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**Subject:** RAls for X-energy's QAPD Rev.4 (EPID: L-2022-TOP-0035)  
**Attachments:** Final RAls - L-2022-TOP-0035.docx

Ingrid,

Attached are the NRC staff's requests for additional information (RAIs) for X Energy, LLC's (X-energy's) submission of Revision 4 of the "X Energy, LLC Topical Report Quality Assurance Program Description" (QAPD) (Agency-wide Documents Access and Management System Accession No. ML22230D075).

The NRC staff anticipates your response to the attached RAls by COB Friday, April 14, 2023..

stephanie

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REQUEST FOR ADDITIONAL INFORMATION  
REGARDING THE X ENERGY, LLC TOPICAL REPORT  
QUALITY ASSURANCE PROGRAM DESCRIPTION, REVISION 4

EPID: L-2022-TOP-0035

PROJECT NO. 99902071

By letter dated August 18, 2022 (Agency-wide Documents Access and Management System Accession No. ML22230D075), X Energy, LLC (X-energy) submitted Revision 4 of the “X Energy, LLC Topical Report Quality Assurance Program Description” (QAPD) for review by the U.S. Nuclear Regulatory Commission (NRC) staff.

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,” sets forth the regulatory requirements related to quality assurance (QA) programs. Appendix B to 10 CFR Part 50 establishes QA requirements for the design, fabrication, construction, and testing of structures, systems, and components (SSCs) for the facility and for managerial and administrative controls to be used to assure safe operation. The pertinent requirements of Appendix B to 10 CFR Part 50 apply to all activities affecting the safety-related functions of those SSCs and include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying SSCs.

Based on the NRC staff’s review of the QAPD topical report (TR), Revision 4, against the requirements in Appendix B to 10 CFR Part 50, the NRC staff has determined that the following requests for additional information (RAI) are needed to complete its review of the QAPD.

RAI 01

Subsection 2.7, “NQA-1 Commitment/Exceptions,” of the QAPD, Revision 4, states, in part, that “Sections 401, items (e) and (g) require the date of certification expiration be included on the qualification record. X-energy considers the certification expiration date to be the date from the certification or recertification date plus the certification interval time and its inclusion on the qualification record is optional.” However, in Section 401, “Inspection and Test Personnel,” of NQA-1---2015, “Quality Assurance Requirements for Nuclear Facility Applications,” only item (g) requires the certification expiration be included on the qualification record. Clarify and provide a technical justification, as applicable, if the intent of the QAPD is to also not include the date of certification/recertification on the qualification record.

## RAI 02

Subsection 7.2, “NQA-1 Commitment/Exceptions,” of the QAPD, Revision 4, states, in part, that “When purchasing commercial-grade calibration or testing services [...], procurement source evaluation and selection measures need not be performed, provided each of the following conditions are met:...” The QAPD then proceeds to list the conditions. However, the following conditions from the NRC’s “Final Safety Evaluation by the Office of Nuclear Reactor Regulation for the Nuclear Energy Institute Technical Report 14-05a, Guidelines for the use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services, Revision 1,” dated November 23, 2020, (ML20322A019) are missing:

- a. Condition 2.1.d - The documented review of the laboratory’s accreditation includes verification that “The laboratory has achieved accreditation based on an on-site accreditation assessment by the selected AB within the past 48 months. The laboratory’s accreditation cannot be based on two consecutive remote accreditation assessments.”
- b. Condition 2.2.f - The purchase documents require that “Performance of the services listed on this order is contingent on the laboratory’s accreditation having been achieved through an on-site accreditation assessment by the AB within the past 48 months.”
- c. Condition 3 - “It is validated at receipt inspection, that the laboratory’s documentation certifies that:
  - 1. The contracted calibration or testing service has been performed in accordance with their [International Standard Organization (ISO)/International Electrotechnical Commission (IEC) 17025:2017, “General Requirements for the Competence of Testing and Calibration Laboratories,”] program, and has been performed within their scope of accreditation, and
  - 2. The purchase order’s requirements are met.”

In addition, the latest edition of ISO/IEC 17025 (2017) needs to be included in the list of conditions.

Clarify why the above listed conditions and the latest edition of ISO/IEC 17025 (2017) are not included in Revision 4 of the QAPD or revise the QAPD to include the conditions.

### RAI 03

Subsection 17.2, "Electronic Records," in Revision 3 of the QAPD states, in part, that "X-energy will manage the storage of QA Records in electronic media consistent with the intent of [Regulatory Issue Summary (RIS)] 2000-18 and associated updated [Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guidelines (TG)] 11-2011, TG 15-2011, TG16-2011, and TG21-2011." However, Subsection 17.2 in Revision 4 of the QAPD states, in part, that "X-energy will manage the storage of QA Records in electronic media consistent with NIRMA Guidelines TG 11-2011, TG15-2011, TG16-2011, and TG21-2011." Clarify if X-energy's QAPD will manage storage of QA records in electronic media consistent with RIS 2000-18, "Guidance on Managing Quality Assurance Records in Electronic Media," dated October 2000 (ML003739359).

### RAI 04

Subsection 18.3, "Exigent Conditions," of the QAPD, Revision 4, states, in part, that "The total allowable extension for exigent conditions is 275 days." The NRC staff has previously approved an extension of 25% for triennial audits or surveys (i.e., 9 months), as documented in the safety evaluation (SE) for Callaway Plant (ML20216A681). Provide a justification for exceeding the grace period that has previously been approved for similar applications by the NRC staff or revise the QAPD to reflect that the total allowable extension for exigent conditions is 9 months.

### RAI 05

Subsection 18.3 of the QAPD, Revision 4, is included under Criterion XVIII; however, its inclusion under Criterion VII (Section 7 of the QAPD) may be more appropriate. Criterion VII addresses the requirements for supplier oversight, which include external audits, while Criterion XVIII addresses the requirements for internal audits. Clarify why Subsection 18.3 is included under Criterion XVIII or revise the QAPD to include the Exigent Conditions provisions under Criterion VII.

## RAI 06

The NRC staff notes that there are substantial differences between X-energy's Xe-100 design and a light-water reactor design and that direct commitment to some quality guidance positions may not be practical. The NRC staff also notes that X-energy removed certain commitments related to non-safety related SSC credited for regulatory events from the QAPD, Revision 4, as compared to Revision 3 of the QAPD. Clarify if X-energy commits to implementing the quality requirements for anticipated transient without scram (ATWS) equipment in accordance with NRC's Generic Letter (GL) 85-06, "Quality Assurance Guidance for ATWS Equipment That Is Not Safety-Related," dated January 16, 1985, and 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 Regulatory Guide (RG) 1.155, "Station Blackout," dated August 1988 (ML003740034).

## RAI 07

Part IV, "Regulatory Commitments," in Revision 3 of the QAPD identified the following documents as the RGs and QA standards selected to supplement and support the implementation of the QAPD:

- RG 1.26, "Quality Group Classifications and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants," Revision 6, dated December 2021 (ML21232A142),
- RG 1.54, "Service Level I, II, III, and In-Scope License Renewal Protective Coatings Applied to Nuclear Power Plants," Revision 3, April 2017 (ML17031A288), and
- Nuclear Energy Institute (NEI) 14-05A, , "Guidelines for the Use of Accreditation in lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," Revision 1, dated September 2020 (ML20259B731).

However, Part IV in Revision 4 of the QAPD did not list RG 1.26, RG 1.54, and NEI 14-05A, Revision 1. Explain X-energy's plans to review the applicable guidance and include justification for that guidance that may not be applicable due to unique design considerations.

## RAI 08

Part IV, "Regulatory Commitments," in the QAPD, Revision 4, states, in part, that "X-energy will implement this guidance ..." when describing its commitment to Revision 3 of RG 1.33 (ML13109A458). Under Subsection 3, "Operational Phase Procedures," of Part V, the QAPD states that, "X-energy follows the guidance of Appendix A to Regulatory Guide 1.33 in identifying the types of activities that should have procedures or instructions to control the activity." Revision 3 of RG 1.33 does not have an Appendix A. Clarify whether Revision 4 of the QAPD is committed to implementing Revision 3 of RG 1.33.