



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

September 4, 2025

Mr. Donald Statile
Director of Licensing, Safety,
and Quality Assurance
REPLOY Power, Inc.
7301 Seneca Falls Loop
Austin, Texas 78739

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION RESPONSE TO
REPLOY POWER, INC.'S REQUEST TO REVIEW "REPLOY POWER
QUALITY ASSURANCE PROGRAM DEVELOPMENT," REVISION 0,
WHITE PAPER (EPID: L-2025-LRM-0105)

Dear Mr. Statile,

By letter dated July 24, 2025, REPLOY Power, Inc. (REPLOY) submitted to the U.S. Nuclear Regulatory Commission (NRC) a white paper titled "REPLOY Power Quality Assurance Program Development," Revision 0 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML25209A135).

REPLOY stated that this white paper provides a concise overview of REPLOY's plans to develop a quality assurance program (QAP). The overview provides the anticipated contents of REPLOY's quality assurance program description (QAPD) as well as the quality assurance manuals (QAMs) that cover specific products and functions under REPLOY's business model. Attachment A to the white paper contains the proposed format for the follow-on quality assurance (QA) topical report. REPLOY requested the NRC staff feedback on this white paper.

REPLOY has outlined the scope of this white paper as follows:

- Development and implementation of REPLOY's QAPD, detailing the approach for organizing the QA function and ensuring compliance with regulatory requirements.
- REPLOY's business model for the submersible power system and the licensing pathways, including Title 10 of the *Code of Federal Regulations* (10 CFR) Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," and Part 50, "Domestic Licensing of Production and Utilization Facilities," frameworks.
- QA criteria and regulatory requirements for various activities, ensuring adherence to 10 CFR Part 50, Appendix B and American Society of Mechanical Engineers' Nuclear Quality Assurance (NQA-1) standard, and a phased implementation plan for the QAPD and associated QAMs.

- References to various regulatory documents and standards that guide the development and implementation of the QAP.

The NRC staff has completed its assessment of the white paper and identified areas where additional details may be necessary, as outlined in the enclosure to this letter.

If you have questions related to this matter, please contact project manager Alina Schiller at (301) 415-8177 or via email at Alina.Schiller@nrc.gov.

Sincerely,



Signed by Jardaneh, Mahmoud
on 09/04/25

Mahmoud Jardaneh, Chief
New Reactor Licensing Branch
Division of New and Renewed Licenses
Office of Nuclear Reactor Regulation

Project No.: 99902132

Enclosure:
As stated

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ASSURANCE PROGRAM DEVELOPMENT," REVISION 0, WHITE PAPER
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DATE	8/27/2025	08/28/2025	09/01/2025	09/04/2025	9/4/25

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**NRC Staff Feedback on REPLOY Power, Inc. Quality Assurance Program Development,
Revision 0, White Paper**

1. Section 4.3.4 does not specify invoking Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, Reporting of Defects and Noncompliance,” for the procurement of items and services.
2. Section 4.3.7 documents REPLOY Power, Inc. (REPLOY)’s plan for the quality assurance program description (QAPD) development for control of purchased materials, equipment, and services. Commercial grade dedication (CGD) is not listed as part of REPLOY’s procurement processes. Please clarify if CGD will be covered in the scope of REPLOY’s quality program.
3. Section 4.3.15 does not discuss REPLOY’s quality program segregating items upon the discovery of nonconformance. This section also does not discuss REPLOY’s quality program dispositioning nonconforming items. Please clarify REPLOY’s commitments to dispositioning and segregating nonconforming items.
4. Section 4.3.16 does not discuss REPLOY’s actions for defining and handling significant conditions adverse to quality.
5. Section 4.3.17 specifies REPLOY’s protocols on Quality Assurance Records. Please clarify if this includes lifetime records.
6. Please specify what type of application (i.e., construction permit, operating license, combined license, early site permit, design certification, etc.) this QAPD will cover.
7. Please clarify if your prototype will be non-power or commercial.
8. Please clarify your commitments to applicable regulatory guides (RGs).
9. Section 3 (Transportation of Deployment Vessels)

The white paper indicates that deployment vessels may be transported with fresh-fueled reactors to their deployment sites and potentially returned with used fuel, with waste shipments from a central hub to a disposal facility. Since these activities may involve the transportation of nuclear fuel and spent fuel in international waters, it is recommended to provide further discussion on how transportation packages, deployment vessels, and associated operations will comply with 10 CFR Part 71, “Packaging and Transportation of Radioactive Material,” requirements, U.S. Department of Transportation’s regulations, and applicable international regulations, such as IAEA SSR-6 requirements where international transport is planned. Clarifying how REPLOY intends to demonstrate compliance with the NRC certificate of compliance (CoC) requirements for Type B or Type AF packages and ensuring alignment with applicable QA requirements under 10 CFR Part 71, Subpart H may help support a more complete understanding of the licensing strategy.

Enclosure

In addition to the requirements in 10 CFR Part 71, the packaging and transport of licensed material are also subject to other NRC QA requirements and to the regulations of other agencies. A factory-fabricated module, whether shipped before operation or after operation, would be subject to the requirements in 10 CFR Part 20, "Standards for Protection Against Radiation," and 10 CFR Part 21. Prior to operation while in transit, a license issued pursuant to 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," would be required for possession of the special nuclear material in the fuel loaded in the module, and a byproduct material license issued pursuant to 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," would be required if the module had been operated for testing and contained fission products. A 10 CFR Part 50, Appendix B QAPD can be applied to meet the QA requirements of these parts.

Waste handling operations would have to be covered by a license. Waste handling operations could also be under the Part 50 license. In 10 CFR 50.54 (ee) outlines the conditions of licenses, including the possession and use of special nuclear material, which encompasses spent nuclear fuel. Also, without understanding design features or activities that are important for personnel safety or environmental protection, it is not clear if a QA program or what elements of a QA program would be appropriate for REPLOY waste handling activities under a Part 70 or Part 50 license.

It is recommended that REPLOY identify the type and characteristics of the waste they plan to handle, identify their proposed activities, conduct safety/environmental analysis as appropriate for their proposed waste handling activities and then identify any QA program they feel is necessary for such licensed waste handling activities (e.g., no formal QA program requirements, adoption of elements of a QA program developed for of their other proposed Part 50 activities)

10. Sections 4.5 and 4.6

Sections 4.5 and 4.6 state that REPLOY intends to rely on an NRC-approved 10 CFR Part 50, Appendix B QAPD to meet the QA requirements of 10 CFR Part 71, Subpart H and 10 CFR Part 72, Subpart G. REPLOY also plans to develop Transportation and Waste Disposition Quality Assurance Manuals (QAMs) to provide crosswalks between the Appendix B QAPD and the applicable 71/72 QA criteria to demonstrate compliance for these activities.

The white paper does not describe the methodology for developing these crosswalks or explain implementation details, such as how REPLOY plans to demonstrate that its Appendix B program, supplemented by the QAMs, would fully satisfy the applicable QA criteria. Recommendations to consider:

- Describing how alignment will be demonstrated between Appendix B QA controls and the QA criteria in 10 CFR Part 71, Subpart H and 10 CFR Part 72, Subpart G, including how any gaps would be addressed through the QAMs.
- Considering how the proposed Appendix B QAPD would be applied to important-to-safety activities under Part 71 using a graded approach and a quality classification/categorization methodology consistent with NRC Regulatory Guide (RG) 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," and NUREG/CR-6407, "Classification of

Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety.” Also, consider where this would be documented (e.g., Nuclear Transport QAM).

- Under 71.101(f) and 72.140(d), applicants intending to apply an Appendix B QAP to activities subject to Parts 71 or 72 must notify the NRC in writing of this intent and obtain approval. Regarding timing of this notification for Part 71, per 71.101(b), each licensee, certificate holder, and applicant for a CoC shall establish ... a QA program. Therefore, if REPLOY plans to be a CoC holder for a transportation packaging under Part 71 in order to ship nuclear fuel, etc., the notification should be submitted at the time of the CoC application. For Part 72, per 72.140(c)(2), approval shall be obtained prior to receipt of spent fuel at the independent spent fuel storage installation, therefore, notification should be submitted with enough time for NRC staff to review and approve before planned receipt of spent fuel.
- The applicant should consider whether the Transportation and Waste Disposition QAMs, which are intended to provide crosswalks, will be submitted for NRC review as part of the QAPD approval process. Since the QAMs appear to be the main driver for demonstrating compliance with Subpart H/G requirements, additional consideration may be needed on how these documents will be used to support NRC approval and oversight. Please also consider the guidance in RG 7.10, Revision 3, under the Level of Detail in QA Program Descriptions section in determining whether to submit the QAMs as part of the approval process. Although it is not required by 10 CFR Part 71 or Part 72 to submit QAMs, if the QAM is submitted as part of the 10 CFR Part 50, Appendix B approval and it contains very detailed information such as implementing procedures/processes, the NRC staff typically would not review the detailed implementing procedure and processes.