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February 03, 2020

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U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
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SUBJECT: Submittal of X Energy, LLC (X-energy) Response to NRC Requests for Additional Information Letter (ML20013G253) for the Review of Topical Report Quality Assurance Program Description (XEQAPD 1.0, Revision 0) for Design Certification of the X-energy Xe-100 Reactor - Non-Proprietary

REFERENCES:

1. Regulatory Engagement Plan for X Energy, LLC's Xe-100 Reactor with schedule for Pre-Application Submittals (XE00-R-R1ZZ-RDZZ-L_000210_Rev 1, June 28, 2019)
2. X Energy, LLC TR QAPD Submittal (XE00-R-R1ZZ-RDZZ-L_000211_Rev 1, July 31, 2019)
3. Letter (ML20013G253) from U.S. Nuclear Regulatory Commission to X Energy, LLC, "Request for Additional Information on the NRC Assessment of the Quality Assurance Program Description for the X-energy XE-100 Nuclear Reactor X-Energy, LLC EPID L-2019-TOP-0020 (January 13, 2020)

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

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

The information provided in Enclosure 1 is nonproprietary.

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

Sincerely,



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



ENCLOSURE 1

X Energy, LLC (X-energy) Response to NRC Requests for Additional Information Letter (ML20013G253) for the Review of Topical Report Quality Assurance Program Description (XEQAPD 1.0, Revision 0) for Design Certification of the X-energy Xe-100 Reactor - Non-Proprietary



1. NRC RAI QUESTION NUMBER: RAI-1

NRC RAI Question

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

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

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

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

X-energy RAI Question Response

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

Corresponding QAPD update to implement the response

PART II QUALITY ASSURANCE PROGRAM DESCRIPTION DETAILS

SECTION 1 ORGANIZATION

This section describes the X-energy organizational structure, functional responsibilities, levels of authority and interfaces for establishing, executing, and verifying QAPD implementation. The organizational structure includes corporate/support and on-site functions required to support the activities associated with license preparation, NRC review of the license application, and NRC rulemaking including interface responsibilities for multiple organizations that perform quality-related functions. Implementing documents assign more specific responsibilities and duties, and define the organizational interfaces involved in conducting activities and duties within the scope of the QAPD. Management ensures that the size of the QA organization is commensurate with its duties and responsibilities assigned. Management gives careful consideration to the timing, extent, and effects of organizational structure changes.



2. NRC RAI QUESTION NUMBER: RAI-2

NRC RAI Question

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

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

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

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

X-energy RAI Question Response

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

Corresponding QAPD update to implement the response

SECTION 2.4 ISSUANCE AND REVISION TO QUALITY ASSURANCE PROGRAM

Administrative control of the QAPD will be in accordance with 10 CFR 50.4(b)(7)(ii). Proposed changes to the QAPD are evaluated by the X-energy SHEQD to ensure that such changes do not degrade safety for previously approved quality assurance controls specified in the QAPD. This document shall be revised as appropriate to incorporate additional QA commitments that may be established during the DC application process. New revisions to the document will be reviewed, at a minimum, by the X-energy SHEQD and approved by the CEO.



3. NRC RAI QUESTION NUMBER: RAI-3

NRC RAI Question

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

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

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

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

X-energy RAI Question Response

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

Corresponding QAPD update to implement the response

SECTION 2.5 PERSONNEL TRAINING AND QUALIFICATIONS

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

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



4. NRC RAI QUESTION NUMBER: RAI-4

NRC RAI Question

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

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

X-energy RAI Question Response

X-energy will change the sentence in X-energy's QAPD Section 7.1 to the effect "X-Energy may utilize audits conducted by outside organizations such as National Laboratories (e.g. INL and ORNL) for supplier qualification provided that the scope and adequacy of the audits meet X-energy requirements. Industry programs applied as input or the basis for supplier qualification may include ASME NQA-1 and ISO/IEC 17025. X-energy will be conducting testing at suppliers, (e.g. irradiation testing). Irrespective what QA program a supplier is using, X-energy will review and supplement supplier's programs where required to make them compliant with 10CFR 50 Appendix B in addition to ASME NQA-1 requirements that have been approved for that purpose. Furthermore, 10CFR21 requirements will be included as well."

Corresponding QAPD update to implement the response

SECTION 7.1 ACCEPTANCE OF ITEM OR SERVICE

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

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

- Items are inspected, identified, and stored to protect against damage, deterioration, or misuse.
- Prospective safety-related items and service suppliers are evaluated to assure only qualified suppliers are used as per X-energy requirements. Qualified suppliers are audited on a triennial basis. In addition, if a subsequent contract or a contract modification significantly changes the scope, methods, or controls performed by a supplier, an audit of the changes is performed, thus starting a new triennial period.
- X-Energy may utilize audits conducted by outside organizations such as National Laboratories (e.g. INL and ORNL) for supplier qualification provided that the scope and adequacy of the audits meet X-



energy requirements. Industry programs applied as input or the basis for supplier qualification may include ASME NQA-1 and ISO/IEC 17025. Irradiation testing will be performed by X-energy suppliers and irrespective what QA program a supplier is using, X-energy will review, and supplement supplier's programs where required to make them compliant with 10CFR 50 Appendix B in addition to ASME NQA-1 requirements. Furthermore, 10CFR21 requirements will be included as well. Documented annual evaluations are performed for qualified suppliers to assure they continue to provide acceptable products and services. The results of the reviews are promptly considered for effect on a supplier's continued qualification and adjustments made as necessary (including corrective actions, adjustments of supplier audit plans, and input to third party auditing entities, as warranted). In addition, results are reviewed periodically to determine if, as a whole, they constitute a significant condition adverse to quality requiring additional action.

- Provisions are made for accepting purchased items and services, such as source verification, receipt inspection, pre and post-installation tests, certificates of conformance, and document reviews (including Certified Material Test Report/Certificate). Acceptance actions/documents should be established by the Purchaser with appropriate input from the Supplier and be completed to ensure that procurement, inspection, and test requirements, as applicable, have been satisfied before relying on the item to perform its intended safety function.
- Controls (subjected to quality and technical requirements, such as the X-energy QA program requirements) are imposed for the selection, determination of suitability for intended use (critical characteristics), evaluation, receipt, and acceptance of commercial-grade services or items to assure they will perform satisfactorily in service in safety-related applications.
- If there is insufficient evidence of implementation of a QA program, the initial evaluation is of the existence of a QA program addressing the scope of services to be provided. The initial audit is performed after the supplier has completed sufficient work to demonstrate that its organization is implementing a QA program.



5. NRC RAI QUESTION NUMBER: RAI-5

NRC RAI Question

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

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

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

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

X-energy RAI Question Response

X-energy will comply and change the sentence in X-energy's QAPD Section 16.1 and remove the reference to 10 CFR 50.55 to the effect "X-Energy has appropriate interfaces between the QAP for corrective actions and the non-QA Reporting Program to satisfy the requirements of 10 CFR 52 and 10 CFR 21 during the DC phase."

Corresponding QAPD update to implement the response

SECTION 16.1 INTERFACE WITH THE REPORTING PROGRAM

X-energy has appropriate interfaces between the QAP for corrective actions and the non-QA Reporting Program to satisfy the requirements of 10 CFR 52 and 10 CFR 21 during the DC phase.



6. NRC RAI QUESTION NUMBER: RAI-6

NRC RAI Question

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

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

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

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

X-energy RAI Question Response

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

Corresponding QAPD update to implement the response

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

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



7. NRC RAI QUESTION NUMBER: RAI-7

NRC RAI Question

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

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

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

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

X-energy RAI Question Response

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

X-energy will update the QAPD Section 9 to the effect "X-energy has established the necessary measures and governing procedures to assure that special processes that require interim process controls to assure quality, such as welding, heat treating, and nondestructive examination, are controlled. These provisions include assuring that special processes are accomplished by qualified personnel using qualified procedures and equipment. Personnel are qualified and special processes are performed in accordance with applicable codes, standards, specifications, criteria or other specially established requirements. Special processes are those where the results are highly dependent on the control of the process or the skill of the operator, or both, and for which the specified quality cannot be fully and readily determined by inspection or test of the final product."

Corresponding QAPD update to implement the response

SECTION 9 CONTROL OF SPECIAL PROCESSES

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



process or the skill of the operator, or both, and for which the specified quality cannot be fully and readily determined by inspection or test of the final product.



8. NRC RAI QUESTION NUMBER: RAI-8

NRC RAI Question

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

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

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

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

X-energy RAI Question Response

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

Corresponding QAPD update to implement the response

SECTION 10 INSPECTION

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



9. NRC RAI QUESTION NUMBER: RAI-9

NRC RAI Question

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

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

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

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

X-energy RAI Question Response

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

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

Corresponding QAPD update to implement the response

SECTION 11 TEST CONTROL

X-energy has established the necessary measures and governing procedures to demonstrate that items subject to the provisions of the QAPD will perform satisfactorily in service, that the plant can be operated safely and as designed, and that the coordinated operation of the plant as a whole is satisfactory as X-energy suppliers will be performing testing (includes fuel and graphite irradiation testing). These programs include criteria for determining when testing is required, such as tests to demonstrate that design



concepts will perform satisfactorily in service. Integrity of data collected during testing and test data supporting critical characteristics shall be qualified according to NQA-1-2015 requirements. These measures and governing procedures include criteria for determining when testing is required to demonstrate that performance of plant systems is in accordance with design. Programs also include provisions to establish and adjust test schedules, and to maintain status for periodic or recurring tests. Tests are performed according to applicable procedures that include, consistent with the effect on safety:

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

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

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



10. NRC RAI QUESTION NUMBER: RAI-10

NRC RAI Question

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

Section 12 of X-Energy's QAPD, "Control of Measuring and Test Equipment," states, in part that X-Energy has established the necessary measures and governing procedures to control the calibration, maintenance, and use of measuring and test equipment (M&TE) that provides data to verify acceptance criteria are met or information important to safe plant operation. The provisions of such procedures cover equipment such as indicating and actuating instruments and gages, tools, reference and transfer standards, and nondestructive examination equipment."

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

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

Paragraph II.L.4 in subsection II.L of SRP Section 17.5 states that "M&TE are calibrated, adjusted, and maintained at prescribed intervals or, prior to use, against certified equipment having known valid relationships to nationally recognized standards. If no nationally recognized standards exist, the bases for calibration are documented."

Paragraph II.L.5 in subsection II.L of SRP Section 17.5 states that "M&TE found out of calibration is tagged or segregated and not used until it is recalibrated. When M&TE is found out of calibration, an evaluation is made and documented of the validity of previous inspection or test results and of the acceptability of items previously inspected or tested. If any measuring or test equipment is consistently found out of calibration, it is repaired or replaced. A calibration is performed when the accuracy of the equipment is suspect."

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

X-energy RAI Question Response

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

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



3) M&TE are calibrated, adjusted, and maintained at prescribed intervals or, prior to use, against certified equipment having known valid relationships to nationally recognized standards. If no nationally recognized standards exist, the bases for calibration are documented.

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

Corresponding QAPD update to implement the response

SECTION 12 CONTROL OF MEASURING AND TEST EQUIPMENT

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

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



11. NRC RAI QUESTION NUMBER: RAI-11

NRC RAI Question

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

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

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

Clarify the applicability of SRP Section 17.5, Subsection II.M, and X-Energy's QAPD Section 13, "Handling, Storage, and Shipping," to the DC application.

X-energy RAI Question Response

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

Corresponding QAPD update to implement the response

SECTION 13 HANDLING, STORAGE, AND SHIPPING

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



12. NRC RAI QUESTION NUMBER: RAI-12

NRC RAI Question

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

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

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

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

X-energy RAI Question Response

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

Corresponding QAPD update to implement the response

SECTION 14 INSPECTION, TEST, AND OPERATING STATUS

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



13. NRC RAI QUESTION NUMBER: RAI-13

NRC RAI Question

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

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

Paragraph II.O.4 in subsection II.O, “Nonconforming Materials, Parts, or Components,” of SRP Section 17.5 states that “Personnel performing evaluations to determine a disposition have demonstrated competence in the specific area they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information.”

Paragraph II.O.5 in subsection II.O of SRP Section 17.5 states that “The disposition, such as use as-is, reject, repair, or rework, of nonconforming items is identified and documented. Technical justification for the acceptability of a nonconforming item, dispositioned repair, or use as-is is documented.”

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

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

X-energy RAI Question Response

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

“X-energy has established the necessary measures and governing procedures to control items, including services that do not conform to specified requirements to prevent inadvertent installation or use. Instructions require that the individual discovering a nonconformance identify, describe, and document the nonconformance in accordance with the requirements of Part II, Section 16. Personnel performing evaluations to determine a disposition have demonstrated competence in the specific area they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information. Controls provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations. Controls are provided to address conditional release of nonconforming items for use on an at-risk basis prior to resolution and disposition of the nonconformance, including maintaining identification of the item and documenting the basis for such release. Conditional release of nonconforming items for installation requires the approval of the designated management. Nonconformances are corrected or resolved prior to depending on the item to perform its intended safety function. Nonconformances are evaluated for impact on operability of quality structures, systems, and components to assure that the final condition



does not adversely affect safety, operation, or maintenance of the item or service. The disposition, such as use as-is, reject, repair, or rework, of nonconforming items is identified and documented. Technical justification for the acceptability of a nonconforming item, dispositioned repair, or use as-is is documented. Reworked, repaired, and replacement items are inspected and tested in accordance with the original inspection and test requirements or specified alternatives. Nonconformances to design requirements dispositioned repair or use-as-is are subject to design control measures commensurate with those applied to the original design. Nonconformance dispositions are reviewed for adequacy, analysis of quality trends, and reports provided to the designated management. Significant trends are reported to management in accordance with X-energy procedures, regulatory requirements, and industry standards.”

Corresponding QAPD update to implement the response

SECTION 15 NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

X-energy has established the necessary measures and governing procedures to control items, including services (e.g. test and irradiated material) that do not conform to specified requirements to prevent inadvertent installation or use as X-energy suppliers will be performing destructive and non-destructive testing for test purposes (includes fuel and graphite irradiation testing). Instructions require that the individual discovering a nonconformance identify, describe, and document the nonconformance in accordance with the requirements of Part II, Section 16. Personnel performing evaluations to determine a disposition have demonstrated competence in the specific area they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information. Controls provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations. Controls are provided to address conditional release of nonconforming items for use on an at-risk basis prior to resolution and disposition of the nonconformance, including maintaining identification of the item and documenting the basis for such release. Conditional release of nonconforming items for installation requires the approval of the designated management. Nonconformances are corrected or resolved prior to depending on the item to perform its intended safety function. Nonconformances are evaluated for impact on operability of quality structures, systems, and components to assure that the final condition does not adversely affect safety, operation, or maintenance of the item or service. The disposition, such as use as-is, reject, repair, or rework, of nonconforming items is identified and documented. Technical justification for the acceptability of a nonconforming item, dispositioned repair, or use as-is is documented. Reworked, repaired, and replacement items are inspected and tested in accordance with the original inspection and test requirements or specified alternatives. Nonconformances to design requirements dispositioned repair or use-as-is are subject to design control measures commensurate with those applied to the original design. Nonconformance dispositions are reviewed for adequacy, analysis of quality trends, and reports provided to the designated management. Significant trends are reported to management in accordance with X-energy procedures, regulatory requirements, and industry standards.



14. NRC RAI QUESTION NUMBER: RAI-14

NRC RAI Question

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

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

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

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

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

X-energy RAI Question Response

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

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

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

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



Corresponding QAPD update to implement the response

PART IV REGULATORY COMMITMENTS

SECTION 1.1 REGULATORY GUIDES

- a. **Regulatory Guide 1.26**, [Revision 5, February 2017] - Quality Group Classifications and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants.

Regulatory Guide 1.26 defines classification of systems and components.

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

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

Regulatory Guide 1.28 describes a method acceptable to the NRC staff for complying with the provisions of Appendix B with regard to establishing and implementing the requisite quality assurance program for the design and construction of nuclear power plants.

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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