

# Hadron Energy Inc.'s Responses to NRC Questions from the Review of QAPD Rev 1

February 19, 2026

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# Agenda

## Part I – Addressing NRC Comments

1. Clarification on Fuel Fabrication Activities
2. Clarification on Licensing Path
3. Supply Chain Oversight During Operations Phase
4. Revisions to QAPD in Pre-Licensing Engagement
5. Applicability of Remote Assessments
6. Clarification on ISO/IEC 17025:2024
7. Clarification on RG 1.33, Revision 3
8. Clarification on GL 85-06, RG 1.155
9. Clerical Correction to Revision Dates
10. Omitted Revision Date for RG 1.189
11. Commitment to Implement Operations Phase
12. Commitment to ASME HRT-1-2016
13. Clarification re: 90-day Grace Period
14. Clarification on Personnel Training
15. Commitment to RG 1.8

## Part II – Changes to Hadron Org Chart

1. Overall Changes
2. Changes to Director, QA Reporting Structure
3. Reallocation of Responsibilities Under CNO
4. Reallocation of Responsibilities Under COO



## Part I – Addressing NRC Comments



# 1. Clarification on Fuel Fabrication Activities

## NRC Comment

- QAPD Section 1.0 “General” includes discussion of Fuel Cycle Facility Quality Assurance in NUREG-2246
- The Executive Summary of the QAPD requests that NRC review and approval of the QAPD Topical Report to satisfy the QA requirements for future applications for 10 CFR Part 52 Manufacturing License and Combined License
- Confirm that this QAPD will be limited to support 10 CFR Part 52 applications. Delete references to fuel fabrication activities under Part 70

## Hadron Response & QAPD Change(s)

- Hadron Energy intends to pursue licensing under 10 CFR Part 52
- This QAPD will be changed to:
  - Reflect a Part 52 licensing strategy
  - Remove references to 10 CFR Part 70 and NUREG-2246
  - Reference the use of NUREG-0800, Section 17.5, “Quality Assurance Program Description- Design Certification, Early Site Permits and New License Applicants”



## 2. Clarification on Licensing Path

### NRC Comment

- QAPD Section 1.1 “Scope and Applicability” states that the program will meet 10 CFR Part 50 and Part 53
- Statement contradicts the previous discussion of the use of 10 CFR Part 52, not the use of Part 50 or 53
- Confirm the licensing process to be followed in a license application to NRC
- Remove references to 10 CFR Part 53

### Hadron Response & QAPD Change(s)

- Hadron Energy confirms intent to utilize the licensing processes under 10 CFR Part 52
- The Executive Summary and Section 1.1 will be modified to remove references to other licensing processes



### 3. Supply Chain Oversight During Operations Phase

#### NRC Comment

- QAPD Section 1.2.3 describes the responsibilities of the supply chain organization during manufacturing
- Section 1.2.3 does not discuss the supply chain organization and responsibilities during the operations phase
- Provide this description in the QAPD

#### Hadron Response & QAPD Change(s)

- Section 1.2.3 will be modified to expand on the supply chain organization during the operations phase



## 4. Revisions to QAPD in Pre-Licensing Engagement

### NRC Comment

- QAPD Section 2.5 “Issuance and Revision to the Quality Assurance Program” states that “Administrative control of this QAPD shall be in accordance with the requirements of 10 CFR 50.54(a) and 10 CFR 50.55(a)”
- The identified regulations apply only to NRC licensees or permit holders. Hadron would be subject to 10 CFR 50.4(7)(ii) for topical reports from non-licensees
- Confirm that QAPD is submitted in accordance with 10 CFR 50.4(7)(ii)

### Hadron Response & QAPD Change(s)

- Hadron Energy confirms that the QAPD under this Topical Report is submitted in accordance with 10 CFR 50.4(7)(ii)
- The QAPD will be changed to reflect this reference and remove references to 10 CFR 50.54(a) and 10 CFR 50.55(a)



## 5. Applicability of Remote Assessments

### NRC Comment

- QAPD Section 7.1.1, “Remote Assessments” states that assessments of suppliers may be performed remotely i.a.w. EPRI Topical Reports and the associated NRC-approved SEs (ML21161A201 and ML20181A445)
- The conditions of included in the SEs only allow use of remote assessments to when a pandemic or state of emergency has been declared and travel is restricted
- Clarify the intent to meet conditions of these SEs during the conditions and, if so, include all of the conditions

### Hadron Response & QAPD Change(s)

- The QAPD will be changed to include the conditions of the SE’s, including that remote assessments cannot be used until a state of emergency or pandemic is declared



## 6. Clarification on ISO/IEC 17025:2024

### NRC Comment

- QAPD Section 7.2 “NQA-1 Commitment/ Exceptions” references ISO/IEC 17025:2024 multiple times
- Rev 1 of NEI 14-05A (endorsed by NRC) recognizes the 2017 edition of ISO/IEC 17025 as the proper basis for the Int’l Laboratory Accreditation Cooperation (ILAC) accreditation process
- Section 3.4 of the NRC SE (ML20322A019) provides the conditions for use of the ILAC process in lieu of a commercial grade survey
- Clarify the intent to use the 2017 edition and NEI 14-05 R1 and add conditions in section 3.4 of the SE in the QAPD

### Hadron Response & QAPD Change(s)

- Hadron intends to use the 2017 edition of ISO/IEC 17025 for ILAC accreditation
- The QAPD will be updated to show the 2017 edition as well as NEI 14-05 Rev. 1



## 7. Clarification on RG 1.33, Revision 3

### NRC Comment

- QAPD Section 2, “Quality Assurance Program” commits to implementing the QAPD across the full reactor lifecycle, including operations
- RG 1.33, “Quality Assurance Program Requirements (Operations)”, Rev 3 describes methods for meeting 10 CFR 50.34(b)(6)(ii) and 10 CFR 52.79(a)(27) and endorses ANSI/ANS 3.2-2012
- Hadron QAPD did not reference RG 1.33 Rev 3 or ANSI/ANS 3.2-2012
- Clarify intent to conform to ANSI/ANS 3.2-2012 as endorsed by RG 1.33 Rev 3 and add a reference in Part IV of the QAPD

### Hadron Response & QAPD Change(s)

- Hadron intends to conform to ANSI/ANS 3.2-2012 as endorsed by RG 1.33 Rev. 3
- RG 1.33 Rev. 3 will be added to the references in Part IV in Revision 2 of the Hadron Energy QAPD



## 8. Clarification on GL 85-06, RG 1.155

### NRC Comment

- 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” when crediting non safety-related SSCs for ATWS and SBO
- Clarify the intent to commit to GL 85-06 and RG 1.155 or describe reasons for not committing to use them

### Hadron Response & QAPD Change(s)

- Hadron commits to GL 85-06 for quality assurance activities related to non-safety related SSCs credited ATWS events
- Hadron also commits to RG 1.155 for non-safety related SSCs credited for station blackout



## 9. Clerical Correction to Revision Dates

### NRC Comment

- The revision dates for RGs 1.234, 1.26, and 1.29 are incorrect
- Update the QAPD to include the revision number and correct dates associated with the RGs

### Hadron Response & QAPD Change(s)

- Hadron will correct the revision dates for the identified regulatory guides. The regulatory guides will be updated to:
  - RG 1.234 Rev. 1 dated March 2024
  - RG 1.26 Rev. 6 dated December 2021
  - RG 1.29 Rev. 6 dated July 2021



# 10. Omitted Revision Date for RG 1.189

## NRC Comment

- Hadron Energy commits to implement the quality requirements to meet 10 CFR 50.48 (Fire Protection) via RG 1.189 “Fire Protection for Nuclear Power Plants”
- There is no revision or date was listed for RG 1.189
- Update QAPD to include the revision number and date associated with RG 1.189

## Hadron Response & QAPD Change(s)

- Hadron Energy will update the commitment to meet 10 CFR 50.48 via RG 1.189 to include:
  - RG 1.189 Rev. 5 dated October 2023



# 11. Commitment to Implement Operations Phase

## NRC Comment

- The holder of a COL under 10 CFR Part 52 is required to meet 10 CFR 50.54(a)(1) and implement the operations phase of the QA program 30 days prior to the scheduled fuel load date
- Hadron did not include this provision in the QAPD Rev 1

## Hadron Response & QAPD Change(s)

- Hadron will include the provision to implement the operations phase of the QA program 30 days prior to the scheduled fuel load date in Revision 2 of the QAPD



## 12. Commitment to ASME HRT-1-2016

### NRC Comment

- QAPD Section 13.0 “Handling, Storage, and Shipping” references NQA-1-2022 Subpart 2.15 “Quality Assurance Requirements for Hoisting, Rigging, and Transporting of Items for Nuclear Power Plants”
- This has been replaced with ASME HRT-1-2016, “Rules for Hoisting, Rigging, and Transporting Equipment for Nuclear Facilities”
- QAPD is missing the commitment to this standard

### Hadron Response & QAPD Change(s)

- Hadron Energy commits to the updated quality assurance requirements for hoisting, rigging and transportation of items for nuclear power plants
- The Hadron QAPD will be updated to reflect the commitment to ASME HRT-1-2016 in lieu of NQA-1-2022 Subpart 2.15



# 13. Clarification re: 90-day Grace Period

## NRC Comment

- 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 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”
- Clarification needed to determine if Hadron intends to meet such restriction

## Hadron Response & QAPD Change(s)

- Hadron Energy intends to meet the restriction as written in SRP Section 17.5 Paragraph II.B.10
- The QAPD will be updated to reflect the intent to meet this restriction and the restriction will be identified in Revision 2 of the QAPD



# 14. Clarification on Personnel Training

## NRC Comment

- Requirements for training and qualification of personnel performing inspections and tests (activities affecting quality) are provided in:
  - 10 CFR 50 App. B Criterion II
  - SRP Section 17.5 Subsection II.T
  - NQA-1-2022 Requirement 2 Section 302
- Hadron QAPD Section 2.6 “Personnel Training and Qualifications” does not address training and qualifications for inspection and test personnel
- Clarification is needed to address these missing requirements

## Hadron Response & QAPD Change(s)

- Hadron Energy commits to training and qualifying inspection and test personnel in accordance with the identified requirements
- Revision 2 of the QAPD will include requirements for the training and qualification of inspection and test personnel in accordance with NQA-1-2022, SRP Section 17.5 Subsection II.T, and 10 CFR 50 App. B



# 15. Commitment to RG 1.8

## NRC Comment

- RG 1.8 is considered acceptable for meeting regulatory requirements associated with the selection, qualification, and training for nuclear power plant personnel
- Hadron Energy's QAPD Part IV, "Regulatory Commitments," does not list RG 1.8
- Clarification is needed on Hadron Energy's Intent to commit to the latest revision of RG 1.8

## Hadron Response & QAPD Change(s)

- Hadron Energy intends to meet the requirements of RG 1.8 with the selection, qualification, and training for nuclear power plant personnel
- RG 1.8 will be added to Part IV of the QAPD in Revision 2

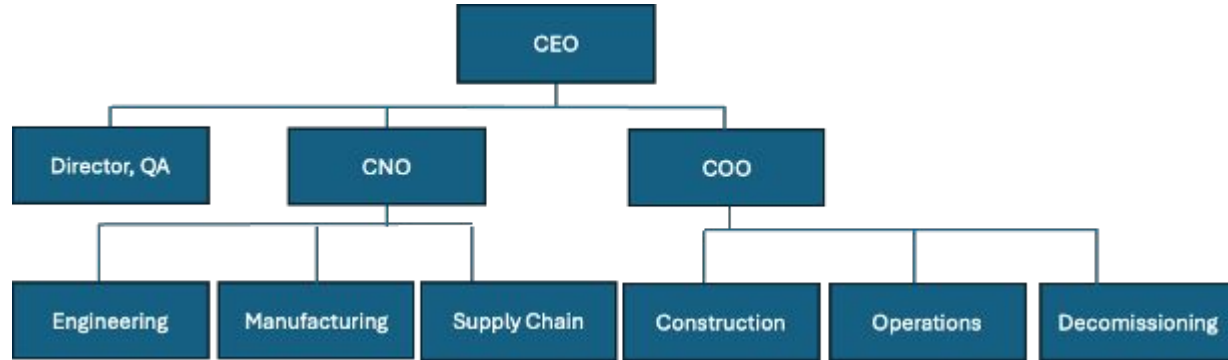


## Part II – Changes to Hadron Org Chart

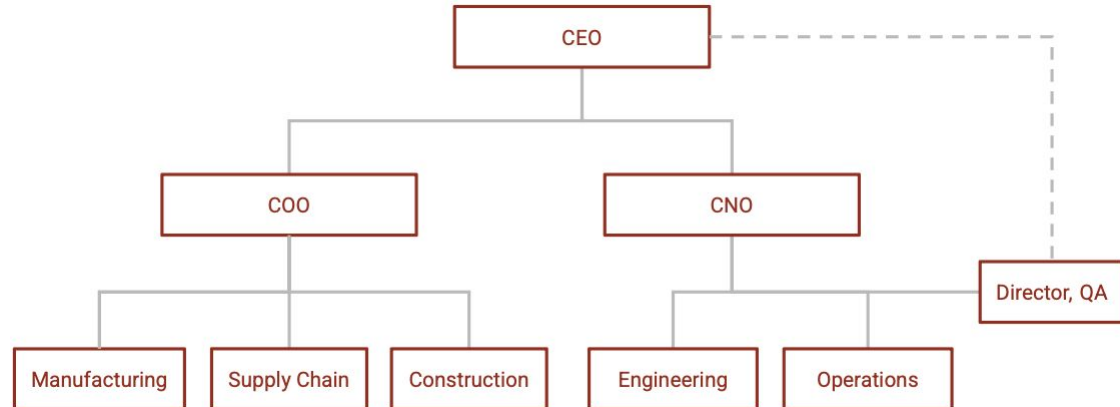


# 1. Overall Changes

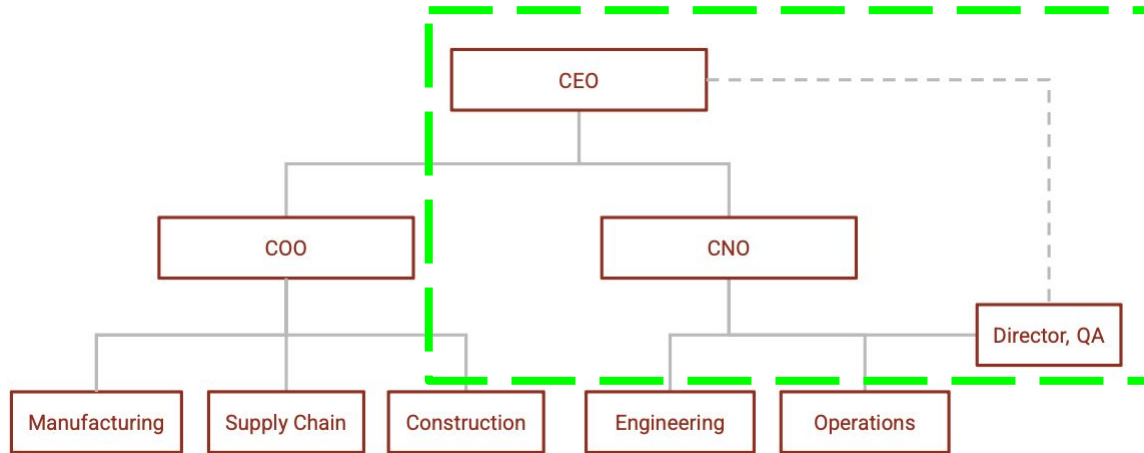
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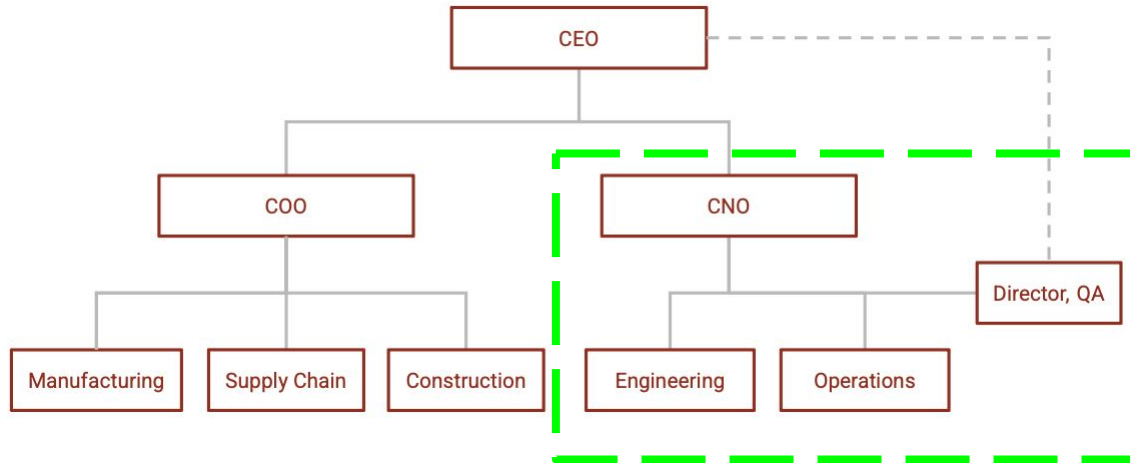
## 2. Changes to Director, QA Reporting Structure



- Director, QA will report to the CNO
- Doing this will enable prompt notification of QA concerns to the CNO and reflects a change in management structure as we enter the public stage of our company



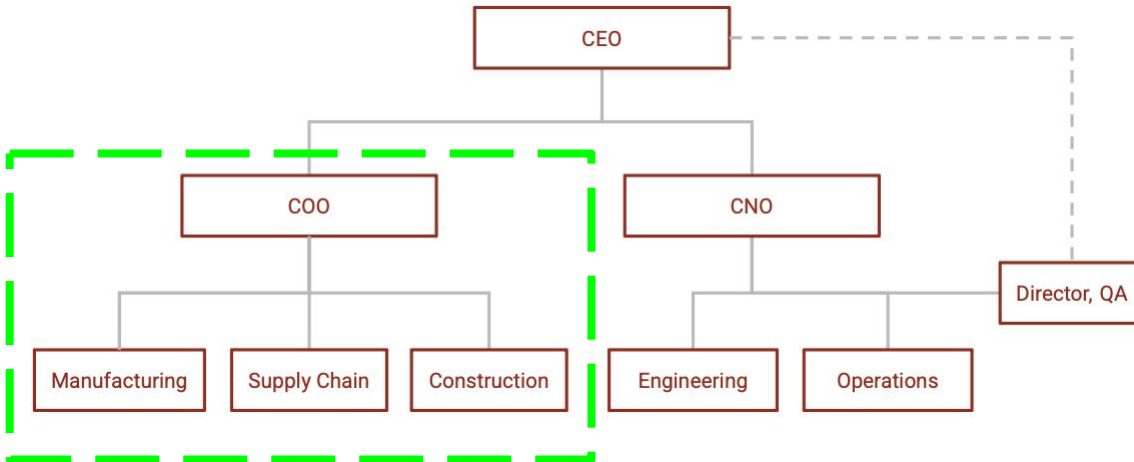
### 3. Reallocation of Responsibilities Under CNO



- CNO will now head Engineering and Operations to reflect the human resources and business units dedicated to nuclear-related safety and design concerns.
- In this context, “Operations” refers to the safe operations of the nuclear power plant, not generic business operations.
- CNO will be in close collaboration with COO on nuclear-adjacent matters, such as the QA of Supply Chain, Construction and Manufacturing processes.



## 4. Reallocation of Responsibilities Under COO



- COO will now lead Manufacturing, Supply Chain and Construction
- Reflects engagement with suppliers, contractors, governments and facilities operators to manufacture and deploy unfueled Hadron MMRs
- COO will be in regular communication with CNO and associated business units to ensure nuclear safety-related needs are met.



# Questions

Approved for Public Release

