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

February 11, 2025

Mr. Stephen Vaughn
Licensing Manager, Xe-100
X Energy, LLC.
530 Gaither Road, Suite 700
Rockville, MD 20850

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION FINAL SAFETY EVALUATION FOR X ENERGY LLC'S QUALITY ASSURANCE PROGRAM DESCRIPTION TOPICAL REPORT, REVISION 6 (EPID NO: L-2022-TOP-0035)

Dear Mr. Vaughn:

By letter dated September 13, 2023 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML23256A159), X Energy, LLC., (X-energy) submitted for the U.S. Nuclear Regulatory Commission (NRC or Commission) staff's review the Revision 6 of its Quality Assurance Program Description (QAPD) topical report (TR). This TR applies to the design, construction, and operations phase activities in support of a standard design approval, a design certification, an early site permit, a limited work authorization, a construction permit, an operating license, and/or a combined license for all X-energy's technologies.

The NRC staff's final safety evaluation (SE) for X-energy's QAPD TR is enclosed. The NRC staff concluded that the QAPD is acceptable, subject to the limitations documented in the SE. The NRC staff requests that X-energy submit an accepted version of the QAPD TR within 3 months of the receipt of this letter. The accepted version shall incorporate this letter and the enclosed SE.

If you have any questions, please contact Adrian Muñiz via email at Adrian.Muniz@nrc.gov.

Sincerely,

John Segala Signed by Segala, John on 02/11/25

John Segala, Chief
Advanced Reactor Licensing Branch 2
Division of Advanced Reactors and Non-Power Production and Utilization Facilities
Office of Nuclear Reactor Regulation

Project No. 99902071

Enclosure: As stated

cc: via X-Energy Xe-100 GovDelivery
jmaddocks@x-energy.com

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION FINAL SAFETY EVALUATION FOR X ENERGY LLC'S QUALITY ASSURANCE PROGRAM DESCRIPTION TOPICAL REPORT, REVISION 6 (EPID NO: L-2022-TOP-0035) DATED: FEBRUARY 11, 2025

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UNITED STATES
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WASHINGTON, D.C. 20555-0001

X ENERGY - DRAFT SAFETY EVALUATION OF THE TOPICAL REPORT QUALITY ASSURANCE PROGRAM DESCRIPTION, REVISION 6 (EPID L-2022-TOP-0035)

Sponsor: X Energy, LLC.

Sponsor Address: 530 Gaither Road, Suite 700
Rockville, MD 20850

Docket /Project No.: 99902071

Submittal Dates: September 13, 2023 (Revision 6)

Submittal Agencywide Documents Access and Management System (ADAMS) Accession Nos.: ML23256A159

Supplement and RAI response letter Dates and ADAMS Accession Nos.: February 20, 2024, ML24051A236

Brief Description of the Topical Report: Revision 6 of X Energy, LLC's (hereafter referred to as X-energy), Quality Assurance Program Description (QAPD) Topical Report (TR), "XEQAPD 1.0," addresses the design, construction, and operations phase activities, as appropriate, in support of a Standard Design Approval (SDA), a Design Certification (DC), an Early Site Permit (ESP), a Limited Work Authorization (LWA), a Construction Permit (CP), an Operating License (OL), and/or a Combined License (COL) for all of X-energy's reactor technologies. X-energy stated that Revision 6 is intended to supersede other revisions of the QAPD TR. Furthermore, the U.S. Nuclear Regulatory Commission (NRC or Commission) staff notes that Revision 6 of the QAPD TR lists and incorporates changes made to the document as a result of previous revisions. Revision 6 of the QAPD states that it 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," 10 CFR Part 71, "Packaging and Transportation of Radioactive Material," (Subpart H), and the American Society of Mechanical Engineers standard NQA-1-2015, "Quality Assurance Program Requirements for Nuclear Facility Applications," (Reference 1) as endorsed by the NRC Regulatory Guide 1.28, "Quality Assurance Program Criteria (Design and Construction)," Revision 5, dated October 2017 (Reference 2). However, in a letter dated July 16, 2024 (ML24198A131), X-energy clarified that the statements in the QAPD TR pertaining to 10 CFR Part 71 are not intended as a request for QAP approval pursuant to 10 CFR 71, nor are they intended to constitute notification that X-energy is intending to apply its 10 CFR 50, Appendix B, QAPD to 10 CFR 71 activities at this time. Therefore, the NRC staff is imposing a limitation to reflect that the QAPD TR is not approved for 10 CFR Part 71 activities. For additional details regarding the submittal, please refer to the documents located at the ADAMS Accession Nos. identified above.

REGULATORY EVALUATION

Appendix B to 10 CFR Part 50 sets forth the regulatory requirements related to quality assurance programs (QAPs). Appendix B to 10 CFR Part 50 establishes quality assurance (QA) requirements for the design, fabrication, construction, and testing of structures, systems, and components (SSCs) for the facility and for the managerial and administrative controls to be used to assure safe operation. 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.

Regulations in 10 CFR 50.10, "License required; limited work authorization," establish the technical information requirements for LWA applications. Under 10 CFR 50.10(d)(3)(i) LWA applications must contain a description of the activities requested to be performed, a safety analysis report (SAR), as required by 10 CFR 50.34, "Contents of applications; technical information," 10 CFR 52.17, "Contents of applications; technical information," or 10 CFR 52.79, "Contents of applications; technical information in final safety analysis report," as applicable, and the design and construction information otherwise required by the Commission's rules and regulations, but limited to those portions of the facility that are within the scope of the LWA.

Regulations in 10 CFR 50.34 establish the technical requirements for CP and OL applications. Under 10 CFR 50.34(a)(7), CP applications must provide a description of the QAP to be applied to the design, fabrication, construction, and testing of the SSCs of the facility. Section 10 CFR 50.34(a)(7) also requires that the description of the QAP include a discussion of how the applicable requirements of Appendix B to 10 CFR Part 50 will be satisfied. Finally, 10 CFR 50.34(b)(6)(ii) requires the OL application to contain information regarding the managerial and administrative controls to be used to assure safe operation consistent with the requirements of Appendix B to 10 CFR Part 50 and a discussion of how such requirements will be satisfied.

Regulations in 10 CFR 50.34(f)(3)(ii) and (iii) specify additional design and construction QA requirements for CP, DC, SDA, and COL applications. These requirements include a list of SSCs subject to QA requirements, independence of the QA organization, QA and quality control (QC) implementation at construction sites, establishing criteria for QA programmatic requirements, the role of QA personnel in quality-related procedures and in design and analysis activities, qualification of QA and QC personnel and sizing of QA staff, and procedures for maintaining "as-built" documentation.

Regulations in 10 CFR 52.17 establish the technical information requirements for ESP applications. Section 52.17(a)(1)(xi) requires that ESP applications provide a description of the QAP applied to site-related activities for the future design, fabrication, construction, and testing of the SSCs of a facility or facilities that may be constructed on the site, including a discussion of how the applicable requirements of Appendix B to 10 CFR Part 50 will be satisfied.

Regulations in 10 CFR 52.47, "Contents of applications; technical information," establish the technical information requirements for DC applications. Section 10 CFR 52.47(a)(19) requires that DC applications provide a description of the QAP applied to the design of the SSCs of the facility. Further, 10 CFR 52.47(a)(19) requires that the description of the QAP include a discussion of how the applicable requirements of Appendix B to 10 CFR Part 50 have been satisfied.

Regulations in 10 CFR 52.79 establish the technical information requirements for COL applications. Section 52.79(a)(25) requires that COL applications provide a description of the QAP applied to the design, and to be applied to the fabrication, construction, and testing of the SSCs of the facility. Further, 10 CFR 52.79(a)(25) requires that the description of the QAP include a discussion of how the applicable requirements of Appendix B to 10 CFR Part 50 have been and will be satisfied, and also include a discussion of how the QAP will be implemented. Finally, 10 CFR 52.79(a)(27) requires that the application contain information regarding the managerial and administrative controls to be used to assure safe operation consistent with the requirements of Appendix B to 10 CFR Part 50 and a discussion of how such requirements will be satisfied.

Regulations in 10 CFR 52.137, "Contents of applications; technical information," establish the technical information requirements for SDA applications. Under 10 CFR 52.137(a)(19) SDA applications must provide a description of the QAP applied to the design of the SSCs of the facility. Section 10 CFR 52.137(a)(19) also requires that the description of the QAP include a discussion of how the applicable requirements of Appendix B to 10 CFR Part 50 have been satisfied.

TECHNICAL EVALUATION

In evaluating the adequacy of X-energy's QAPD TR, the NRC staff utilized the guidance contained in Section 17.5 of the Standard Review Plan (SRP) 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 (Reference 3), which provides guidance to the NRC staff for the review of a QAPD for DC, ESP, COL, CP, and OL applicants. Section 17.5 of the SRP is based on Appendix B to 10 CFR Part 50 and describes the regulatory and industry guidance on methods the staff determined to be acceptable for meeting the requirements of Appendix B to 10 CFR Part 50. Section 17.5 of the SRP does not specifically address SDAs and LWAs. However, the requirements of Appendix B to 10 CFR Part 50 that apply to a COL encompass the quality-related activities for an SDA or an LWA. The ASME standard NQA-1-2015 Edition, upon which X-energy's QAPD is based, is endorsed (with certain exceptions and clarifications) by the NRC in Revision 5 of RG 1.28, as providing an adequate basis for complying with Appendix B to 10 CFR Part 50.

1.0 Quality Assurance Program Overview

Revision 6 of X-energy's QAPD TR provides for the control of X-energy's activities affecting the quality and performance of safety-related SSCs and select non-safety-related SSCs to the design, construction, and operations phase activities, including those in support of an SDA, a DC, an ESP, an LWA, a CP, an OL, and/or a COL for all of X-energy's reactor technologies. Revision 6 of X-energy's QAPD TR notes that in addition to developing Generation IV high-temperature gas cooled reactors for terrestrial applications, it is also focused on "applying [its] knowledge and expertise in the development of space nuclear applications; and designing and manufacturing the fuel to power [its] proprietary designs and other reactor technologies." The NRC staff's determinations in this SE are only for activities related to X-energy's reactor technologies in terrestrial applications.

1.1 Organization

X-energy's 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 QAP during the design, construction, and operations phases. X-energy's QAPD satisfies the requirements of 10 CFR 50.34(f)(3)(iii)(A) by providing that independence be maintained between the organization(s) performing the checking (QA and control) functions and the organizations performing the functions. In addition, X-energy's QAPD complies with the requirements of 10 CFR 50.34(f)(3)(iii)(F) by providing that applicable management is responsible to size the QA organization commensurate with the duties and responsibilities assigned. During the construction and operational phases, this responsibility transitions to the Site Executive.

X-energy's QAPD establishes that the QA organization has sufficient authority, direct access to responsible levels of management, organizational freedom, and access to work to perform the QA function, including sufficient independence from cost and schedule when opposed to safety function considerations. In addition, the responsibility and authority for planning, establishing, and implementing an effective overall QAP are clearly described and defined, including identifying the position responsible for directing and managing X-energy's QAP during the design, construction, and operational phases.

X-energy's 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. This authority extends to off-site work performed by suppliers that furnish safety-related materials and services to X-energy.

X-energy's QAPD commits to implement the quality standards described in NQA-1-2015, Requirement 1, "Organization," without further clarifications or exceptions. The NRC staff reviewed X-energy's organization controls in accordance with the applicable review guidance in SRP 17.5 and determined they comply with the requirements of Criterion I, "Organization," of Appendix B to 10 CFR Part 50, and therefore, are acceptable.

1.2 Quality Assurance Program

X-energy's QAPD conforms to SRP Section 17.5, Subsection II.B, for establishing the necessary measures to implement a QAP to ensure that the design, construction, and operation of a facility using X-energy's technology, is in accordance with governing regulations and license requirements. The QAP applies to those quality-related activities that involve the functions of safety-related SSCs associated with the design, fabrication, construction, and testing of the SSCs of the facility, and to the managerial and administrative controls used to ensure safe operation of a facility using X-energy's technology. Examples of ESP, CP/OL, or COL program safety-related activities include, but are not limited to, site-specific engineering related to safety-related SSCs, site geotechnical investigations, site engineering analysis, seismic analysis, and meteorological analysis.

X-energy will maintain a list or a system to identify which SSCs and activities X-energy's QAP applies to. X-energy may delegate all or part of the activities associated with planning, establishing, and implementing the QAP, but X-energy retains responsibility for its effectiveness. In addition, X-energy's QAPD provides measures to assess the adequacy of the QAP to assure its effective implementation at least once each year or at least during the life of the activity,

whichever is shorter. Further, X-energy's QAP allows a grace period of 90 days to activities (e.g., audits and annual evaluations of suppliers) that are required to be performed on a periodic basis. When this grace period is used, the next scheduled date for the activity is based on the original activity scheduled date and not on the date that the activity was performed. If the activity is performed early, the next schedule date is based on the date the activity was performed. 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.

The NRC staff reviewed X-energy's QAPD in accordance with SRP Section 17.5, paragraphs II.S and II.T and determined it provides the necessary measures to establish and maintain formal indoctrination and training programs for personnel performing, verifying, or maintaining activities within the scope of the QAP to ensure that suitable proficiency is achieved and maintained. In addition, X-energy's QAPD provides the minimum training requirements for all personnel responsible for the implementation of X-energy's QAP.

X-energy's QAPD commits to implement the quality standards described in NQA-1-2015, Requirement 2, "Quality Assurance Program," and the regulatory positions described in Revision 5 of RG 1.28, with the following clarifications and exceptions.

1. For Section 302, "Inspection and Test," X-energy commits to the use of NQA-1-2015, Subpart 3.1-2.3 guidance.

   The NRC staff evaluated this proposed clarification and determined that the guidance in Subpart 3.1-2.3 can be used to meet the requirements of Appendix B to 10 CFR Part 50 and is equivalent to the NRC staff review guidance in SRP Section 17.5, paragraph II.T.5. Therefore, the NRC staff determined that the use of Subpart 3.1-2.3 of NQA-1-2015 for qualification of inspection and test personnel acceptable.

2. X-energy follows Section 301, "Nondestructive Examination (NDE)," for qualification of non-destructive examination personnel (NDE), except that X-energy will follow the applicable standard cited in the version(s) of Section III, "Rules for Construction of Nuclear Facility Components," and Section XI, "Rules for Inservice Inspection of Nuclear Power Plant Components," of the ASME Boiler and Pressure Vessel (B&PV) Code approved by the NRC for use at X-energy sites for the scope of activities governed by these cited standards.

   The regulations in 10 CFR 50.55a, "Codes and Standards," endorses versions of ASME B&PV Code Sections III and XI for activities within the scope of these sections. Therefore, the NRC staff determined that the exception proposed for the use of Sections III and XI of the ASME B&PV Code for qualification of NDE personnel to be acceptable.

3. Section 401, "Inspection and Test Personnel," item (g), requires that the certification expiration date be included on the qualification record. X-energy considers the certification expiration date to be the date from the certification or recertification date plus the certification interval time, and its inclusion on the qualification record is optional.

   The NRC staff evaluated this exception and determined that the date of certification establishes the expiration date, when combined with the certification interval. The certification interval is normally a function of a code or standard and is identified in the organization's procedure and having both dates on the form is redundant. The use of this exception was previously approved in the NRC staff's safety evaluation (SE) for Kairos

Power, LLC., TR KP-TR-007-NP, “Quality Assurance Program for the Kairos Power Fluoride Salt-Cooled High Temperature Reactor,” Revision 3, dated November 16, 2021 (Reference 4). Therefore, the NRC staff determined this exception to be acceptable.

The NRC staff reviewed X-energy’s QAP controls in accordance with the applicable review guidance in SRP 17.5 and determined they comply with the requirements of Criterion II, “Quality Assurance Program,” of Appendix B to 10 CFR Part 50, and therefore, are acceptable.

1.3 Design Control

X-energy’s 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 QAP. X-energy’s design control 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 (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. In addition, X-energy’s QAPD complies with the requirements of 10 CFR 50.34(f)(3)(iii)(H) by providing for design documents to be reviewed by individuals knowledgeable in QA to ensure that the documents contain the necessary QA requirements. Further, changes to design inputs, final designs, field changes, and temporary and permanent modifications to operating facilities are justified and subject to design control measures commensurate with those applied to the original design.

X-energy’s 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 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.

X-energy’s QAPD governs the development, procurement, testing, maintenance, control, and use of computer applications and digital equipment software when used in safety-related applications and designated non-safety-related applications. 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.

X-energy’s QAPD commits to implement 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,” Subpart 2.14, “Quality Assurance Requirements for Commercial-Grade Items and Services,” and Subpart 2.20, “Quality Assurance Requirements for Subsurface Investigations for Nuclear Facilities,” without further clarifications or exceptions. The NRC staff reviewed X-energy’s design controls in accordance with the applicable review

guidance in SRP 17.5 and determined they comply with the requirements of Criterion III, "Design Control," of Appendix B to 10 CFR Part 50, and therefore, are acceptable.

1.4 Procurement Document Control

X-energy's QAPD conforms to SRP Section 17.5, Subsection II.D, for establishing the necessary measures and governing procedures to ensure that purchased items, computer programs, and services are subject to the appropriate quality and technical requirements. 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 to the extent necessary, procurement documents shall require suppliers to have a documented QAP that meets the applicable requirements of Appendix B to 10 CFR Part 50 based on the procurement scope or, alternatively, it allows the supplier to work under X-energy's approved QAP.

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

1. Section 100, "General," states that to the extent necessary, procurement documents shall require suppliers to have a QAP consistent with applicable requirements. For services performed by a supplier, X-energy's procurement documents may allow the supplier to work under X-energy's QAP, including implementing procedures, in lieu of the supplier having its own QAP.

   The NRC staff evaluated this proposed clarification and determined that it provides adequate control for establishing and executing the responsibilities for the QAP. Criterion IV, "Procurement Document Control," of Appendix B to 10 CFR Part 50, requires suppliers to have a QAP consistent with the regulations. In Section 3.2.4 of the "Final Safety Evaluation for Technical Report NEI 06-14, Quality Assurance Program Description," Revision 7, dated November 3, 2009 (Reference 5), the NRC staff determined this clarification to be acceptable. Therefore, the NRC staff determined that this clarification is acceptable.

2. Section 300, "Procurement Document Review," and Section 400, "Procurement Document Changes," of Requirement 4, require the review of technical and QAP requirements of procurement documents prior to the 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 QA requirements of the procurement.

   The NRC staff evaluated this proposed clarification and determined that it provides adequate QA review of procurement documents before awarding the contract and after any change to the contract consistent Reference 5. Therefore, the NRC staff determined that this clarification is acceptable.

3. Section 202, "Technical Requirements," and Section 203, "Quality Assurance Program Requirements," require that the technical and quality requirements be specified in the procurement documents. As a clarification, 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 X-energy's QAP, Part II, Section 7, "Control of Purchased Material, Equipment, and Services."

The NRC staff evaluated this proposed clarification and determined that it is consistent with the 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 NRC staff's review guidance in SRP Section 17.5, paragraphs II.V.1.d and II.V.1.e.

The NRC staff reviewed X-energy's procurement document controls in accordance with the applicable review guidance in SRP 17.5 and determined they comply with the requirements of Criterion IV, "Procurement Document Control," of Appendix B to 10 CFR Part 50, and therefore, are acceptable.

1.5 Instructions, Procedures, and Drawings

X-energy's 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 QAP as described in X-energy's QAPD.

X-energy's 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 reviewed X-energy's instructions, procedures, and drawings controls in accordance with the applicable review guidance in SRP 17.5 and determined they comply with the requirements of Criterion V, "Instructions, Procedures, and Drawings," of Appendix B to 10 CFR Part 50, and therefore, are acceptable.

1.6 Document Control

X-energy's 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 ensure that document changes, 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. X-energy also maintains a list of all controlled documents identifying the current approved revision or date, so personnel can readily determine the appropriate document for use. In addition, X-energy's QAPD complies with the requirements of 10 CFR 50.34(f)(3)(iii)(C) by ensuring that during the design, ESP, or construction phases, procedures for design, construction, and installation are also reviewed by the organization responsible for quality verification to ensure quality assurance measures have been appropriately applied. Further, X-energy's QAPD meets the requirements of 10 CFR 50.34(f)(3)(iii)(G) by providing that the types of documents to be controlled include as-built drawings.

X-energy's QAPD commits to the quality standards described in NQA-1-2015, Requirement 6, "Document Control," without further clarifications or exceptions. The NRC staff reviewed X-energy's document controls in accordance with the applicable review guidance in SRP 17.5 and determined they comply with the requirements of Criterion VI, "Document Control," of Appendix B to 10 CFR Part 50, and therefore, are acceptable.

1.7 Control of Purchased Material, Equipment, and Services

X-energy's 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 supplier evaluation and selection, the evaluation of objective evidence of quality furnished by the supplier, source verification and inspection, audit, and the examination of items or services.

X-energy's 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's importance to safety, complexity, quantity, and the frequency of procurement. In addition, X-energy's QAPD provides for evaluating suppliers to ensure that only qualified suppliers are used in accordance with X-energy's QAP requirements.

X-energy's QAPD provides for utilizing audits conducted by outside organizations 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," 2017 Edition (Reference 6). X-energy will also perform and document annual evaluations of qualified suppliers to ensure that these suppliers continue to provide acceptable products and services.

X-energy's 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 items or services to ensure that they will perform satisfactorily in-service in safety-related applications.

X-energy's 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 Revision 5 of RG 1.28, with the following clarifications and exceptions:

1. "X-energy considers that 10 CFR Part 50 and 10 CFR Part 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 X-energy plant(s), are not required to be evaluated or audited."

   The staff's current regulatory position regarding this exception is documented in a Tennessee Valley Authority's (TVA) SE dated December 12, 2023 (ML23254A050). The NRC staff verified that the X-energy QAPD commitments associated with supplier oversight activities are the same as those provided in the TVA New Nuclear QAPD. Therefore, the NRC staff's position associated with this exception, as documented in the TVA New Nuclear

QAPD SE, applies to the X-energy QAPD. As discussed in the TVA SE pertaining to Part 50 and Part 52 power reactor licensees, each of these licensees' QAPDs is approved by the NRC staff and subsequent changes to the QAPD can be made consistent with the requirements in 10 CFR 50.54(a) and 10 CFR 50.55(f), as applicable. Since this reasoning pertains to power reactor licensees, the NRC staff is limiting the proposed exception to other Part 50 and Part 52 power reactor licenses. This is identified as Limitation and Condition 3. The NRC staff concludes that the requested exception regarding audit and evaluation is acceptable subject to the applicable limitations described in the TVA New Nuclear QAPD SE, which are included in the Limitations and Conditions section of this SE, for the control of purchased material, equipment, and services.

2. X-energy proposes to implement the guidance from the 2020 Nuclear Energy Institute (NEI) document Number 14-05A, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," Revision 1 (Reference 10), 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 November 23, 2020 (Reference 11), the NRC staff concluded that NEI 14-05A, 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, provided certain conditions are met. The NRC staff evaluated this proposed clarification and determined that it is consistent with the NRC's SE (Reference 11) and the NRC staff's endorsement of NEI 14-05A, Revision 1 in RG 1.28, Revision 6, which is the NRC staff'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 clarification is acceptable.

3. 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 for documents to be available at the site. Following the completion of the construction period, sufficient as-built documentation will be turned over to X-energy or to the applicable licensee to support operations. X-energy or the applicable licensee's records management system will provide for the timely retrieval of necessary records.

   The NRC staff evaluated this proposed exception and determined that it 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. The NRC staff's evaluation of X-energy's use of electronic records is documented in Section 1.17 of this SE. Therefore, the NRC staff concluded that this exception is acceptable.

4. For commercial-grade items as described in Subpart 2.14 of NQA-1-2015, quality verification requirements are established and described in X-energy's documents to provide the necessary assurance that 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 is consistent with the NRC staff's review guidance in SRP Section 17.5, Subsection II, Item G. Therefore, the NRC staff concluded that this clarification is acceptable.

5. "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 10 CFR Part 21. Therefore, the NRC staff concluded that this clarification is acceptable.

6. Exigent Conditions

   X-energy's QAPD provides for extending up to 25 percent of the frequency of triennial audits or commercial-grade surveys during exigent conditions. The total allowable extension for exigent conditions is 9 months. Under the 25 percent extension, X-energy would not have to reset the "audit clock" backwards when the audit or commercial-grade survey is finally performed to the original date that the audit or commercial-grade survey should have been performed. X-energy's QAPD states that this unique grace period can be applied if the following exigent conditions exist including, but are not limited to:

   - Declaration of a national emergency or state of emergency impacting X-energy's facilities or supplier infrastructure.

   - Natural disaster, weather emergency, or other severe localized or national weather event or resulting damage to or impacting X-energy's facilities or supplier infrastructure.

   - Localized outbreak of a severe health concern to the public impacting X-energy's facilities or supplier infrastructure.

   In addition, the X-energy QAPD states that the date that the audit or commercial-grade survey is finally performed would be the start of the new triennial audit or commercial-grade survey frequency. Furthermore, it states that X-energy will perform an evaluation of the

supplier's QAP and document the results. The use of the 25 percent frequency extension for audits and commercial-grade surveys during extenuating circumstances was previously approved in the NRC staff's SE for a change to Callaway Plant's Operating Quality Assurance Manual, dated August 6, 2020 (Reference 7).

X-energy's QAPD provides for performing fully remote or provisional remote assessments during exigent conditions due to restricted access or travel to the supplier provided that the audit or commercial-grade survey is conducted in accordance with the Electric Power Research Institute's (EPRI) Technical Report No. 3002020796, "Remote Assessment Techniques: Planning and Conducting Audits and Surveys Using Remote Techniques During Exigent Conditions," dated April 2021. The use of EPRI Technical Report No. 3002020796 was previously approved during the Coronavirus Disease 2019 (COVID-19) public health emergency (PHE) in the NRC staff's SE for a change to Southern Nuclear Operating Company's Quality Assurance TR, dated June 22, 2021 (Reference 8).

Further, X-energy's QAPD provides for performing fully remote source verifications during exigent conditions in accordance with the guidance in EPRI Technical Report No. 3002019436, "Remote Source Verification During a Pandemic or Similar State of Emergency: Screening Criteria and Process Guidance," Revision 0, dated April 2020. The use of EPRI Technical Report No. 3002019436 was previously approved in the NRC staff's SE for a change to Columbia Generating Station's Operational Quality Assurance Program Description, dated July 7, 2020 (Reference 9).

The NRC staff notes that the COVID-19 PHE expired on May 11, 2023; therefore, the provisions for audit extension and remote source verification under exigent conditions, as described above, can no longer be used unless new exigent conditions exist.

The NRC staff reviewed X-energy's purchased material, equipment, and services controls are in accordance with SRP 17.5 and determined they comply with the requirements of Criterion VII of Appendix B to 10 CFR Part 50, and therefore, are acceptable.

1.8 Identification and Control of Materials, Parts, and Components

X-energy's 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. 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.

X-energy's 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 reviewed X-energy's identification and controls for materials, parts, and components are in accordance with SRP 17.5 and determined they 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.

1.9 Control of Special Processes

X-energy's QAPD conforms to SRP Section 17.5, Subsection II.I, for establishing the necessary measures and governing procedures to ensure that special processes such as welding, heat treating, and non-destructive examination are controlled. 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. 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.

X-energy's 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 reviewed X-energy's control of special processes in accordance with SRP 17.5 and determined that it complies with the requirements of Criterion IX, "Control of Special Processes," of Appendix B to 10 CFR Part 50, and therefore, are acceptable.

1.10 Inspection

X-energy's QAPD conforms to SRP Section 17.5, Subsection II.J, for establishing the necessary measures and governing procedures to implement inspections that ensure items, services, and activities affecting safety, meet established requirements and conform to applicable documented specifications, instructions, procedures, and design documents. Types of inspections may include those verifications related to procurement, such as source, in-process, final, and receipt inspection, as well as construction, installation, maintenance, modification, in-service, and operations activities. These types of inspections will be performed by properly qualified personnel independent of those who performed or directly supervised the work, and the inspection results will be documented.

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, reinspection 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.

X-energy's QAPD commits to the quality standards described in NQA-1-2015, Requirement 10, "Inspection," and Subpart 2.5, "Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete, Structural Steel, Soils, and Foundations for Nuclear Facilities," and Subpart 2.8, "Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Items for Nuclear Facilities," without further clarifications or exceptions. The NRC staff reviewed X-energy's inspection controls in accordance with the applicable review guidance in SRP 17.5 and determined they comply with the requirements of Criterion X, "Inspection," of Appendix B to 10 CFR Part 50, and therefore, are acceptable.

1.11 Test Control

X-energy's 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, that the plant can be operated safely as designed, and that the operation of the plant is satisfactory. Test programs include criteria for determining when testing is required, such as proof tests before installation, pre-operational tests, post-maintenance tests, post-modification tests, in-service tests, and operational tests to demonstrate that the performance of plant systems is in accordance with its design. Test programs also include provisions to establish and adjust test schedules, and to maintain the status for periodic or recurring tests. Tests are performed in accordance with 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 ensure that the test requirements have been satisfied. If acceptance criteria are not met, re-testing is performed as needed to confirm acceptability following the correction of the system or equipment deficiencies that caused the failure.

X-energy's QAPD commits to the quality standards described in NQA-1-2015, Requirement 11, "Test Control," and Subpart 2.7 without further clarifications or exceptions. The NRC staff reviewed X-energy's test controls in accordance with the applicable review guidance in SRP 17.5 and determined they comply with the requirements of Criterion XI, "Test Control," of Appendix B to 10 CFR Part 50, and therefore, are acceptable.

1.12 Control of Measuring and Test Equipment

X-energy's 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 for information important to safe plant operation. 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 is labeled, tagged, or otherwise controlled to indicate its calibration status and to ensure its traceability to calibration test data.

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 that is found to be out of calibration is tagged or segregated and not used until it is recalibrated. When M&TE is found to be 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 to be out of calibration, it is repaired or replaced. A calibration is performed when the accuracy of the equipment is suspect.

X-energy's 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 reviewed X-energy's M&TE controls in accordance with the applicable review guidance in SRP 17.5 and determined they 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.

1.13 Handling, Storage, and Shipping

X-energy's 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 items to prevent inadvertent damage or loss, and to minimize deterioration. Items are appropriately marked and labeled during packaging, shipping, handling, and storage to identify, maintain, and preserve the item's integrity and provide an indication of the needs for special controls. Any special controls (e.g., containers, shock absorbers, accelerometers, inert gas atmospheres, specific moisture content levels, and temperature levels) are provided when required to maintain acceptable quality. In addition, any special or additional handling, storage, shipping, cleaning, and preservation requirements are identified in the procurement documents and applicable procedures.

Special handling tools and equipment are controlled to ensure safe and adequate handling. These special handling tools and equipment are inspected and tested in accordance with procedures at specified time intervals or prior to use. X-energy's QAPD establishes housekeeping practices to account for conditions or environments that could affect the quality of SSCs within the plant. This includes the 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).

X-energy's QAPD commits to the quality standards described in NQA-1-2015, Requirement 13, "Handling, Storage, and Shipping," without further clarifications or exceptions. X-energy's QAPD also commits, during the construction and operational phases of the plant, to conform with Subpart 2.1, "Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components for Nuclear Facilities," Subpart 2.2, "Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Nuclear Facilities," and Subpart 2.3, "Quality Assurance Requirements for Housekeeping at Nuclear Facilities," with the following clarifications and exceptions:

1. Subpart 2.1, Section 301, "Cleanness Classification," and Section 302, "Cleanness Class Criteria," establish criteria for classifying items into cleanness classes and requirements for each class. Instead of using the cleanness level system of Subpart 2.1, X-energy may establish cleanness requirements on a case-by-case basis, consistent with the other provisions of Subpart 2.1. X-energy establishes appropriate cleanliness controls for work on safety-related equipment to minimize the introduction of foreign material and to maintain system/component cleanliness throughout maintenance or modification activities, including documented verification of the absence of foreign material prior to system closure.

   The NRC staff evaluated this proposed exception and determined that it is consistent with the NRC staff review guidance provided in SRP Section 17.5. In addition, this exception was previously approved in the NRC staff's SE for Nuclear Management Company's (NMC) QA TR dated March 24, 2005 (Reference 12). Therefore, the NRC staff concluded that this exception is acceptable.

2. Subpart 2.2, Section 201, "Classification of Items," establishes criteria for classifying items into protection levels. Instead of classifying items into protection levels during the

operational phase, X-energy may establish controls for the packaging, shipping, handling, and storage of such items on a case-by-case basis with due regard for the item's complexity, use, and sensitivity to damage. Prior to installation or use, the items are inspected and serviced as necessary to ensure that no damage or deterioration exists which could affect their function.

The NRC staff evaluated this proposed exception and determined that it is consistent with the NRC staff review guidance provided in SRP Section 17.5. In addition, this exception was previously approved in the NRC staff's SE for NMC's QA TR dated March 24, 2005. Therefore, the NRC staff concluded that this exception is acceptable.

3. Subpart 2.2, Section 606, "Storage Records," requires written records to be prepared containing information regarding personnel access. As an exception to this requirement, X-energy's documents establish controls for storage areas that describe those whom are authorized, to access areas and the requirements for recording access of personnel. However, these records of access are not considered quality records and will be retained in accordance with the administrative controls of the applicable plant.

   In the Final Safety Evaluation for Technical Report NEI 06-14, the NRC staff evaluated this proposed exception and determined that these records of access are not considered quality records. The NRC staff evaluated this exception and determined that these records do not meet the classification of a quality record as defined in NQA-1-2015, Requirement 17, "Quality Assurance Records." Therefore, the NRC staff concluded that this exception is acceptable.

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

   The NRC staff evaluated this proposed exception and determined that it is consistent with the NRC staff review guidance in SRP Section 17.5. In addition, this exception was previously approved in the NRC staff's SE for NMC's QA TR dated March 24, 2005. Therefore, the NRC staff concluded that this exception is acceptable.

The NRC staff reviewed X-energy's handling, storage, and shipping controls in accordance with the applicable review guidance in SRP 17.5 and determined they comply with the requirements of Criterion XIII, "Handling, Storage, and Shipping," of Appendix B to 10 CFR Part 50, and therefore, are acceptable.

1.14 Inspection, Test, and Operating Status

X-energy's 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. Measures are

provided for the verification of inspections, tests, and operating status to preclude 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 modifications are controlled by procedures that include requirements for appropriate installation and removal, independent/concurrent verifications, and status tracking.

X-energy's 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 reviewed X-energy's inspection, test, and operating status controls in accordance with the applicable review guidance in SRP 17.5 and determined they comply with the requirements of Criterion XIV, "Inspection, Test, and Operating Status," of Appendix B to 10 CFR Part 50, and therefore, are acceptable.

1.15 Nonconforming Materials, Parts, or Components

X-energy's 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. Controls provide for the identification, documentation, evaluation, segregation (when practical), and disposition of non-conforming items, and notification to affected organizations. Controls are also provided to address conditional release of non-conforming items for use with appropriate controls prior to resolution and disposition of the non-conformance, including maintaining identification of the item and documenting the basis for such release.

Nonconformances 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. The disposition of nonconformances, such as "use as-is," "reject," "repair," or "rework," is identified and documented along with the technical justification. 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.

X-energy's QAPD provides for establishing the appropriate interfaces between the QAP for the 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, 10 CFR 50.55, "Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses," and/or 10 CFR Part 21, during the design, construction, and operational phases.

X-energy's 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 reviewed X-energy's nonconforming materials, parts, or components controls in accordance with the applicable review guidance in SRP 17.5 and determined they comply with the requirements of Criterion XV, "Nonconforming Materials, Parts, or Components," of Appendix B to 10 CFR Part 50, and therefore, are acceptable.

1.16 Corrective Action

X-energy's 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. X-energy's 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's 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 maintains responsibility for the effectiveness of corrective action measures.

X-energy's QAPD provides for establishing the appropriate interfaces between the QAP for corrective actions and the non-QA Reporting program in order to satisfy the requirements of 10 CFR Part 52, 10 CFR 50.55, and 10 CFR Part 21 during the design, construction, and operational phases.

X-energy's QAPD commits to the quality standards described in NQA-1-2015, Requirement 16, "Corrective Action," without further clarifications or exceptions. The NRC staff reviewed X-energy's corrective action controls in accordance with the applicable review guidance in SRP 17.5 and determined they comply with the requirements of Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50, and therefore, are acceptable.

1.17 Quality Assurance Records

X-energy's 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.

X-energy's QAPD establishes measures to ensure that sufficient records of completed items and activities affecting quality are appropriately stored. Records of activities for design, engineering, procurement, manufacturing, construction, inspection and test, installation, pre-operation, start-up, operations, maintenance, modification, and audits and their retention times are defined in appropriate procedures. The records and retention times are based on Regulatory Position C.3.a of 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 provides that those more restrictive requirements will be met.

When managing QA records in electronic media, X-energy's QAPD commits to following the guidelines found in the 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."

X-energy's 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 reviewed X-energy's QA records controls in accordance with the applicable review guidance in SRP 17.5 and determined they comply with the requirements of Criterion XVII, "Quality Assurance Records," of Appendix B to 10 CFR Part 50, and therefore, are acceptable.

1.18 Audits

X-energy's 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.

X-energy's 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's QAP. Prior to placing the facility in operation, internal audits are performed in such a manner as to ensure that an audit of all applicable QAP 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. After placing the facility in operation, internal audits are performed in such a manner as to ensure that an audit of all applicable QAP elements is completed for each functional area within a period of 2 years. Internal audit frequencies of well-established activities conducted after placing the facility in operation may be extended 1 year at a time beyond the above 2 year interval based on the results of an annual evaluation of the applicable functional area and objective evidence that the functional area activities are being satisfactorily accomplished. However, the internal audit frequency interval should not exceed a maximum of 4 years.

The scope of the audit is determined by the quality status and safety importance of the activities being performed. 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 QA management responsible for the day-to-day program. External audits determine the adequacy of a supplier's QAP and are conducted as described in Section 7 of X-energy's QAPD and Section 3.1.7 of this SE.

X-energy's 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.

X-energy's QAPD commits to the quality standards described in NQA-1-2015, Requirement 18, "Audits," and the regulatory positions described in Revision 5 of RG 1.28, without further clarifications or exceptions. The NRC staff reviewed X-energy's audit controls in accordance with the applicable review guidance in SRP 17.5 and determined they comply with the requirements of Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50, and therefore, are acceptable.

2.0 Non-Safety-Related SSC Quality Control

2.1 Non-Safety-Related SSCs With Special Treatment

The NRC staff reviewed X-energy's QAPD against the review guidance of SRP Section 17.5, Paragraph II.U.1, and determined it establishes necessary measures and governing procedures to address certain non-safety-related SSCs for which Appendix B to 10 CFR Part 50 is not applicable but are considered significant contributors to plant safety. X-energy's QAPD applies specific controls to those items in a selective manner to target characteristics or critical attributes that render the SSC a significant contributor to plant safety.

2.2 Non-Safety-Related SSCs Credited for Regulatory Events

In establishing the quality requirements for non-safety-related SSCs credited for regulatory events, X-energy's QAPD follows the NRC staff's review guidance in SRP Section 17.5, Paragraph II.U.2, and X-energy commits to implement the following:

- Regulatory Position 1.7, "Quality Assurance," in RG 1.189, "Fire Protection for Nuclear Power Plants," Revision 4, for the fire protection system.

- Part III, Section 1, of X-energy's QAPD, for implementing the quality requirements for the anticipated transient without scram (ATWS) equipment to the extent that any equipment has been identified to be important to safety in case of ATWS.

- Part III, Section 1 of X-energy's QAPD, for implementing the quality requirements for the station blackout (SBO) equipment to the extent that any equipment has been identified to be important to safety in case of SBO.

3.0 Regulatory Commitments

The NRC staff reviewed X-energy's QAPD against the review guidance of SRP Section 17.5, paragraph II.V for establishing QAP commitments and determined X-energy identified the extent of conformance with these RGs and other QA standards to supplement and support the QAP, as applicable:

- RG 1.8, "Qualification and Training of Personnel for Nuclear Power Plants," Revision 4, dated June 2019. RG 1.8 provides guidance that is acceptable to the NRC staff regarding qualifications and training for nuclear power plant personnel.

- 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 QAP for the design and construction of nuclear power plants.

- RG 1.33, "Quality Assurance Program Requirements (Operations)," Revision 3, dated June 2013. RG 1.33 describes a method acceptable to the NRC staff for complying with the Commission's regulations regarding overall QAP requirements for the operation phase of nuclear power plants.

- Appendix A, “High Temperature Reactor Quality Group Classification,” of RG 1.87, “Acceptability of ASME Code, Section III, Division 5, “High Temperature Reactors,”” Revision 2, dated January 2023. Appendix A of RG 1.87 describes a method acceptable to the NRC staff for establishing quality group assignments of mechanical systems and components of non-light-water reactors for all the safety classification methods and provides guidance on selecting an appropriate design standard once the classification methods are used to determine the classification of each system and component.

- 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 Section 1.1 through Section 1.18 of this SE.

- NEI 14-05A, “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 1.7 of this SE.

- NIRMA TGs 11-2011, 15-2011, 16-2011, and 21-2011; as described in Section 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 within the applicable license application (e.g., safety analysis reports). 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 license application review, as applicable. This is identified as Limitation 2.

- RG 1.29, “Seismic Design Classification,” Revision 5, dated July 2016. RG 1.29 defines light water reactor systems required to withstand a safe shutdown earthquake.

- 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 the 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.

X-energy's QAPD satisfies 10 CFR 50.34(f)(3)(ii) by providing that the QA list required by Criterion II of Appendix B to 10 CFR Part 50 includes all SSCs important to safety[1]. X-energy's QAPD satisfies 10 CFR 50.34(f)(3)(iii)(D) by establishing criteria for determining QA programmatic requirements. X-energy's QAPD commits to conformance with ASME NQA-1-2015, as endorsed by RG 1.28, Revision 5. X-energy's QAPD also commits to conformance with RG 1.33, Revision 3 for operations phase specific QA requirements.

The NRC staff determined that X-energy's QA controls, as described in the QAPD, in accordance with the NRC staff's review guidance in SRP Section 17.5 and determined they comply with the requirements of Appendix B to 10 CFR Part 50, and therefore, are acceptable. X-energy's commitment to conformance with NQA-1 also satisfies 10 CFR 50.34(f)(3)(iii)(B) by establishing criteria for performing QA control functions at construction to the maximum extent feasible. Subpart 2.8, "Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Items for Nuclear Facilities," provides amplified requirements, in part, for inspection and testing during the construction phase and into operations. Subpart 2.8 requires material verification, receipt inspection, preinstallation verification, physical installation inspections, installation area inspections, post-installation inspections, inspections of work areas and the work in progress, pressure testing, and ensuring systems are cleaned and maintained once installed. This also includes inspection and testing during the preoperational phase of construction.

LIMITATIONS AND CONDITIONS

The NRC has identified the following limitations associated with X-energy's QAPD:

Limitation No. 1

X-energy's QAPD, Revision 6, is not approved for 10 CFR Part 71 activities.

Limitation No. 2

X-energy stated that it did not include a commitment to conform with the applicable regulatory guidance in the following RGs: 1.29, 1.164, and 1.231, and 1.234. X-energy will have to address in any license application relying on this TR its conformance with the applicable regulatory positions provided in the RGs or justify exceptions thereto.

Limitation No. 3

The exception to not perform audits or evaluations for procurements from other Parts 50 and 52 licensees only applies when X-energy procures from other Parts 50 and 52 power reactor licensees.

[1] For licensing applications referencing this TR using the process described in NEI 18-04, "Risk-Informed Performance-Based Technology Inclusive Guidance for Non-Light Water Reactor Licensing Basis Development," Revision 1, as endorsed in RG 1.233, "Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors," SSCs classified as safety-related (SR) and NSRST are important-to-safety SSCs as discussed in this TR.

Limitation No. 4

When X-energy procures from other manufacturing licensees where inspections during the fabrication or manufacturing process are required to assure quality, X-energy must establish measures for source verification for these procurements, as required by Criterion VII of Appendix B to 10 CFR Part 50.

CONCLUSION

X-energy's 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 QAP 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, with the exception of the limitations discussed above.

X-energy's 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 programmatic controls.

X-energy's 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 10 CFR 50.10(d)(3)(i), 10 CFR 50.34(a)(7), 10 CFR 50.34(b)(6)(ii), 10 CFR 50.34(f)(3)(ii) and (iii), 10 CFR 52.17(a)(1)(xi), 10 CFR 52.47(a)(19), 10 CFR 52.79(a)(25), 10 CFR 52.79(a)(27), 10 CFR 52.137(a)(19), and Appendix B to 10 CFR Part 50. On the basis of its review of the X-energy's QAPD, the NRC staff concludes, subject to the limitations above, that:

- X-energy's 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 X-energy's QAP is applicable.

- X-energy's 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 non-safety-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.

- X-energy's QAPD adequately applies to activities and items that are important to safety.

- X-energy's QAPD adequately establishes controls that, when properly implemented, comply with the applicable requirements of 10 CFR Part 50, 10 CFR 50.34(f), 10 CFR Part 52, 10 CFR 50.55, Appendix B to 10 CFR Part 50, and 10 CFR Part 21, consistent with the criteria contained in NRC staff's review guidance 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, Revision 6, adequately describes X-energy's QAP. Accordingly, subject to the limitations discussed above, the NRC staff concludes that X-energy's QAPD, Revision 6, complies with the applicable NRC regulations and conforms with applicable industry standards and can be used by X-energy for activities associated with the design, construction, testing, and operations phase activities for its reactor technologies in terrestrial applications, including those in support of an SDA, a DC, an ESP, an LWA, a CP, an OL, and/or a COL.

REFERENCES

1. American Society of Mechanical Engineers NQA-1-2015, "Quality Assurance Program Requirements for Nuclear Facility Applications," New York, NY, dated February 20, 2015.

2. Regulatory Guide (RG) 1.28, "Quality Assurance Program Criteria (Design and Construction)," Revision 5, dated October 2017 (ML17207A293).

3. 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 (ML15037A441).

4. Final Safety Evaluation for Kairos Power, LLC TR No. KP-TR-007-NP, "Quality Assurance Program for the Kairos Power Fluoride Salt-Cooled High Temperature Reactor," Revision 3, dated November 16, 2021 (ML21308A597).

5. Final Safety Evaluation for Technical Report NEI 06-14, "Quality Assurance Program Description," Revision 7, dated November 3, 2009 (ML092650695).

6. International Standard Organization (ISO)/International Electrotechnical Commission (IEC) 17025, "General Requirements for the Competence of Testing and Calibration Laboratories," 2017 Edition.

7. Letter to Mr. Fadi Diya, Senior Vice President and Chief Nuclear Officer, Ameren Missouri, "Callaway Plant, Unit No. 1 - Operating Quality Assurance Manual Change Revision 34b, dated August 6, 2020 (ML20216A681).

8. Letter to Ms. Cheryl A. Gayheart, Regulatory Affairs Director, Southern Nuclear Operating Co., Inc., "Edwin I. Hatch Nuclear Power Plant, Units 1 and 2; Joseph M. Farley Nuclear Plant, Units 1 and 2; Vogtle Electric Generating Plans, Units 1 and 2; and Associated Independent Spent Fuel Storage Facilities - Reduction in Commitment to the Quality Assurance Topical Report," dated June 22, 2021 (ML21161A201).

9. Letter to Mr. Bradley J. Sawatzke, Chief Executive Officer, Energy Northwest, "Columbia Generating Station - Reduction in Commitment to the Operational Quality Assurance Program Description," dated July 7, 2020 (ML20181A445).

10. NEI 14-05A, "Guidelines for the Use of Accreditation in Lieu of Commercial-Grade Surveys for Procurement of Laboratory Calibration and Test Services," Revision 1, dated September 2020 (ML20259B731).

11. Final Safety Evaluation by the Office of Nuclear Reactor Regulation for the Nuclear Energy

Institute Technical Report NEI 14-05A, “Guidelines for the Use of Accreditation in Lieu of Commercial-Grade Surveys for Procurement of Laboratory Calibration and Test Services,” dated November 23, 2020 (ML20322A019).

12. Letter to Mr. Edward J. Weinkam, Director, Regulatory Services, Nuclear Management Company, LLC, “Approval of Nuclear Management Company Quality Assurance Topical Report,” dated March 24, 2005 (ML050700416).

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