control of access to work areas, and protection of equipment (as well as radioactive contamination control and storage of solid radioactive waste). Housekeeping practices help ensure that only proper materials, equipment, processes, and procedures are used and that the quality of items is not degraded. Necessary procedures or work instructions, such as for electrical bus and control center cleaning, cleaning of control consoles, and radioactive decontamination, are developed and used.

13.2. NQA-1 COMMITMENT/EXCEPTIONS

In establishing provisions for handling, storage, and shipping, X-energy commits to compliance with NQA-1-2015, Requirement 13. X-energy also commits, during the construction and operational phase of the plant, to compliance with the requirements of NQA-1-2015, Subpart 2.1, Subpart 2.2, Subpart 2.3, and Subpart 3.2-2.1, with the following clarifications and exceptions:

NQA-1-2015, Subpart 2.1

- Subpart 2.1, Sections 301 and 302 establish criteria for classifying items into cleanliness classes and requirements for each class. Instead of using the cleanliness level system of Subpart 2.1, X-energy may establish cleanliness requirements on a case-by-case basis, consistent with the other provisions of Subpart 2.1. X-energy establishes appropriate cleanliness controls for work on safety-related equipment to minimize introduction of foreign material and maintain system/component



cleanliness throughout maintenance or modification activities, including documented verification of absence of foreign material prior to system closure.

NQA-1-2015, Subpart 2.2

- Subpart 2.2, Section 201 establishes criteria for classifying items into protection levels. Instead of classifying items into protection levels during the operational phase, X-energy may establish controls for the packaging, shipping, handling, and storage of such items on a case-by-case basis with due regard for the item's complexity, use, and sensitivity to damage. Prior to installation or use, the items are inspected and serviced as necessary to ensure that no damage or deterioration exists which could affect their function.
- Subpart 2.2, Section 606 requires written records be prepared containing information on personnel access. As an alternative to this requirement, X-energy documents establish controls for storage areas that describe those authorized to access areas and the requirements for recording access of personnel. However, these records of access are not considered quality records and will be retained in accordance with the administrative controls of the applicable plant.

NQA-1-2015, Subpart 2.3

- Subpart 2.3, Section 202 requires the establishment of five zone designations for housekeeping cleanliness controls. Instead of the five-level zone designation, X-energy bases its control over housekeeping activities on a consideration of what is necessary and appropriate for the activity involved. The controls are implemented through procedures or instructions which, in the case of maintenance or modification work, are developed on a case-by-case basis. Factors considered in developing the procedures and instructions include cleanliness control, personnel safety, fire prevention and protection, radiation control, and security. The procedures and instructions make use of standard janitorial and work practices to the extent possible.



14. INSPECTION, TEST, AND OPERATING STATUS

X-energy has established the necessary measures and governing procedures to identify the inspection, test, and operating status of items and components subject to the provisions of the QAPD, in order to maintain personnel and reactor safety and avoid inadvertent operation of equipment. Where necessary to preclude inadvertent bypassing of inspections or tests, or to preclude inadvertent operation, these measures require the inspection, test, or operating status be verified before release, fabrication, receipt, installation, test or use. These measures also establish the necessary authorities and controls for the application and removal of status indicators or labels.

In addition, temporary design changes (temporary modifications), such as temporary bypass lines, electrical jumpers and lifted wires, and temporary trip-point settings, are controlled by procedures that include requirements for appropriate installation and removal, independent/concurrent verifications, and status tracking.

Administrative procedures also describe the measures taken to control altering the sequence of required tests, inspections, and other operations. Review and approval for these actions is subject to the same control as taken during the original review and approval of tests, inspections, and other operations.

14.1. NQA-1 COMMITMENT

In establishing measures for control of inspection, test, and operating status, X-energy commits to compliance with NQA-1-2015, Requirement 14.



15. NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

X-energy has established the necessary measures and governing procedures to control items, including services that do not conform to specified requirements, to prevent inadvertent installation or use. Instructions require that the individual discovering a nonconformance identify, describe, and document the nonconformance in accordance with the requirements of Part II, Section 16. Personnel performing evaluations to determine a disposition have demonstrated competence in the specific area they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information.

Controls provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations. Controls are provided to address conditional release of nonconforming items for use on an at-risk basis prior to resolution and disposition of the nonconformance, including maintaining identification of the item and documenting the basis for such release. Conditional release of nonconforming items for installation requires the approval of the designated management. Nonconformances are corrected or resolved prior to depending on the item to perform its intended safety function. Nonconformances are evaluated for impact on operability of quality structures, systems, and components to ensure that the final condition does not adversely affect safety, operation, or maintenance of the item or service. The disposition, such as use as-is, reject, repair, or rework of nonconforming items is identified and documented. Technical justification for the acceptability of a nonconforming item, dispositioned repair, or use as-is is documented. Reworked, repaired, and replacement items are inspected and tested in accordance with the original inspection and test requirements or specified alternatives. Nonconformances to design requirements, dispositioned repair, or use as-is are subject to design control measures commensurate with those applied to the original design. Nonconformance dispositions are reviewed for adequacy, analysis of quality trends, and reports provided to the designated management. Significant trends are reported to management in accordance with X-energy procedures, regulatory requirements, and industry standards.

15.1. INTERFACE WITH THE REPORTING PROGRAM

X-energy has appropriate interfaces between the QAP for identification and control of nonconforming materials, parts, or components, and the non-QA Reporting Program to satisfy the requirements of 10 CFR 52, 10 CFR 50.55 and/or 10 CFR 21 during ESP/CP/COL design and construction, and 10 CFR 21 during operations.

15.2. NQA-1 COMMITMENT

In establishing measures for nonconforming materials, parts, or components, X-energy commits to compliance with NQA-1-2015, Requirement 15.



16. CORRECTIVE ACTION

X-energy has established the necessary measures and governing procedures to promptly identify, control, document, classify, and correct conditions adverse to quality. X-energy procedures ensure that corrective actions are documented and initiated following the determination of conditions adverse to quality, in accordance with regulatory requirements and applicable quality standards. X-energy procedures require personnel to identify known conditions adverse to quality. When complex issues arise where it cannot be readily determined if a condition adverse to quality exists, X-energy documents establish the requirements for documentation and timely evaluation of the issue. Reports of conditions adverse to quality are analyzed to identify trends. Significant conditions adverse to quality and significant adverse trends are documented and reported to responsible management. In the case of a significant condition adverse to quality, the cause is determined and actions to preclude recurrence are taken.

In the case of suppliers working on safety-related activities, or other similar situations, X-energy may delegate specific responsibilities for corrective actions, but X-energy maintains responsibility for the effectiveness of corrective action measures.

16.1. INTERFACE WITH THE REPORTING PROGRAM

X-energy has appropriate interfaces between the QAP for corrective actions and the non-QA Reporting Program to satisfy the requirements of 10 CFR 52, 10 CFR 50.55 and/or 10 CFR 21 during ESP/CP/COL design and construction, and 10 CFR 21 during operations.

16.2. NQA-1 COMMITMENT

In establishing provisions for corrective action, X-energy commits to compliance with NQA-1-2015, Requirement 16.



17. QUALITY ASSURANCE RECORDS

X-energy has the necessary measures and governing procedures to ensure that sufficient records of items and activities affecting quality are developed, reviewed, approved, issued, used, and revised to reflect completed work. The provisions of such procedures establish the scope of the records retention program for X-energy and include requirements for records administration, including receipt, preservation, retention, storage, safekeeping, retrieval, access controls, user privileges, and final disposition. For activities governed by 10 CFR 71, these provisions address the specific requirements of Section 71.135.

17.1. RECORD RETENTION

Measures are established that ensure that sufficient records of completed items and activities affecting quality are appropriately stored. Records of activities for design, engineering, procurement, manufacturing, construction, inspection and test, installation, pre-operation, start-up, operations, maintenance, modification, and audits and their retention times are defined in appropriate procedures. The records and retention times are based on Regulatory Position C.3.a of Regulatory Guide 1.28, Revision 5 for design, construction, and initial start-up. Retention times for operational phase records are based on construction records that are similar in nature. In addition, X-energy uses 10 CFR 71.135 to establish the types of records that will be created and retained in support of transportation operations governed by 10 CFR 71. In all cases where state, local, or other agencies have more restrictive requirements for record retention, those requirements will be met.

17.2. ELECTRONIC RECORDS

When using optical disks for electronic records storage and retrieval systems, X-energy complies with the NRC guidance in Generic Letter 88-18, "Plant Record Storage on Optical Disks." X-energy will manage the storage of QA Records in electronic media consistent with NIRMA Guidelines TG 11-2011, TG15-2011, TG16-2011, and TG21-2011.

17.3. NQA-1 COMMITMENT/EXCEPTIONS

In establishing provisions for records, X-energy commits to compliance with NQA-1-2015, Requirement 17, and regulatory positions stated in Regulatory Guide 1.28, Rev 5.



18. AUDITS

X-energy has established the necessary measures and governing procedures to implement audits to verify that activities covered by the QAPD are performed in conformance with the established requirements and performance criteria are met. The audit programs are themselves reviewed for effectiveness as a part of the overall audit process.

18.1. PERFORMANCE OF AUDITS

Internal audits of selected aspects of the licensing, design, construction, and operating phase activities are performed with a frequency commensurate with the safety significance of the activity and in a manner which ensures that audits of safety-related activities are completed. During early activities, audits will focus on areas including, but not limited to, design, site investigation, document control, procurement, and corrective action. Functional areas of an organization's QA program for auditing include, at a minimum, verification of compliance and effectiveness of implementation of internal rules and procedures (e.g., operating, design, procurement, maintenance, modification, refueling, surveillance, test, security, radiation control procedures, and the emergency plan), Technical Specifications, regulations and license conditions, programs for training, retraining, qualification and performance of the operating staff, observation of performance of operating, refueling, maintenance, and modification activities, and corrective actions, including associated record keeping.

The audits are scheduled on a formal preplanned audit schedule and in a manner to provide coverage and coordination with ongoing activities, based on the status and importance of the activity. Scheduled audits are supplemented by additional audits of specific subjects when necessary to provide adequate coverage. The scope of the audit is determined by the quality status and safety importance of the activities being performed. These audits are conducted by trained personnel not having direct responsibilities in the area being audited and in accordance with preplanned and approved audit plans or checklists, under the direction of a qualified Lead Auditor and the cognizance of the X-energy Quality Assurance management responsible for the day-to-day program, as documented in Part II, Section 1.

X-energy is responsible for conducting periodic internal and external audits. Internal audits are conducted to determine the adequacy of programs and procedures (by representative sampling), and to determine if they are meaningful and comply with the overall QAPD. External audits determine the adequacy of a supplier or contractor quality assurance program and are issued to the management of the audited organization and applicable X-energy management.

The results of each audit are reported in writing to the Senior Executive responsible for the Quality Assurance Program, or designee, as appropriate. Additional internal distribution is made to other concerned management levels and to management of the internal audited organizations or activities, in accordance with approved procedures.

Management responds to all audit findings and initiates corrective action where indicated. Where corrective action measures are indicated, documented follow-up of applicable areas, through inspections, review, re-audits, or other appropriate means, is conducted to verify implementation and effectiveness of assigned corrective action.

Audits of suppliers of safety-related components and/or services are conducted as described in Part II, Section 7.



18.2. INTERNAL AUDITS

Internal audits of organization and facility activities, conducted prior to placing the facility in operation, should be performed in such a manner as to ensure that an audit of all applicable QA program elements is completed for each functional area at least once each year or at least once during the life of the activity, whichever is shorter.

Internal audits of activities conducted after placing the facility in operation should be performed in such a manner as to ensure that an audit of all applicable QA program elements is completed for each functional area within a period of two years. Internal audit frequencies of well-established activities conducted after placing the facility in operation may be extended one year at a time beyond the above two-year interval based on the results of an annual evaluation of the applicable functional area and objective evidence that the functional area activities are being satisfactorily accomplished. The evaluation should include a detailed performance analysis of the functional area based upon applicable internal and external source data and due consideration of the impact of any functional area changes in responsibility, resources, or management. However, the internal audit frequency interval should not exceed a maximum of four years. If an adverse trend is identified in the applicable functional area, the extension of the internal audit frequency interval should be rescinded, and an audit scheduled as soon as practicable.

During the operational phase, audits are performed at a frequency commensurate with the safety significance of the activities and in such a manner to assure audits of all applicable QA program elements are completed within a period of two years. These audits will include, at a minimum, activities in the following areas:

- The conformance of facility operation to provisions contained within the Technical Specifications and applicable license conditions, including administrative controls.
- The performance, training, and qualifications of the facility staff.
- The performance of activities required by the QAPD to meet the criteria of 10 CFR 50, Appendix B.
- The Fire Protection Program and implementing procedures. A fire protection equipment and program implementation inspection and audit are conducted utilizing either a qualified off-site licensed fire protection engineer or an outside qualified fire protection consultant.
- Other activities and documents considered appropriate by the Site Executive.

Audits may also be used to meet the periodic review requirements of the code for the Security, Emergency Preparedness, and Radiological Protection programs within the provisions of the applicable code.

Internal audits include verification of compliance and effectiveness of the administrative controls established for implementing the requirements of the QAPD; regulations and license provisions; provisions for training, retraining, qualification, and performance of personnel performing activities covered by the QAPD; corrective actions taken following abnormal occurrences; and observation of the performance of construction, fabrication, operating, refueling, maintenance, and modification activities including associated record keeping.

18.3. EXIGENT CONDITIONS

Under exigent conditions, the audit or survey interval may be extended up to 25% of the periodicity of the triennial audit or survey when performance of such activities is not feasible. The total allowable extension for exigent conditions is 275 days. This unique grace period can be applied if exigent conditions exist including, but not limited to the following:



- Declaration of a national emergency or state of emergency impacting X-energy facilities or Supplier infrastructure,
- Natural disaster, weather emergency or other severe localized or national weather event or resulting damage to or impacting X-energy facilities or Supplier infrastructure, or
- Localized outbreak of a severe health concern to the public impacting X-energy facilities or Supplier infrastructure

Under these exigent conditions, the grace period clock reset under Regulatory Guide 1.28, Rev. 4 does not apply; the audit performed within this extension period resets the triennial clock. The 25% grace period extension is applicable to domestic and international suppliers.

During the use of the 25% extension, an evaluation of the supplier's program shall be performed and the documented results used to determine any necessary adjustments to their qualification status. Suppliers on the X-energy Evaluated Supplier List (ESL) may be maintained during the 25% extension period provided the following actions are taken and the results satisfactory:

- Verification that:
 - the supplier is still implementing a quality assurance program that meets 10 CFR 50 Appendix B or
 - commercial suppliers surveyed are still maintaining adequate controls for activities affecting quality.
- Monitor ongoing and previous supplier performance promptly, considering the impact of the following types of information:
 - results of receipt inspection activities or other operating experience,
 - review of supplier-furnished documents and records such as certificates of conformance, nonconformance notices, and corrective actions, and
 - results of audits and inspections from other sources (e.g., customer, American Society of Mechanical Engineers (ASME), NIAC audits or NRC inspections).
- In the event of a new procurement activity or change to existing procurements that significantly extends the scope or changes the method/controls for activities performed by the supplier, the evaluation shall document the justification that the change(s) are adequately addressed by the supplier's quality assurance program or mitigating actions are taken by X-energy.

Fully remote or provisional remote assessments may be conducted during exigent conditions due to restricted access or travel to the supplier providing the audit or survey is conducted in accordance with EPRI TR 3002020796 and per the following:

- The audit or survey is performed only for previously qualified suppliers to renew their qualifications, and
- A screening process is used to determine if remote audits or surveys are appropriate and can be applied effectively to evaluate, observe, and verify performance of activities, and applicable quality and technical requirements of interest can be reviewed.

X-energy maintains and updates the QAP as necessary to support ongoing X-energy activities. Prior to manufacturing and construction, the QAP will be revised as necessary to identify the QA controls applicable for manufacturing and construction activities.



18.4. NQA-1 COMMITMENT

In establishing the independent audit program, X-energy commits to compliance with NQA-1-2015, Requirement 18 and the regulatory positions stated in Regulatory Guide 1.28, Rev. 5.



PART III NON-SAFETY-RELATED SSC QUALITY CONTROL

1. NON-SAFETY-RELATED SSCs - SIGNIFICANT CONTRIBUTORS TO PLANT SAFETY

Specific program controls are applied to non-safety-related SSCs, for which 10 CFR 50, Appendix B is not applicable, that are significant contributors to plant safety. The specific program controls consistent with applicable sections of the QAPD are applied to those items in a selected manner, targeted at those characteristics or critical attributes that render the SSC a significant contributor to plant safety.

The following clarify the applicability of the QA Program to the non-safety-related SSCs and related activities, including the identification of exceptions to the QA Program described in Part II, Sections 1 through 18 taken for non-safety-related SSCs.

1.1. ORGANIZATION

The verification activities described in this part may be performed by the X-energy line organization. The QA organization described in Part II is not required to perform these functions.

1.2. QA PROGRAM

X-energy QA requirements for non-safety-related SSCs are established in the QAPD and appropriate procedures. Suppliers of these SSCs or related services describe the quality controls applied in appropriate procedures. A new or separate QA program is not required.

1.3. DESIGN CONTROL

X-energy has design control measures to ensure that the contractually 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.

1.4. PROCUREMENT DOCUMENT CONTROL

Procurement documents for items and services obtained by or for X-energy either include or reference documents describing applicable design bases, design requirements, and other requirements necessary to ensure component performance. The procurement documents are controlled to address deviations from the specified requirements.

1.5. INSTRUCTIONS, PROCEDURES, AND DRAWINGS

X-energy provides documents such as, but not limited to, written instructions, plant procedures, drawings, supplier technical manuals, and special instructions in work orders, to 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.



1.6. DOCUMENT CONTROL

X-energy controls the issuance and change of documents that specify quality requirements or prescribe activities affecting quality, 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.

1.7. CONTROL OF PURCHASED ITEMS AND SERVICES

X-energy employs measures, such as inspection of items or documents upon receipt, or acceptance testing, to ensure that all purchased items and services conform to appropriate procurement documents.

1.8. IDENTIFICATION AND CONTROL OF PURCHASED ITEMS

X-energy employs measures where necessary 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.

1.9. CONTROL OF SPECIAL PROCESSES

X-energy employs process and procedure controls for special processes, including welding, heat treating, and non-destructive testing. These controls are based on applicable codes, standards, specifications, criteria, or other special requirements for the special process.

1.10. INSPECTION

X-energy requires the use of documented instructions 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 are from the same discipline and have experience related to the work being inspected.

1.11. TEST CONTROL

X-energy employs measures 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.

1.12. CONTROL OF MEASURING AND TEST EQUIPMENT (M&TE)

X-energy employs measures to control M&TE use and requires calibration and adjustment at specific intervals or prior to use.



1.13. HANDLING, STORAGE, AND SHIPPING

X-energy employs measures 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.

1.14. INSPECTION, TEST, AND OPERATING STATUS

X-energy employs measures to identify items that have satisfactorily passed required tests and inspections and to indicate the status of inspection, test, and operability as appropriate.

1.15. CONTROL OF NONCONFORMING ITEMS

X-energy employs measures to identify and control items that do not conform to specified requirements to prevent their inadvertent installation or use.

1.16. CORRECTIVE ACTION

X-energy employs measures to ensure that failures, malfunctions, deficiencies, deviations, defective components, and nonconformances are properly identified, reported, and corrected.

1.17. RECORDS

X-energy employs measures 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.

1.18. AUDITS

X-energy employs measures for line management to periodically review and document the adequacy of the process, including taking any necessary corrective action. Audits independent of line management are not required. 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. Where the measures of this part (Part III) are implemented by the same programs, processes, or procedures as the comparable activities of Part II, the audits performed under the provisions of Part II may be used to satisfy the review requirements of this Section (Part III, Section 1.18).



2. NONSAFETY-RELATED SSCS CREDITED FOR REGULATORY EVENTS

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

- X-energy implements quality requirements for the fire protection system in accordance with Regulatory Position 1.7, "Quality Assurance," in Regulatory Guide 1.189, "Fire Protection for Nuclear Power Plants," Revision 4.
- X-energy implements the quality requirements for non-safety-related, safety significant ATWS equipment in accordance with Part III, Section1.
- X-energy implements quality requirements for non-safety-related, safety significant SBO equipment in accordance with Part III, Section1.



PART IV REGULATORY COMMITMENTS

1. NRC REGULATORY GUIDES AND QUALITY ASSURANCE STANDARDS

This section identifies the NRC Regulatory Guides (RG) and the other quality assurance standards which have been selected to supplement and support the X-energy QAPD. X-energy identifies the extent of conformance with these RGs and quality assurance standards as described below or within applicable license application documents submitted in accordance with 10 CFR 50 (e.g., LWA, CP, OL) and 10 CFR 52 (e.g., ESP, DC, COL, SDA), as applicable. Commitment to a particular RG or standard does not constitute a commitment to other RGs or standards that may be referenced therein.

1.1. REGULATORY GUIDES

- **Regulatory Guide 1.8**, Rev. 4, June 2019, Qualification and Training of Personnel for Nuclear Power Plants

Regulatory Guide 1.8 provides guidance that is acceptable to the NRC staff regarding qualifications and training for nuclear power plant personnel .

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

Regulatory Guide 1.28 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.

X-energy will implement this guidance and will identify exceptions to the applicable regulatory position guidance provided in this regulatory guide in applicable license applications (e.g., safety analysis reports).

- **Regulatory Guide 1.29**, [Revision. 5, July 2016] - Seismic Design Classification

Regulatory Guide 1.29 defines systems required to withstand a safe shutdown earthquake (SSE).

X-energy will identify conformance with the applicable regulatory position guidance provided in this regulatory guide in applicable license applications (e.g., safety analysis reports).

- **Regulatory Guide 1.33**, Rev. 3, June 2013, Quality Assurance Program Requirements (Operations)

Regulatory Guide 1.33 describes a method acceptable to the NRC staff for complying with the Commission's regulations with regard to overall quality assurance program requirements for the operation phase of nuclear power plants. X-energy will implement this guidance and will identify exceptions to the applicable regulatory position guidance provided in this regulatory guide in applicable license applications (e.g., safety analysis reports).

- **Regulatory Guide 1.164**, [Revision 0, June 2017], Dedication of Commercial-Grade Items for Use in Nuclear Power Plants.

Regulatory Guide 1.164 describes methods that the staff of the U.S. Nuclear Regulatory Commission (NRC) considers acceptable in meeting regulatory requirements for dedication of commercial-grade items and services used in nuclear power plants.

X-energy identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in applicable license applications (e.g., safety analysis reports).



- **Regulatory Guide 1.231**, [Revision 0, January 2017], Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Safety-Related Applications for Nuclear Power Plants.

Regulatory Guide 1.231 describes methods that the staff of the U.S. Nuclear Regulatory Commission (NRC) considers acceptable in meeting regulatory requirements for acceptance and dedication of commercial-grade design and analysis computer programs used in safety-related applications for nuclear power plants.

X-energy identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in applicable license applications (e.g., safety analysis reports).

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

Regulatory Guide 1.234 describes methods that the staff of the U.S. Nuclear Regulatory Commission (NRC) considers acceptable for complying with the provisions of Title 10 of the Code of Federal Regulations (10 CFR) Part 21, "Reporting of Defects and Noncompliance."

X-energy identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in applicable license applications (e.g., safety analysis reports).

1.2. STANDARDS

- **ASME NQA-1-2015** - Quality Assurance Requirements for Nuclear Facility Applications

X-energy commits to NQA-1-2015 Parts I and II, as described in Parts II and V of this document with specific identification of exceptions or clarification. X-energy commits to NQA-1-2015 Parts III and IV only as specifically noted in Parts II and V of this document.

- **Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guides (TGs)**

X-energy commits to NIRMA TGs as described in Part II, Section 17 of this document.



PART V ADDITIONAL QUALITY ASSURANCE AND ADMINISTRATIVE CONTROLS FOR THE PLANT OPERATIONAL PHASE

X-energy includes the requirements of Part V that follow when establishing the necessary measures and governing procedures for the operational phase of the plant. Implementation of the additional controls in this section shall apply 30 days prior to initial fuel load for COL holders in accordance with 10 CFR 50.54(a)(1) and 90 days prior to initial fuel load for construction permit holders.

1. SECTION 1 DEFINITIONS

X-Energy uses the definitions of terms as provided in Section 400 of the Introduction of NQA-1-2015 in interpreting the requirements of NQA-1 and the other standards to which the QAPD commits. In addition, definitions are provided for the following terms not covered in NQA-1:

Administrative controls: rules, orders, instructions, procedures, policies, practices, and designations of authority and responsibility

Experiments: performance of plant operations carried out under controlled conditions in order to establish characteristics or values not previously known

Independent review: review completed by personnel not having direct responsibility for the work function under review, regardless of whether they operate as a part of an organizational unit or as individual staff members (see review)

Nuclear power plant: any plant using a nuclear reactor to produce electric power, process steam, or provide space heating

On-site operating organization: on-site personnel concerned with the operation, maintenance, and certain technical services

Operating activities: work functions associated with normal operation and maintenance of the plant, and technical services routinely assigned to the on-site operating organization

Operational phase: that period of time during which the principal activity is associated with normal operation of the plant. This phase of plant life is considered to begin formally with commencement of initial fuel loading and ends with plant decommissioning

Review: a deliberately critical examination, including observation of plant operation, evaluation of assessment results, procedures, certain contemplated actions, and after-the-fact investigations of abnormal conditions

Supervision: direction of personnel activities or monitoring of plant functions by an individual responsible and accountable for the activities they direct or monitor

Surveillance testing: periodic testing to verify that safety-related structures, systems, and components continue to function or are in a state of readiness to perform their functions

System: an integral part of nuclear power plant comprising components which may be operated or used as a separate entity to perform a specific function



2. REVIEW OF ACTIVITIES AFFECTING SAFE PLANT OPERATION

2.1. ON-SITE OPERATING ORGANIZATION REVIEW

The X-energy on-site organization employs reviews, both periodic and as situations demand, to evaluate plant operations and plan future activities. The important elements of the reviews are documented and subjects of potential concern for the independent review described below are brought to the attention of Operations Phase Management. The reviews are part of the normal duties of plant supervisory personnel in order to provide timely and continuing monitoring of operating activities, in order to assist Operations Phase Management in keeping abreast of general plant conditions and to verify that day-to-day operations are conducted safely in accordance with the established administrative controls. Operations Phase Management ensures the timely referral of the applicable matters discussed in the reviews to appropriate management and independent reviewers.

2.2. INDEPENDENT REVIEW

Activities occurring during the operational phase shall be independently reviewed on a periodic basis. The independent review program shall be functional prior to initial core loading. The independent review function performs the following:

- Reviews proposed changes to the facility as described in the Final Safety Analysis Report (FSAR). A site independent review group also verifies that changes do not adversely affect safety and if a technical specification change or NRC review is required.
- Reviews proposed tests and experiments not described in the FSAR prior to implementation. Verifies the determination of whether changes to proposed tests and experiments not described in the FSAR require a technical specification change or license amendment.
- Reviews proposed technical specification changes and license amendments relating to nuclear safety prior to NRC submittal and implementation, except in those cases where the change is identical to a previously approved change.
- Reviews violations, deviations, and events that are required to be reported to the NRC. This review includes the results of investigations and recommendations resulting from such investigations, to prevent or reduce the probability of recurrence of the event.
- Reviews any matter related to nuclear safety that is requested by the Site Executive or Operations Management or any Independent Review Group member.
- Reviews corrective actions for significant conditions adverse to quality.
- Reviews internal audit reports.
- Reviews the adequacy of the internal audit program every 24 months.

Independent Review Group

A formally established group functions as an Independent Review Group (IRG). In discharging its review responsibilities, the IRG keeps safety considerations paramount when opposed to cost or schedule considerations. The IRG performs its functions in the following manner:

- An Independent Review Group is assigned independent review responsibilities and reports to the Site Executive.



- The Independent Review Group is composed of no less than 5 persons; no more than a minority of members are from the on-site operating organization.
- For example, at least 3 of the 5 members must be from off-site if there are 5 members in the group. A minimum of the chairman or alternative chairman and 2 members must be present for all meetings.
- During the period of initial operation, meetings are conducted no less frequently than once per calendar quarter. Afterwards, meetings are conducted no less than twice a year.
- Results of the meeting are documented and recorded.
- Consultants and contractors are used for the review of complex problems beyond the expertise of the off-site/on-site independent review group.
- Persons on the Independent Review Group are qualified as follows:

Chairman of the Independent Review Group

Education: Baccalaureate in engineering or related science

Minimum experience: Six (6) years combined managerial and technical support

Independent Review Group members

Education: Baccalaureate in engineering or related science for those personnel required to review problems in nuclear power plant operations, nuclear engineering, chemistry and radiochemistry, metallurgy, non-destructive testing, instrumentation and control, radiological safety, mechanical engineering, or electrical engineering.

High school diploma for those independent review personnel required to review problems in administrative control and quality assurance practices, training, and emergency plans and related procedures and equipment.

Minimum experience: Five (5) years in their own area of responsibility (nuclear power plant operations, nuclear engineering, chemistry and radiochemistry, metallurgy, non-destructive testing, instrumentation and control, radiological safety, mechanical engineering, and electrical engineering, administrative control and quality assurance practices, training, and emergency plans and related procedures and equipment).



3. OPERATIONAL PHASE PROCEDURES

The following is a description of the various types of procedures used by X-energy to govern the design, operation, and maintenance of its nuclear generating plants. X-energy follows the guidance of Appendix A to Regulatory Guide 1.33 in identifying the types of activities that should have procedures or instructions to control the activity. Each procedure shall be sufficiently detailed for a qualified individual to perform the required function without direct supervision, but need not provide a complete description of the system or plant process.

3.1. FORMAT AND CONTENT

Procedure format and content may vary from one facility to another; however, procedures include the following elements as appropriate to the purpose or task to be described.

Title/Status

Each procedure is given a title descriptive of the work or subject it addresses and includes a revision number and/or date and an approval status.

Purpose/Statement of Applicability/Scope

The purpose for which the procedure is intended is clearly stated (if not clear from the title). The systems, structures, components, processes or conditions to which the procedure applies are also clearly described.

References

Applicable references, including reference to appropriate Technical Specifications, are required. References are included within the body of the procedure when the sequence of steps requires other tasks to be performed (according to the reference) prior to or concurrent with a particular step.

Prerequisites/Initial Conditions

Prerequisites/initial conditions identify independent actions or procedures that must be accomplished and plant conditions which must exist prior to performing the procedure; including prerequisites applicable to only a specific portion of a procedure.

Precautions

Precautions alert the user to those important measures to be used to protect equipment and personnel, including the public, or to avoid an abnormal or emergency situation during performance of the procedure. Cautionary notes applicable to specific steps are included in the main body of the procedure and are identified as such.

Limitations and actions

Limitations on the parameters being controlled and appropriate corrective measures to return the parameter to the normal control band are specified.

Main body

The main body of the procedure contains the step-by-step instructions in the degree of detail necessary for performing the required function or task.

Acceptance criteria

The acceptance criteria provide the quantitative or qualitative criteria against which the success or failure (as of a test-type activity) of the step or action would be judged.



Checklists

Complex procedures utilize checklists which may be included as part of the procedure or appended to it.

3.2. PROCEDURE TYPES

Procedure types may vary from one location to the other based on scope of activities; however, procedures are developed in each of the following categories.

Administrative Control Procedures

These include administrative procedures, directives, policies, standards, and similar documents that control the programmatic aspects of facility activities. These administrative documents ensure that the requirements of regulatory and license commitments are properly implemented. Several levels of administrative controls are applied ranging from those affecting the entire Company to those prepared at the implementing group level. These documents establish responsibilities, interfaces, and standard methods (rules of practice) for implementing programs. In addition to the administrative controls described throughout this QAPD, instructions governing the following activities are provided:

Operating Orders/Procedures

Instructions of general and continuing applicability to the conduct of business to the plant staff are provided. Examples include, but are not limited to, job turnover and relief, designation of confines of the control room, definition of duties of operators and others, transmittal of operating data to management, filing of charts, limitations on access to certain areas and equipment, shipping and receiving instructions. Provisions are made for periodic review and updating of these documents, where appropriate.

Special Orders

Management instructions, which have short-term applicability and require dissemination, are issued to encompass special operations, housekeeping, data taking, publications and their distribution, plotting process parameters, personnel actions, or other similar matters. Provisions are made for periodic review, updating, and cancellation of these documents, where appropriate.

Plant Security and Visitor Control

Procedures or instructions developed to supplement features and physical barriers designed to control access to the plant and, as appropriate, to vital areas within the plant. Information concerning specific design features and administrative provisions of the plant security program is confidential and thus accorded limited distribution. The security and visitor control procedures consider, for example, physical provisions, such as: fences and lighting; lock controls for doors, gates and compartments containing sensitive equipment; and provisions for traffic and access control.

Administrative provisions, such as: visitor sign-in and sign-out procedures; escorts and badges for visitors; emphasis on inspection, observation, and challenging of strangers by operating crews; and a program of pre-employment screening for potential employees are also considered.

Temporary Procedures

Temporary procedures may be used to direct operations during testing, refueling, maintenance, and modifications, to provide guidance in unusual situations not within the scope of the normal procedures. These procedures ensure orderly and uniform operations for short periods when the plant, a system, or a component of a system is performing in a manner not covered by existing detailed procedures or when it has been modified or extended in such a manner that portions of existing procedures do not apply.



Temporary Procedures include designation of the period of time during which they may be used and are subject to the procedure review process as applicable.

Engineering Procedures

These documents provide instructions for the preparation of engineering documents, engineering analysis, and implementation of engineering programs. This includes activities such as designs; calculations; fabrication, equipment, construction, and installation specifications; drawings; analysis and topical reports; and testing plans or procedures. They include appropriate references to industry codes and standards, design inputs, and technical requirements.

Configuration Management Procedures

These documents provide instructions for the responsibility and authority for functions that affect the configuration of the facility including activities such as operations, design, maintenance, construction, licensing, and procurement. X-energy shall establish and document a time or event when configuration management shall be established for the facility.

Installation Procedures

These documents provide instructions for the installation of components generally related to new construction and certain modification activities. They include appropriate reference to industry standards, installation specifications, design drawings, and supplier and technical manuals for the performance of activities. These documents include provisions, such as hold or witness points, for conducting and recording results of required inspections or tests. These documents may include applicable inspection and test instructions subject to the requirements for test and inspection procedures below.

System Procedures

These documents contain instructions for energizing, filling, venting, draining, starting up, shutting down, changing modes of operation, and other instructions appropriate for the coolant flow control, or any other systems available for short-term or long-term control of reactivity, making deliberate load changes, responding to unanticipated load changes, and adjusting operating parameters.

Process Monitoring Procedures

These documents contain instructions for monitoring performance of plant systems to ensure that core thermal margins and coolant quality are maintained in acceptable status at all times, that integrity of fission product barriers is maintained, and that engineered safety features and emergency equipment are in a state of readiness to keep the plant in a safe condition if needed. Maximum and minimum limits for process parameters are appropriately identified. Operating procedures address the appropriate nature and frequency of this monitoring.

Fuel Handling Procedures

These documents contain instructions for core alterations, accountability of fuel and partial or complete refueling operations that include, for example, continuous monitoring of neutron flux throughout core loading, periodic data recording, audible annunciation of abnormal flux increases, and evaluation of core neutron multiplication to verify safety of loading increments. Procedures are also provided for receipt and inspection of new fuel, and for new and spent fuel movement. Fuel handling procedures include prerequisites to verify the status of systems required for fuel handling and movement; inspection of replacement fuel and control rods; designation of proper tools, proper conditions for spent fuel movement, proper conditions for fuel cask loading and movement; and status of protective instrumentation. These procedures provide requirements for fuel movement, rules for minimum operable instrumentation, actions



for response to fuel damage, verification of shutdown margin, communications associated with, criteria for, and verification of fuel movement, and documentation of fuel locations.

Maintenance Procedures

These documents contain instructions in sufficient detail to permit maintenance work to be performed correctly and safely, and include provisions, such as hold or witness points, for conducting and recording results of required inspections or tests. These documents may include applicable inspection or test instructions subject to the requirements for test and inspection procedures below. Appropriate referencing to other procedures, standards, specifications, or supplier manuals is provided. When not provided through other documents, instructions for equipment removal and return to service, and applicable radiation protection measures (such as protective clothing and radiation monitoring) will be included. Additional maintenance procedure requirements are addressed in NQA-1-2015, Subpart 2.18, Section 202, Procedures.

Radiation Control Procedures

These documents contain instructions for implementation of the radiation control program requirements necessary to meet regulatory commitments, including acquisition of data and use of equipment to perform necessary radiation surveys, measurements and evaluations for the assessment and control of radiation hazards. These procedures provide requirements for monitoring both external and internal exposures of employees, utilizing accepted techniques; routine radiation surveys of work areas; effluent and environmental monitoring in the vicinity of the plant; radiation monitoring of maintenance and special work activities, and for maintaining records demonstrating the adequacy of measures taken to control radiation exposures to employees and others.

Calibration and Test Procedures

These documents contain instructions for periodic calibration and testing of instrumentation and control systems, and for periodic calibration of measuring and test equipment used in activities affecting the quality of these systems. These documents provide for meeting surveillance requirements and for ensuring measurement accuracy adequate to keep safety-related parameters within operational and safety limits.

Chemical and Radiochemical Control Procedures

These documents contain instructions for chemical and radiochemical control activities and include: the nature and frequency of sampling and analyses; instructions for maintaining coolant quality within prescribed limits; and limitations on concentrations of agents that could cause corrosive attack, foul heat transfer surfaces, or become sources of radiation hazards due to activation. These documents also provide for the control, treatment and management of radioactive wastes, and control of radioactive calibration sources.

Emergency Operating Procedures

These documents contain instructions for response to potential emergencies so that a trained operator will know in advance the expected course of events that will identify an emergency and the immediate actions that are taken in response. Format and content of emergency procedures are based on NUREG and Owner's Group(s) guidance that identify potential emergency conditions and require such procedures to include, as appropriate, a title, symptoms to aid in identification of the nature of the emergency, automatic actions to be expected from protective systems, immediate operator actions for operation of controls or confirmation of automatic actions, and subsequent operator actions to return the reactor to a normal condition or provide for a safe extended shutdown period under abnormal or emergency conditions.



Emergency Plan Implementing Procedures

These documents contain instructions for activating the Emergency Response Organization and facilities, protective action levels, organizing emergency response actions, establishing necessary communications with local, state, and federal agencies, and for periodically testing the procedures, communications, and alarm systems to ensure they function properly. Format and content of such procedures are such that requirements of each facility's NRC approved Emergency Plan are met.

Test and Inspection Procedures

These documents provide the necessary measures to ensure quality is achieved and maintained for the nuclear facilities. The instructions for tests and inspections may be included within other procedures, such as installation and maintenance procedures, but will contain the objectives, acceptance criteria, prerequisites for performing the test or inspection, limiting conditions, and appropriate instructions for performing the test or inspection, as applicable. These procedures also specify any special equipment or calibrations required to conduct the test or inspection and provide for appropriate documentation and evaluation by responsible authority to ensure test or inspection requirements have been satisfied. Where necessary, hold or witness points are identified within the procedures and require appropriate approval for the work to continue beyond the designated point. These procedures provide for recording the date, identifying those performing the test or inspection, as-found condition, corrective actions performed (if any), and as-left condition, as appropriate for the subject test or inspection.



4. CONTROL OF SYSTEMS AND EQUIPMENT IN THE OPERATIONAL PHASE

Permission to release systems and equipment for maintenance or modification is controlled by designated operating personnel and documented. Measures, such as installation of tags or locks and releasing stored energy, are used to ensure personnel and equipment safety. When entry into a closed system is required, X-energy has established control measures to prevent entry of extraneous material and to assure that foreign material is removed before the system is reclosed.

Administrative procedures require the designated operating personnel to verify that the system or equipment can be released and determine the length of time it may be out of service. In making this determination, attention is given to the potentially degraded degree of protection where one subsystem of a redundant safety system is not available for service. Conditions to be considered in preparing equipment for maintenance include, for example: shutdown margin; establishment of a path for decay heat removal; temperature and pressure of the system; valves between work and hazardous material; venting, draining and flushing; entry into closed vessels; hazardous atmospheres; handling hazardous materials; and electrical hazards.

When systems or equipment are ready to be returned to service, designated operating personnel control placing the items in service and document its functional acceptability. Attention is given to restoration of normal conditions, such as removal of jumpers or signals used in maintenance or testing, or actions such as returning valves, breakers or switches to proper start-up or operating positions from "test" or "manual" positions. Where necessary, the equipment placed into service receives additional surveillance during the run-in period.

Independent verifications, where appropriate, are used to ensure that the necessary measures have been implemented correctly. The minimum requirements and standards for using independent verification are established in company documents.



5. PLANT MAINTENANCE

X-energy establishes controls for the maintenance or modification of items and equipment subject to this QAPD to ensure quality at least equivalent to that specified in original design bases and requirements, such that safety-related SSCs are maintained in a manner that ensures their ability to perform their intended safety function(s). Maintenance activities (both corrective and preventive) are scheduled and planned so as not to unnecessarily compromise the safety of the plant.

In establishing controls for plant maintenance, X-energy commits to compliance with NQA-1-2015, Subpart 2.18, with the following clarifications:

- Where Subpart 2.18 refers to the requirements of ANS-3.2, it shall be interpreted to mean the applicable standards and requirements established within the QAPD.
- Section 203 requires cleanliness during maintenance to be in accordance with Subpart 2.1. The commitment to Subpart 2.1 is described in the QAPD, Part II, Section 13.2.