

**NRC STAFF'S PRELIMINARY QUESTIONS
ON THE NRC ASSESSMENT OF HADRON ENERGY
QUALITY ASSURANCE PROGRAM DESCRIPTION TOPICAL REPORT**

On October 14, 2025, Hadron Energy submitted their Quality Assurance Program Description (QAPD) Topical Report (TR) Revision 1 (ADAMS Accession No. ML25287A168) for the U.S. Nuclear Regulatory Commission (NRC) staff review. Revision 1 of the TR was determined by the NRC staff to be acceptable for review by letter dated December 1, 2025 (ML25248A302).

The NRC staff has completed an initial review of Hadron's QAPD Revision 1 topical report and developed a set of preliminary questions to improve its understanding of the information presented in the report. The questions are intended to:

- Obtain clarification regarding material in the topical report
- Promptly identify areas where additional information may be needed
- Facilitate discussions and continue effective communication

The NRC staff requests that Hadron Energy propose times to discuss the attached preliminary questions in a public meeting. Based on the outcome of its discussions with Hadron Energy on the topics identified below, the NRC staff may develop formal requests for additional information to complete its review of the topical report.

1. QAPD Section 1.0 "General" states, in part, that "This document has been prepared with consideration for the guidance provided in NUREG-0800, Section 17.5, as well as the principles for a risk-informed, performance-based program detailed in NUREG-2246, "Fuel Cycle Facility Quality Assurance."

The "Executive Summary" of the QAPD states, in part, that "Hadron Energy requests NRC review and approval of this topical report for use in satisfying the quality assurance requirements for future license applications submitted in accordance with 10 CFR Part 52, including a Manufacturing License (ML) and a Combined License (COL)."

Issue – Fuel fabrication activities are outside the scope of 10 CFR Part 52.

Information need - Confirm that this QAPD will be limited to support 10 CFR Part 52 applications. If so, delete any references to fuel fabrication activities associated with 10 CFR Part 70.

2. QAPD Section 1.1 "Scope and Applicability" states, in part, that "While this program is established to meet the requirements of 10 CFR Part 50 and its implementation, particularly the graded approach to quality, is designed to be consistent with the technology-inclusive framework of 10 CFR Part 53."

Issue – This statement appears to contradict the intent of the QAPD as described in the QAPD's "Executive Summary." Licensing processes detailed in 10 CFR Part 52 differ from the processes detailed in 10 CFR Part 50 and Part 53 (not yet a final rule).

Information need – confirm the licensing process you intend to follow when submitting an application to the NRC. Also, remove any reference to 10 CFR Part 53 since this regulation is not final.

3. QAPD Section 1.2.3 “Supply Chain” describes the responsibilities of the supply chain organization during the manufacturing of the Hadron MMR.

Issue – the supply chain organization and its responsibilities during the operations phase was not described in the QAPD.

Information need – provide such description in the QAPD.

4. QAPD Section 2.5 “Issuance and Revision to the Quality Assurance Program” states, in part, that “Administrative control of this QAPD shall be in accordance with the requirements of 10 CFR 50.54(a) and 10 CFR 50.55(f), as applicable.”

Issue - These two regulations are only applicable to NRC licensees or permit holders. As a non-licensee, Hadron would be subject to 10 CFR 50.4(7)(ii), which states, in part, that “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.”

Information need - Confirm that any changes to Hadron’s QAPD will be submitted to the NRC for review and approval in accordance with 10 CFR 50.4(7)(ii).

5. QAPD Section 7.1.1 “Remote Assessments” states, in part, that “Hadron Energy may perform remote assessments of suppliers in accordance with the following Electric Power Research Institute (EPRI) Technical Reports and the associated NRC-approved Safety Evaluation Report (Accession No. ML21161A201:

EPRI TR-3002019436-A, Remote Source Verification During a Pandemic or Similar State of Emergency – Screening Criteria and Process Guidance (2020)

EPRI TR-3002020796, Remote Assessment Techniques: Planning and Conducting Audits and Surveys Using Remote Techniques During Exigent Conditions (2021)”

Issue - In the Safety Evaluation (SE) dated June 22, 2021 (ML21161A201) and SE dated July 7, 2020 (ML20181A445) the NRC staff determined that the implementation of EPRI Technical Reports 3002020796 and EPRI TR-3002019436-A respectively, will continue to meet the requirements of Criterion VII of Appendix B to 10 CFR Part 50, and, therefore, was acceptable. However, the NRC staff notes that the conditions included in these SEs must be met before implementing the guidance in EPRI Technical Reports (TRs).

Specifically, Section 3.0 of SE dated June 22, 2021, states the following regarding the conditions for use: “The proposed change will provide alternate methods of conducting audits and CGSs at the contractor or subcontractor source under certain conditions. The use of these methods of verification will only be applicable when a pandemic or similar state of emergency has been declared restricting access or travel to and/or from those locations affected by State and national declarations. Furthermore, these methods (i.e. provisional and fully remote assessments) are to be used for those previously qualified

suppliers to renew their qualifications. These methods are not to be used to qualify new suppliers.”

Section 3.0 of SE dated July 7, 2020, states the following regarding the conditions for use: “The use of this method of verification will only be applicable when a pandemic or similar state of emergency has been declared restricting access or travel to and/or from those locations affected by State and national declarations. The proposed change would not apply to other quality assurance activities, such as vendor audits or surveys used to qualify a vendor’s QA program.”

Information need - clarify if you intend to meet the conditions included in the SEs referenced above when implementing the referenced EPRI TRs during exigent conditions. If so, include all the conditions in the QAPD.

NOTE: note that according to Information Notice 2025-04 “Use of Approved Quality Assurance Alternatives During Exigent Conditions,” dated August 6, 2025 (ML25121A128), the QA alternatives described above may no longer be implemented unless a new exigent condition exists.

6. QAPD Section 7.2 “NQA-1 Commitment/Exceptions” references ISO/IEC 17025:2024 multiple times.

Issue - Revision 1 of NEI 14-05A, as endorsed by the NRC, recognizes the 2017 edition of ISO/IEC 17025 as the basis for the ILAC accreditation process and there is no 2024 edition.

NEI 14-05A, Revision 1, was endorsed by the NRC SE, “Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services,” dated November 23, 2020 (ML20322A019). Section 3.4, “Implementation of the ILAC Accreditation Process in Lieu of a Commercial Grade Survey,” of the SE includes a series of actions and steps that are necessary for a licensee and/or a supplier of basic components to accept accreditation of domestic and international calibration and test laboratory services by ILAC MRA signatories in lieu of performing a commercial-grade survey as part of the commercial-grade dedication process.

Information need-

1. Clarify if you intend to follow the 2017 edition of ISO/IEC 17025.
2. Clarify if Hadron plans to commit and implement Revision 1 of NEI 14-05A, as endorsed by the NRC. If so, state so in the QAPD and include all the conditions referenced in Section 3.4 of the SE in the QAPD.

7. QAPD Section 2 “Quality Assurance Program” states, in part, that “Hadron Energy has established and is committed to implementing the QAP as described in this QAPD. The program governs all aspects of work important to the safety of the nuclear facility across its full lifecycle, including design, manufacturing, construction, and operation.”

RG 1.33, “Quality Assurance Program Requirements (Operation),” Revision 3, describes methods that the NRC staff considers actable for complying with the provisions of regulations in 10 CFR 50.34(b)(6)(ii) and 10 CFR 52.79(a)(27). RG 1.33 endorses

ANSI/ANS 3.2-2012, "Managerial, Administrative, and Quality Assurance Controls for Operational Phase of Nuclear Power Plants."

Issue - Part IV of the QAPD provides a list and descriptions of RGs and quality assurance standards that Hadron commits to conformance with. The NRC staff reviewed this list and finds that the list does not include commitment to RG 1.33, Revision 3 or ANSI/ANS 3.2-2012.

Information need - Clarify whether Hadron will conform to the guidance in ANSI/ANS 3.2-2012, as endorsed by RG 1.33, Revision 3. If so, reference RG 1.33 as part of the commitments included in Part IV of the QAPD. If Hadron doesn't intend to commit to this RG, describe the reasons for not doing so.

8. SRP Section 17.5, Sections U.2.b and U.2.c specify requirements and reference Generic Letter (GL) 85-06 "Quality Assurance Guidance for ATWS Equipment that Is Not Safety Related," and RG 1.155, "Station Blackout," for nonsafety-related SSCs credited for ATWS and SBO respectively.

Issue – QAPD Section 2.0 "Nonsafety-related SSCs credited for Regulatory Events" does not include a reference to these NRC documents.

Information need – clarify if Hadron intends to commit to the GL and RG. If Hadron doesn't intend to commit to this GL and RG, describe the reasons for not doing so.

9. QAPD Part IV "Regulatory Commitments" references revisions and dates for several RGs Hadron commits to. The latest revision for RG 1.234 Revision 1 is dated March 2024; RG 1.26 Revision 6 is dated December 2021; and RG 1.29 Revision 6 is dated July 2021.

Issue – The revision dates for RGs 1.234, 1.26 and 1.29 are incorrect.

Information need - update the QAPD to include the revision # and correct dates associated with these RGs. If you don't intend to commit to the latest revisions of these RGs, explain the rationale for not committing to meeting the latest revision.

10. QAPD Section 2.0 "Nonsafety-related SSCs Credited for Regulatory Events" states, in part that, "Fire Protection (10 CFR 50.48): Hadron Energy shall implement the quality requirements for the fire protection system in accordance with the guidance of Regulatory Guide 1.189, "Fire Protection for Nuclear Power Plants."

Issue – No revision or date was provided for RG 1.189

Information need - update the QAPD to include the revision # and date associated with this RG.

11. Regulations in 10 CFR 50.54(a)(1) require a holder of a COL under 10 CFR Part 52 to implement the operation phase of a QA program 30 days prior to the scheduled date of the initial loading of fuel.

Issue – such provision is not included in QAPD Revision 1.

Information need – include such provision in the QAPD.

12. QAPD Section 13.0 “Handling, Storage, and Shipping” states that: During the operational phase, controls shall be established over hoisting, rigging, and transport activities to the extent necessary to protect the integrity of the items involved, as well as any potentially affected nearby structures and components.”

NQA-1-2022 Subpart 2.15 “Quality Assurance Requirements for Hoisting, Rigging, and Transporting of Items for Nuclear Power Plants” has been replaced with ASME HRT-1-2016, “Rules for Hoisting, Rigging, and Transporting Equipment for Nuclear Facilities”

Information need – state if Hadron intends to meet the controls included in ASME HRT-1-2016 for hoisting, rigging, and transport activities.

13. QAPD Section 2 states, that, “For activities required to be performed on a periodic basis, a grace period of up to 90 days may be applied.”

SRP Section 17.5, Paragraph II.B.10 states, in part, that “The grace period does not allow the “clock” for a particular activity to be reset forward. The “clock” for an activity is reset backwards by performing the activity early.

Information need – clarify if Hadron intends to meet such restriction when it applies this extension. If so, please update the QAPD accordingly.

14. 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.

NQA-1-2022 Requirement 2 Section 302 “Inspection and Test” include specific requirements for personnel performing inspections and tests.

Issue - Hadron QAPD Section 2.6, “Personnel Training and Qualifications,” does not provide a requirement for the training and qualification of inspection and test personnel.

Information need - Clarify how Hadron’s QAPD addresses the training and qualification requirements for inspection and test personnel.

15. QAPD Part IV “Regulatory Commitments” references revisions and dates for several RGs Hadron commits to.

Issue - The staff notes that Hadron has not listed RG 1.8, “Qualification and Training of Personnel for Nuclear Power Plants” as part of QAPD Part IV. The NRC staff considers this RG as acceptable for meeting regulatory requirements associated with the selection, qualifications, and training for nuclear power plant personnel.

Information need - Clarify whether Hadron intends to commit to the latest revision of RG 1.8.