Hadron Energy, Inc.
3 Twin Dolphin Dr #260
Redwood City, CA 94065

July 31, 2025

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555–0001

Subject: Second Amended Hadron Energy Microreactor Pre-Application Regulatory Engagement Plan for Standardized Microreactor Design

Dear Mr. Sayoc,

Hadron Energy, Inc. (Hadron Energy) submits the enclosed **Second Amended Pre-Application Regulatory Engagement Plan (REP)** for the Hadron Energy Microreactor (MMR) standardized design. This document supersedes the First Amended REP submitted on July 1, 2025.

This Second Amended REP reflects a significant evolution in our business model, operational plans, and regulatory strategy, incorporating valuable feedback from the NRC staff from our meeting on July 8, 2025. The key strategic changes from the previously submitted version are summarized as follows:

1. **Revised Licensing Strategy:** The plan to seek a Standard Design Approval (SDA) has been removed. Our regulatory strategy is now focused on pursuing a Manufacturing License (ML) under 10 CFR Part 52, Subpart F as the primary vehicle for obtaining NRC approval of the standardized design. This will be followed by Combined Licenses (COLs) under 10 CFR Part 52, Subpart C for each operating site.
2. **Revised Business Model:** Hadron Energy will be the owner and operator of the deployed microreactors. Consequently, Hadron Energy, not a customer or partner, will be the applicant for the COLs, assuming full lifecycle responsibility, including plant decommissioning.
3. **Revised Transportation and Operational Strategy:** The plan to transport a fueled reactor has been revised. The current strategy involves transporting the unfueled reactor module, with fuel shipped separately by Hadron Energy under a 10 CFR Part 71 license. The reactor is now designed for periodic on-site refueling, and spent fuel will be managed on-site via a licensed Independent Spent Fuel Storage Installation (ISFSI) under 10 CFR Part 72.

4. **Quality Assurance Program Schedule:** The submittal of the Quality Assurance Program Description (QAPD) Topical Report has been moved from July 2025 to September 2025. This adjustment allows us to incorporate feedback from additional quality assurance personnel we are hiring.
5. **Streamlined, Overlapping Review Schedule:** Consistent with the national priority to support the deployment of advanced nuclear technology, our plan now targets an 18-month review schedule for both the ML and COL applications. The COL application will be submitted for overlapping review with the ML application.
6. **Adjusted HALEU Target**: Mindful of significant Material Control & Accounting (MC&A) costs associated with transporting HALEU fuel over 10%, Hadron is targeting HALEU fuel with a 9.9% enrichment for use in its reactor.

These updates provide a clear and comprehensive framework for our continued pre-application engagement. We believe this revised strategy is more efficient and directly aligned with the Commission's regulatory framework. To the extent that this framework is improved or made more efficient through ongoing efforts by NRC to modernize its regulations, Hadron Energy will revise this engagement accordingly.

In view of the significant changes to the regulatory pathway presented in this REP, especially as it relates to the transportation methodology, we request additional engagement from the NRC on these changes in the form of a public meeting.

Should you have any questions or require further clarification regarding this submission, please contact our primary point of contact, Samuel Gibson, at sgibson@hadronenergy.com or (605) 929-7913.

Sincerely,

Samuel Gibson
Founder & CEO
Hadron Energy, Inc.

Enclosures:

1. Second Amended Hadron Energy Microreactor Pre-Application Regulatory Engagement Plan

Manny Sayoc, New Reactor, Safety Review, and Environmental Review Project Manager
301 415 4084
emmanuel.sayoc@nrc.gov

EXECUTIVE SUMMARY

Hadron Energy, Inc. (Hadron Energy) is developing a standardized, LEU-fueled, light-water cooled and moderated Modular Microreactor (MMR) design, which it will also own and operate. This Second Amended Regulatory Engagement Plan (REP) outlines an efficient and achievable strategy for interacting with the U.S. Nuclear Regulatory Commission (NRC) staff during the pre-application phase.

Hadron Energy's primary regulatory path involves two main, overlapping components: obtaining a Manufacturing License (ML) under 10 CFR Part 52, Subpart F to authorize factory production of the standardized design, and obtaining a Combined License (COL) under 10 CFR Part 52, Subpart C for the construction, operation, and decommissioning of the first microreactor. The COL application will be submitted for overlapping review with the ML application, with a target 18-month review schedule for each. Hadron Energy will also pursue licenses under 10 CFR Part 71 for the transportation of nuclear material and 10 CFR Part 72 for on-site spent fuel storage.

Key areas for early engagement include the content of the ML application, flexible siting approaches, staffing, and the technical basis for on-site refueling, spent fuel management, and decommissioning funding assurance. This REP provides a predictable framework for these interactions, with the goal of submitting high-quality applications.

1. INTRODUCTION/PURPOSE OF REP

This Second Amended Regulatory Engagement Plan (REP) has been developed by Hadron Energy, Inc. (Hadron Energy) to facilitate communication and collaboration with the U.S. Nuclear Regulatory Commission (NRC) staff regarding the licensing of the Hadron Energy Microreactor standardized design. It documents Hadron Energy's proposed licensing approach, identifies topics for engagement, outlines schedule expectations, and serves as a roadmap for pre-application interactions. The primary purpose is to reduce regulatory uncertainty by fostering early dialogue and establishing mutual understanding.

1.1 Contact Information

For routine communication and coordination, the primary point of contact for Hadron Energy is:

Samuel Gibson
Title: Chief Executive Officer
Email: sgibson@hadronenergy.com
Phone: (605) 929-7913
Mailing Address: Hadron Energy, Inc., 3 Twin Dolphin Dr #260, Redwood City, CA 94065

Additional points of contact for specific technical or project management areas will be provided directly to the assigned NRC staff project manager.

1.2 Company/Project Structure

Hadron Energy, Inc. ("Hadron Energy") is committed to a productive and transparent regulatory engagement with the NRC throughout the licensing process. Established in 2024 as a privately held Delaware C-corporation, Hadron Energy is focused on the design, manufacturing, licensing, deployment, and operation of the standardized Hadron MMR.

Hadron Energy currently operates as a standalone entity and is not a subsidiary of, nor formally affiliated with, any parent corporation. Ownership is held domestically, and funding is primarily secured through private investment sources, including venture capital and strategic partnerships. Hadron Energy confirms that it is not under foreign ownership, control, or domination (FOCD) as defined by the Atomic Energy Act and relevant NRC regulations (10 CFR 50.38).

The Hadron MMR project is managed internally by Hadron Energy personnel. Key management and technical staff possess significant experience in relevant fields, including nuclear engineering, advanced reactor design, regulatory affairs, quality assurance, nuclear reactor operations and project management. Quality assurance programs suitable for the planned activities are under development and will be implemented consistent with regulatory requirements.

Hadron Energy understands the requirement under 10 CFR 50.33(f) and 10 CFR 52.77 to demonstrate financial qualification. Current funding is sufficient for planned pre-application activities, and Hadron Energy has a phased financing strategy aligned with project development and licensing milestones. Detailed financial information demonstrating qualification for the manufacturing and operational activities will be provided in the respective ML and COL applications.

Project schedules and the scope of NRC engagement are dependent on available funding. Hadron Energy is committed to proactive communication with the NRC project manager regarding resource planning and any potential budgetary constraints that could impact agreed-upon schedules (See also Section 9.2). The project currently does not receive U.S. government cost-share funding.

1.3 Summary Strategic Project Approach/Goals

Hadron Energy's strategic approach centers on the efficient design, manufacturing, and deployment of a standardized, factory-built, transportable 10 MWe light-water microreactor.

Our intended regulatory path involves two main, overlapping efforts:

1. **Manufacturing License (ML):** Pursuing an ML under 10 CFR Part 52, Subpart F for the standardized design.
2. **Combined License (COL):** Pursuing a COL under 10 CFR Part 52, Subpart C for the construction, operation, and decommissioning of our first reactor deployment. The COL

application will be submitted for review while the ML application is also under review.

The manufactured reactor module will be transported unfueled, with all fuel handling, loading, on-site storage, and refueling managed under the site-specific Combined License. This strategy is predicated on the submission of high-quality documents and intensive, collaborative engagement with the NRC staff to support an efficient review schedule.

1.4 Background

The Hadron MMR design is based on proven light-water reactor (LWR) technology, leveraging decades of operational experience, established materials data, and validated analytical methods. Grounding the design in established LWR principles minimizes technical risk associated with core reactor technology and allows regulatory review to focus efficiently on the novel aspects of our implementation.

Hadron Energy's primary innovation lies not in the core reactor physics, but in leveraging existing regulatory certainty into smaller, advanced reactors that benefit from standardized factory manufacturing and enhanced deployment flexibility. This approach is driven by the strategic goal of providing modular, secure, reliable, and cost-effective carbon-free power for remote communities and critical infrastructure.

To rigorously validate the integrated design, including control systems and operational concepts, Hadron Energy is investing significantly in advanced simulation and testing infrastructure. This includes the development of a high-fidelity digital twin, which will be rigorously qualified and utilized in conjunction with targeted hardware testing within a robust Quality Assurance program planned for compliance with American Society of Mechanical Engineers (ASME) NQA-1 (Quality Assurance for Nuclear Facility) standards.

1.5 REP Approach

This REP outlines our framework for proactive interaction with the NRC staff, consistent with NEI 18-06. The schedule in Section 9.1 details planned interactions. Recognizing that project plans and timelines evolve, Hadron Energy views this REP as a living document. We intend to formally review and update this REP, in consultation with the NRC Project Manager, approximately every six months, or more frequently if significant changes in strategy, scope, or schedule occur. These updates will incorporate NRC feedback and reflect the most current project planning.

Beyond the formal REP updates, any significant deviations from the plans or schedules outlined herein will be communicated promptly to the NRC staff project manager. Hadron Energy welcomes regular communication with the NRC staff and proposes periodic meetings (e.g., quarterly or as needed based on activity levels) to discuss progress and upcoming activities during active pre-application phases.

2 TECHNOLOGY SUMMARY

The Hadron MMR is designed as a standardized, transportable power source utilizing established light-water reactor (LWR) principles. This summary provides a high-level overview relevant to regulatory review. More detailed technical information will be provided in subsequent white papers and technical reports identified in Section 9.1.

2.1 Size

- **Thermal Power:** 30-35 MWth (nominal).
- **Electric Output:** 10 MWe net electric output (nominal).
- **Physical Size:** Designed to fit within the dimensional envelope of a standard International Standards Organization (ISO) shipping container to facilitate transport via conventional road, rail, air, or sea logistics.

2.2 Fuel

- **Fuel Type and Form:** The Hadron MMR uses High-Assay Low-Enriched Uranium (HALEU) dioxide (UO_2) fuel, fabricated into conventional cylindrical pellets and encased in cladding materials—such as zirconium alloys—that are well-characterized through decades of commercial LWR operation. This familiar geometry and material selection supports predictable thermal-mechanical behavior, effective heat transfer, and robust fission product retention, while facilitating licensing by leveraging an extensive base of existing fuel performance data.
- **Enrichment:** The uranium will be enriched to less than 10% U-235, with a target of 9.9%. This is consistent with HALEU classification but remains at the lower end of the HALEU spectrum.
- **Fuel Qualification Approach:** Fuel performance is expected to be supported in part by applicable data from existing HALEU programs and historic LWR fuel testing. Recognizing the unique configuration and operating environment of the Hadron MMR, a dedicated fuel qualification strategy will also be developed. This may include integral effects testing, modeling, and analytical validation in accordance with NRC Regulatory Guides and American Nuclear Standards Institute (ANSI)/American Nuclear Society (ANS) standards.
- **Fuel Handling and Lifecycle:** To best benefit from established standards and methods for the safe transport of nuclear fuel, and to accommodate a design that uses lower-enriched HALEU fuel, the reactor will be loaded with fuel and refueled on site. Accordingly:
    - The reactor module is shipped unfueled.
    - New fuel is transported to the site using standard, certified packages and licensed carriers, compliant with 10 CFR Part 71.
    - Initial fuel load and periodic on-site refueling are performed under the authority of Hadron Energy's Combined License.

    - Spent fuel is cooled in an on-site spent fuel pool, then transferred to a licensed on-site Independent Spent Fuel Storage Installation (ISFSI).
    - The plant is then decommissioned by Hadron Energy.

This strategy enhances regulatory certainty and safety by utilizing standard, licensed transportation methods for fuel and aligning spent fuel management with the proven, on-site storage framework of 10 CFR Part 72 used by the existing U.S. nuclear fleet.

2.3 Coolant

- **Primary Coolant:** The Hadron MMR uses light water (H_2O) as the primary coolant.

2.4 Moderation

- **Moderator:** The Hadron MMR uses light water (H_2O) as the neutron moderator.

2.5 Containment/Confinement

Radionuclide retention in the Hadron MMR is achieved through a robust, multi-layered defense-in-depth containment strategy. This strategy is designed to ensure the safe confinement of radioactive materials under normal operating conditions and during postulated accident scenarios. The approach incorporates both passive and engineered barriers, including:

- **Fuel Pellets (First Barrier):** The ceramic uranium dioxide (UO2) fuel pellets contain the radioactive fission products created during the nuclear reaction. They are designed to retain these products within the fuel matrix.
- **Fuel Cladding (Second Barrier):** The fuel cladding, which encapsulates the fuel pellets and retains the majority of fission products. The cladding material is selected for its high-temperature performance, corrosion resistance, and proven in-reactor behavior. Cladding integrity is maintained under all anticipated operational occurrences and design basis accidents, supported by validated fuel performance modeling.
- **Primary Coolant System Boundary (Third Barrier):** The primary coolant system, including the Reactor Pressure Vessel (RPV) and associated piping and components, forms the second containment barrier. This boundary is constructed from high-grade, corrosion-resistant stainless steel and is designed to retain its structural and sealing integrity under both normal conditions and transients. Comprehensive engineering evaluations, including finite element analysis and fracture mechanics assessments, are conducted to demonstrate performance under thermal, pressure, and seismic loads. The RPV is sized and tested to exceed the stress margins required by ASME Section III standards and relevant NRC guidance.
- **Containment Structure (Fourth Barrier):** A robust containment structure surrounds the primary system and provides an additional layer of radionuclide retention. This structure is designed to withstand internal pressure from postulated accidents, such as a loss-of-coolant accident (LOCA), as well as external hazards including seismic and

transportation-induced loads. The containment may be a sealed metallic or composite enclosure, tailored to the transportable reactor architecture and fully compliant with 10 CFR Part 50 Appendix A General Design Criteria.

- **Functional Containment and Passive Safety Features**: In addition to physical barriers, the Hadron MMR leverages functional containment principles—such as pressure suppression, passive heat removal, negative power coefficient, and inherent safety features of the reactor core design—to minimize radionuclide mobilization and potential release. The integrated system design ensures that even in the unlikely event of fuel damage, radionuclide transport is significantly impeded by a combination of thermal-hydraulic, chemical, and material barriers.

All containment barriers will be evaluated through safety assessments using NRC-endorsed tools and methodologies, including deterministic methodologies and/or probabilistic risk assessment and alternatives thereto as directed by section 208(a)(1)(E) of the ADVANCE Act of 2024. These analyses are performed to demonstrate that the design meets or exceeds regulatory dose limits under design basis accidents and beyond design basis events. Supporting documentation, including technical reports, test data, and modeling results, will be provided in the MLA. Preliminary results and safety case insights will also be shared with NRC staff during the pre-application engagement phase to support early alignment and transparent regulatory review.

2.6 Usage

- **Primary Use:** Electricity generation (10 MWe).
- **Applications:** The reactor is optimized for deployment in locations where conventional grid power is unavailable, unreliable, or logistically impractical. Primary applications include:
    - Replacement of diesel generators in remote communities, disaster relief zones, and off-grid industrial operations.
    - Power supply for military or scientific installations requiring secure, mobile, and independent energy.
    - Grid support functions such as peak shaving, renewable firming, or backup power in localized high-demand areas (e.g., data centers).
    - Non-power applications, such as hydrogen production or desalination facilities.

2.7 Technology Readiness

- **Core Technology:** The Hadron MMR is built on mature LWR technology, with established fuel forms, materials, and safety principles that support a high degree of technical readiness.
- **Innovation:** Focused on areas that enhance deployment and operational flexibility—specifically modular packaging, factory manufacturing, transportability and inherent safety.

- **Validation:** Supported by an advanced digital twin platform and a comprehensive hardware testing program.

2.8 Fuel Cycle Considerations

- **Front-End**: Utilizes the HALEU supply chain; fueling and refueling performed on-site by Hadron Energy.
- **Back-End**: On-site management of spent fuel in a pool, followed by transfer to a licensed on-site ISFSI under Hadron Energy's operational control, followed by site decommissioning.

2.9 Other Key Features (Transportability, Production, Operations Model)

- **Transportability:** Designed for standard shipping logistics, minimizing special handling. Post-transport verification methods will be employed.
- **Production:** Assembly-line manufacturing for consistency and cost-efficiency. Factory Acceptance Testing (FAT) performed prior to shipment.
- **Operations Model:** Designed for primary monitoring and control from a certified central control facility, minimizing routine onsite staffing needs while ensuring robust oversight. Features high levels of automation and inherent safety characteristics that default the reactor to safe shutdown states upon detection of off-normal conditions or loss of communication. The core safety argument relies on this combination of inherent safety, reliable automation, defense-in-depth in monitoring and control systems, and continuous oversight by qualified operators. Detailed justification demonstrating how this model meets the underlying safety intent of NRC operational and staffing regulations will be provided through focused engagement, as described in Section 3.8.3.C.

3 REGULATORY STRATEGY

This section outlines Hadron Energy's planned regulatory strategy for licensing the Hadron MMR. This strategy reflects current design maturity and regulatory understanding, including insights from NRC staff communications such as SECY-24-0008 (“Rulemaking Plan for Regulatory Framework for Micro-Reactors”) and may evolve based on ongoing technical development and feedback received during pre-application engagement with the NRC Staff.

3.1 Application Type

Hadron Energy plans to utilize a combination of licensing frameworks best suited for our design and deployment model.

- **Manufacturing License (10 CFR 52 Subpart F)** This is Hadron Energy's first major licensing path. We intend to apply for an ML under 10 CFR Part 52, Subpart F. The ML

application will contain the complete design information, including a Final Safety Analysis Report (FSAR), and will serve as the basis for the NRC's review and approval of the standardized design.

- **Combined License (10 CFR 52 Subpart C)** Hadron Energy will prepare and submit a COL application for our first deployment site to be reviewed in parallel with the ML application. The COL application will reference the ML application for all standard design information and will provide the required site-specific information (environmental report, security plan, physical security plan, emergency plan, etc.) and the Decommissioning Funding Plan. The authority to possess fuel, load the reactor, operate the plant, conduct on-site refueling, and ultimately decommission the facility is granted within the COL.
- **Special Nuclear Material Licenses (10 CFR Part 70)** Hadron Energy's licensing strategy is designed to integrate the authority to possess and use Special Nuclear Material (SNM) within the primary facility operating license, rather than through a separate Part 70 license. The authority for Hadron Energy to possess, receive, and handle SNM at a commercial operating site will be granted under our 10 CFR Part 52 Combined License for that site. The COL application will include all necessary information to demonstrate compliance with applicable Part 70 requirements, including those for material control and accounting under 10 CFR Part 74.
- **Transportation (10 CFR Part 71)** Hadron Energy will seek a license as a shipper of radioactive material under 10 CFR Part 71. This license will authorize Hadron Energy to transport fresh fuel from the fuel fabricator to our licensed reactor sites, and to transport spent fuel between our sites or to a disposal facility, should one become available. Our Part 71 transportation program will be developed to meet all applicable NRC requirements for packaging, safety, and security. We will exclusively use NRC-certified transportation packages (i.e., those with a Certificate of Compliance).
- **Independent Spent Fuel Storage Installation (10 CFR Part 72)** To manage spent fuel on-site after it has been sufficiently cooled in the spent fuel pool, Hadron Energy will apply for a site-specific license under 10 CFR Part 72 to construct and operate an Independent Spent Fuel Storage Installation (ISFSI). This application will be submitted after the COL is issued, with sufficient lead time to allow for construction and operation before the first fuel is ready to be moved from the pool to dry storage.

Hadron Energy has evaluated alternative licensing paths and is actively monitoring the development of 10 CFR Part 53 and other rules relating to the rapid deployment of low consequence reactors and microreactors. In the event that this framework becomes available for use before Hadron Energy files its applications, Hadron Energy will consider the framework's applicability to the Hadron MMR and, if appropriate, engage with the NRC concerning the feasibility of pursuing this framework as an alternative to, or in addition to, the framework described in this REP.

3.2 National Environmental Policy Act (NEPA)

Hadron Energy understands its responsibility under 10 CFR Part 51 to provide comprehensive environmental information supporting the NRC staff's preparation of NEPA documentation (e.g.,

Environmental Assessment or Environmental Impact Statement). For Hadron Energy's Manufacturing License application under 10 CFR Part 52, Subpart F, an Environmental Report (ER) will be developed and submitted. This ER will address the environmental impacts associated with the proposed manufacturing facility and its operations, consistent with 10 CFR Part 51 requirements for such a license.

Each subsequent site-specific Combined License Application (COLA) must then include a separate, detailed ER compliant with the requirements of 10 CFR §51.45 and §51.50(c). These site-specific ERs will be prepared using applicable NRC guidance, primarily Regulatory Guide 4.2, "Preparation of Environmental Reports for Nuclear Power Stations."

Recognizing that the Hadron MMR's intended rapid deployment capability may differ from prior NRC experience with large light-water reactors where sites are selected years in advance, we anticipate a need for early engagement regarding the site-specific NEPA process. A key aspect to address is efficiently preparing and reviewing ERs when specific deployment sites may not be identified until closer to the deployment date. To address this, Hadron Energy is designing the reactor for compatibility with a wide range of site conditions and intends to proactively engage with NRC staff on developing agile approaches for these site-specific environmental reviews. As encouraged by NRC guidance for potentially novel approaches, engagement topics will likely include exploring the feasibility and acceptability of using bounding analyses or site parameter envelopes within the ERs to streamline the review process for future COLAs, ensuring timely deployment while fully meeting all NEPA requirements. (This topic relates to the siting strategy discussed further in Section 3.8.2).

Furthermore, acknowledging the comprehensive scope outlined in 10 CFR Part 51 and NRC guidance, these site-specific ERs will fully analyze potential environmental impacts associated with the entire Hadron MMR lifecycle. This includes incorporating considerations unique to our approach, such as those related to factory fabrication, transportation, operational characteristics, fuel management, and the planned return-to-facility decommissioning strategy, ensuring a thorough evaluation consistent with NEPA requirements.

3.3 Principal Design Criteria (PDC)

As the Hadron MMR is based on LWR technology, the General Design Criteria (GDC) established in 10 CFR Part 50, Appendix A, provide the fundamental basis for developing the project-specific Principal Design Criteria (PDC). Consequently, guidance developed specifically for non-LWRs, such as Regulatory Guide 1.232, is not considered the primary basis for the Hadron MMR PDC.

Hadron Energy recognizes, however, that certain unique aspects of the microreactor design and operational concept – including its small physical size, transportability, and flexible deployment – necessitate a careful evaluation of the applicability of each GDC; and appreciate that the NRC has acknowledged that some of the current GDCs may not be applicable to advanced designs. Thus, Hadron Energy will seek early engagement with the NRC on which GDCs Hadron Energy

is expected to meet; or what alternative or supplemental criteria are needed to address the specific design features adequately.

Where deviations or alternative criteria are proposed, Hadron Energy will develop robust technical justifications. These justifications will demonstrate how the underlying safety intent of the GDC is met by the proposed approach or explain why a specific GDC may not be applicable. This process may leverage insights from risk-informed and performance-based (RIPB) methodologies where appropriate to support the technical basis.

Consistent with NRC guidance encouraging early dialogue on novel aspects, Hadron Energy plans to proactively engage with NRC staff on the proposed PDC framework during the pre-application phase. This engagement, potentially utilizing white papers, topical reports, or targeted technical meetings, aims to foster mutual understanding and alignment on the PDC well before the formal ML application submittal. Establishing clarity on the PDC is considered essential for an efficient licensing process and is linked to the Key Issues discussed further in Section 3.8.

3.4 Selection of Applicable Guidance

Hadron Energy is leveraging key industry and NRC guidance in preparing this REP, notably NEI 18-06. For the development of our ML application and COL application, and to support subsequent Combined License (COL) applications under 10 CFR Part 52, we anticipate using the following primary NRC guidance documents. We recognize that guidance developed primarily for large LWRs may require interpretation or adaptation for the Hadron MMR, and we are committed to early engagement with NRC staff regarding such cases, consistent with NRC staff encouragement for robust pre-application interactions for advanced reactors.

Guidance Primarily Informing Application Content and Safety Review:

- **NUREG-0800 (Standard Review Plan - SRP):** The SRP will be the primary guide for the technical content, level of detail, and safety review expectations for the ML application. It will also inform the content expected in FSARs for COLs that reference the ML and manufactured unit. This includes addressing operational programs (SRP Section 13.4), for which we intend to develop standardized approaches suitable for microreactors to support efficient review, potentially seeking early feedback via topical reports or other mechanisms. We will identify and provide technical justification for any areas where SRP sections may not directly apply or where alternative approaches are proposed due to the specific features of the Hadron MMR.
- **RG 1.233 / NEI 18-04 (Licensing Modernization Project - LMP):** Hadron Energy intends to utilize the technology-inclusive, risk-informed, and performance-based methodology described in this guidance (endorsed by RG 1.233) to develop the safety case, establish performance requirements, and classify Structures, Systems, and Components (SSCs).
- **NUREG-0933 / GIMCS (Generic Issues Management and Control Systems):** We will monitor the Generic Issues Program (GIP) and address applicable unresolved safety

issues and medium/high-priority generic safety issues relevant to our design in our Part 52 applications, as required.

Guidance Primarily Informing Application Format and Structure:

- **RG 1.206 (COL Applications):** Although primarily focused on COLs and currently under revision, this guidance (or its successor incorporating transitions from RG 1.70) will inform the overall format and content organization of the ML application FSAR to facilitate efficient development and later referencing in COLAs. It will also directly inform the COLA structure.

Guidance Relevant to Site-Specific COL Applications:

- **RG 4.2 (Environmental Reports) & NUREG-1555 (Environmental Standard Review Plans (ESRP)):** These documents will guide the preparation of site-specific ERs required only for the COLAs and will inform our understanding of the NRC's environmental review process.
- **RG 4.7 (General Site Suitability Criteria):** This guidance, potentially supplemented by industry approaches like the EPRI Siting Guide, will be considered during site selection and evaluation activities performed in support of future COLA submissions.

Regarding NUREG-1537 (Non-Power Reactors): The Hadron MMR is being licensed as a power reactor under 10 CFR Part 52, making NUREG-1537 inapplicable as primary licensing basis guidance. However, we recognize this document contains insights into NRC perspectives on graded safety analysis and proportionate regulatory approaches for smaller reactors, and indeed, SECY-24-0008 presents an option to the Commission to treat microreactors like non-power reactors. Accordingly, we may reference these concepts in future technical discussions with NRC staff regarding potential graded or streamlined approaches within the Part 52 framework, where technically justified for the microreactor scale.

Hadron Energy will proactively engage with NRC staff to discuss the applicability, interpretation, and potential adaptation of existing guidance documents throughout the pre-application and application review phases.

3.5 Use of Standards and Industry Guidance

Hadron Energy recognizes the importance of leveraging established consensus standards and pertinent industry guidance to ensure a robust design basis and facilitate an efficient regulatory review process. We intend to incorporate applicable standards and guidance throughout our design, analysis, quality assurance program, and application development activities. Early engagement with NRC staff is planned where standards might be applied in novel ways or where specific interpretations are key to the design basis.

3.5.1 Consensus Standards

Hadron Energy will reference applicable consensus standards developed by Standards Development Organizations (SDOs) such as the American Society of Mechanical Engineers (ASME), the American Nuclear Society (ANS), and the Institute of Electrical and Electronics Engineers (IEEE). Our approach will prioritize the use of standards endorsed by the NRC (e.g., via Regulatory Guides or incorporation by reference, such as in 10 CFR § 50.55a). We plan to initiate discussions with NRC staff, potentially via targeted technical meetings early in the pre-application phase (e.g., within the first year), regarding the specific standards and editions intended for use in the licensing basis.

3.5.2 Nuclear Energy Institute (NEI) Guidance

We will utilize relevant guidance documents developed by the NEI where applicable. Key documents informing our regulatory strategy and approach include NEI 18-06 ("Guidelines for Development of a Regulatory Engagement Plan") and NEI 18-04 ("Risk-Informed Performance-Based Technology Inclusive Guidance for Non-Light Water Reactor Licensing Basis Development," methodology supporting the Licensing Modernization Project, endorsed by RG 1.233). Other NEI technical reports and guidance related to areas such as quality assurance or operational programs will be reviewed for applicability and referenced as appropriate.

3.5.3 Electric Power Research Institute (EPRI) Guidance

Hadron Energy will also review and reference applicable technical reports and guidance documents from the EPRI. This includes evaluating the relevance of foundational documents, such as potentially the Advanced Light Water Reactor Utility Requirements Document (ALWR URD) or EPRI's ongoing work related to advanced reactors, materials reliability, or other technical areas pertinent to the Hadron MMR design and operation.

3.6 Assessing Alignments/Gaps

Hadron Energy understands that proactively identifying and resolving potential gaps or misalignments between our novel microreactor design, operational concepts, and the existing regulatory framework is crucial for minimizing regulatory risk and achieving an efficient review. Drawing insights from previous industry efforts (e.g., NuScale's gap analyses, Next Generation Nuclear Plant (NGNP) issue papers), we intend to conduct a systematic assessment during the pre-application phase and utilize targeted interactions to achieve mutual understanding with NRC staff on these areas prior to the ML application submittal.

Early in the pre-application phase, Hadron Energy will perform and document a focused regulatory assessment. This assessment will identify specific areas potentially requiring dedicated engagement, such as:

- Novel design features (e.g., related to transportability and unique safety systems) and their alignment with existing regulations.
- Proposed adaptations or alternative approaches for meeting the intent of Principal Design Criteria derived from 10 CFR 50 Appendix A (linked to Section 3.3).
- Sections of the Standard Review Plan (NUREG-0800) where standard review approaches may need interpretation, supplementation, or tailoring for a microreactor design, potentially leveraging risk-informed insights from our LMP-based safety case (linked to Section 3.4).
- Areas where existing regulatory guidance may lack sufficient detail or may warrant clarification for microreactor applications.

The findings from this assessment will serve as a key input for planning pre-application interactions. Hadron Energy intends to utilize appropriate mechanisms, such as targeted white papers, topical reports, or technical meetings, to proactively engage with NRC staff on the identified topics. The primary objectives of this engagement are to:

- Clearly articulate Hadron Energy's proposed technical and regulatory approach in areas identified during the assessment.
- Discuss the technical basis for any proposed alternative compliance methods or guidance adaptations.
- Seek timely NRC feedback to foster alignment on the path forward for resolving potential issues before the ML application is finalized and submitted.

3.7 Design-Centered Review Approach

Hadron Energy is familiar with the Design-Centered Review Approach (DCRA) described in NRC guidance, which historically facilitated efficient reviews by coordinating standard design content. While a formal multi-applicant Design-Centered Work Group (DCWG) is not applicable since Hadron Energy will be the sole applicant for all COLs, our fundamental regulatory strategy fully embraces the core principles and goals of the DCRA.

Our approach—obtaining an NRC design approval through the ML for a standardized microreactor that will then be referenced in a series of our own subsequent COL applications—is the epitome of design standardization. This ensures that the NRC reviews the standard design once and in-depth, allowing for a highly focused and efficient review of site-specific information in each follow-on COL. This maximizes regulatory efficiency, ensures consistency across our fleet, and provides predictability for both Hadron Energy and the NRC, directly achieving the intended benefits of the DCRA.

3.8 Key Issues

Hadron Energy recognizes that early identification and collaborative resolution of key technical and regulatory topics associated with our novel microreactor design and deployment model are essential for an efficient licensing process. We intend to proactively engage with NRC staff on

these topics using mechanisms such as targeted technical meetings, white papers, and topical reports, with the goal of achieving mutual understanding and resolving potential issues prior to the ML application submission.

3.8.1 Generic Issues

Hadron Energy will monitor the NRC's Generic Issues Program (GIP) through NUREG-0933 and the online GIMCS. We will assess the applicability of unresolved safety issues and medium/high-priority generic safety issues to the Hadron MMR design and address them as required in our 10 CFR Part 52 applications. We will engage with NRC staff if clarification on the applicability or proposed resolution of a generic issue is needed.

3.8.2 New Reactor Issues

We will actively track policy and technical issue resolution status for Small Modular Reactors (SMRs), microreactors and advanced reactors via NRC webpages (e.g., resolved policy issues lists) and engagement with industry groups (e.g., NEI, Nuclear Innovation Alliance). We will incorporate relevant resolved positions into our licensing basis and engage on any emerging policy issues pertinent to our design and licensing strategy.

3.8.3 Selected Specific Topics for Engagement

The following represent key technical and regulatory topics, based on the Hadron MMR's specific features and common areas identified in NRC guidance, that we anticipate warranting focused pre-application engagement:

- **(A) Transportation and Logistics**
    - Topic: Establishing and licensing a 10 CFR Part 71 transportation program for new and spent nuclear fuel, and coordinating the logistics of shipping the unfueled reactor module.
    - Engagement Approach: We plan to engage with NRC staff via a white paper to outline the proposed structure of our Part 71 transportation program, including our approach to quality assurance, security, and emergency response procedures. This will be followed by a formal license application. We will also engage via technical meetings to discuss the interface between the shipment of the unfueled module and the separate shipment of fuel, ensuring a clear understanding of documentation and post-transport verifications required before fuel loading at an operational site.
- **(B) Site Selection & Evaluation / External Hazards and Plant Parameter Envelope**
    - Topic: Developing a bounding site envelope, or Plant Parameter Envelope (PPE), to be included in the Manufacturing License application, ensuring the standardized design accommodates a wide range of potential deployment site conditions and external hazards (seismic, flooding, etc.).
    - Engagement Approach: We will engage NRC staff on the development and acceptance of the proposed PPE methodology. We plan to submit a white paper,

potentially followed by a topical report, that defines the bounding site characteristics, the methodology for selecting them, and the approach for demonstrating in a future COL application that a specific site falls within the approved envelope.

- **(C) Staffing Needs and Centralized Observation:**
  - Topic: Justifying the operational concept of a central monitoring facility supported by essential on-site operators, and demonstrating compliance with NRC operational and staffing regulations (e.g., 10 CFR 50.54(k)).
  - Engagement Approach: We will submit focused white papers and potentially a topical report to articulate the core safety arguments and present the detailed Concept of Operations (CONOPS). These submittals will provide comprehensive justification, including Human Factors Engineering (HFE) analysis, to demonstrate how the integrated system of technology, procedures, and personnel ensures safe operation and meets the underlying safety intent of relevant regulations.
- **(D) Emergency Planning (EP):**
  - Topic: Establishing an appropriate, scalable Emergency Planning Zone (EPZ) and emergency plan consistent with the microreactor's small size, potential source term, and design features.
  - Engagement Approach: We plan to develop the EP approach using risk-informed, performance-based principles, potentially aligning with emerging NRC guidance or rules for SMRs/advanced reactors (e.g., 10 CFR 50.160). We intend to submit a white paper outlining the proposed EP methodology, including the EPZ sizing basis, for NRC feedback prior to submitting the first COL application.
- **(E) Fuel Qualification:**
  - Topic: Confirming the adequacy of the fuel qualification basis for the specific HALEU fuel design, including leveraging existing LWR/HALEU data and identifying any necessary supplemental testing or analysis.
  - Engagement Approach: We plan to submit a Fuel Qualification Topical Report for NRC review and approval. This report will detail the qualification strategy, data sources, testing plans (if any), performance criteria, and the analytical models used to demonstrate fuel performance under normal and accident conditions.
- **(F) Digital Instrumentation & Control (I&C) / Cyber Security:**
  - Topic: Ensuring the digital I&C system meets regulatory requirements for reliability, qualification, independence, and cyber security (per RG 1.152, NEI 08-09, etc.).
  - Engagement Approach: We plan to submit a Topical Report or focused white papers addressing the digital I&C architecture, defense-in-depth and diversity, the cyber security program, and the comprehensive Validation and Verification (V&V) strategy. The V&V strategy will detail the methodology for qualifying the digital twin and how simulation results will be integrated with and validated against hardware testing data.
- **(G) Accident Analysis Methodology / Probabilistic Risk Assessment (PRA):**

    - Topic: Defining and justifying the methodologies used for accident analysis (transient and accident sequences) and PRA, consistent with the LMP approach.
    - Engagement Approach: We will engage via technical meetings and potentially white papers or topical reports on the selection of Licensing Basis Events (LBEs), PRA scope and methodology (addressing microreactor-specific features), and the use of codes and models, ensuring alignment with NRC expectations (e.g., RG 1.203) and the risk-informed, performance-based framework.
- **(H) Quality Assurance (QA) Program:**
    - Topic: Ensuring timely NRC acceptance of the Quality Assurance Program Description (QAPD) governing design, manufacturing, and deployment activities.
    - Engagement Approach: We will submit the QAPD as a Topical Report, based on NQA-1, for NRC review and approval early in the pre-application phase. We anticipate and welcome a subsequent NRC audit or inspection focused on the development and initial implementation of our QA program.
- **(I) ITAAC Development:**
    - Topic: Developing appropriate ITAAC for the standard design scope to be included in the Manufacturing License.
    - Engagement Approach: We plan to discuss the proposed scope and content of standard design ITAAC with NRC staff, potentially submitting a white paper or topical report outlining the ITAAC development methodology and key ITAAC examples for review and feedback.
- **(J) Spent Fuel Management (ISFSI):**
    - Topic: Defining the licensing and technical basis for the on-site storage of spent nuclear fuel in a licensed ISFSI.
    - Engagement Approach: The COL application will include a commitment to license a site-specific ISFSI under 10 CFR Part 72. We plan to engage with NRC staff via a white paper to outline our strategy for the ISFSI license application, including the proposed design and safety analysis approach, to ensure a clear understanding of the interface between the Part 52 COL and the Part 72 specific license.
- **(K) On-Site Refueling:**
    - Topic: Defining the design features and supporting technical information necessary to enable Hadron Energy to safely and efficiently conduct on-site refueling under a 10 CFR Part 52 COL.
    - Engagement Approach: While the COL authorizes refueling operations, the ML application must demonstrate the design's capability. We plan to engage the NRC via a white paper to discuss the scope of design information related to refueling (e.g., fuel handling equipment, spent fuel pool design, analysis of potential refueling accidents) that should be included in the ML application to facilitate future COL reviews.
- **(L) Decommissioning Planning and Funding Assurance:**
    - Topic: Development of a credible decommissioning cost estimate and a robust funding plan to ensure financial assurance for decommissioning, as required by 10 CFR 50.75 for each COL.

- Engagement Approach: Hadron Energy will engage with the NRC via a white paper to outline our proposed methodology for developing the site-specific decommissioning cost estimate and the structure of our proposed decommissioning funding plan. The goal is to gain early feedback on the approach before the formal submittal of the first COL application.

3.9 NRC Review Timeframes and Applicant Commitments

Hadron Energy is cognizant of the NRC's historical review schedules, which have been influenced by the complexity of large LWR applications (e.g., benchmarks around ~39-42 months post-docketing for Design Certifications or complex Standard Design Approvals (SDAs), and ~30 months for COLs referencing approved designs). Recent activity, however, has shown that a more expedited timeline is feasible with a sufficiently motivated and efficient applicant. Given the recent success of Kairos Hermes 1 (which took under 2 years for a CP) and Kairos Hermes 2(< 18 months), we are confident that a shorter timetable can be accomplished.

By proactively identifying and addressing key technical and regulatory topics before submitting the ML and COL application, coupled with the utilization of proven LWR technology and the inherently reduced complexity of the Hadron MMR design, we commit to facilitate a focused and predictable review process. Based on these factors and relevant precedents (such as aspects of the NuScale Standard Design Approval (SDA) review), Hadron Energy proposes a target review duration of approximately 18 months following successful application acceptance for both the ML and the COL. Achieving this target is contingent upon Hadron executing this REP, submitting complete and thorough documents to the NRC, and facilitating a mutual commitment to timely interactions.

Hadron Energy believes this 18-month target review duration for the MLA and COLA is ambitious but achievable due to several key factors:

- **Targeted Pre-application Resolution**: This REP outlines a strategy focused on resolving the most significant and novel technical/regulatory issues (e.g., transportation, manufacturing conditions, and siting methodology) through focused white papers and topical reports before the ML and COL application submittals.
- **Leveraging Approved Methods**: Seeking formal NRC approval via Topical Reports for key methodologies (e.g., QAPD, PDC development) prior to ML submission streamlines the final review.
- **Technology Maturity**: The design's foundation in proven LWR technology reduces risks associated with fundamental reactor physics, materials, and coolant behavior.
- **Design Simplicity and Standardization**: The microreactor's smaller scale, reduced system complexity compared to large LWRs, and emphasis on a standardized, factory-produced design will simplify the scope of review.
- **Factory Testing**: Comprehensive FAT, potentially including zero-power physics tests, can provide significant data to support ITAAC closure for the standard design scope. Achieving this target is contingent upon the timely submission of high-quality documents by Hadron Energy, the successful execution of the pre-application engagement plan

leading to early resolution of key issues, and the availability of NRC resources. Hadron Energy is committed to proactive communication and collaboration to facilitate this efficient review pathway.

To further support an efficient and predictable review schedule post-submittal, Hadron Energy commits to:

- Providing high-quality, complete responses to Requests for Additional Information (RAIs) within 30 days of receipt, unless a different timeframe is mutually agreed upon with the NRC project manager based on the complexity of the request.
- Facilitating NRC staff access to supporting technical information, calculations, procedures, test data, and analyses through mechanisms such as an electronic reading room, audits, or other agreed-upon methods, to support efficient verification and validation of application content.

4 PRE-APPLICATION ENGAGEMENT

This section details Hadron Energy's plan for interacting with the NRC staff prior to submitting the MLA. The goal is to facilitate mutual understanding, identify and resolve key issues early, and support an efficient formal review process.

4.1 Identification of Topics

Effective pre-application engagement requires a clear focus on the most critical technical and regulatory topics. Based on the Regulatory Strategy (Section 3) and the Key Technical and Regulatory Topics identified (Section 3.8), Hadron Energy has prioritized the following areas for focused engagement with NRC staff. This prioritization considers factors such as regulatory significance, potential impact on the project schedule, design novelty requiring early alignment, resource implications, and overall licensing risk, consistent with NRC guidance. The prioritization may be adjusted based on NRC feedback and evolving project needs.

High Priority Engagement Topics:

- **Licensing Path Confirmation:** Ongoing dialogue to confirm alignment on the planned licensing pathway for Hadron Energy, which includes a ML. This includes discussing how these licenses will interface with subsequent site-specific COLs.
- **Principal Design Criteria (PDC) Basis:** Detailed discussion and alignment on the proposed PDC, including the application and interpretation of 10 CFR 50 App A GDC, and the justification for any proposed alternative or supplemental criteria (Ref: Sec 3.3, 3.8.3).
- **Transportation Licensing Approach:** Resolution of the regulatory approach for compliance for transporting unfueled reactors; as well as consideration of 10 CFR Part 70 relating to the transfer of special nuclear material as covered under the COLA.

- **Siting Methodology:** Agreement on the methodology and acceptance criteria for the proposed bounding site envelope PPE approach to address flexible siting needs (Ref: Sec 3.2, 3.8.3.B).
- **Quality Assurance Program:** Timely review and acceptance of the QAPD Topical Report to support regulated activities (Ref: Sec 3.8.3.H).
- **Licensing Modernization Project (LMP):** Discussing the application and implementation of the LMP methodology (per NEI 18-04 / RG 1.233) for developing the risk-informed, performance-based safety case (Ref: Sec 3.4, 3.8.3.G).

Other Important Engagement Topics:

- **Validation & Verification (V&V) Methodology:** Discussing and seeking feedback on the comprehensive V&V strategy for the design.
- **Specific Technical Subjects:** Addressing detailed technical topics via planned white papers and topical reports as outlined in Section 3.8.3 (e.g., Fuel Qualification, Digital I&C/Cyber, EP Approach, Accident Analysis/PRA, ITAAC development) and scheduled in Section 9.1.
- **Standards and Guidance Application:** Confirming the applicability and interpretation of specific consensus standards and NRC guidance documents (Ref: Sec 3.5).
- **Generic & Policy Issue Monitoring:** Maintaining awareness and discussing the applicability of relevant NRC Generic Issues and evolving New Reactor Policy Issues (Ref: Sec 3.8.1, 3.8.2).

4.2 Types and Frequency of Interactions

Hadron Energy proposes a variety of interaction methods to facilitate effective communication, timely issue resolution, and efficient knowledge transfer during the pre-application phase. The specific type and frequency of interactions will be coordinated with the NRC Project Manager and may evolve based on project needs, complexity of topics, and resource availability for both Hadron Energy and the NRC staff.

4.2.1 Routine Project Management Discussions

We plan to hold regular project management discussions with the assigned NRC staff project manager(s). The purpose of these meetings will be to discuss project status, review progress against the REP schedule (Section 9.1), coordinate upcoming activities and submittals, manage action items, and discuss resource planning. These formal meetings may be supplemented by informal phone calls and emails for routine coordination.

4.2.2 Project Management "Drop-Ins"

Hadron Energy understands the potential utility of periodic, non-public 'drop-in' meetings with the NRC project management team, potentially including NRC management, for high-level strategic discussions, forward planning, and schedule coordination, distinct from detailed

technical reviews or regulatory decisions. We will coordinate with the NRC PM regarding the appropriateness and scheduling of any such meetings.

4.2.3 Technical Discussions

Focused technical meetings involving relevant NRC staff reviewers and management will be requested, typically aligned with the submittal and review of white papers and topical reports (see schedule in Section 9.1). These meetings are crucial for in-depth discussion of specific technical and regulatory topics identified in Section 4.1. We also intend to request pre-submittal meetings prior to the formal submission of major reports (like Topical Reports) to discuss scope, objectives, content, and review expectations, aiming to enhance the quality and reviewability of submittals. These technical meetings will generally be public unless specific proprietary or sensitive information necessitates closure in accordance with NRC procedures.

4.2.4 NRC Staff Familiarization

We are committed to providing opportunities for NRC staff to gain familiarity with the Hadron MMR technology, design features, operational concepts, and project status. This may include focused technical presentations, tailored briefings, responses to informal questions, access to technical experts, and potentially coordinated visits to Hadron Energy facilities or key testing sites, as deemed appropriate and beneficial by the NRC project manager.

4.2.5 Written Submittals

Proactive and well-structured written submittals are central to our pre-application engagement strategy, providing formal documented input for NRC staff review and feedback.

- **White Papers (WPs):** These will be used frequently as a primary mechanism for proactively addressing the most critical technical and regulatory topics identified in Section 4.1 early in the pre-application phase. They are intended to introduce technical concepts, present detailed proposed regulatory approaches and their justification (including core safety arguments where applicable), frame potential challenges associated with novel design features or operational concepts (e.g., transportation and V&V), present preliminary analyses, and solicit timely, focused NRC staff feedback. By providing substantive technical detail and proposed resolution paths in these focused documents, Hadron Energy aims to facilitate efficient NRC review, reduce regulatory uncertainty, and resolve key issues prior to investing resources in formal Topical Reports or the final ML application.
- **Topical Reports (TRs):** These will be used more selectively for seeking formal NRC review and approval (via a Safety Evaluation Report - SER) on significant methodologies, analyses, or program descriptions intended for direct reference in the license application (e.g., Quality Assurance Program Description, PDC development methodology, specific analysis methods). We understand TRs undergo a formal review process (per LIC-500) and require significant time and resources.

- **Technical Reports (TeRs):** These may be developed and submitted as needed to provide detailed background information, data, or complex analyses supporting specific points made in White Papers, Topical Reports, or future application sections. We will discuss NRC expectations regarding the review and docketing status (auditable vs. formal submittal) for such reports.

4.2.6 Early Advisory Council on Reactor Safeguards (ACRS) Engagement

Hadron Energy recognizes the statutory role of the ACRS in the licensing process. As the ML development progresses and key technical approaches mature, we will coordinate proactively with NRC staff regarding the appropriate strategy, timing, and scope for engaging with the ACRS on the Hadron MMR design and safety case.

4.2.7 Escalation of Issues

While our goal is a fully collaborative relationship, Hadron Energy understands that disagreements on complex technical or regulatory issues can occur. To ensure timely resolution, we will work with the assigned NRC Project Manager early in the engagement process to establish a clear, mutually agreeable, tiered pathway for escalating differing views. This process will aim to address issues efficiently and professionally at the appropriate technical and management levels within both organizations.

4.3 NRC Feedback

Hadron Energy seeks clear, timely, and constructive feedback from the NRC staff throughout the pre-application phase to inform design development, refine regulatory approaches, and minimize uncertainty prior to application submission. We understand that the nature and formality of feedback vary depending on the interaction type and submittal maturity, and we aim to establish clear, mutual expectations for each major engagement activity.

4.3.1 Feedback as a Function of Submittal Type

Based on NRC guidance and practice, our expectations for the primary forms of feedback are:

- **Topical Reports:** Formal NRC technical review culminating in the issuance of a Safety Evaluation Report (SER) documenting the staff's findings and approval basis for the specific scope reviewed.
- **White Papers & Technical Reports:** Written feedback, typically via official correspondence (e.g., letters), summarizing NRC staff's preliminary assessment, observations, comments, and questions, identifying areas potentially needing further development, clarification, or future regulatory review.
- **Technical & Project Management Meetings:** Publicly available meeting summaries issued by NRC staff documenting attendees, key topics discussed, information

exchanged, action items, and any significant agreements or preliminary conclusions reached.

Recognizing the value of iterative dialogue during design development, Hadron Energy anticipates utilizing White Papers frequently to obtain timely preliminary feedback before committing resources to more formal Topical Reports requiring extensive review time.

4.3.2 "Finality"

Hadron Energy understands the importance of appropriately interpreting the regulatory significance, or "finality," of pre-application feedback. We acknowledge that:

- Feedback on early-stage concepts, preliminary analyses, or informal submittals like White Papers is generally considered preliminary, non-binding, and intended to inform the applicant's ongoing work. Such feedback may evolve as the design matures, additional information becomes available, or relevant NRC policy develops.
- Formal feedback, such as an SER issued for an approved Topical Report, provides a higher degree of regulatory certainty specifically for the scope and technical basis reviewed, contingent upon the stability of the underlying information referenced in the application.

We are committed to open communication with the NRC project manager regarding the intended scope of review, the expected form and timing of feedback, and the associated regulatory significance for each major interaction and submittal.

4.4 Schedule Considerations

The detailed proposed schedule outlining planned pre-application interactions and submittals is presented in Section 9.1 of this REP. Hadron Energy recognizes that successful execution of this schedule requires commitment and coordination from both Hadron Energy and the NRC. We understand schedules are dynamic and depend significantly on factors including applicant progress in providing high-quality information, the complexity of technical and regulatory topics, and NRC staff resource availability amidst competing priorities.

To foster predictability and manage the pre-application schedule effectively, Hadron Energy proposes a collaborative approach centered on:

- **Mutual Schedule Alignment:** Seeking agreement with the NRC Project Manager on the planned timing for key submittals and interactions, establishing a shared understanding of the near-term roadmap, and adjusting proactively based on readiness and resource considerations.
- **Review Duration Expectations:** Discussing and aligning with NRC staff on realistic, projected review durations for major submittals (e.g., Topical Reports, White Papers), acknowledging that these are estimates and may be influenced by the content quality, emerging technical issues, or resource availability.

- **Proactive Communication:** Committing to promptly and transparently communicating any significant anticipated delays or changes to the planned schedule originating from Hadron Energy's activities. We anticipate open dialogue regarding potential impacts arising from NRC resource allocation or review findings.
- **Periodic Performance Review:** Regularly reviewing progress against the REP schedule baseline during routine project management discussions (Ref: Sec 4.2.1) to identify potential issues early and make necessary adjustments.

This collaborative approach to schedule management is intended to support the overall goal of an efficient and predictable pre-application engagement process.

4.5 Relation to Other Proceedings and Reviews

4.5.1 Related NRC Reviews

At this time, Hadron Energy is not aware of other ongoing NRC reviews or proceedings that directly conflict with or procedurally impact the planned pre-application activities for the Hadron MMR. We recognize that future COL applications referencing the Hadron ML might be submitted and reviewed concurrently with, or shortly after, the ML review itself. Hadron Energy is committed to working collaboratively with NRC staff to coordinate these reviews efficiently, potentially establishing protocols for handling Requests for Additional Information (RAIs) or other matters related to standard design content that may arise during the COL review, consistent with NRC practice.

4.5.2 Other Review Bodies and Consultations

Hadron Energy anticipates potential interactions or coordination with the following other entities:

- **U.S. Department of Energy (DOE):** Hadron Energy does not currently anticipate a formal DOE regulatory role in the commercial licensing under 10 CFR Part 52. Coordination on non-regulatory matters (e.g., related to siting, security, or emergency planning) could occur if future deployments involve DOE facilities.
- **Other U.S. Agencies and Consultations (Relevant to Future COLAs):** Hadron Energy acknowledges that ML and COL applications will require coordination and potential permits or consultations with various other federal, state, local, and Tribal entities. This will include necessary interactions with agencies such as the U.S. Army Corps of Engineers (USACE) concerning water resources and permits, the Federal Emergency Management Agency (FEMA) regarding offsite emergency preparedness findings, the U.S. Department of Transportation (DOT) regarding the importation of any potential foreign source of HALEU fuel and accompanying International Atomic Energy Agency (IAEA) safeguards; the U.S. Fish and Wildlife Service (US FWS) and relevant state agencies under NEPA and the Endangered Species Act, State Historic Preservation Officers (SHPOs), and affected Federally-recognized tribes. Engagement

with these entities will be planned and initiated as part of the COLA development process.

4.6 Pre-Application Site Visits, Audits, and Inspections

Hadron Energy understands the value of NRC staff audits, inspections, and observations during the pre-application phase to facilitate regulatory understanding, verify key program implementations, and identify potential issues early. We welcome opportunities for such interactions where appropriate and beneficial, and commit to coordinating closely with the NRC Project Manager on the objectives, scope, logistics, and scheduling of any planned visits, audits, or inspections.

4.6.1 Quality Assurance

As detailed in the project schedule (Section 9.1), Hadron Energy plans to submit its QAPD as a Topical Report early in the pre-application phase. We anticipate and welcome a subsequent NRC audit or inspection focused on the development and initial implementation of our QA program. This provides an opportunity to demonstrate compliance with regulatory requirements (e.g., 10 CFR Part 50, Appendix B, or NQA-1 standards) before significant safety-related design, procurement, or fabrication activities commence.

4.6.2 Testing

Hadron Energy has a comprehensive testing program planned to provide critical data for design validation and the licensing basis, with key milestones outlined in Section 9.1.2. We welcome opportunities, coordinated through the NRC Project Manager, for NRC staff observation of key tests (e.g., passive safety system demonstrations or critical component qualification tests) or audits related to testing facilities, methodologies, data acquisition, and quality controls.

4.6.3 Site-Related Visits and Audits

Hadron Energy acknowledges that site-related visits and audits pertaining to Hadron Energy's proposed reactor manufacturing facility and sites of the COL application may be relevant during the pre-application and review phases.

4.6.4 Security/Critical Infrastructure

Similarly, security assessments related to Hadron Energy's proposed reactor manufacturing facility may be pertinent during the pre-application and review phases for our Manufacturing License application and COL application.

4.6.5 Vendor/Supplier Audits/Supply Chain

Dedicated NRC audits or inspections focused specifically on individual vendors or suppliers are not anticipated during the early pre-application phase. Should specific circumstances warrant

NRC review at a vendor facility later in the design, testing, or procurement process, Hadron Energy will coordinate such activities fully with the NRC Project Manager.

5 APPLICATION PROCESS

This section outlines Hadron Energy's planned approach for transitioning from the pre-application engagement activities described in Section 4 to the formal ML application process, including key steps leading up to and immediately following application submission.

5.1 Readiness Assessment Audit

To maximize the likelihood of the submitted application being accepted for formal review, Hadron Energy intends to request an NRC pre-application readiness assessment audit approximately six months prior to our target ML application submittal date. Based on the current schedule (Section 9.1), this request is targeted for December 2026, with the audit potentially occurring in February 2027. We plan to provide a substantially complete draft ML application, representing the intended final content and format, for NRC staff review during this audit.

5.2 Application Submittal

- **Target Date:** Hadron Energy plans to submit its applications on the following dates, and commit to communicating any necessary changes to this target submittal date to the NRC staff as early as possible:
    - **June 2027.** Submission of Manufacturing License Application (MLA)
    - **September 2027.** Submission of 10 CFR Part 71 Transportation License
    - **September 2028.** Submission of Combined License Application (COLA)
    - **May 2032.** Submission of 10 CFR Part 72 ISFSI License Application.
- **Format and Access:** Hadron Energy intends to submit all applications electronically via the NRC's E-Submittal system, coordinating with NRC staff on specific requirements. Supporting, non-docketed information required for NRC review (e.g., detailed calculations, analyses, procedures) will be made readily available to NRC staff via a secure electronic reading room or other mutually agreed-upon method.
- **Licensing Sequence:** The Manufacturing License Application (MLA) will be submitted first, followed by the Combined License Application, which will be submitted while the MLA is under review.

5.3 Acceptance Review and Docketing

Hadron Energy understands that upon receipt, the NRC staff will conduct a formal acceptance review of its applications. Hadron Energy is committed to submitting a high-quality, complete application designed to meet the criteria for acceptance and facilitate docketing.

5.4 NRC Processes

Hadron Energy acknowledges and will actively monitor the standard NRC administrative and regulatory processes initiated following successful application acceptance and docketing.

6 POST-APPLICATION ENGAGEMENT

This section briefly outlines planned engagement following the acceptance and docketing of the MLA and COLA. Details will be refined closer to the application submittal date and documented in future REP updates.

6.1 Technical Meetings

Hadron Energy anticipates an increased frequency of technical meetings with NRC staff during the formal review phase to discuss specific technical details, clarify application content, and resolve emerging issues identified during the review. We commit to making our technical subject matter experts readily available to participate effectively in such meetings (whether held in-person, via telephone, or web conference). We understand most technical meetings require public notification (typically 10 working days in advance) unless specific sensitive information warrants closure, and we will coordinate all scheduling through the assigned NRC project manager.

6.2 Audits and Inspections

We expect and welcome focused NRC audits and inspections during the application review as crucial mechanisms for efficiently verifying detailed technical information, calculations, QA program implementation fidelity, test results, and potentially vendor oversight activities. Hadron Energy will work collaboratively with NRC staff to plan and schedule these interactions to minimize disruption while providing necessary access.

6.3 Submittal of Additional Information

6.3.1 Supplemental Information

Hadron Energy is committed to maintaining the accuracy and completeness of the docketed application. We will submit supplemental information promptly as needed to update the application regarding significant design changes, organizational changes, or to provide substantive clarifications identified through interactions with NRC staff. We will notify the NRC project manager in advance regarding the timing and content of planned supplemental submittals.

6.3.2 Requests for Additional Information (RAIs)

We understand the Request for Additional Information (RAI) process is a primary tool for the NRC's detailed technical review. We will utilize the electronic RAI (eRAI) system and are committed to providing high-quality, complete, and timely responses. Our goal is to submit responses within the standard 30-day timeframe referenced in NRC guidance (e.g., NRO-REG-101, "Processing Requests for Additional Information"), unless the technical complexity of a specific RAI necessitates proactive discussion and agreement with the NRC staff on an alternative, mutually acceptable response schedule. RAI responses will clearly identify any resulting impacts on the application text.

6.3.3 Application Revisions/Updates

Hadron Energy will prepare and submit formal updates to the MLA and COLA (i.e., revised FSAR chapters) periodically during the review cycle. These updates will incorporate responses to RAIs, supplemental information, and any other necessary changes to ensure the application accurately reflects the current design and licensing basis. The specific frequency and timing of these formal updates will be discussed and agreed upon with the NRC staff, potentially aligning with the completion of major review phases or other key schedule milestones.

6.4 Frequency of Interactions

To ensure consistent communication, alignment on priorities, and proactive management of the review process, Hadron Energy proposes to continue regular project management meetings with the NRC project manager and key staff throughout the application review phase.

6.5 Review Phases and Schedule

Following application docketing, Hadron Energy anticipates the NRC staff will develop and issue the official, detailed review schedule, including specific review phases and target milestone dates. While acknowledging this schedule is determined by the NRC and contingent on factors such as review findings, resource availability, and application complexity, Hadron Energy proposes the following illustrative schedule milestones for planning purposes. These are based on our target 18-month review duration:

Phase	Milestone Description	Proposed Target Date
Submittal	Submission of Topical Report 1: QAPD	September 2025
Submittal	Submission of Topical Report 2: PDC	December 2025
Submittal	Submission of Topical Report 3: Fuel Qualification	February 2026
Submittal	Manufacturing License Application Submittal	June 2027

Acceptance	Manufacturing License Application Accepted	August 2027
Submittal	Part 71 License Application Submittal	September 2027
Acceptance	Part 71 License Application Accepted	November 2027
Submittal	Combined License Application Submittal	February 2028
Acceptance	Combined License Application Accepted	April 2028
Final Action	Manufacturing License Issued	February 2029
Final Action	Part 71 License Issued	March 2029
Final Action	Combined License Issued	October 2029
Submission	Part 72 License Application Submittal	May 2031
Acceptance	Part 72 License Application Accepted	July 2031
Final Action	Part 72 License Issued	January 2033

This schedule will be updated in future REP revisions based on the formal schedule established by the NRC staff post-docketing.

6.6 Relation to Other Proceedings/Reviews

No other related NRC proceedings are anticipated to directly impact the reviews for Hadron Energy's applications beyond their inherent interdependencies as part of our overall licensing strategy.

7 WITHHELD INFORMATION

Hadron Energy is committed to transparency and will minimize the amount of information withheld from public disclosure to the greatest extent practicable. However, protection of proprietary commercial information (trade secrets) and security-sensitive information is necessary. This REP itself does not contain proprietary or security-sensitive information requiring withholding.

7.1 Classified Information

Hadron Energy does not anticipate the need to generate, receive, or handle classified information (National Security Information or Restricted Data) for the planned commercial microreactor applications.

7.2 Safeguards Information (SGI)

Hadron Energy recognizes that aspects of the physical security design and potentially material control and accounting may constitute SGI. An SGI protection program compliant with 10 CFR Part 73 and associated guidance (e.g., RG 5.79) will be established early in the project timeline (target within the first 12 months of pre-application engagement) to ensure proper handling procedures are in place before such information is generated or potentially received (e.g., design-basis threat information).

7.3 SUNSI and SRI

Hadron Energy acknowledges the category of Sensitive Unclassified Non-Safeguards Information (SUNSI), including Security-Related Information (SRI), and will handle such information appropriately if generated or received, consistent with NRC guidance and 10 CFR §2.390.

7.4 10 CFR 2.390 and Withholding Information from Public Disclosure

Where necessary to protect trade secrets or confidential commercial/financial information, Hadron Energy will request withholding from public disclosure pursuant to 10 CFR §2.390. Such requests will include the required affidavit and justification. A detailed review of §2.390 requirements will be conducted, and any necessary clarifications sought from NRC staff.

7.5 Other Information Control Requirements

Hadron Energy does not currently anticipate needing to handle information subject to other specific control requirements relevant to NRC interactions, such as Export Control information (10 CFR Part 110/Part 810), Applied Technology (AT), or Official Use Only (OUO), as the project is currently focused on domestic commercial deployment and does not involve government contracts stipulating such controls.

8 PARTNERSHIPS AND INDUSTRY PARTICIPATION

Hadron Energy engages with various industry organizations and government bodies.

8.1 Design-Centered Work Group

Not applicable at this stage.

8.2 Nuclear Energy Institute (NEI)

Hadron Energy is a member of the Nuclear Energy Institute (NEI) and participates in relevant NEI working groups and task forces (e.g., Advanced Reactor Working Group) and utilizes NEI guidance documents where appropriate.

8.3 Standard Development Organizations (SDOs)

Hadron Energy relies on consensus standards from SDOs (ANS, ASME, etc.) and participates in standards development activities relevant to microreactors where feasible.

8.4 Department of Energy (DOE)

Hadron Energy will coordinate with DOE as needed, particularly if future activities involve DOE sites or funding mechanisms impacting NRC interactions.

8.5 Other Organizations (EPRI)

Hadron Energy coordinates with and references guidance from the Electric Power Research Institute (EPRI) where applicable to its LWR technology base.

8.6 International Considerations

Hadron Energy is not considering engagement with any international agency or foreign government at this time.

9 OTHER TOPICS

9.1 Schedule

The following schedule represents Hadron Energy's current planning basis. It outlines an ambitious but achievable timeline that is predicated on the successful and efficient execution of the pre-application engagement strategy, including timely development of high-quality submittals by Hadron Energy and responsive feedback and review by the NRC staff. Key dependencies include the early resolution of high-priority technical topics (as identified in Section 4.1) and the availability of resources for both parties. Hadron Energy is committed to the periodic review and update of this schedule in collaboration with the NRC staff (as described in Section 1.5) to reflect project progress, technical findings, and any necessary adjustments.

Planned Date	Activity	Type
April 2025	Submission of Letter of Intent	Submittal (Done)
May 2025	Submission of Initial REP	Submittal (Done)

Sep 2025	**Submission of Topical Report 1: QAPD**	**Topical Report Sub.**
Dec 2025	**Submission of Topical Report 2: PDC**	**Topical Report Sub.**
Feb 2026	**Submission of Topical Report 3: Fuel Qualification**	**Topical Report Sub.**
Mar 2026	Submission of White Paper 1: Siting Strategy / PPE	White Paper Sub.
Apr 2026	Submission of White Paper 2: V&V Strategy	White Paper Sub.
Jul 2026	Submission of White Paper 3: Staffing CONOPS	White Paper Sub.
Oct 2026	Submission of White Paper 4: Decommissioning Funding Strategy	White Paper Sub.
Jan 2027	Submission of White Paper 5: Transportation Program	White Paper Sub.
Apr 2027	Submission of White Paper 6: ISFSI Licensing Strategy	White Paper Sub.
Dec 2026	Submission of Readiness Assessment Audit Request (MLA focused)	Request Submittal
Feb 2027	Potential Readiness Assessment Audit (MLA focused) by NRC Staff	NRC Audit
Jun 2027	**Submission of Manufacturing License Application (MLA)**	**Application Sub.**
July 2027	Submission of Readiness Assessment Audit Request (COLA focused)	Request Submittal
Aug 2027	Potential Acceptance/Docketing of MLA	NRC Action
Sep 2027	**Submission of 10 CFR Part 71 Transportation License App.**	**Application Sub.**
Oct 2027	Potential Readiness Assessment Audit (COLA focused) by NRC Staff	NRC Audit
Nov 2027	Potential Acceptance/Docketing of Part 71 App.	NRC Action
Feb 2028	**Submission of COLA - First Site (by Hadron Energy)**	**Application Sub.**
Apr 2028	Potential Acceptance/Docketing of COLA	NRC Action
Feb 2029	Potential Issuance of Manufacturing License (ML)	NRC Action
May 2029	Potential Issuance of 10 CFR Part 71 License	NRC Action
Oct 2029	Potential Issuance of Combined License (COL)	NRC Action
Apr 2031	**Submission of 10 CFR Part 72 ISFSI License App.**	**Application Sub.**
Jun 2031	Potential Acceptance/Docketing of Part 72 App.	NRC Action
Dec 2032	Potential Issuance of 10 CFR Part 72 License	NRC Action

Note: "Potential Review" indicates estimated NRC staff review periods following submission.

9.2 Budget

Hadron Energy understands that NRC review activities are typically fee-recoverable under 10 CFR Part 170. We plan to engage with the NRC staff project manager to understand estimated review costs associated with planned interactions (meetings, report reviews, audits) and the formal application review. Budgetary considerations and resource planning will be part of ongoing project management discussions to ensure alignment and predictability. We will inquire about any applicable fee waiver opportunities, although none are currently anticipated for this commercial project.

Hadron Energy is aware of the 50% reduction in NRC fees for advanced reactor applicants and pre-applicants beginning on October 1, 2025, and understands that this pre-application engagement is eligible for the reduced fees.

10 REFERENCES

1. Nuclear Energy Institute, NEI 18-06, Rev. 0, “Guidelines for Development of a Regulatory Engagement Plan,” June 2018.
2. U.S. Code of Federal Regulations, Title 10, Part 52, Subpart C, “Combined Licenses.” (10 CFR 52 Subpart C)
3. U.S. Nuclear Regulatory Commission, NUREG-1226, “Development and Utilization of the NRC Policy Statement on the Regulation of Advanced Nuclear Power Plants,” June 1988.
4. U.S. Code of Federal Regulations, Title 10, Part 50, Appendix A, “General Design Criteria for Nuclear Power Plants.” (10 CFR 50 Appendix A)
5. U.S. Nuclear Regulatory Commission, NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition.” (SRP)
6. U.S. Nuclear Regulatory Commission, Regulatory Guide 1.206, Rev. 1, “Combined License Applications for Nuclear Power Plants,” October 2018.
7. U.S. Nuclear Regulatory Commission, Regulatory Guide 1.233, "Guidance for a Technology-inclusive, Risk-informed, and Performance-based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors."
8. Nuclear Energy Institute, NEI 18-04, Rev 1, "Risk-Informed Performance-Based Guidance for Non-Light Water Reactor Licensing Basis Development."
9. U.S. Nuclear Regulatory Commission, NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors."
10. U.S. Nuclear Regulatory Commission, NRO-REG-100, Rev. 2, “Acceptance Review Process for Early Site Permit, Design Certification, and Combined License Applications,” December 18, 2014 (ADAMS ML14078A152).
11. U.S. Code of Federal Regulations, Title 10, Part 71, “Packaging and Transportation of Radioactive Material.”
12. U.S. Nuclear Regulatory Commission, "Micro-reactors Licensing Strategies," (ADAMS ML21235A418).

13. U.S. Code of Federal Regulations, Title 10, Part 73, “Physical Protection of Plants and Materials.”
14. U.S. Nuclear Regulatory Commission, Regulatory Guide 5.79, “Protection of Safeguards Information.”
15. U.S. Code of Federal Regulations, Title 10, Section 2.390, “Public inspections, exemptions, requests for withholding.” (10 CFR 2.390)
16. Memorandum of Cooperation on Advanced Reactor and Small Modular Reactor Technologies between the United States Nuclear Regulatory Commission and the Canadian Nuclear Safety Commission (ADAMS ML19275D578).
17. U.S. Nuclear Regulatory Commission, NRO-REG-104, “Pre-Application Readiness Assessment.”
18. Nuclear Energy Institute, NEI 11-04A, Rev 0, "Nuclear Generation Quality Assurance Program Description."
19. Electric Power Research Institute, “Advanced Nuclear Technology: Advanced Light Water Reactor Utility Requirements Document,” Revision 13, December 2014.
20. U.S. Code of Federal Regulations, Title 10, Part 51, “Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions.” [1]
21. U.S. Nuclear Regulatory Commission, Regulatory Guide 4.2, "Preparation of Environmental Reports for Nuclear Power Plants."
22. U.S. Nuclear Regulatory Commission, NUREG-1555, "Standard Review Plans for Environmental Reviews for Nuclear Power Plants." (ESRP)
23. U.S. Code of Federal Regulations, Title 10, Part 2, “Agency Rules of Practice and Procedure.”
24. U.S. Code of Federal Regulations, Title 10, Part 110, “Export and Import of Nuclear Equipment and Material.”
25. "U.S. Code of Federal Regulations, Title 10, Part 52, Subpart F, “Manufacturing Licenses.” (10 CFR 52 Subpart F)
26. "U.S. Code of Federal Regulations, Title 10, Part 70, “Domestic Licensing of Special Nuclear Material.” (10 CFR Part 70)