

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

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The following requests for additional information (RAIs) are based on the U.S. Nuclear Regulatory Commission (NRC) staff's review of X-Energy LLC's (X-Energy's) Quality Assurance Program Description (QAPD) for the Xe-100 nuclear power reactor. This requested information is necessary to demonstrate X-Energy's compliance with Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," and 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants." The responses to these RAIs about quality assurance program controls will support the NRC staff's reasonable assurance determination.

The NRC staff reviewed the X-Energy QAPD based on X-Energy's plans to submit a design certification application. 10 CFR 52.47(a)(19) states, in part, that "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." Regulatory Guide 1.28, "Quality Assurance Program Criteria (Design and Construction), Revision 5, dated October 2017, endorses NQA-1, "Quality Assurance Requirements for Nuclear Facility Applications," as one acceptable method to meet the requirements of Appendix B to 10 CFR Part 50. NQA-1 provides the "how to" details to meet the requirements of 10 CFR 52.47(a)(19). When an applicant submits the QAPD as part of a licensing request, the NRC staff will determine if the applicant has established the necessary controls to comply with the applicable requirements of Appendix B to 10 CFR Part 50, consistent with the criteria contained in NUREG-0800, "Standard Review Plan," Section 17.5, "Quality Assurance Program Description - Design Certification, Early Site Permit, and New License Applicants," Revision 1, dated August 2015. Although NUREG 0800 is guidance for the NRC staff related to the review of light-water reactor (LWR) applications, the quality assurance program guidance in Section 17.5 can also be applied to non-LWRs, as the guidance is not design based.

ORGANIZATION

RAI-1: 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."

Enclosure

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.

QUALITY ASSURANCE PROGRAM

RAI-2: 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).

RAI-3: 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.

CONTROL OF PURCHASED EQUIPMENT, MATERIALS, AND SERVICES

RAI-4: 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.

CORRECTIVE ACTION

RAI-5: 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.

APPLICABILITY OF APPENDIX B CRITERIA TO X-ENERGY’S DESIGN CERTIFICATION APPLICATION

For RAIs 6 through 13 below, consider the following statement from X-Energy’s Executive Summary from the Design Certification (DC) application when answering the specific RAI. The statement reads: “The QAPD addresses design QA activities in support of Design Certification (DC) and does not address QA activities associated with construction that occur once construction begins (e.g., design change process to capture as-built, fabrication, weld qualification, etc.).”

IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

RAI-6: 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.

CONTROL OF SPECIAL PROCESSES

RAI-7: 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.

INSPECTION

RAI-8: 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.

TEST CONTROL

RAI-9: 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.

CONTROL OF MEASURING AND TEST EQUIPMENT

RAI-10: 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.

HANDLING, STORAGE, AND SHIPPING

RAI-11: 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.

INSPECTION, TEST, AND OPERATING STATUS

RAI-12: 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.

NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

RAI-13: 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.

NRC REGULATORY GUIDES AND QUALITY ASSURANCE STANDARDS

RAI-14: 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.