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04-Dec-2020

XE00-Q-Q1ZZ-RDZZ-L_000211_Rev 5

Docket No. 99902071

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

**SUBJECT: X Energy, LLC (X-energy)
Topical Report Submittal
Revision 3-A to X Energy, LLC (X-energy) Quality Assurance Program Description (QAPD)
– Non-Proprietary**

REFERENCE:

1. Regulatory Engagement Plan for X Energy, LLC's Xe-100 Reactor with schedule for Pre-Application Submittals (XE00-R-R1ZZ-RDZZ-L_000210_Rev 1, June 28, 2019)(ML19177A399)
2. X Energy, LLC TR QAPD Submittal (XE00-R-R1ZZ-RDZZ-L_000211_Rev 1, July 31, 2019)(ML19213A059)
3. Letter (ML20013G253) 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 (January 13, 2020)
4. Letter from X Energy, LLC (ML20035E617) to U.S. Nuclear Regulatory Commission, "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" dated February 3, 2020.
5. Letter from X Energy, LLC (ML20104C134) to U.S. Nuclear Regulatory Commission, "Submittal of Revision 1 to X Energy, LLC (X-energy) Quality Assurance Program Description (QAPD) for Design Certification of the X-energy Xe-100 Reactor - Non-Proprietary" (April 08, 2020).
6. Letter (ML20140A333) from U.S. Nuclear Regulatory Commission to X Energy, LLC, 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).
7. Letter (ML20233A910) from U.S. Nuclear Regulatory Commission to X Energy, LLC, Final 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).



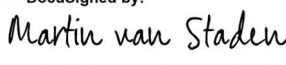
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In a letter dated July 31, 2019, X Energy, LLC (X-energy) submitted the topical report entitled "Submittal of X Energy, LLC (X-energy) Quality Assurance Program Description (QAPD) for Design Certification of the X-energy Xe-100 Reactor - Non-Proprietary" (Reference 2) to the U.S. Nuclear Regulatory Commission (NRC) for review and approval. In a letter dated January 13, 2020 (Reference 3), the NRC Staff provided Requests for Additional Information (RAIs) regarding the subject topical report. X Energy, LLC provided its response to the RAI by letter dated February 3, 2020 (Reference 4). In a letter dated February 21, 2020 (Reference 5), X-energy provided a revised version of the QAPD (Revision 1) for NRC review, prior to the Staff's preparation of a Safety Evaluation Report. The revised QAPD version, incorporated the changes submitted as part of X-energy's RAI response, and included changes to the X-energy organizational structure. In a letter dated April 8, 2020, X-energy provided a revised version of the QAPD (Revision 2) for NRC review, prior to the Staff's preparation of a Draft Safety Evaluation Report. The revised QAPD version incorporated the change discussed in a clarification call with NRC staff regarding X-energy's commitments to the Regulatory Guides listed in Part IV of the QAPD on Tuesday, April 7, 2020. X-energy provided a revised version of the QAPD (Revision 3) that incorporated the changes requested in a letter (Reference 6) from the NRC to X Energy, LLC on July 13, 2020 along with a draft safety evaluation report. The NRC accepted the changes and issued the final safety evaluation report (Reference 7) on August 4, 2020.

The enclosure to this letter provides the approved version of the topical report (Revision 3-A) which includes the NRC's final safety evaluation and earlier requests for additional information and X-energy's responses. X-energy has reviewed these references for proprietary information and agrees it 1) does not contain proprietary information and 2) may be publicly released.

If you have any questions or need any additional information, please contact Travis Chapman at tchapman@x-energy.com or (240) 495-0651.

Sincerely,

DocuSigned by:

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Martin van Staden
Vice President, Design Engineering & Xe-100 Program Manager
X Energy, LLC

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Nuclear Regulatory Commission

Benjamin Beasley

Lucieann Vechioli Feliciano

Enclosure:

- 1) "X Energy, LLC Topical Report, Quality Assurance Program Description (Non-Proprietary)"



X Energy, LLC
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Enclosure 1
X Energy, LLC Topical Report
Quality Assurance Program Description
(Non-Proprietary)



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C	X Energy, LLC Topical Report, Quality Assurance Program Description, Revision 3-A



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Section A



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
WASHINGTON, D.C. 20555-0001

September 4, 2020

Mr. Harlan Bowers
President
X-Energy, LLC
801 Thompson Avenue
Rockville, MD 20852

**SUBJECT: 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)**

Dear Mr. Bowers:

By letter dated July 31, 2019 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19213A059), X-Energy, LLC (X-Energy), submitted for U.S. Nuclear Regulatory Commission (NRC) staff review its Topical Report (TR) XEQAPD, "Quality Assurance Program Description, Revision 0". The XEQAPD was submitted in accordance with the guidance of NUREG-0800, "Standard Review Plan (SRP) for the Review of Safety Analysis Reports for Nuclear Power Plants," Section 17.5, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicant," Revision 1, dated August 2015. By letter dated February 21, 2020 (ADAMS Accession No. ML20052C884), X-Energy responded to the NRC staff's request for additional information (RAI) and provided Revision 1 to TR XEQAPD. Following a clarification call on April 7, 2020, X-Energy submitted Revision 2 to topical report XEQAPD by letter dated April 8, 2020 (ADAMS Accession No. ML20104C134).

Subsequently, by letter dated July 13, 2020 (ADAMS Accession No. ML20142A286, non-public), the staff's draft safety evaluation (SE) was provided for your determination of whether the draft SE contained proprietary information. In addition, as part of its review of Revision 2 of the XEQAPD, the staff identified two issues that would need to be addressed as part of an application for a design certification (ADAMS Accession No. ML20140A333). First, the NRC staff noted that X-Energy listed Revision 2, dated October 2010 as the most current edition of Regulatory Guide (RG) 1.54. However, the latest edition of RG 1.54 is Revision 3, issued in April 2017. Second, the NRC staff noted that Subsection 7.2, "NQA-1 Commitments and Exceptions," states, in part, "X-energy considers that other 10 CFR Parts 50 and 52 licensees...". The word "other" implied that X-Energy is a licensee, which is not appropriate. By letter dated August 7, 2020 (ADAMS Accession No. ML20220A413), X-Energy voluntarily provided Revision 3 to topical report XEQAPD to address these two issues and confirmed that the draft SE did not contain proprietary information. Enclosed is a copy of the NRC staff's final SE for the XEQAPD TR.

Based on its review, the NRC staff concludes that X-Energy's topical report XEQAPD-NP, Revision 3 satisfies the quality assurance requirements of Appendix B to Title 10 of the *Code of Federal Regulations* Part 50. The enclosed Final SE defines the basis for acceptance of the TR and it is being made publicly available in full based on your confirmation that it contains no proprietary information.

In accordance with the NRC's published information on Topical Reports available at <https://www.nrc.gov/about-nrc/regulatory/licensing/topical-reports.html> and the NRC's internal guidance in LIC-500, we request that X-Energy publish the accepted version of this TR within 3 months of receipt of this letter. The accepted version shall incorporate this letter and the enclosed SE after the title page. Also, the accepted version must contain historical review information, including NRC RAIs and your responses after the title page. The accepted versions shall include a "-A" (designating accepted) following the TR identification number.

As an alternative to including the RAIs and RAI responses behind the title page, if changes to the TR were provided to the NRC staff to support the resolution of RAI responses, and the NRC staff reviewed and approved those changes as described in the RAI responses, there are two ways that the accepted version can capture the RAIs:

1. The RAIs and RAI responses can be included as an Appendix to the accepted version.
2. The RAIs and RAI responses can be captured in the form of a table (inserted after the final SE) which summarizes the changes as shown in the accepted version of the TR. The table should reference the specific RAIs and RAI responses which resulted in any changes, as shown in the accepted version of the TR.

If you have any questions or comments concerning this matter, please contact Lucieann Vechioli at 301-415-6035 or via email at Lucieann.Vechioli@nrc.gov.

Sincerely,

Benjamin G. Beasley, Chief
Advanced Reactor Licensing Branch
Division of Advanced Reactors and Non-
Power Production and Utilization Facilities
Office of Nuclear Reactor Regulation

Project No. 99902071

Enclosure:
Final Safety Evaluation

cc: See next page

SUBJECT: 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)
DATED: SEPTEMBER 04, 2020

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ADAMS Accession No. ML20233A910***via -email****NRC-002**

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DATE	9/3/2020	9/4/2020	

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**UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001**

FINAL SAFETY EVALUATION BY
THE OFFICE OF NUCLEAR REACTOR REGULATION
REGARDING THE X-ENERGY TOPICAL REPORT
XEQAPD, "QUALITY ASSURANCE PROGRAM DESCRIPTION," REVISION 3
FOR THE DESIGN CERTIFICATION OF THE XE-100 NUCLEAR POWER REACTOR
EPID NO. L-2019-TOP-0020

1.0 INTRODUCTION

By letter dated July 31, 2019 (Reference 1), X-Energy, LLC (hereafter referred to as X-Energy), submitted for U.S. Nuclear Regulatory Commission (NRC) staff review its topical report (TR) XEQAPD, "Quality Assurance Program Description," Revision 0, in accordance with the guidance of NUREG-0800, "Standard Review Plan (SRP) for the Review of Safety Analysis Reports for Nuclear Power Plants," Section 17.5, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants," Revision 1, dated August 2015 (Reference 2). By letter dated February 3, 2020 (Reference 3), X-Energy responded to the NRC staff's request for additional information and provided Revision 1 of Topical Report XEQAPD (Reference 4). X-Energy submitted Revision 2 to topical report XEQAPD by letter dated April 8, 2020 (Reference 5). By letter dated July 13, 2020 (ADAMS Accession No. ML20142A286, non-public), the NRC provided its draft safety evaluation (SE) to the applicant for its determination of whether the draft SE contained any of its proprietary information. Additionally, the staff identified two issues the applicant would be expected to address as part of a design certification application (Reference 13). By letter dated August 7, 2020 (Reference 6), X-Energy voluntarily provided Revision 3 to TR XEQAPD addressing these two issues.

The X-Energy Quality Assurance Program Description (QAPD) TR addresses design activities in support of a design certification (DC) for the Xe-100 nuclear power reactor. The QAPD is based on the applicable portions of both Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations*, (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," and American Society of Mechanical Engineers (ASME) NQA-1-2015, "Quality Assurance Program Requirements for Nuclear Facilities," (Reference 7), as endorsed by NRC Regulatory Guide (RG) 1.28, "Quality Assurance Program Criteria (Design and Construction)," Revision 5 (Reference 8).

2.0 REGULATORY EVALUATION

The Commission's regulatory requirements related to quality assurance (QA) programs are set forth in Appendix A, "General Design Criteria for Nuclear Power Plants," General Design

Enclosure

Criterion 1 (GDC 1), "Quality standards and records," to 10 CFR Part 50, which requires that a QA program be established and implemented, 10 CFR 52.47(a)(19), "Contents of applications; technical information," and Appendix B to 10 CFR Part 50.

Under 10 CFR 52.47(a), a DC application must contain the technically relevant information in a final safety analysis report (FSAR) that describes the facility, presents the design bases and the limits on its operation, and presents a safety analysis of the structures, systems, and components (SSCs) and of the facility. Under 10 CFR 52.47(a)(8), a FSAR must include the information necessary to demonstrate compliance with any technically relevant portions of the Three Mile Island requirements set forth in 10 CFR 50.34(f), which includes information to address the applicant's technical qualifications and management structure and competence. Additionally, under 10 CFR 52.47(a)(19), the FSAR must include a description of the QA program to be applied to the design of the SSCs of the facility. In addition, 10 CFR 52.47(a)(19) requires that the description of the QA program for a nuclear power plant include a discussion of how the applicable requirements of Appendix B to 10 CFR Part 50 are satisfied. Appendix B to 10 CFR Part 50 establishes QA requirements for the design, fabrication, construction, and testing of SSCs for the facility. The pertinent requirements of Appendix B to 10 CFR Part 50 apply to all activities affecting the safety-related functions of those SSCs and include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying SSCs.

3.0 EVALUATION

In evaluating the adequacy of the X-Energy QAPD TR, the NRC staff utilized the guidance contained in Section 17.5 of the SRP, which provides guidance to the staff for the review of a QAPD for design certification, early site permit, combined license, construction permit, and operating license applicants. Section 17.5 of the SRP is based on Appendix B to 10 CFR Part 50 and describes regulatory and industry guidance determined to be acceptable methods for meeting the requirements of Appendix B to 10 CFR Part 50. The ASME standard NQA-1-2015 Edition, upon which the X-Energy QAPD is based, is endorsed with certain exceptions and clarifications by NRC in RG 1.28, Revision 5.

3.1 Quality Assurance Program Overview

Topical report XEQAPD, Revision 3, provides for the control of X-Energy's activities affecting the quality and performance of SSCs related to the design activities in support of a DC application for the Xe-100 nuclear power reactor.

3.1.1 Organization

The X-Energy QAPD conforms to SRP Section 17.5, Subsection II.A for providing an organizational description that includes an organizational structure, functional responsibilities, levels of authority, and interfaces for establishing, executing, and verifying the implementation of X-Energy's QA program. The X-Energy QAPD establishes independence between the organization performing checking functions related to the QA program and the organization responsible for performing the functions. The X-Energy QAPD also provides for management to be responsible to size the QA organization commensurate with the duties and responsibilities assigned. In addition, responsibility and authority for planning, establishing, and implementing an effective overall QA program are clearly described and defined, including identifying the person responsible for directing and managing the onsite QA program.

The X-Energy QAPD provides the authority and responsibility to stop work in progress not being done in accordance with approved procedures or where safety of personnel or SSC integrity may be jeopardized.

The X-Energy QAPD commits to the quality standards described in NQA-1-2015, Requirement 1, "Organization," without further clarifications or exceptions. The NRC staff determined that X-Energy's organization controls as described above comply with the requirements of Criterion I, "Organization," of Appendix B to 10 CFR Part 50, and therefore, are acceptable.

3.1.2 Quality Assurance Program

The X-Energy QAPD conforms to SRP Section 17.5, Subsection II.B for establishing the necessary measures to implement a QA program to ensure that the design of X-Energy's Xe-100 nuclear power reactor is in accordance with governing regulations and license requirements. The QA program applies to those quality-related activities that involve the functions of SSCs associated with the design (including DC activities) of X-Energy's Xe-100 nuclear power reactor, the fuel characterization, and to the managerial and administrative controls to be used to assure the X-Energy's Xe-100 nuclear power reactor complies with the applicable regulatory requirements. Examples of DC program safety-related activities include, but are not limited to, basic and detail design, determination of SSC safety classification, design configuration management, and document control. A list or system used to identify which SSCs and activities the QA program applies to is maintained at X-Energy. In addition, X-Energy may delegate all or part of the activities associated with planning, establishing, and implementing the QA program, but retains responsibility for its effectiveness.

The X-Energy QAPD provides measures to assess the adequacy of the QA program to assure its effective implementation at least once each year or at least during the life of the activity, whichever is shorter. In addition, X-Energy's QA program applies a grace period of 90 days to scheduled audits and annual evaluations of supplier performance. The grace period does not allow the "clock" for a particular activity to be reset forward. However, the "clock" for an activity is reset backward by performing the activity early. X-Energy may also delegate all or part of the activities of planning, establishing, and implementing the QA program for which they are responsible for to others, but retain the responsibility for the QA program's effectiveness.

The X-Energy QAPD conforms to SRP Section 17.5, paragraphs II.S and II.T, for describing the necessary measures to establish and maintain formal indoctrination and training programs for personnel performing, verifying, or maintaining activities within the scope of the QA program to assure that suitable proficiency is achieved and maintained. The X-Energy QAPD provides the minimum training requirements for all personnel responsible for implementation of X-Energy's QA program.

The X-Energy QAPD commits to the quality standards described in NQA-1-2015, Requirement 2, "Quality Assurance Program," as modified by the regulatory positions described in RG 1.28, Revision 5, without further clarifications or exceptions. The NRC staff determined that X-Energy's QA program controls as described above comply with the requirements of Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50, and therefore, are acceptable.

3.1.3 Design Control

The X-Energy QAPD conforms to SRP Section 17.5, Subsection II.C, for establishing the necessary measures to control the design, design changes, and temporary modifications of

items that are subject to the provisions of the QA program. The X-Energy design process includes provisions to control design inputs, outputs, changes, interfaces, records, and organizational interfaces within X-Energy and with its suppliers. These provisions assure that design inputs (e.g., design bases and the performance, regulatory, quality, and quality verification requirements) are correctly translated into design outputs (e.g., analyses, specifications, drawings, procedures, and instructions). In addition, X-Energy's QAPD provides for design documents to be reviewed by individuals knowledgeable in QA to ensure that the documents contain the necessary QA requirements.

The X-Energy QAPD provides 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 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. Verification methods may include, but are not limited to, design reviews, alternative calculations, and qualification testing.

The X-Energy 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 nonsafety-related applications. Pre-verified computer programs are controlled using a software configuration management process. X-Energy and its suppliers are responsible for developing, approving, and issuing procedures, as necessary, to control the use of such computer application and digital equipment software. Procedures require that the application software be assigned a proper quality classification and that the associated quality requirements be consistent with this classification.

The X-Energy QAPD commits to the quality standards described in NQA-1-2015, Requirement 3, "Design Control," Subpart 2.7, "Quality Assurance Requirements for Computer Software for Nuclear Facility Applications," and Subpart 2.14, "Quality Assurance Requirements for Commercial-Grade Items and Services," without further clarifications or exceptions. The NRC staff determined that X-Energy's design controls as described above comply with the requirements of Criterion III, "Design Control," of Appendix B to 10 CFR Part 50, and therefore, are acceptable.

3.1.4 Procurement Document Control

The X-Energy QAPD conforms to SRP Section 17.5, Subsection II.D, for establishing the necessary administrative controls and processes to ensure that applicable regulatory, technical, and QA program requirements are included or referenced in procurement documents. The applicable technical, regulatory, administrative, quality, and reporting requirements (e.g., specifications, codes, standards, tests, inspections, special processes, and 10 CFR Part 21, "Reporting of Defects and Noncompliance") are invoked for the procurement of items and services. In addition, X-Energy's QAPD states that procurement documents require suppliers to have a documented QA program that meets the applicable requirements of Appendix B to 10 CFR Part 50, as necessary based on the procurement scope or, alternatively, the QAPD allows the supplier to work under X-Energy's approved QA program.

The X-Energy QAPD commits to the quality standards described in NQA-1-2015, Requirement 4, "Procurement Document Control," with the following clarifications and exceptions:

- With regards to service performed by a supplier, X-Energy's procurement documents may allow the supplier to work under X-Energy's QA program, including implementing procedures, in lieu of the supplier having its own QA program.

The NRC staff evaluated this proposed alternative and determined that it provides adequate control for establishing and executing the responsibilities for the QA program. In addition, Criterion IV, "Procurement Document Control," of Appendix B to 10 CFR Part 50, requires suppliers to have a QA program consistent with the regulations. Therefore, the NRC staff concluded that this alternative is acceptable.

- Sections 300, "Procurement Document Review," and 400, "Procurement Document Changes," of Requirement 4, require the review of technical and QA program requirements of procurement documents prior to award of a contract and for procurement document changes. X-Energy is proposing to satisfy this requirement through the review of the procurement specification, when the specification contains the technical and QA requirements of the procurement.

The NRC staff evaluated this proposed alternative and determined that it provides adequate QA review of procurement documents before awarding the contract and after any change to the contract. Therefore, the NRC staff concluded that this alternative is acceptable.

- 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 Section 7, "Control of Purchased Material, Equipment, and Services," of X-Energy's QAPD.

The NRC staff evaluated this proposed alternative and determined that is consistent with NRC staff guidance provided in Generic Letter (GL) 89-02, "Actions to Improve the detection of Counterfeit and Fraudulently Marked Products," dated March 21, 1989, and GL 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs," dated April 9, 1991, as delineated in SRP Section 17.5, paragraphs II.V.1.d and II.V.1.e.

The NRC staff determined that X-Energy's procurement document controls as described above comply with the requirements of Criterion IV of Appendix B to 10 CFR Part 50, and therefore, are acceptable.

3.1.5 Instructions, Procedures, and Drawings

The X-Energy QAPD conforms to SRP Section 17.5, Subsection II.E, for establishing 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 QA program as described in X-Energy's QAPD.

The X-Energy QAPD commits to the quality standards described in NQA-1-2015, Requirement 5, "Instructions, Procedures, and Drawings," without further clarifications or exceptions. The NRC staff determined that X-Energy's controls for instructions, procedures, and drawings as

described above comply with the requirements of Criterion V, "Instructions, Procedures, and Drawings," of Appendix B to 10 CFR Part 50, and therefore, are acceptable.

3.1.6 Document Control

The X-Energy QAPD conforms to SRP Section 17.5, Subsection II.F, for establishing 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, are controlled. X-Energy's QAPD provides measures to assure that documents, including revisions or changes (other than those defined in implementing procedures as minor changes), are reviewed and approved by the same organization that performed the original review and approval unless other organizations are specifically designated. X-Energy maintains a list of all controlled documents, identifying the current approved revision or date, so personnel can determine the appropriate document for use.

The X-Energy QAPD commits to the quality standards described in NQA-1-2015, Requirement 6, "Document Control," without further clarifications or exceptions. The NRC staff determined that X-Energy's document controls as described above comply with the requirements of Criterion VI, "Document Control," of Appendix B to 10 CFR Part 50, and therefore, are acceptable.

3.1.7 Control of Purchased Material, Equipment, and Services

The X-Energy QAPD conforms to SRP Section 17.5, Subsection II.G, for establishing the necessary measures and governing procedures to control the procurement of items and services to ensure conformance with specified requirements. These measures provide for the evaluation of prospective suppliers and selection of qualified suppliers only, evaluation of objective evidence of on-going acceptable quality furnished by the supplier, source verification and inspection, audit, and examination of items or services.

The X-Energy QAPD 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. In addition, X-Energy's QAPD provides for auditing and evaluating suppliers to ensure that qualified suppliers continue to provide acceptable products and services.

The X-Energy QAPD provides for utilizing audits conducted by outside organizations such as National Laboratories for supplier qualification provided that the scope and adequacy of the audits meet X-Energy's requirements. Industry programs applied as input or the basis for supplier qualification may include ASME NQA-1 and the International Standard Organization (ISO)/International Electrotechnical Commission (IEC) 17025, "General Requirements for the Competence of Testing and Calibration Laboratories." X-Energy plans to use suppliers to perform irradiation testing and will ensure that these suppliers are implementing a QA program that meets the requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21. X-Energy will also perform annual evaluations of qualified suppliers to document that these suppliers continue to provide acceptable products and services.

The X-Energy QAPD provides for using source verification, receipt inspection, pre- and post-installation tests, certificates of conformance, and review of documentation (e.g., Certified

Material Test Reports/Certificates) for accepting purchased items and services. In addition, controls are implemented for the selection, determination of suitability for intended use (critical characteristics), evaluation, receipt, and acceptance of commercial-grade services or items to assure they will perform satisfactorily in service in safety-related applications.

The X-Energy QAPD commits to implement the quality standards described in NQA-1-2015, Requirement 7, "Control of Purchased Items and Services," Subpart 2.14, "Quality Assurance Requirements for Commercial Grade Items and Services," and the regulatory positions described in RG 1.28, Revision 5, with the following clarifications and exceptions:

- X-Energy considers that 10 CFR Part 50 and 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants" licensees, Authorized Nuclear Inspection (ANI) agencies, National Institute of Standards and Technology (NIST), or other State and Federal agencies, which may provide items or services to X-Energy, are not required to be evaluated or audited.

The NRC staff acknowledges that 10 CFR Part 50 and 10 CFR Part 52 licensees, ANI agencies, NIST, or other State and Federal agencies work under their own quality programs, and no additional audit or evaluation is required by X-Energy. The NRC staff determined that this approach is acceptable for DC applicants as these are organizations known to the NRC to have QA programs that meet the requirements of Appendix B to 10 CFR Part 50 or are organizations with proven abilities and disciplines. However, X-Energy is still responsible for ensuring that the items and services procured conform to the applicable criteria in Appendix B to 10 CFR Part 50, ASME B&PV Code requirements, and other regulatory requirements and commitments. X-Energy is also responsible for ensuring that procured items or services are suitable for the intended application, as well as for documenting the associated evaluation.

The NRC staff evaluated this proposed alternative and determined that it provides an appropriate level of quality and safety. Therefore, the NRC staff concluded that this alternative is acceptable.

- X-Energy will implement the guidance from Nuclear Energy Institute (NEI) 14-05, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," Revision 1 (Reference 8), for using the International Laboratory Accreditation (ILAC) accreditation process in lieu of performing commercial-grade surveys as part of the commercial-grade dedication process. In an SE dated February 9, 2015 (Reference 9), the NRC staff concluded that NEI 14-05, Revision 1, provides an acceptable approach for licensees and suppliers of basic components for using the ILAC accreditation process in lieu of performing commercial-grade surveys as part of the commercial-grade dedication process.

The NRC staff evaluated this proposed alternative and determined that it is consistent with the NRC's current regulatory position regarding the acceptability of procuring commercial-grade calibration and testing services from laboratories accredited by ILAC. Therefore, the NRC staff concluded that this alternative is acceptable.

- Section 501, "General," of Requirement 7, requires documentary evidence showing that items conform to procurement requirements shall be available at the nuclear facility site prior to installation or use. 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 this

requirement. Following completion of the construction period, sufficient as-built documentation will be turned over to X-Energy to support operations. X-Energy's records management system will provide for timely retrieval of necessary records.

The NRC staff evaluated this proposed alternative and determined that this alternative meets Criterion VII, "Control of Purchased Material, Equipment, and Services" of Appendix B to 10 CFR Part 50. Criterion VII requires documentary evidence that items conform to procurement documents to be available at the nuclear facility before installation or use. This provision would allow for accessing and reviewing the necessary procurement documents at the site before installation and use. Therefore, the NRC staff concluded that this alternative is acceptable.

- For commercial-grade items, quality verification requirements are established and described in X-Energy's documents to provide the necessary assurance an item will perform satisfactorily in service. X-Energy's 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.

The NRC staff evaluated this clarification and determined that the controls for commercial-grade dedication conform to SRP Section 17.5. Therefore, the NRC staff concluded that this clarification is acceptable.

- X-Energy will assume 10 CFR Part 21 reporting responsibility for all items that X-Energy dedicates as safety-related.

The purpose of 10 CFR Part 21 states that any individual director or responsible officer of a firm constructing, owning, operating, or supplying the components of any licensed or regulated facility or activity, who obtains information reasonably indicating: (a) that the facility, activity or basic component supplied to such facility or activity fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to substantial safety hazards; or (b) that the facility, activity, or basic component supplied to such facility or activity contains defects, which could create a substantial safety hazard, must immediately notify the Commission of such failure to comply or such defect, unless he has actual knowledge that the Commission has been adequately informed of such defect or failure to comply.

The NRC staff evaluated this clarification and determined that it ensures that 10 CFR Part 21 reportability requirements encompass all items that are dedicated as safety-related and does not remove the supplier's responsibilities under Part 21. Therefore, the NRC staff concluded that this clarification is acceptable.

The NRC staff determined that X-Energy's controls for purchased material, equipment, and services as described above comply with the requirements of Criterion VII, of Appendix B to 10 CFR Part 50, and therefore, are acceptable.

3.1.8 Identification and Control of Materials, Parts, and Components

The X-Energy QAPD conforms to SRP Section 17.5, Subsection II.H, for establishing the necessary measures and governing procedures to identify and control items to prevent the use of incorrect or defective items as X-Energy will be purchasing materials, parts and components for testing purposes (includes fuel and graphite irradiation testing that will be performed by X-Energy's suppliers). Identification and control measures include controls for consumable

materials and items with a limited shelf-life. Identification of items is maintained throughout fabrication, erection, installation, and use so that the materials, parts or components can be traced back to its documentation, consistent with the item's effect on safety. The location and identification methods are selected so the function or quality of the item being identified is not affected.

The X-Energy QAPD commits to the quality standards described in NQA-1-2015, Requirement 8, "Identification and Control of Items," without further clarifications or exceptions. The NRC staff determined that X-Energy's identification and controls for materials, parts, and components as described above comply with the requirements of Criterion VIII, "Identification and Control of Materials, Parts, and Components," of Appendix B to 10 CFR Part 50, and therefore, are acceptable.

3.1.9 Control of Special Processes

The X-Energy QAPD conforms to SRP Section 17.5, Subsection II.I, for establishing the necessary measures and governing procedures to assure that special processes such as welding, heat treating, and non-destructive examination are controlled as X-Energy's suppliers will be performing destructive and non-destructive testing for test purposes (includes fuel and graphite irradiation testing). Special processes are accomplished by qualified personnel using qualified procedures and equipment, and in accordance with applicable codes, standards, specifications, criteria, or other special requirements. Qualification records of personnel are controlled and retained.

The X-Energy QAPD commits to the quality standards described in NQA-1-2015, Requirement 9, "Control of Special Processes," without further clarifications or exceptions. The NRC staff determined that X-Energy's control of special processes as described above comply with the requirements of Criterion IX, "Control of Special Processes," of Appendix B to 10 CFR Part 50, and therefore, are acceptable.

3.1.10 Inspection

The X-Energy QAPD conforms to SRP Section 17.5, Subsection II.J, for establishing the necessary measures and governing procedures to implement inspections that assure items, services, and activities affecting safety meet established requirements and conform to applicable documented specifications, instructions, procedures, and design documents as 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). Types of inspections may include source, in-process, final, and receipt inspection. These types of inspections will be performed by properly qualified personnel independent of those who performed or directly supervised the work, as well as including the documentation of inspection results.

X-Energy's inspection program establishes requirements for planning the inspections such as: (1) the party responsible for performing the inspection; (2) application of hold points; (3) acceptance criteria; (4) frequency of inspections; (5) and the identification of special tools required to perform the inspection. Inspection plans are based on: (1) the importance of the item to safety; (2) complexity of the item; (3) technical requirements to be met; and (4) design specifications. Inspection information and results, such as rejection, acceptance criteria, re-inspection results, and the person(s) performing the inspection are documented. The documentation of this information is responsibility of the inspector, reviewed by authorized

personnel qualified to evaluate the technical adequacy of the inspection results, and controlled by instructions, procedures, and drawings.

The X-Energy QAPD commits to the quality standards described in NQA-1-2015, Requirement 10, "Inspection," without further clarifications or exceptions. The NRC staff determined that X-Energy's inspection controls as described above comply with the requirements of Criterion X, "Inspection," of Appendix B to 10 CFR Part 50, and therefore, are acceptable.

3.1.11 Test Control

The X-Energy QAPD conforms to SRP Section 17.5, Subsection II.K, for establishing the necessary measures and governing procedures to demonstrate that items subject to the provisions of the QAPD will perform satisfactorily in service as X-Energy's suppliers will be performing testing (includes graphite and irradiation testing). Test programs include criteria for determining when testing is required in order to demonstrate that performance of equipment and plant systems are in accordance with the design. Test programs also include provisions to establish and adjust test schedules, and to maintain status for periodic or recurring tests when applicable. Tests are performed according to applicable procedures that include, consistent with the effect on safety: (1) instructions and prerequisites to perform the tests; (2) use of proper test equipment; (3) acceptance criteria; and (4) mandatory verification points as necessary to confirm satisfactory test completion; (5) adequate test instrumentation is available; and (6) testing is performed under suitable environmental testing 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.

The X-Energy QAPD commits to the quality standards described in NQA-1-2015, Requirement 11, "Test Control," and Subpart 2.7, "Quality Assurance Requirements for Computer Software for Nuclear Facility Applications," without further clarifications or exceptions. The NRC staff determined that X-Energy's testing controls as described above comply with the requirements of Criterion XI, "Test Control," of Appendix B to 10 CFR Part 50, and therefore, are acceptable.

3.1.12 Control of Measuring and Test Equipment

The X-Energy QAPD conforms to SRP Section 17.5, Subsection II.L, for establishing 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 as X-Energy's suppliers will be performing destructive and non-destructive testing (NDT) for test purposes (includes fuel and irradiation testing). The M&TE is labeled, tagged, or otherwise controlled to indicate its calibration status and to ensure its traceability to calibration test data. The types of equipment covered by the program (e.g., instruments, tools, gages, reference and transfer standards, and non-destructive examination equipment) are defined.

The M&TE are 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. The M&TE found out of calibration is tagged or segregated and not used until it is recalibrated. When M&TE is found out of calibration, an evaluation is performed and documented to determine the validity of previous inspection or test results and of the acceptability of items previously inspected or tested with that equipment. If any M&TE is consistently found out of calibration, it is repaired or replaced. A calibration is performed when the accuracy of the equipment is suspect.

The X-Energy QAPD commits to the quality standards described in NQA-1-2015, Requirement 12, "Control of Measuring and Test Equipment," without further clarifications or exceptions. The NRC staff determined that X-Energy's controls for M&TE as described above comply with the requirements of Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50, and therefore, are acceptable.

3.1.13 Handling, Storage, and Shipping

The X-Energy QAPD conforms to SRP Section 17.5, Subsection II.M, for establishing the necessary measures and governing procedures to control the handling, storage, packaging, shipping, cleaning, and preservation of test and irradiated items to prevent inadvertent damage or loss, and to minimize deterioration as X-Energy's suppliers will perform testing and irradiation for test purposes (includes fuel and graphite irradiation testing). Items are appropriately marked and labeled during packaging, shipping, handling, and storage to identify, maintain, and preserve the item's integrity and provide indication of the needs for special controls. Any special controls (i.e., shock absorbers, inert gas atmospheres, temperature levels, etc.) are provided when required. In addition, any special or additional handling, storage, shipping, cleaning, and preservation requirements are identified in the procurement documents. Special handling tools and equipment are controlled to ensure safe and adequate handling. These special tools and handling equipment are inspected and tested in accordance with procedures at specified time intervals or prior to use. In addition, cleanliness controls are provided to ensure that the quality of items is not degraded.

The X-Energy QAPD commits to the quality standards described in NQA-1-2015, Requirement 13, "Handling, Storage, and Shipping," without further clarifications or exceptions. The NRC staff determined that X-Energy's controls for handling, storage, and shipping as described above comply with the requirements of Criterion XIII, "Handling, Storage, and Shipping" of Appendix B to 10 CFR Part 50, and therefore, are acceptable.

3.1.14 Inspection, Test, and Operating Status

The X-Energy QAPD conforms to SRP Section 17.5, Subsection II.N, for establishing 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 as X-Energy's suppliers will perform testing and irradiation for test purposes (includes fuel and graphite irradiation testing). Measures are provided for the verification of inspections, tests, and operating status to preclude bypassing of inspection or tests. Temporary design modifications are controlled by procedures which incorporate the applicable requirements.

The X-Energy QAPD commits to the quality standards described in NQA-1-2015, Requirement 14, "Inspection, Test, and Operating Status" without further clarifications or exceptions. The NRC staff determined that X-Energy's inspection, test, and operating status controls as described above comply with the requirements of Criterion XIV, "Inspection, Test, and Operating Status," of Appendix B to 10 CFR Part 50, and therefore, are acceptable.

3.1.15 Nonconforming Materials, Parts, or Components

The X-Energy QAPD conforms to SRP Section 17.5, Subsection II.O, for establishing the necessary measures and governing procedures to control items, including services that do not

conform to specified requirements, to prevent inadvertent installation or use as X-Energy suppliers will be performing destructive and NDT for test purposes (includes fuel and graphite irradiation testing). Controls provide for the identification, documentation, evaluation, segregation (when practical), disposition of nonconforming items, and notification to affected organizations. Nonconforming items are corrected or resolved before relying on the item to perform its intended safety function.

Nonconforming items are evaluated for impact on the operability of quality SSCs to ensure that the final condition does not adversely affect safety, operation, or maintenance of the item or service. Non-conforming items which are dispositioned "repair" or "use-as-is" are subject to design control measures commensurate with those applied to the original design. Non-conformance dispositions are reviewed for adequacy, analysis of quality trends, and reported to designated management. Significant trends are reported to management in accordance with X-Energy's procedures, regulatory requirements, and industry standards.

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. 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. In addition, X-Energy's QAPD provides for establishing the appropriate interfaces between the QA program for identification and control of nonconforming materials, parts, or components, and the non-QA reporting program in order to satisfy the requirements of 10 CFR Part 52 and 10 CFR Part 21.

The X-Energy QAPD commits to the quality standards described in NQA-1-2015, Requirement 15, "Control of Nonconforming Items," without further clarifications or exceptions. The NRC staff determined that X-Energy's controls for nonconforming materials, parts, or components as described above comply with the requirements of Criterion XV, "Nonconforming Materials, Parts, or Components," of Appendix B to 10 CFR Part 50, and therefore, are acceptable.

3.1.16 Corrective Action

The X-Energy QAPD conforms to SRP Section 17.5, Subsection II.P, for establishing the necessary measures and governing procedures to promptly identify, control, document, classify, and correct conditions adverse to quality. X-Energy's QAPD provides for procedures to 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. The X-Energy QAPD also requires personnel to identify known conditions adverse to quality. 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.

The X-Energy QAPD provides for establishing the appropriate interfaces between the QA Program for corrective actions and the non-QA Reporting program to satisfy the requirements of 10 CFR Part 52 and 10 CFR Part 21 during the DC phase.

The X-Energy QAPD commits to the quality standards described in NQA-1-2015, Requirement 16, "Corrective Action," without further clarifications or exceptions. The NRC staff determined that X-Energy's corrective action controls as described above comply with the requirements of Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50, and therefore, are acceptable.

3.1.17 Quality Assurance Records

The X-Energy QAPD conforms to SRP Section 17.5, Subsection II.Q, for establishing the necessary measures to ensure that enough 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.

The X-Energy QAPD establishes measures to ensure that sufficient records (e.g., design, engineering, procurement, manufacturing, inspection, test, and audits) of completed items and activities affecting quality are appropriately stored. The records and retention times are based on Regulatory Position C.3.a of RG 1.28, Revision 5. In all cases where state, local, or other agencies have more restrictive requirements for record retention, X-Energy's QAPD clarified that those requirements will be met.

When using optical disks for electronic records storage and retrieval systems, X-Energy's QAPD complies with the NRC guidance provided in NRC's GL 88-18, "Plant Record Storage on Optical Disks," Regulatory Issue Summary (RIS) 2000-18, "Guidance on Managing Quality Assurance Records in Electronic Media," and the associated Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guidelines (TG), including TG 11-2011, "Authentication of Records and Media," TG 15-2011, "Management of Electronic Records," TG 16-2011, "Software Configuration Management and Quality Assurance," and TG 21-2011, "Electronic Records Protection and Restoration."

The X-Energy QAPD commits to the quality standards described in NQA-1-2015, Requirement 17, "Quality Assurance Records," and the regulatory positions described in RG 1.28, Revision 5, without further clarifications or exceptions. The NRC staff determined that X-Energy's controls for QA records as described above comply with the requirements of Criterion XVII, "Quality Assurance Records," of Appendix B to 10 CFR Part 50, and therefore, are acceptable.

3.1.18 Audits

The X-Energy QAPD conforms to SRP Section 17.5, Subsection II.R, for establishing the necessary measures 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 program is also reviewed for effectiveness as part of the overall audit process.

The X-Energy QAPD provides for conducting periodic internal and external audits. Internal audits are conducted to determine the adequacy of programs and procedures, and to determine if they are meaningful and comply with the overall X-Energy QA program. Internal audits are performed in such a manner as to assure 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. 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 X-Energy's Safety, Health, Environmental and Quality Director. External audits determine the adequacy of a supplier's QA program and are conducted as described in Section 7 of X-Energy's QAPD and Section 3.1.7 of this SE.

The X-Energy QAPD provides for all audit results to be documented and reviewed by responsible management. Management responds to all audit findings and initiates corrective actions where indicated. In addition, where corrective actions are indicated, a documented follow-up of the applicable areas through inspections, review, re-audits, or other appropriate means is conducted to verify the implementation and effectiveness of the assigned corrective actions.

The X-Energy QAPD commits to the quality standards described in NQA-1-2015, Requirement 18, "Audits," and the regulatory positions described in RG 1.28, Revision 5, without further clarifications or exceptions. The NRC staff determined that X-Energy's QA controls for audits as described above comply with the requirements of Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50, and therefore, are acceptable.

3.2 NonSafety-Related SSC Quality Control

3.2.1 NonSafety-Related SSCs - Significant Contributors to Plant Safety

The X-Energy QAPD conforms to SRP Section 17.5, Paragraph II.U.1, for establishing specific program controls applied to nonsafety-related SSCs that are significant contributors to plant safety, for which the requirements of Appendix B to 10 CFR Part 50 are not applicable. The X-Energy QAPD applies specific controls to those items in a selected manner, targeted at those characteristics or critical attributes that render the SSC a significant contributor to plant safety, consistent with applicable sections of X-Energy's QAPD.

3.2.2 NonSafety-Related SSCs Credited for Regulatory Events

In establishing the quality requirements for nonsafety-related SSCs credited for regulatory events, X-Energy's QAPD conforms to SRP Section 17.5, Paragraph II.U.2, and X-Energy commits to the following regulatory guidance:

- The quality requirements for anticipated transient without scram (ATWS) equipment in accordance with NRC's GL 85-06, "Quality Assurance Guidance for ATWS Equipment That Is Not Safety-Related," dated January 16, 1985 (Reference 10).
- The quality requirements for station blackout (SBO) equipment in accordance with Regulatory Position 3.5, "Quality Assurance and Specific Guidance for SBO Equipment That Is Not Safety-Related," and Appendix A, "Quality Assurance Guidance for Non-Safety Systems and Equipment," in RG 1.155, "Station Blackout," dated August 1988 (Reference 11).

3.3 Regulatory Commitments

The X-Energy QAPD conforms to SRP Section 17.5, paragraph II.V, for establishing QA program commitments. X-Energy commits to comply with the following NRC RGs and other QA standards to supplement and support the QA program, as applicable:

- RG 1.28, "Quality Assurance Program Criteria (Design and Construction)," Revision 5, dated October 2017. RG 1.28 describes a method acceptable to the NRC staff for complying with the provisions of Appendix B to 10 CFR Part 50 with regards to establishing and implementing the requisite QA program for the design of nuclear power plants.
- ASME NQA-1-2015, "Quality Assurance Requirements for Nuclear Facility Applications," Part I, "Requirements for Quality Assurance Programs for Nuclear Facilities," and Part II, "Quality Assurance Requirements for Nuclear Facility Applications," as described above in Sections 3.1.1 through 3.1.18 of this SE.
- NEI 14-05, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," Revision 1, as described in Section 3.1.7 of this SE.
- NIRMAs TGs 11-2011, 15-2011, 16-2011, and 21-2011 as described in Section 3.1.17 of this SE.

For the RGs listed below, X-Energy stated that conformance and exceptions for the applicable regulatory position guidance provided in the RGs would be identified in the DC application. The NRC staff acknowledges that because of the substantial differences between X-Energy's plant design and a light water reactor design, direct commitment to these RGs may not be appropriate. Therefore, the NRC staff identified that the review of X-Energy's commitments and exceptions to the RGs listed below were not assessed as part of this review and will be addressed as part of the DC application review.

- RG 1.26, "Quality Group Classifications and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants," Revision 5, dated February 2017. RG 1.26 defines classification of systems and components.
- RG 1.29, "Seismic Design Classification for Nuclear Power Plants," Revision 5, dated July 2016. RG 1.29 defines the systems required to withstand a safe shutdown earthquake.
- RG 1.54, "Service Level I, II, and III Protective Coatings Applied to Nuclear Power Plants," Revision 3, April 2017. RG 1.54 provides guidance for the application of protective coatings within nuclear power plants to protect surfaces from corrosion, contamination from radionuclides, and for wear protection.
- RG 1.164, "Dedication of Commercial-Grade Items for Use in Nuclear Power Plants," Revision 0, dated June 2017. RG 1.164 describes methods acceptable to the NRC staff for complying with the regulatory requirements for dedication of commercial-grade items and services used in nuclear power plants.

- RG 1.231, "Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Safety-Related Applications for Nuclear Power Plants," Revision 0, dated January 2017. RG 1.231 describes methods acceptable to the NRC staff for complying with the regulatory requirements for acceptance and dedication of commercial-grade design and analysis computer programs used in safety-related applications for nuclear power plants.
- RG 1.234, "Evaluating Deviations and Reporting Defects and Noncompliance Under 10 CFR Part 21," Revision 0, dated April 2018. RG 1.234 describes methods acceptable to the NRC staff for complying with the provisions of 10 CFR Part 21.

4.0 CONCLUSION

The X-Energy QAPD delineates the policies, processes, and controls established by X-Energy and associated implementing documents relative to U.S. domestic licensing requirements for nuclear power plants. Together, the QA program documents defined in the QAPD provide for control of X-Energy's activities that affect the quality of safety-related nuclear plant SSCs and include all planned and systematic activities necessary to provide adequate confidence that such SSCs will perform satisfactorily in service.

The X-Energy QAPD may also be applied to certain equipment and activities that are not safety-related, but support safe plant operations, or where other NRC guidance establishes program requirements.

The X-Energy QAPD conforms to the format of SRP Section 17.5. The NRC staff used the acceptance criteria of SRP Section 17.5 as the basis for evaluating the compliance of X-Energy's QAPD with the provisions of GDC 1, 10 CFR 52.47(a)(19), and Appendix B to 10 CFR Part 50. On the basis of its review of the X-Energy QAPD, the NRC staff concludes that:

- The X-Energy QAPD adequately describes the authority and responsibility of management and supervisory personnel, performance and verification personnel, and self-assessment personnel, in relation to activities to which the X-Energy QA program is applicable.
- The X-Energy QAPD adequately provides for organizations and personnel to perform verification and self-assessment functions related to X-Energy's activities that affect the quality of safety-related nuclear plant SSCs, as well as select nonsafety-related SSCs, with these organizations and personnel having the authority and independence to conduct activities without undue influence from those directly responsible for costs and schedules.
- The X-Energy QAPD adequately applies to activities and items that are important to safety.
- The X-Energy QAPD adequately establishes controls that, when properly implemented, comply with the requirements of 10 CFR Part 52, Appendix B to 10 CFR 50, and 10 CFR Part 21, consistent with the criteria contained in SRP Section 17.5, as well as the relevant regulatory guidance.

On the basis of its review, as documented above, the NRC staff determined that X-Energy's QAPD adequately describes X-Energy's QA program. Accordingly, the NRC staff concludes that X-Energy's QA program complies with the applicable NRC regulations and industry standards and can be used by X-Energy for activities associated with a DC application for the Xe-100 nuclear power reactor.

Principal Contributor: Yamir Diaz-Castillo

Date:

5.0 REFERENCES

1. Letter from Harlan Bowers, President, X-Energy, to the NRC Document Control Desk, "Submittal of X-Energy, LLC (X-energy) Quality Assurance Program Description (QAPD) for Design Certification of the X-energy Xe-100 Reactor - Non-Proprietary," dated July 31, 2019 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19213A059)
2. NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," Section 17.5, "Quality Assurance Program Description – Design Certification, Early Site Permit and New License Applicants," Revision 1, dated August 2015 (ADAMS Accession No. ML15037A441)
3. Letter from Harlan Bowers, President, X-Energy, to the NRC Document Control Desk, "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," dated February 3 2020 (ADAMS Accession No. ML20035E617)
4. Letter from Harlan Bowers, President, X-Energy, to the NRC Document Control Desk, "Submittal of Revision 1 to X-Energy, LLC (X-energy) Quality Assurance Program Description (QAPD) for Design Certification of the X-energy Xe-100 Reactor - Non-Proprietary," dated February 21, 2020 (ADAMS Accession No. ML20052C884)
5. Letter from Harlan Bowers, President, X-Energy, to the NRC Document Control Desk, "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," dated April 8, 2020 (ADAMS Accession No. ML20104C134)
6. Letter from Martin Van Staden, VP Design Engineering, X Energy, to the NRC Document Control Desk, "Topical Report Submittal, Revision 3 to Quality Assurance Program Description (QAPD) for Design Certification of the X-energy Xe-100 Reactor - Non-Proprietary," dated August 7, 2020 (ADAMS Accession No. ML20220A413)
7. American Society of Mechanical Engineers NQA-1-2015, "Quality Assurance Program Requirements for Nuclear Facilities," New York, NY, dated February 20, 2015
8. Regulatory Guide (RG) 1.28, "Quality Assurance Program Criteria (Design and Construction)," Revision 5, dated October 2017 (ADAMS Accession No. ML17207A293)
9. NEI 14-05A, "Guidelines for the Use of Accreditation in Lieu of Commercial-Grade Surveys for Procurement of Laboratory Calibration and Test Services," Revision 0 (ADAMS Accession No. ML15075A434)
10. Final Safety Evaluation for Technical Report NEI 14-05, "Guidelines for the Use of Accreditation in Lieu of Commercial-Grade Surveys for Procurement of Laboratory Calibration and Test Services," Revision 1, dated February 9, 2015 (ADAMS Accession No. ML14322A535)

11. Generic Letter 85-06, "Quality Assurance Guidance for ATWS Equipment That Is Not Safety-Related," dated April 16, 1985 (ADAMS Accession No. ML031140390)
12. RG 1.155, "Station Blackout," dated August 1988 (ADAMS Accession No. ML003740034)
13. Letter from Benjamin Beasley, NRC, to Harlan Bowers, X-Energy, LLC, 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) (ADAMS Accession No. ML20140A333)



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Section B



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February 03, 2020

XE00-Q-Q1ZZ-RDZZ-L_000229_Rev 1

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Rockville, MD 20852-2738

SUBJECT: 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

REFERENCES:

1. Regulatory Engagement Plan for X Energy, LLC's Xe-100 Reactor with schedule for Pre-Application Submittals (XE00-R-R1ZZ-RDZZ-L_000210_Rev 1, June 28, 2019)
2. X Energy, LLC TR QAPD Submittal (XE00-R-R1ZZ-RDZZ-L_000211_Rev 1, July 31, 2019)
3. Letter (ML20013G253) 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 (January 13, 2020)

In a letter dated July 31, 2019, X Energy, LLC (X-energy) submitted the topical report entitled "Submittal of X Energy, LLC (X-energy) Quality Assurance Program Description (QAPD) for Design Certification of the X-energy Xe-100 Reactor - Non-Proprietary (Reference 2). In a letter dated January 13, 2020 (Reference 3), the NRC Staff provided Requests for Additional Information (RAIs) regarding the subject topical report.

The purpose of this letter is to provide X-energy responses to the NRC RAIs. Enclosure 1 provides the X-energy responses to RAI-1 to RAI-14.

The information provided in Enclosure 1 is nonproprietary.

If you have any questions, please feel free to contact me at (301) 358-5678 Ext. 5678 or at hbowers@x-energy.com.

Sincerely,



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Enclosure 1: X-energy Response to NRC Request for Additional Information Letter (ML20013G253),
for XEQAPD 1.0_Quality Assurance Program Description Rev 0, for Design Certification
of the X-energy Xe-100 Reactor



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X Energy, LLC Response to NRC Requests for Additional Information Letter
(ML20013G253) for Review of TR Quality Assurance Program Description
(XEQAPD 1.0, Revision 0)

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Revision: 1

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ENCLOSURE 1

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



1. NRC RAI QUESTION NUMBER: RAI-1

NRC RAI Question

Criterion I, "Organization," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50 states, in part, "Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance [QA] program may take various forms, provided that the persons and organizations assigned the quality assurance functions have the required authority and organizational freedom."

NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition" (SRP), Section 17.5, "Quality Assurance Program Description— Design Certification, Early Site Permit and New License Applicants," Subsection II.A, "Organization," paragraph 11, states, in part, that "Management ensures that the size of the QA organization is commensurate with its duties and responsibilities."

Three-Mile Island (TMI)-related requirement 10 CFR 50.34(f)(3)(iii)(F), states, in part, that the quality assurance (QA) program be established based on consideration of sizing the QA staff commensurate with its duties and responsibilities. However, X-Energy's QAPD Section 1, "Organization," does not provide a requirement to ensure the adequate sizing of the QA organization.

Clarify how X-Energy will implement measures to ensure that the size of the QA organization is commensurate with its duties and responsibilities in order to meet the TMI-related requirement.

X-energy RAI Question Response

X-energy will comply and include a sentence in X-energy's QAPD Section 1, "Organization," to the effect "The X-energy quality assurance function is responsible to size the quality assurance staff commensurate with the duties and responsibilities assigned."

Corresponding QAPD update to implement the response

PART II QUALITY ASSURANCE PROGRAM DESCRIPTION DETAILS

SECTION 1 ORGANIZATION

This section describes the X-energy organizational structure, functional responsibilities, levels of authority and interfaces for establishing, executing, and verifying QAPD implementation. The organizational structure includes corporate/support and on-site functions required to support the activities associated with license preparation, NRC review of the license application, and NRC rulemaking 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 ensures that the size of the QA organization is commensurate with its duties and responsibilities assigned. Management gives careful consideration to the timing, extent, and effects of organizational structure changes.



2. NRC RAI QUESTION NUMBER: RAI-2

NRC RAI Question

In 10 CFR 50.4(b)(7)(ii), the NRC states, "A change to an NRC-accepted quality assurance topical report from nonlicensees (i.e., architect/engineers, NSSS suppliers, fuel suppliers, constructors, etc.) must be submitted to the NRC's Document Control Desk. If the communication is on paper, the signed original must be sent."

In 10 CFR 52.47(a)(19), the NRC states that "A description of the quality assurance program applied to the design of the structures, systems, and components of the facility. Appendix B to 10 CFR part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," sets forth the requirements for quality assurance programs for nuclear power plants. The description of the quality assurance program for a nuclear power plant shall include a discussion of how the applicable requirements of Appendix B to 10 CFR Part 50 were satisfied."

X-Energy's QAPD Section 2.4, "Issuance and Revision to Quality Assurance Program," states, in part, that "Administrative control of the QAPD will be in accordance with 10 CFR Part 50.55(f)." However, 10 CFR 50.55(f) applies only to construction permits, early site permits, combined licenses, and manufacturing licenses.

Clarify why X-Energy is committing to the requirements of 10 CFR 50.55(f) instead of 10 CFR 50.4(b)(7)(ii).

X-energy RAI Question Response

X-energy will comply and update the sentence in X-energy's QAPD Section 2.4 by replacing 10 CFR Part 50.55(f) with 10 CFR 50.4(b)(7)(ii) in Section 2.4 to the effect "Administrative control of the QAPD will be in accordance with 10 CFR 50.4(b)(7)(ii)."

Corresponding QAPD update to implement the response

SECTION 2.4 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 the X-energy SHEQD to ensure that such changes do not degrade safety for previously approved quality assurance controls specified in the QAPD. This document shall be revised as appropriate to incorporate additional QA commitments that may be established during the DC application process. New revisions to the document will be reviewed, at a minimum, by the X-energy SHEQD and approved by the CEO.



3. NRC RAI QUESTION NUMBER: RAI-3

NRC RAI Question

Criterion II of Appendix B to 10 CFR Part 50 states, in part, “The program shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained.”

SRP Section 17.5, Subsection II.T, “Training and Qualification - Inspection and Test (Criterion II),” provides the training and qualification requirements for inspection and test personnel.

X-Energy’s QAPD Section 2.5, “Personnel Training and Qualifications,” does not provide a requirement for the training and qualification of inspection and test personnel.

Clarify how X-Energy’s QAPD is addressing the training and qualification requirements for inspection and test personnel.

X-energy RAI Question Response

X-energy will comply and include a sentence in X-energy’s QAPD Section 2.5 to the effect “X-energy ensures compliance of the training and qualification requirements for inspection and test personnel.”

Corresponding QAPD update to implement the response

SECTION 2.5 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, as appropriate:

- 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.
- X-energy also ensures compliance of the training and qualification requirements for inspection and test personnel.



4. NRC RAI QUESTION NUMBER: RAI-4

NRC RAI Question

Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50, states, in part, "The effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services." X-Energy's QAPD Section 7.1, "Acceptance of Item or Service," states, in part, that "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, such as those applied by ASME are used as input or the basis for supplier qualification whenever appropriate."

Clarify what type of outside organization and industry programs X-Energy will use as a basis for qualifying suppliers.

X-energy RAI Question Response

X-energy will change the sentence in X-energy's QAPD Section 7.1 to the effect "X-Energy may utilize audits conducted by outside organizations such as National Laboratories (e.g. INL and ORNL) 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. X-energy will be conducting testing at suppliers, (e.g. irradiation testing). Irrespective what QA program a supplier is using, X-energy will review and supplement supplier's programs where required to make them compliant with 10CFR 50 Appendix B in addition to ASME NQA-1 requirements that have been approved for that purpose. Furthermore, 10CFR21 requirements will be included as well."

Corresponding QAPD update to implement the response

SECTION 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, as appropriate, during DC activities. Verifications occur at the appropriate phases of the procurement process, including, as necessary, verification of activities of suppliers below the first tier.

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

- 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 as 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 such as National Laboratories (e.g. INL and ORNL) 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. Irradiation testing will be performed by X-energy suppliers and irrespective what QA program a supplier is using, X-energy will review, and supplement supplier's programs where required to make them compliant with 10CFR 50 Appendix B in addition to ASME NQA-1 requirements. Furthermore, 10CFR21 requirements will be included as well. Documented annual evaluations are performed for qualified suppliers to assure they continue to provide acceptable products and services. 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, as warranted). In addition, results are reviewed periodically to determine if, as a whole, they constitute a significant condition adverse to quality requiring additional action.

- 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, as applicable, have been satisfied before relying on the item to perform its intended safety function.
- 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 assure 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.



5. NRC RAI QUESTION NUMBER: RAI-5

NRC RAI Question

Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50, states, "Measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management."

X-Energy's QAPD Section 16.1, "Interface with the Reporting Program," states that "X-Energy has appropriate interfaces between the QAP for corrective actions and the non-QA Reporting Program to satisfy the requirements of 10 CFR 50.55, 10 CFR 52 and 10 CFR 21 during the DC phase."

10 CFR 55.55, "Conditions of Construction Permits, Early Site Permits, Combined Licenses, and Manufacturing Licenses," is not applicable to a DC application.

Clarify how the X-Energy will provide measures for identification, evaluation, and reporting of defects and noncompliance during design certification consistent with 10 CFR Part 21 and 10 CFR Part 52 requirements.

X-energy RAI Question Response

X-energy will comply and change the sentence in X-energy's QAPD Section 16.1 and remove the reference to 10 CFR 50.55 to the effect "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 and 10 CFR 21 during the DC phase."

Corresponding QAPD update to implement the response

SECTION 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 and 10 CFR 21 during the DC phase.



6. NRC RAI QUESTION NUMBER: RAI-6

NRC RAI Question

Criterion VIII, "Identification and Control of Materials, Parts, and Components," of Appendix B to 10 CFR Part 50, states, "Measures shall be established for the identification and control of materials, parts, and components, including partially fabricated assemblies. These measures shall assure that identification of the item is maintained by heat number, part number, serial number, or other appropriate means, either on the item or on records traceable to the item, as required throughout fabrication, erection, installation, and use of the item. These identification and control measures shall be designed to prevent the use of incorrect or defective material, parts, and components."

X-Energy's QAPD Section 8.1, "NQA-1 Commitment," states that "In establishing provisions for identification and control of items, X-Energy commits to compliance with NQA-1-2015, Requirement 8."

SRP Section 17.5, Subsection II.H, "Identification and Control of Materials, Parts, and Components," generally does not apply to a DC application.

Clarify the applicability of SRP Section 17.5, Subsection II.H, and X-Energy's QAPD Section 8, "Identification and Control of Materials, Parts, and Components," to the DC application.

X-energy RAI Question Response

X-energy will establish measures for the identification and control of materials, parts, and components as X-energy will be purchasing materials, parts and components for test purposes (e.g. may include fuel and graphite irradiation testing) and therefore we find applicability in Criterion VIII of Appendix B to 10 CFR Part 50 and thus the commitment to compliance with NQA 1 2015, Requirement 8.

Corresponding QAPD update to implement the response

SECTION 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 as X-energy will be purchasing materials, parts and components for test purposes (includes fuel and graphite irradiation testing that will be performed by X-energy suppliers). 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.



7. NRC RAI QUESTION NUMBER: RAI-7

NRC RAI Question

Criterion IX, "Control of Special Processes," of Appendix B to 10 CFR Part 50, states, "Measures shall be established to assure that special processes, including welding, heat treating, and nondestructive testing, are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements."

X-Energy's QAPD Section 9.1, "NQA-1 Commitment," states, "In establishing measures for the control of special processes, X-Energy commits to compliance with NQA-1-2015, Requirement 9."

SRP Section 17.5, Subsection II.I, "Control of Special Processes," generally does not apply to a DC application.

Clarify the applicability of SRP Section 17.5, Subsection II.I, and X-Energy's QAPD Section 9, "Control of Special Processes," to the DC application.

X-energy RAI Question Response

X-energy will be performing destructive and non-destructive testing for test purposes (e.g. may include fuel and graphite irradiation testing) and therefore we find applicability in Criterion IX of Appendix B to 10 CFR Part 50 and thus the commitment to compliance with NQA 1 2015, Requirement 9.

X-energy will update the QAPD Section 9 to the effect "X-energy has established the necessary measures and governing procedures to assure that special processes that require interim process controls to assure quality, such as welding, heat treating, and nondestructive examination, are controlled. These provisions include assuring 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."

Corresponding QAPD update to implement the response

SECTION 9 CONTROL OF SPECIAL PROCESSES

X-energy has established the necessary measures and governing procedures to assure that special processes that require interim process controls to assure quality, such as welding, heat treating, and nondestructive examination, are controlled as X-energy suppliers will be performing destructive and non-destructive testing for test purposes (includes fuel and graphite irradiation testing). These provisions include assuring 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. The qualification program requirements of personnel are described in Part II, Section 2 of this QAPD. Records that demonstrate the qualification of personnel are controlled and retained according to Part II, Section 17 of this QAPD. Special processes are those where the results are highly dependent on the control of the



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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.



8. NRC RAI QUESTION NUMBER: RAI-8

NRC RAI Question

Criterion X, "Inspection," of Appendix B to 10 CFR Part 50, states, "A program for inspection of activities affecting quality shall be established and executed by or for the organization performing the activity to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity. Such inspection shall be performed by individuals other than those who performed the activity being inspected. Examinations, measurements, or tests of material or products processed shall be performed for each work operation where necessary to assure quality. If inspection of processed material or products is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel shall be provided. Both inspection and process monitoring shall be provided when control is inadequate without both. If mandatory inspection hold points, which require witnessing or inspecting by the applicant's designated representative and beyond which work shall not proceed without the consent of its designated representative are required, the specific hold points shall be indicated in appropriate documents."

X-Energy's QAPD Section 10.3, "NQA-1 Commitment/Exceptions," states that "In establishing inspection requirements, X-Energy commits to comply with NQA-1-2015, Requirement 10 and subparts 2.4, 2.5, and 2.8 for establishing appropriate inspection requirements."

SRP Section 17.5, Subsection II.J, "Inspection," generally does not apply to a DC application.

Clarify the applicability of SRP Section 17.5, Subsection II.J, and X-Energy's QAPD Section 10, "Inspection," to the DC application.

X-energy RAI Question Response

X-energy will be performing inspection on destructive and non-destructive testing for test purposes (e.g. may include fuel and graphite irradiation testing) and therefore we find applicability in Criterion X of Appendix B to 10 CFR Part 50 and thus the commitment to compliance with NQA 1 2015, Requirement 10 and subparts 2.4, 2.5, and 2.8 for establishing appropriate inspection requirements.

Corresponding QAPD update to implement the response

SECTION 10 INSPECTION

X-energy has established the necessary measures and governing procedures to implement inspections that assure items, services, and activities affecting safety meet established requirements and conform to applicable documented specifications, instructions, procedures, and design documents as 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 activities. Inspections are carried out by properly qualified persons independent of those who performed or directly supervised the work. Inspection results are documented.



9. NRC RAI QUESTION NUMBER: RAI-9

NRC RAI Question

Criterion XI, "Test Control," of Appendix B to 10 CFR Part 50, states, "A test program shall be established to assure that all testing required to demonstrate that structures, systems, and components will perform satisfactorily in service is identified and performed in accordance with written test procedures which incorporate the requirements and acceptance limits contained in applicable design documents. The test program shall include, as appropriate, proof tests prior to installation, preoperational tests, and operational tests during nuclear power plant or fuel reprocessing plant operation, of structures, systems, and components. Test procedures shall include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions. Test results shall be documented and evaluated to assure that test requirements have been satisfied."

Section 11 of X-Energy's QAPD, "Test Control," states, in part, that "Tests are performed according to applicable procedures that include, consistent with the effect on safety: (1) Instructions and prerequisites to perform the tests, (2) Use of proper test equipment, (3) Acceptance criteria, and (4) mandatory verification points as necessary to confirm satisfactory test completion."

Paragraph II.K.4 in Subsection II.K, "Test Control," of SRP Section 17.5 states, in part, that "Test Procedures shall include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions."

Clarify how the criteria of performing the test under suitable environmental conditions is being met in X-Energy's proposed QAPD.

X-energy RAI Question Response

X-energy will update the QAPD Section 11 in part, to include the following to the effect "Tests are performed according to applicable procedures that include, consistent with the effect on safety:

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

Corresponding QAPD update to implement the response

SECTION 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 as X-energy suppliers will be performing testing (includes fuel and graphite irradiation testing). These programs include criteria for determining when testing is required, such as tests to demonstrate that design



concepts will perform satisfactorily in service. Integrity of data collected during testing and test data supporting critical characteristics shall be qualified according to NQA-1-2015 requirements. These measures and governing procedures include criteria for determining when testing is required 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, consistent with the effect on safety:

- 1) Instructions and prerequisites to perform the tests,
- 2) Use of proper test equipment,
- 3) Acceptance criteria, and
- 4) Mandatory verification points as necessary to confirm satisfactory test completion,
- 5) 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.

Except for computer program testing, which is addressed in 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 Safety Analysis Report (SAR). 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 of this QAPD.



10. NRC RAI QUESTION NUMBER: RAI-10

NRC RAI Question

Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50, states, "Measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits."

Section 12 of X-Energy's QAPD, "Control of Measuring and Test Equipment," states, in part that 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 or information important to safe plant operation. The provisions of such procedures cover equipment such as indicating and actuating instruments and gages, tools, reference and transfer standards, and nondestructive examination equipment."

Paragraph II.L.2 in subsection II.L, "Control of Measuring and Test Equipment," of SRP Section 17.5 states that "M&TE is labeled, tagged, or otherwise controlled to indicate its calibration status and to ensure its traceability to calibration test data."

Paragraph II.L.3 in subsection II.L of SRP Section 17.5 states that "The types of equipment covered by the program (e.g., instruments, tools, gages, reference and transfer standards, and nondestructive examination equipment) are defined."

Paragraph II.L.4 in subsection II.L of SRP Section 17.5 states that "M&TE are 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."

Paragraph II.L.5 in subsection II.L of SRP Section 17.5 states that "M&TE found out of calibration is tagged or segregated and not used until it is recalibrated. When M&TE is found 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 out of calibration, it is repaired or replaced. A calibration is performed when the accuracy of the equipment is suspect."

Clarify how these items are being met in X-Energy's proposed QAPD.

X-energy RAI Question Response

X-energy will update the QAPD Section 12 in part, to include the following to the effect "X-energy applies the following controls with regards to measuring and test equipment:

- 1) The types of equipment covered by the program (e.g., instruments, tools, gages, reference and transfer standards, and nondestructive examination equipment) are defined.
- 2) M&TE is labeled, tagged, or otherwise controlled to indicate its calibration status and to ensure its traceability to calibration test data.



3) M&TE are 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.

4) M&TE found out of calibration is tagged or segregated and not used until it is recalibrated. When measuring and test equipment is found 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 out of calibration, it is repaired or replaced. A calibration is performed when the accuracy of the equipment is suspect.”

Corresponding QAPD update to implement the response

SECTION 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 or information important to safe plant operation as 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 gages, tools, reference and transfer standards, and nondestructive examination equipment. X-energy applies the following controls with regards to measuring and test equipment:

- 1) The types of equipment covered by the program (e.g., instruments, tools, gages, reference and transfer standards, and nondestructive examination equipment) are defined.
- 2) M&TE is labeled, tagged, or otherwise controlled to indicate its calibration status and to ensure its traceability to calibration test data.
- 3) M&TE are 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.
- 4) M&TE found out of calibration is tagged or segregated and not used until it is recalibrated. When measuring and test equipment is found 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 out of calibration, it is repaired or replaced. A calibration is performed when the accuracy of the equipment is suspect.



11. NRC RAI QUESTION NUMBER: RAI-11

NRC RAI Question

Criterion XIII, "Handling, Storage, and Shipping," of Appendix B to 10 CFR Part 50, states, "Measures shall be established to control the handling, storage, shipping, cleaning and preservation of material and equipment in accordance with work and inspection instructions to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, specific moisture content levels, and temperature levels, shall be specified and provided."

X-Energy's QAPD Section 12.1, "NQA-1 Commitment/Exceptions," states that "In establishing provisions for handling, storage, and shipping, X-Energy commits to compliance with NQA-1- 2015, Requirement 13."

SRP Section 17.5, Subsection II.M, "Handling, Storage, and Shipping," is generally not applicable to a DC application.

Clarify 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.

X-energy RAI Question Response

X-energy will be performing handling, storage, and shipping of test and irradiated material for test purposes (e.g. may include fuel and graphite irradiation testing) and therefore we find applicability in Criterion XIII of Appendix B to 10 CFR Part 50 and thus the commitment to compliance with NQA 1 2015, Requirement 13.

Corresponding QAPD update to implement the response

SECTION 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 test and irradiated items to prevent inadvertent damage or loss, and to minimize deterioration as X-energy suppliers will perform testing and irradiation for test purposes (includes fuel and graphite irradiation testing). 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.



12. NRC RAI QUESTION NUMBER: RAI-12

NRC RAI Question

Criterion XIV, "Inspection, Test, and Operating Status," of Appendix B to 10 CFR Part 50, states, "Measures shall be established to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the nuclear power plant or fuel reprocessing plant. These measures shall provide for the identification of items which have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of such inspections and tests. Measures shall also be established for indicating the operating status of structures, systems, and components of the nuclear power plant or fuel reprocessing plant, such as by tagging valves and switches, to prevent inadvertent operation."

X-Energy's QAPD Section 14.1, "NQA-1 Commitment," states that "In establishing measures for control of inspection, test, and operating status, X-Energy commits to compliance with NQA-1- 2015, Requirement 14."

SRP Section 17.5, Subsection II.N, "Inspection, Test, and Operating Status," generally does not apply to a DC application.

Clarify the applicability of SRP Section 17.5, Subsection II.N, and X-Energy's QAPD Section 14, "Inspection, Test, and Operating Status," to the DC application.

X-energy RAI Question Response

X-energy will establish measures to identify the status of inspections and tests performed of test and irradiated material for test purposes (e.g. may include fuel and graphite irradiation testing) and therefore we find applicability in Criterion XIV of Appendix B to 10 CFR Part 50 and thus the commitment to compliance with NQA 1 2015, Requirement 14.

Corresponding QAPD update to implement the response

SECTION 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 as X-energy suppliers will perform testing and irradiation for test purposes (includes fuel and graphite irradiation testing). 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.



13. NRC RAI QUESTION NUMBER: RAI-13

NRC RAI Question

Criterion XV, "Nonconforming Materials, Parts, or Components," of Appendix B to 10 CFR Part 50, states, "Measures shall be established to control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation. These measures shall include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items shall be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures."

Section 15 of X-Energy's QAPD, "Nonconforming Materials, parts or Components," states, in part, that "Instructions require that the individual discovering a nonconformance identify, describe, and document the nonconformance in accordance with the requirements of Part II, Section 16."

Paragraph II.O.4 in subsection II.O, "Nonconforming Materials, Parts, or Components," of SRP Section 17.5 states that "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."

Paragraph II.O.5 in subsection II.O of SRP Section 17.5 states that "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."

Paragraph II.O.6 in subsection II.O of SRP Section 17.5 states that "Reworked, repaired, and replacement items are inspected and tested in accordance with the original inspection and test requirements or specified alternatives."

Clarify how these items are being met in X-Energy's proposed QAPD.

X-energy RAI Question Response

X-energy will include the requirements and update the QAPD Section 15, to the effect:

"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 assure 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.”

Corresponding QAPD update to implement the response

SECTION 15 NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

X-energy has established the necessary measures and governing procedures to control items, including services (e.g. test and irradiated material) that do not conform to specified requirements to prevent inadvertent installation or use as X-energy suppliers will be performing destructive and non-destructive testing for test purposes (includes fuel and graphite irradiation testing). 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 assure 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.



14. NRC RAI QUESTION NUMBER: RAI-14

NRC RAI Question

In 10 CFR 52.47(a)(9), the NRC states, in part, “For applications for light-watercooled nuclear power plants, an evaluation of the standard plant design against the Standard Review Plan (SRP) revision in effect 6 months before the docket date of the application. The evaluation required by this section shall include an identification and description of all differences in design features, analytical techniques, and procedural measures proposed for the design and those corresponding features, techniques, and measures given in the SRP acceptance criteria.

Where a difference exists, the evaluation shall discuss how the proposed alternative provides an acceptable method of complying with the Commission's regulations, or portions thereof, that underlie the corresponding SRP acceptance criteria.”

X-Energy's QAPD Section 1.1, “Regulatory Guides,” Part IV, “Regulatory Commitments,” states that the applicant is committed to meeting the guidance in RG 1.8, “Qualification and Training of Personnel for Nuclear Power Plants,” Revision 3, issued May 2000, and RG 1.29, “Seismic Design Classification,” Revision 4, issued March 2007.

RG 1.8 is not applicable to a DC application, and the NRC revised RG 1.29 in July 2016. Further, the NRC staff noted that X-Energy is not committed to the following recently issued RGs:

- a. RG 1.231, “Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Safety-Related Applications for Nuclear Power Plants,” Revision 0, dated January 2017.
 - b. RG 1.164, “Dedication of Commercial-Grade Items for Use in Nuclear Power Plants,” Revision 0, dated June 2017.
 - c. RG 1.234, “Evaluating Deviations and Reporting Defects and Noncompliance Under 10 CFR Part 21,” Revision 0, dated April 2018.
1. Clarify the applicability of RG 1.8 to X-Energy's DC application and whether you intent to commit to RGs 1.231, 1.164, and 1.234.
 2. Justify why the X-Energy QAPD does not commit to meeting the latest revision of RG 1.29.

X-energy RAI Question Response

X-energy will comply and remove RG 1.8 in the QAPD Part IV, Section 1.1, “Regulatory Guides,” to the effect.

X-energy will comply and update the Regulatory Guide in the QAPD Part IV, Section 1.1, “Regulatory Guides,” RG 1.29 to [Rev. 5, July 2016].

X-energy will comply and update the Regulatory Guides in the QAPD Part IV, Section 1.1, “Regulatory Guides,” to include the following:

- a. RG 1.231 [Rev. 0, January 2017].
- b. RG 1.164 [Rev. 0, June 2017].
- c. RG 1.234 [Rev. 0, April 2018].



Corresponding QAPD update to implement the response

PART IV REGULATORY COMMITMENTS

SECTION 1.1 REGULATORY GUIDES

- a. **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.

Regulatory Guide 1.26 defines classification of systems and components.

The Xe-100 reactor design is a High Temperature Gas-Cooled Reactor and is significantly different from the design of light water reactors, upon which this regulatory guidance is based. As such, the conventional quality group classifications may not be directly applicable. The unique features of the Xe-100 design and the equivalence of their design safety functions, including application to committed regulatory guidance, will be detailed in the DCD.

- b. **Regulatory Guide 1.28**, [Revision. 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 identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in the DCD.

- c. **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 identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in the DCD. Applicable Regulatory Positions will be detailed in the DCD.

- d. **Regulatory Guide 1.54**, [Revision 2, October 2010] - Service Level I, II, and III Protective Coatings Applied to Nuclear Power Plants.

Regulatory Guide 1.54 provides guidance for the application of protective coatings within nuclear power plants to protect surfaces from corrosion, contamination from radionuclides, and for wear protection.

X-energy identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in the DCD.

- e. **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 the DCD.

- f. **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 the DCD.

- g. **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 the DCD.



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Section C



X Energy, LLC Topical Report

Quality Assurance Program Description

Configuration Classification	: Quality Documentation
Revision	: 3-A
Status	: Approved
Issue Date	: 07-Aug-2020
Project	: Xe-100



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 X-energy Reactor Plant project. An Integrated Management System (IMS) documents how X-energy structures its quality system, quality management practices and requirements for quality assurance to support quality, health & safety and environmental objectives and to effectively manage quality. 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 this QAPD.

The QAPD addresses design QA activities in support of Design Certification (DC) and does not address QA activities associated with construction that occur once construction begins (e.g., design change process to capture as-built, fabrication, weld qualification, etc.).

The QAPD is divided into four parts: 1.0 - Introduction; 2.0 - Quality Assurance Program Description Details; 3.0 - Nonsafety-Related SSC Quality Control; and 4.0— Regulatory Commitments.



QUALITY POLICY

The vision of X Energy, LLC (X-energy), an engineering design and services company, 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 built on our values of Integrity, Safety, Customers and Employees (ISCE). ISCE attributes of integrity and workforce safety together define our safety culture and are uncompromised in our day-to-day operations. This means company leadership, policies and procedures all work together to ensure that all employees are supported, equipped, empowered and encouraged to provide the highest-quality work products. Our management system has been defined and implemented to produce solutions that comply with the letter and intent of all applicable local, state and federal 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 investors and customers, our lifeline, 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 Quality Assurance Program (QAP) 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 QAP at X-energy ensures established quality objectives are continually reviewed and measured, and shortcomings addressed if they arise. We continually evaluate and review our QAP to ensure its effectiveness and that the Program yields the intended results.

Our ISCE culture, along with our QAP, 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.

Kamal S. Ghaffarian, PhD
Founder



CONFIGURATION CONTROL

Document Change History




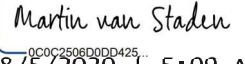


Rev.	Date	Section or Page Affected	Changes
0	31-Jul-2019		Original document
1	12-Feb-2020	Title page	Revised revision number and revised issue date
		All pages	Revised revision number
		Document Approvals, page 6	Revised Reviewer
		Part II, Section 1, page 15	Revised per RAI-1, implementing measures 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 a basis for qualifying suppliers
		Part II, Section 16.1, page 37	Revised as per RAI-5, removed the reference to 10 CFR 50.55
		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 Section 8, "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 Section 9, "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 Section 10, "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



Rev.	Date	Section or Page Affected	Changes
		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 Section 14, "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: 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
		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 [Rev 3] as directed by the draft Safety Evaluation (ML20142A333).



Document Approval

Action	Designation	Name	Signature	Date
Preparer	SHEQ Director	LT Odendaal	<small>DocuSigned by:</small>  <small>2306B067D917495</small> 8/4/2020 4:42 PM EDT	
Reviewer	VP Reactor Business Development	J Harper	<small>DocuSigned by:</small>  <small>E2B4C821B954422</small> 8/4/2020 1:52 PM PDT	
Reviewer	CFO/VP Business Operations	M Gigliotti	<small>DocuSigned by:</small>  <small>7B754BB859454F5</small> 8/5/2020 1:59 AM PDT	
Reviewer	VP Design Engineering/Xe-100 Program Manager	MP van Staden	<small>DocuSigned by:</small>  <small>0C0C2506D0DD425</small> 8/5/2020 5:09 AM CDT	
Reviewer	SVP/CNO	EJ Mulder	<small>DocuSigned by:</small>  <small>D7F7B2C3947E4A6</small> 8/5/2020 9:25 AM EDT	
Approver	CEO	JC Sell	<small>DocuSigned by:</small>  <small>4B5C862AE06D4B4</small> 8/6/2020 12:07 PM EDT	



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ABBREVIATIONS

This list contains the abbreviations used in this document.

Abbreviation or Acronym	Definition
ASME	American Society for Mechanical Engineers
ATWS	Anticipated Transients Without Scram
CEO	Chief Executive Officer
CFO	Chief Financial Officer
CFR	Code of Federal Regulations
CNO	Chief Nuclear Officer
DC	Design Certification
DCD	Design Control Document
DOE	Department of Energy
EMS	Environmental Management System
FOA	Funding Opportunity Announcement
IMS	Integrated Management System
LRA	Licensing and Regulatory Affairs
MSM	Management System Manuals
M&TE	Measuring and Test Equipment
NEI	Nuclear Energy Institute
NIRMA	Nuclear Information and Records Management Association, Inc.
NQA	Nuclear Quality Assurance
NRC	Nuclear Regulatory Commission
NUREG	Nuclear Regulatory Guide
PMRD	Program Manager Reactor Development
QA	Quality Assurance
QAP	Quality Assurance Program
QAPD	Quality Assurance Program Description
QC	Quality Control
QMS	Quality Management System
RG	Regulatory Guides
RIS	Regulatory Issue Summary



Abbreviation or Acronym	Definition
SAR	Safety Analysis Report
SBO	Station Blackout
SE	Systems Engineering
SHEQ	Safety, Health, Environment & Quality
SHEQD	Safety, Health, Environment & Quality Director
SMS	Safety Management System
SSC	Structures, Systems and Components
SSE	Safe Shutdown Earthquake
SVP	Senior Vice President
VP	Vice President
VPBO	Vice President Business Operations
VPFD	Vice President Fuels Development
VPRBD	Vice President Reactor Business Development
WBS	Work Breakdown Structure
TGs	Technical Guides
X-energy	X Energy, LLC



PART I INTRODUCTION

1. SECTION 1 GENERAL

X-energy's Quality Assurance Program Description (QAPD) is the top-level policy document that establishes the Quality Assurance policy and assigns major functional responsibilities for Design Certification (DC) activities conducted by or for X-energy. The QAPD describes the methods and establishes Quality Assurance (QA) and administrative control requirements that meet 10 CFR 50, Appendix B and 10 CFR 52 and is based on 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 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 design 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.

The QAP is applied using a graded approach to any Structure, System, Component (SSC), activity, or organization that is essential to safe, reliable, and efficient performance as well as to all applicable phases of the life cycle and to all types of applicable activities, including any activities independent of a facility that may affect performance (e.g., transportation of nuclear materials) of those activities.

The QAP is integrated with other X-energy management systems, including the Quality Management System (QMS), Safety Management System (SMS), and Environmental Management System (EMS). All of these management systems function collectively to ensure safe and compliant work that meets regulatory requirements and customer expectations. An implementation matrix identifies the correct implementation procedure for X-energy QAP requirements. The QAP requirements shall be implemented through the use of this QAPD in conjunction with the X-energy Management System Manuals (MSM).

Functional responsibilities and levels of authority are identified in roles, responsibilities, accountabilities and authorities documents, which are developed for each management position. Specific responsibilities for implementing QAP requirements are identified in the associated implementing procedures.

1.1. SCOPE/ APPLICABILITY

The QAPD applies to DC activities of the reactor plant affecting the quality and performance of safety-related structures, systems, and components, including, but not limited to:

- Designing
- Safety related analysis and evaluation
- Software V&V
- Storing
- Procuring
- Shipping
- Receiving
- Cleaning
- Testing
- Inspecting
- Training
- Handling



Safety-related Structures, Systems and Components (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.

The policy of X-energy is to assure a high degree of availability and reliability of the nuclear plant(s) while ensuring the health and safety of its workers and the public. 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 operations, or where other NRC guidance establishes quality assurance requirements. Implementing documents establish program element applicability.

The definitions provided in ASME NQA-1-2015 apply to select terms as used in this document.



PART II QUALITY ASSURANCE PROGRAM DESCRIPTION DETAILS

1. SECTION 1 ORGANIZATION

This section describes the X-energy organizational structure, functional responsibilities, levels of authority and interfaces for establishing, executing, and verifying QAPD implementation. The organizational structure includes corporate/support and on-site functions required to support the activities associated with license preparation, NRC review of the license application, and NRC rulemaking 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 ensures that the size of the QA organization is commensurate with its duties and responsibilities assigned. Management gives careful consideration to the timing, extent, and effects of organizational structure changes.

X-energy is led by the CEO who is supported by the President and a team consisting of a Board of Advisors, a Technical Advisory Group as well as a Customer Advisory Council. The organization reporting to the President includes the Senior Vice President (SVP)/Chief Nuclear Officer (CNO), Safety, Health, Environmental & Quality Director (SHEQD), Program Manager Reactor Development, Vice President (VP)/Program Manager Fuels Development, VP Reactor Business Development and the Chief Financial Officer (CFO)/VP Business Operations. The X-energy organization is shown in Figure 1.

Additional services will be provided to X-energy by partnering with suppliers where required. When services are contracted, these contractors are evaluated and approved prior to performing safety-related work. Contractor technical interfaces and performance will be managed by the appropriate assigned VP. The quality interfaces with contractors will be managed by the Safety, Health, Environmental & Quality Director (SHEQD).

The following sections describe the reporting relationships, functional responsibilities and authorities for organizations implementing and supporting the X-energy DC QAP. The X-energy leadership team maintains clear lines of authority and communication. X-energy's organizational structure is designed to support an agile approach to projects.

1.1. Chief Executive Officer (CEO)

The CEO is responsible for all aspects of design of X-energy's nuclear plants. The CEO is also responsible for all technical and administrative support activities provided by X-energy and contractors. The CEO directs the President in fulfillment of his responsibilities. The CEO reports to the X-energy Board of Directors with respect to all matters. Furthermore, he actively supports the safety culture and ensure integration of quality and safety in all business processes.

1.2. President

The President reports to the CEO and is responsible for the establishment and implementation of the X-energy QAPD. The President also directs the planning and development of X-energy staff, and organization resources. The President is responsible for the actions of the VPs/SVPs in fulfillment of their



responsibilities. The President is responsible for the administration of reactor development, fuels development, nuclear licensing and may provide support activities for X-energy under the QAPD. The President actively supports the safety culture and ensure integration of quality and safety in all business processes.

1.3. Senior Vice President (SVP)/Chief Nuclear Officer (CNO)

The Chief Nuclear Officer (CNO) reports to the President and is responsible for ensuring X-energy programs, products, and processes deliver the highest technical quality and nuclear safety. The CNO actively supports the safety culture and ensure integration of quality in all applicable processes by complying with the requirements of the Quality Assurance Program.

1.4. Program Manager Reactor Development (PMRD)

The PMRD reports to the President and defines and directs implementation of the scope of the Reactor Development program, including accountability for all deliverables, Work Breakdown Structure (WBS), the timeline, performance measurement, budgets, and success criteria. The PMRD oversees the Licensing and Regulatory Affairs, Systems Engineering (SE) and design function, definition/allocation of system requirements, work scope, deliverables, milestones and estimated budget to be assigned to X-energy departments, subcontractors, and partners; negotiates with those organizations to document and agree to final scope, deliverables, and timeline. The PMRD is the final decision maker on approaches based on technical, quality, schedule and cost factors. The PMRD actively supports the safety culture and ensure integration of quality in all relevant processes by complying with the requirements of the Quality Assurance Program.

1.5. Analysis & Testing Manager

Refer to the Reactor Development Organization in Figure 2. The Analysis & Testing Manager reports to the Program Manager Reactor Development. The Analysis & Testing Manager is responsible to provide engineering and analysis documentation that justifies and explains the design solutions and is responsible for leading the analysis and testing teams in their evaluation, development, and maturation of documentation, that supports the integrity of the design through analysis and/or testing where required. Develops the Engineering Analysis Plan. Identifies resource requirements for execution of the Engineering Analysis Plan. Develops and integrates engineering analysis schedule and budget. Develops a Physical Test Plan. Ensures the technical design integrity. Provides design and analysis related policies, procedures, codes, standards. Directs and coordinates the analysis and design teams to ensure technical dependencies and conflicts are addressed in a way that satisfies program needs. In coordination with the Analysis Control Board, support selection of analytical tools, software, hardware and methods to be applied by the design and analysis teams, based on delivery schedules, team capabilities, program needs, and NQA-1 requirements. Defines analysis verification and validation methodologies to appropriate nuclear standards. Identifies data needs that meet program requirements and for obtaining or developing required data. Identifies research and technology maturation needs that are required to meet program deployment and operational goals. Supports risk trades to determine the most viable approach to



accomplishing design/analysis goals. Interfaces with the Engineering Manager and the Contracts & Procurement Manager on subcontracts and directs assigned subcontractor day-to-day performance. Initiates, executes and manages prototyping and/or testing efforts based on verification requirements defined by the Engineering team. The Analysis & Testing Manager is accountable to the Program Manager Reactor Development for ensuring technical integrity of the design selections and accountable to the Engineering Manager for developing and maintaining technologies and capabilities that support the integrity of the design. The Analysis & Testing Manager actively supports the safety culture and ensure integration of quality in all relevant processes by complying with the requirements of the Quality Assurance Program.

1.6. Engineering Manager

Refer to the Reactor Development Organization in Figure 2. The Engineering Manager (EM) is responsible for and manages the technical effort to develop the Xe-100 system. His responsibilities include the development and maintenance of the technical requirements system configuration from the plant to the contract end item level. He is primarily responsible for the technical development of a product that conforms to all technical requirements. The EM is the key manager of all the engineering work on the project. He is responsible to implement high integrity repeatable System Engineering processes, ensures proper system, technical and engineering integration, monitors and evaluates technical risks and provide technical oversight and support. Responsibilities include Technical Planning, Technical Assessment, Requirements Management, Configuration Management (hardware and software configuration), Technical Data Management, and Interface Management.

The EM is accountable to the PMRD for meeting program objectives and meeting the technical requirements. His approval authority includes managing of the requirements verification and validation processes, all functional analysis and functional allocation documents, all design requirement documentations and technical specifications, all System Design Description documentation, all system and sub-system functional and physical architecture definitions, all interface documents and contract end item verification documents. The Engineering Manager actively supports the safety culture and ensure integration of quality in all relevant processes by complying with the requirements of the Quality Assurance Program.

1.7. Licensing and Regulatory Affairs (LRA)

Refer to the Reactor Development Organization in Figure 2. LRA reports to the Program Manager Reactor Development and is responsible for developing, implementing, and monitoring the X-energy licensing effort. LRA designs the overall licensing approach, develops and tracks progress against the licensing schedules and roadmap, and provides recommendations for senior management approval. LRA is the principal point of contact with the NRC and other regulatory agencies on regulatory issues. LRA is responsible for identifying requirements for engineering white papers, technical reports, and topical reports; directing the completion of these products; and providing them to the NRC according to an agreed upon schedule. LRA actively supports the safety culture and ensure integration of quality in licensing processes by complying with the requirements of the Quality Assurance Program.



1.8. Vice President (VP)/Program Manager Fuels Development (VPFD)

The VPFD reports to the President and manages the Department of Energy (DOE)/ Funding Opportunity Announcement (FOA) programs. He is also responsible for all aspects of fuel & fuel plant research, design and development activities, and other research related to fuel and fuel remediation. The VPFD ensures coordination across critical business units, such as engineering, licensing and plant production/construction/operations, to ensure Xe-100 fuel types are developed and delivered to the site. In conjunction with the Fuel Regulatory Affairs, the VPFD confers with local regulatory agencies to ensure local environmental quality standards and industrial practices are complied with. The VPFD actively supports the safety culture and ensure integration of quality in the DOE and Fuel programs by complying with the requirements of the Fuels Quality Assurance Program.

1.9. Vice President Reactor Business Development (VPRBD)

The VPRBD reports to the President and is responsible and have authority to develop, maintain and evolve X-Energy's overall business strategy and business plans. The VPRBD actively supports the safety culture and ensure integration of quality in business development by complying with the requirements of the Quality Assurance Program.

1.10. Chief Financial Officer (CFO)/Vice President Business Operations (VPBO)

The CFO/VPBO reports to the President and is responsible and accountable for all X-energy business operations. It includes information technology, investor relations, accounting & financial matters, administration, legal, commercial and contracts management as well as property management. The CFO/VPBO develops predictive financial models, prepare financial forecasts and performs on-going financial analyses to verify the financial performance of X-energy. The CFO/VPBO actively supports the safety culture and ensure integration of quality in business operations by complying with the requirements of the Quality Assurance Program.

1.11. Quality Assurance

The X-energy Quality Assurance Organization is responsible for independently planning and performing activities to verify the development and effective implementation of the X-energy QAP including but not limited to Engineering, Licensing, Document Control, Corrective Action Program and Procurement that support the DC process.

1.12. Safety, Health, Environmental & Quality Director (SHEQD)

The SHEQD reports to the President with an independent line function to the CEO and oversees the X-energy functions for Safety, Health, Environment & Quality (SHEQ). The SHEQD is responsible for developing and maintaining the X-energy QAPD, evaluating compliance to Quality Assurance Program requirements, and managing Quality Assurance Organization resources. The SHEQD is responsible for the verification of implementation of the QAP described in this document. The SHEQD 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 vendor audits. The SHEQD has sufficient independence from other priorities to bring forward issues affecting safety and quality and makes judgments regarding quality in all areas regarding X-energy's design activities as appropriate. The SHEQD has the independence, authority, responsibility, and organizational freedom to bring unresolved issues/risks directly to the CEO to obtain resolution. The SHEQD establishes, oversees, facilitates, provides and encourages appropriate company quality and safety training. The SHEQD reports to top management regarding the status of the QAP and, where appropriate, concerns over significant hazards and risks and recommendations for improvement. The SHEQD is responsible to ensure the regular review of the QAP.

1.13. Authority to Stop Work

Quality Assurance and Quality Control Inspection personnel have the authority, and the responsibility, to stop work in progress which is not being done in accordance with approved procedures or where safety of personnel 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.

1.14. Quality Assurance Organizational Independence

For the DC phase, 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.

1.15. NQA-1 Commitment

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

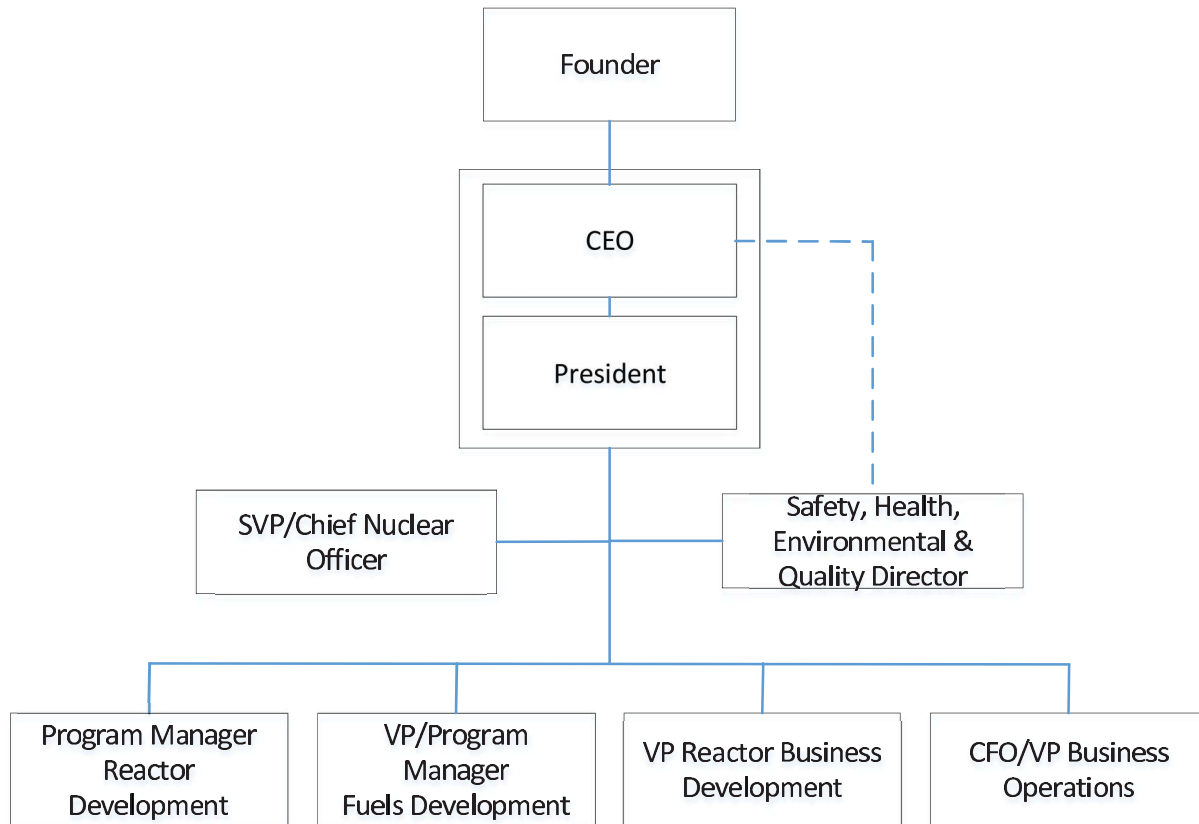


Figure 1: X-energy Organization

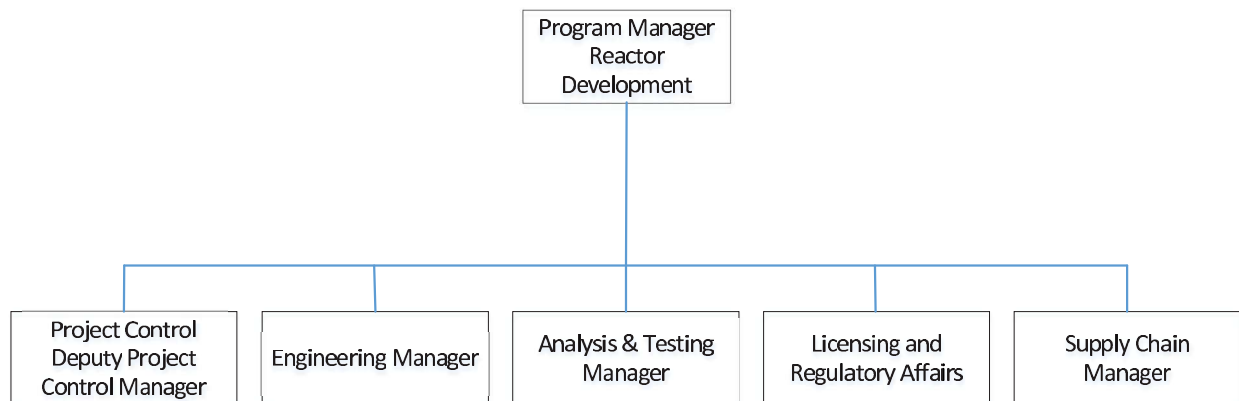


Figure 2: Reactor Development Organization



2. SECTION 2 QUALITY ASSURANCE PROGRAM

X-energy has established the necessary measures and governing procedures to implement the QAP as described in this QAPD. X-energy is committed to implementing the QAP in all aspects of work that apply to the safety of the nuclear plant(s) 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 of this QAPD.

The objective of the QAP is to assure that X-energy's nuclear generating plant(s) are designed in accordance with governing regulations and DC 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 structures, systems, and components (SSCs) associated with the design (including Design Certification activities) of the X-energy reactor, the fuel characterization, and to the managerial and administrative controls to be used to assure the X-energy reactor complies with applicable regulatory requirements. Examples of DC program safety-related activities include but are not limited to basic and detail design; determination of SSC safety class; design configuration management; and document control. A list or system that identifies SSCs and activities to which this program applies is maintained at X-energy. Regulatory Guide 1.26 is used as guidance for this list or system. Cost and scheduling functions 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 nonsafety-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 selected manner, targeted at those characteristics or critical attributes that qualifies 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 assure compliance with the supplier's or principle contractor's QAPD and implementing procedures. In addition, routine interfaces with the supplier's personnel provide added assurance that quality expectations are met.

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 scheduled audits and annual evaluations of supplier performance. 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 the activity was actually 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. The X-energy SHEQD 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 of this QAPD, 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. 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.

2.4. 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 the X-energy SHEQD to ensure that such changes do not degrade safety for previously approved quality assurance controls specified in the QAPD. This document shall be revised as appropriate to incorporate additional QA commitments that may be established during the DC application process. New revisions to the document will be reviewed, at a minimum, by the X-energy SHEQD and approved by the CEO.



2.5. 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, as appropriate:

- 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.
- X-energy also ensures compliance of the training and qualification requirements for inspection and test personnel.

The minimum qualifications of the SHEQD are that he or she holds 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 a Lead Auditor (prior to being designated a Lead Auditor) are effective communication skills (both in writing and orally) and specific training to assure auditing competence with regards to knowledge and understanding of ASME NQA-1-2015 and other nuclear-related codes, standards, regulations, and regulatory guides, structure and understanding of QA programs, auditing techniques, planning of audits and on-the-job training. Audit participation requirements (subject to review and acceptance by the organization responsible for quality assurance audits and/or the certifying authority prior to their use for qualification) are that a Lead Auditor participates in a minimum of five quality assurance audits within a period of time not to exceed 3 year prior to the date of qualification, one audit of which shall be a nuclear quality assurance audit within the year prior to qualification. Participation in independent assessments including team assessment activities such as operations readiness reviews and regulatory inspections/surveys may be used to satisfy up to four of the five required quality assurance audits. Lead Auditors shall pass an examination that evaluates comprehension of and ability to apply the required body of knowledge. Special requirements are that the proficiency of the Lead Auditor must be maintained through either regular and active participation in the audit process, review and study of codes, standards, procedures, instructions, and other documents related to quality assurance program and program auditing, participation in training program(s). senior management will assess the Lead Auditor's proficiency annually and extend the qualification, require retraining, or require requalification.



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 Group 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.

2.6. NQA-1 Commitment / Exceptions

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

3. SECTION 3 DESIGN CONTROL

X-energy has established and implements a process to control the design, design changes, and temporary modifications 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 and final designs 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, as applicable. 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 assure 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 nonsafety-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 is 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. 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.

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 assure that interfaces, interchangeability, safety, fit, and function, as applicable, 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 X-energy's 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.
- Section 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, Section 7, "Control of Purchased Material, Equipment and Services."

5. SECTION 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 of this QAPD. 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's 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:

- (1) The written procedure to be present and followed step-by-step while the task is being performed,
- (2) The user to have committed the procedure steps to memory,
- (3) 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 as applicable, 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. SECTION 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,
- Coordinating and controlling interface documents and procedures.

The types of documents to be controlled include:

- Design 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,
- Technical specifications,
- Nonconformance reports and corrective action reports.



6.1. Review and Approval of Documents

Documents are reviewed for adequacy by qualified persons other than the preparer. During the DC, procedures for design activities are also reviewed by the Quality Department to ensure quality assurance measures have been appropriately applied. The documented review signifies concurrence. 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. 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. SECTION 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 assure conformance with specified requirements. Such control provides for the following as appropriate: prospective supplier evaluation and selection of only qualified suppliers, evaluation of objective evidence of on-going acceptable 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, as appropriate, during DC activities. Verifications occur at the appropriate phases of the procurement process, including, as necessary, verification of activities of suppliers below the first tier.

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

- 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 as 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 such as National Laboratories (e.g. INL and ORNL) 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. Irradiation testing will be performed by X-energy suppliers and irrespective what QA program a supplier is using, X-energy will review, and supplement supplier's programs where required to make them compliant with 10CFR 50 Appendix B in addition to ASME NQA-1 requirements. Furthermore, 10CFR21 requirements will be included as well. Documented annual evaluations are performed for qualified suppliers to assure they continue to provide acceptable products and services. 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, as warranted). In addition, results are reviewed periodically to determine if, as a whole, they constitute a significant condition adverse to quality requiring additional action.
- 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, as applicable, have been satisfied before relying on the item to perform its intended safety function.
- 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 assure 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.

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 14-05, Rev. 1 for the use of accreditation in lieu of commercial grade surveys in procuring laboratory calibration and test services.
- 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.
- 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 all items that X-energy dedicates as safety-related.

8. SECTION 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 as X-energy will be purchasing materials, parts and components for test purposes (includes fuel and graphite irradiation testing that will be performed by X-energy suppliers). 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. SECTION 9 CONTROL OF SPECIAL PROCESSES

X-energy has established the necessary measures and governing procedures to assure that special processes that require interim process controls to assure quality, such as welding, heat treating, and nondestructive examination, are controlled as X-energy suppliers will be performing destructive and non-destructive testing for test purposes (includes fuel and graphite irradiation testing). These provisions include assuring 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. The qualification program requirements of personnel are described in Part II, Section 2 of this QAPD. Records



that demonstrate the qualification of personnel are controlled and retained according to Part II, Section 17 of this QAPD. 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. SECTION 10 INSPECTION

X-energy has established the necessary measures and governing procedures to implement inspections that assure items, services, and activities affecting safety meet established requirements and conform to applicable documented specifications, instructions, procedures, and design documents as 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 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:

- 1) At the source of supplied items or services,
- 2) In-process during fabrication at a supplier's facility or at a *X-energy* facility,
- 3) For final acceptance of fabricated and/or installed items during construction, and
- 4) Upon receipt of items involved in design development testing.

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 may include qualified inspectors or engineers. Inspection plans are based on, as 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 shall establish a qualification program for personnel performing quality inspections. The qualification program requirements are described in Part II, Section 2 of this QAPD. 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 2.4, 2.5, and 2.8 for establishing appropriate inspection requirements.

11. SECTION 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 as X-energy suppliers will be performing testing (includes fuel and graphite irradiation testing). These programs include criteria for determining when testing is required, such as tests to demonstrate that design concepts will perform satisfactorily in service. Integrity of data collected during testing and test data supporting critical characteristics shall be qualified according to NQA-1-2015 requirements. These measures and governing procedures include criteria for determining when testing is required 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, consistent with the effect on safety:

- 1) Instructions and prerequisites to perform the tests,
- 2) Use of proper test equipment,
- 3) Acceptance criteria,
- 4) Mandatory verification points as necessary to confirm satisfactory test completion, and
- 5) 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.

Except for computer program testing, which is addressed in 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 Safety Analysis Report (SAR). 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 of this QAPD.

11.1. NQA-1 Commitment for Computer Program Testing

X-energy establishes and implements provisions to assure 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 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. SECTION 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 or information important to safe plant operation as 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 gages, tools, reference and transfer standards, and nondestructive examination equipment. X-energy applies the following controls with regards to measuring and test equipment:

- a. The types of equipment covered by the program (e.g., instruments, tools, gages, reference and transfer standards, and nondestructive examination equipment) are defined.
- b. M&TE is labeled, tagged, or otherwise controlled to indicate its calibration status and to ensure its traceability to calibration test data.
- c. M&TE are 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.
- d. M&TE found out of calibration is tagged or segregated and not used until it is recalibrated. When measuring and test equipment is found 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 out of calibration, it is repaired or replaced. A calibration is performed when the accuracy of the equipment is suspect.

12.1. 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. SECTION 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 test and irradiated items to prevent inadvertent damage or loss, and to minimize deterioration as X-energy suppliers will perform testing and irradiation for test purposes (includes fuel and graphite irradiation testing). 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. 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. 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 assure 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 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.

14. SECTION 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 as X-energy suppliers will perform testing and irradiation for test purposes (includes fuel and graphite irradiation



testing). 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. SECTION 15 NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

X-energy has established the necessary measures and governing procedures to control items, including services (e.g. test and irradiated material) that do not conform to specified requirements to prevent inadvertent installation or use as X-energy suppliers will be performing destructive and non-destructive testing for test purposes (includes fuel and graphite irradiation testing). 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 assure 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 and 10 CFR 21 during the DC phase.

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. SECTION 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 assure 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 and 10 CFR 21 during the DC phase.

16.2. NQA-1 COMMITMENT

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

17. SECTION 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.

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, inspection, test, 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 as applicable for the DC Project. 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 the intent of RIS 2000-18 and associated updated 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. SECTION 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 DC Project activities are performed with a frequency commensurate with the safety significance of the activity and in a manner which assures that audits of safety-related activities are completed. During the early portions of DC activities, audits will focus on areas including, but not limited to, design, 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., design, procurement, surveillance, and test); Technical Specifications, regulations, programs for training, retraining, qualification of personnel, 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 SHEQD responsible for the day to day program as documented in Part II, Section 1 of this QAPD.

The X-energy SHEQD 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 CEO, 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 of this QAPD.

18.2. Internal Audits

Internal audits should be performed in such a manner as to assure 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 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 audit findings; and, observation of the performance of activities including associated record keeping.

18.3. 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 NONSAFETY-RELATED SSC QUALITY CONTROL

1. SECTION 1 NONSAFETY-RELATED SSCS - SIGNIFICANT CONTRIBUTORS TO PLANT SAFETY

Specific program controls are applied to nonsafety-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 nonsafety-related SSCs and related activities, including the identification of exceptions to the QA Program described in Part II, Sections 1 through 18 taken for nonsafety-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 nonsafety-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 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 nondestructive 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 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. SECTION 2 NONSAFETY-RELATED SSCS CREDITED FOR REGULATORY EVENTS

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

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- Generic Letter 85-06, "Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related".
- Regulatory Position 3.5, "Quality Assurance and Specific Guidance for SBO Equipment That Is Not Safety Related," and Appendix A, "Quality Assurance Guidance for Nonsafety Systems and Equipment," in Regulatory Guide 1.155 Revision 0 August 1988, "Station Blackout".

The Xe-100 reactor design is a High Temperature Gas-Cooled Reactor and is significantly different from the design of light water reactors, upon which this regulatory guidance is based. As such, some of the guidance in the above documents may not be directly applicable. The unique features of the Xe-100 design and application to committed regulatory guidance, will be detailed in the Xe-100 DCD.



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 complies with these standards to the extent described or referenced. Commitment to a particular RG or standard does not constitute a commitment to other RGs or standards that may be referenced therein. See the DCD for the X-energy evaluation of conformance with the guidance in NRC Regulatory Guides in effect six months prior to the submittal date of the application.

1.1. Regulatory Guides

- a. **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.

Regulatory Guide 1.26 defines classification of systems and components.

The Xe-100 reactor design is a High Temperature Gas-Cooled Reactor and is significantly different from the design of light water reactors, upon which this regulatory guidance is based. As such, the conventional quality group classifications may not be directly applicable. The unique features of the Xe-100 design and the equivalence of their design safety functions, including application to committed regulatory guidance, will be detailed in the DCD.

- b. **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 identifies conformance for the applicable regulatory position guidance provided in this regulatory guide in the DCD.

- c. **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 identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in the DCD. Applicable Regulatory Positions will be detailed in the DCD.

- d. **Regulatory Guide 1.54**, [Revision 3, April 2017] - Service Level I, II, and III Protective Coatings Applied to Nuclear Power Plants

Regulatory Guide 1.54 provides guidance for the application of protective coatings within nuclear power plants to protect surfaces from corrosion, contamination from radionuclides, and for wear protection.



X-energy identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in the DCD.

- e. **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 the DCD.

- f. **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 the DCD.

- g. **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 the DCD.

1.2. Standards

- a. **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 Part II of this document with specific identification of exceptions or clarification. X-energy commits to NQA-1-2015 Part III only as specifically noted in Part II of this document.

- b. **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.

- c. **NEI 14-05, Revision 1**

X-energy commits to 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 as described in Part II, Section 7 of this document.