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,

/RA/

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

DISTRIBUTION:
E-mail
PUBLIC
LVechioliFeliciano
BBeasley
RidsNRRDanu Resource
RidsNrrDanuUARL Resourse
RidsNrrDroIQVB Resource
RidsNrrLASLent Resource
RidsOgcMailCenter Resource
RidsACRS_MailCTR Resource
DWidmayer

---

hbowers@x-energy.com
martinvs@x-energy.com
theoo@x-energy.com
TChapman@x-energy.com

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

OFFICE	NRR/DANU/UARL/PM*	NRR/DANU/UARL/LA*	OGC*
NAME	LVechioli	SLent	JEzell
DATE	8/20/2020	8/20/2020	9/2/2020
OFFICE	NRR/DRO/IQVB/BC*	NRR/DANU/UARL/BC*	
NAME	KKavanagh	BBeasley	
DATE	9/3/2020	9/4/2020	

OFFICIAL RECORD COPY

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

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.

- NIRMA 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)