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July 31, 2024

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Washington, DC 20555-0001

Subject: NEI Proposal Paper "Regulations of Rapid High-Volume Deployable Reactors in Remote Applications (RHDRA) and Other Advanced Reactors"

Project Number: 689

Dear Dr. Gavrilas:

With nuclear power on the advent of an unprecedented opportunity, the NRC, industry, and even Congress have identified the need for modernization of regulatory processes. Advanced reactors bring with them very different manufacturing, construction, and operational models, coupled with vastly different business models that will enable and require adaptation of the regulatory processes that have developed to date. The Nuclear Energy Institute (NEI)[1] and its members are providing the attached proposal paper outlining proposed changes to the Nuclear Regulatory Commission's (NRC) processes, guidance and regulations that would achieve a more modern regulatory framework that will maintain safety and provide a more effective and efficient approach to address the unique considerations of rapid high-volume deployable reactors in remote applications (RHDRA). These proposals are focused on attaining the regulatory efficiency and agility required for large-scale microreactor deployment, but many could be applicable to larger advanced (light-water and non-light water) reactors. These proposals align with and expand upon the NRC's valuable efforts to establish a modern and efficient regulatory framework for new and advanced reactors consistent with the 2019 Nuclear Energy Innovation and Modernization Act (NEIMA). These proposals would also form the basis for risk-informed and performance-based strategies and guidance to license and regulate micro-reactors that meet the requirements in Section 208 of the ADVANCE Act of 2024. Furthermore, these proposals could satisfy, in part, other requirements in the ADVANCE Act that are contained in Sections 206, 505, 506 and 507. Input specific to those and other sections of the ADVANCE Act will be provided separately.

[1] The Nuclear Energy Institute (NEI) is responsible for establishing unified policy on behalf of its members relating to matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include entities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect and engineering firms, fuel cycle facilities, nuclear materials licensees, and other organizations involved in the nuclear energy industry.

Need for Near Term Regulatory Clarity

NEI's members pursuing rapid, high-volume deployable reactors require clarity by the end of 2024 on the scope and pace of regulatory modernization that could be achieved. This clarity is needed by the market in order to enable investments and customer commitments to deployment. To this end, we seek NRC feedback on whether the NRC agrees that:

1) these topics need to be addressed in order to enable the business model for RHDRA,
2) it is reasonably foreseeable that the identified desired outcomes are achievable and there are no fundamental deficiencies or gaps in the proposed approaches,
3) implementing the proposed approaches would enable deployment timelines of 6 months from site identification to operations and regulatory costs that are less than 1% of total costs,
4) many of the proposed approaches should be applied in a graded approach to also create a more effective and efficient regulatory framework for other advanced reactors, and
5) the NRC supports including these proposed approaches in efforts to implement changes directed by the ADVANCE Act within the next 3 years.

Addressing these topics and providing regulatory clarity is necessary to determine whether the stated endpoint (described as "desired outcomes" in the paper) can be achieved. It is not our intent to prescribe the steps to reach that endpoint. Rather, the goal is to understand whether the intended business models can be supported by the regulatory processes. While it will eventually be necessary to outline the steps to be taken toward these endpoints (e.g., First-of-a-Kind (FOAK) deployment, additional early deployments, exemptions, rulemakings, etc.), the key near-term issue is to gain clarity on whether it is feasible to enable the business models. If clarity on the business model timelines cannot be obtained or there is uncertainty whether the endpoints are achievable, then new customers, markets and business models will not be pursued. If the NRC cannot provide the needed clarity that the endpoints are achievable, then these customers and markets have expressed that they will abandon the use of nuclear technologies and will be forced to pursue other technologies that may not be as well suited to providing reliable and affordable energy, or may emit more carbon and have greater impacts on the public health, safety and environment than nuclear technologies.

Goal of the Set of Proposed Approaches

The set of proposed regulatory enhancements are expected to enable more widespread adoption of nuclear energy. If implemented, these proposed approaches would enable the NRC to provide reasonable assurance of adequate protection of the public health and safety and the environment in pursuit of the overall goal of the Atomic Energy Act to "make the maximum contribution to the general welfare" … "to the maximum extent consistent with the common defense and security and with the health and safety of the public." The attached paper on the "Regulation of Rapid High-Volume Deployable Reactors in Remote Applications and Other Advanced Reactors" contains the complete contents of the alternative approaches being proposed for which each separately would significantly improve the effectiveness and efficiency of

NRC's regulation of new nuclear reactors, and collectively would enable even greater improvements and facilitate the adoption of nuclear technologies for new applications and business models.

Fundamentally, there are three changes that are being sought, for which all of the proposed solutions for the 31 identified issues are needed to accomplish:

1. Adapting the regulatory approaches for technologies, like non-power reactors, to advanced reactors that have a similar order of magnitude of potential consequences in order to provide reasonable assurance of adequate protection of the public health and safety, and the environment; and so that licensing and regulation of advanced reactors is efficient and does not unnecessarily limit the use and deployment of nuclear energy, or the benefits of nuclear energy to society;

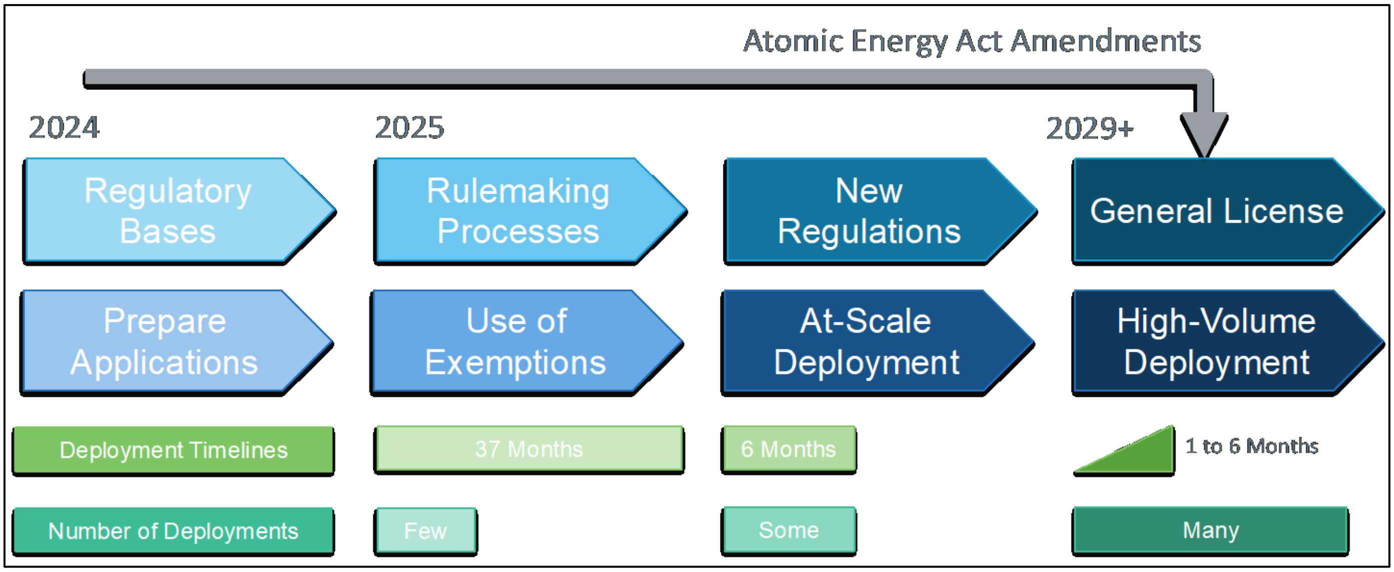
2. Creating a rapid efficient and repeatable licensing (ReLic) process that can achieve 6 month deployment times by:

    a. completing all, or as much as possible, of the safety and environmental reviews and public engagement processes at one-time, prior to the identification of a specific site, and

    b. performing a site license review that only verifies that the site characteristics, which are based on pre-existing generic data as much as possible, conform to the minimum set of site parameters in the envelope established in the one-time up-front reviews; and

3. Establishing performance-based and graded approaches, including for staffing size appropriate to the functions determined to be dependent upon human actions, and locations, based upon the design of the advanced reactor (including inherent safety features, advanced technology and automatic systems).

The proposed approaches would achieve an effective and efficient regulatory process that would enable shorter deployment times. Over time, and through repetitive Nth-of-a-kind (NOAK) use of the process, the NRC could modernize a licensing process that today precludes deployments in less than 49 months (for 12-month safety and envirionmental reviews), and create a licensing process that enables deployments in as few as 6 months within the authorities granted by the existing Atomic Energy Act (AEA). This would occur as the NRC is able to implement the tools discussed in the proposal paper, and as the NRC gains experience in licensing rapid high-volume deployable reactors. As illustrated in the figure, this is expected to begin with development of regulatory bases over the next 12 months, and followed by that rulemakings to achieve the 3 year timeline required in Section 208 of the ADVANCE Act. With an amendment to the AEA to authorize the use of a general license for rapid high-volume deployable reactors, the NRC could achieve a regulatory framework that enables deployments in a month or less.



Background on the Development of the Proposed Approaches

NEI identified that enabling alternative business modles is an industry priority in our February 12, 2024, letter to the NRC, "NEI Input on Regulatory Priorities for New and Advanced Reactors."[2] In that letter we stated that "*the NRC may need to take more aggressive steps to modernize the regulatory framework to meet the varied carbon-free energy needs of the nation. Some current business plans envision widespread deployment of approved micro-reactors within a matter of six months.*"

NEI's proposed approaches in this paper were developed to enable a specific rapid high-volume deployable reactor (RHDRA) business model, while also enabling other business models that were not specifically defined in terms of the interface with the regulatory framework. The RHDRA business model adopted the business requirements identified by Shepherd Power in a letter to the NRC dated February 14, 2024,[3] for the use of reliable and affordable nuclear heat and power to oil and gas operations, and which stated that micro-reactors are the *"best technical option for achieving their decarbonization and, aggregated together, imply a very large and immediate domestic market….the size and importance of this opportunity…cannot be overstated."* The two business case requirements relevant to the NRC regulatory framework that are necessary to enable the business model are: 1) "*takes no more than 180 days from the date a precise location is identified for a microreactor to the time it is deployed and operating"* and 2) *"the overall licensing and ongoing oversight costs need to be less than 1% of the total cost of manufacture and operations."*

The NRC has done a considerable amount of work that encompass the broad range of advanced reactor technologies and various intended applications of this technology. Much of this work would benefit rapid high-volume deployable reactors, and includes the Part 53 rulemaking and the Advanced Nuclear Reactor

[2] ML24043A249
[3] ML24068A021

Generic Environmental Impact Statement. The NRC has also done a considerable amount of work more specifically applicable with micro-reactors and manufacturing licenses that has also established a foundation for many of the topics addressed in this paper. This includes NRC SECY-20-0093 and SECY-24-0008. Related to these, NEI has also provided input and proposals on these topics in our 2019[4] and 2021[5] papers to the NRC.

The NRC held a public meeting on May 14, 2024, to discuss the rapid deployment business models and potential need for regulatory changes. In that meeting, the NRC stated that they have plans to develop a paper addressing the regulatory topics related to the rapid high-volume deployable reactor business model later this year for the Commission's approval. To inform the NRC's efforts, NEI developed the Concept Paper for the "Regulation of Rapid High-Volume Deployable Reactors in Remote Applications" that we transmitted to the NRC on May 31, 2024.[6] The goal of that paper was to provide insight into the technology characteristics, concepts of deployment and operations, and concepts for alternative regulatory approaches that the industry has been discussing.

As discussed in that paper, many substantive changes are needed to create processes and alternative regulatory approaches to enable business models for RHDRA that would meet the business case requirements identified for the oil and gas applications, and could also enable business models for other industries that are hard to decarbonize and/or have market characteristics that are similar. The market potential for nuclear energy in markets that would utilize this type of business model could be in the multiple 1,000s of operating reactors by 2050. Therefore, safely and efficiently enabling these business models is important to meeting the U.S. needs for more nuclear energy to achieve our climate, energy, environmental, economic, and national security goals.

There is no doubt that the idea of deploying reactors within 6 months of a site identification requires the shattering of old paradigms. To this end, the industry's effort does not start with current approaches and incrementally change them. As outlined in the many attachments, the approach was to start with the endpoint in mind and identify what it would take to safely and securely meet the deployment needs. This meant questioning the basis for current approaches and challenging whether safety and protection of the environment can be assured in entirely new ways.

Applicability of the Proposed Approaches

A central goal of the attached proposal paper is to enable alternative approaches developed to enable the RHDRA business model to be used for, as broadly as possible, all advanced reactor technologies (light-water and non-light water) and business models. This is built upon the establishment of technology-inclusive, performance-based, risk-informed and graded approaches. This goal for broad/general applicability is balanced against the need to develop approaches that specifically enable RHDRA and

[4] ML19319C497
[5] ML21197A103
[6] ML24152A324

other advanced reactors in other applications by addressing the unique considerations of those technologies, and concept of deployment and operations.

Twenty of the 31 proposed approaches are expected to be applicable to any advanced reactor. However, only one (elimination of the Mandatory Hearing) is applicable to all advanced reactors equally. For the other 19 generic topic areas, the approaches are graded such that advanced reactors that meet more stringent conditions are able to realize greater benefits. The outcome of these graded approaches is a consistent level of protection of the public health and safety, and the environment, across a wide range of technologies and concepts of deployment and operations. In this way, the unique aspects of RHDRA and other similar advanced reactors can be most appropriately addressed, while also ensuring maximum applicability to all advanced reactors.

Extent of Regulatory Changes

The proposed alternative approaches cover 31 topic areas that need to be addressed. Industry is aware of NRC efforts addressing about half of these areas to-date, and of the topics that the NRC has been working to address for advanced reactors, many of those NRC's efforts have not considered the technological capabilities, concepts of deployment and operations, concepts of alternative regulatory approaches, or the new ideas included in the attached paper. The NRC discussed at the July 24, 2024, public meeting additional topics planned for an NRC white paper related to RHDRA. The attached proposal provides input into those topics and discusses other topics the NRC will need to address. Other topics may also benefit from alternative approaches for advanced reactors (e.g., decommissioning, population siting, quality assurance), but they are not included since they were not determined to need alternative approaches to enable rapid high-volume deployable reactors for remote applications.

Nearly all of these 31 topics are expected to require changes to the regulations. Due to the broad range of topics and novel approaches being proposed, there are a large number of requirements that would need to be changed, eliminated, or added to modernize the NRC regulatory framework and achieve a more effective and efficient regulatory framework for advanced reactors, including RHDRA and micro-reactors. The attached paper identifies over 30 regulations, which could represent more than 100 requirements that would require changes to address the set of issues in the paper. Where possible, the topic papers identify specific requirements that would need to be changed, and in other cases where more regulatory analysis is needed, regulatory changes are identified at the Part or Subpart level. It is important that the alternative regulatory approaches be available for licensing under Parts 50 and 52 and a future Part 53. The NRC could pursue changes to these regulations by incorporating them into existing rulemakings (e.g., Parts 50 and 52 Lessons Learned, Part 53, Advanced Nuclear Reactor Generic Environmental Impact Statement, and Categorical Exclusions) or through a new rulemaking.

There may be benefits to near-term Commission policy decisions on whether the NRC should pursue some areas with significant deviation from prior NRC practices. These areas may include:

- Adapting regulatory approaches for non-power reactors that would be more effective and efficient to protect the public health and safety for commercial power reactors that have similar potential consequences,

- Establishing a rapid efficient repeatable licensing (ReLic) process that enables prior NRC approvals on safety and environmental matters through generic technology-inclusive rulemakings (E.g., GEIS, CatEx), design approvals (e.g., ML, DC, SDA) and licensee pre-approvals (e.g., financial and technical qualification, plans and programs for operations, security and emergency planning), and NRC reviews of site license applications that focus on verification of compliance with the site parameter enveloped established through those prior approvals, and

- Allowing operational concepts that would include 1) one on-site individual, and 2) no on-site individuals with a staffed remote operations facility, which are enabled through design feactures and technologies like automatic and autonomous operations.

Notably, there are few topics for which Congressional action, such as an amendment to the Atomic Energy Act, is recommended to achieve the proposed approaches, or which would enable other options for addressing the topics that are identified but not proposed as the recommended approach. To the extent that the NRC agrees that these proposed approaches 1) could be implemented in ways that protect the public health and safety, and the environment, 2) would improve the effectiveness and efficiency of the regulatory framework for advanced reactor, or would enable new business models, and 3) need Congressional action to implement, we request that the NRC make these conclusions known to Congress and request Congressional authorization to pursue those approaches. There are also some identified options for which Congressional action could enable more effective and efficient regulation of RHDRA and other advanced reactors, but were not recommended as the preferred approach.

Process for Implementing the Proposed Approaches

It is recognized that the implementation of the proposed approaches could take several years to develop the details and promulgate through rulemaking. NRC development of regulatory bases in the near-term would support reducing regulatory uncertainty that is preventing customers from considering RHDRA and other advanced reactors with novel business models, as well as serve as the basis for processing a parallel path of exemptions for near term applications, and rulemaking for longer term applications.

All of the identified topic areas will need to be addressed, and the establishment of NRC’s regulatory bases for all of these topics by December 2025 would be an excellent starting point. This should include the comprehensive set of viable approaches that enables the business model and establishes reasonable performance criteria for designs. It should also include concepts of deployment and operations that enable the market development of alternative uses of these technologies for industrial and other applications.

However, we propose a prioritization of topics based on the impacts of a lack of regulatory clarity. Our assessment of the priority and urgency of achieving clarity is in the following table. A full analysis and summary of the regulatory changes and relative priorites is in Section 2.4 of the attached paper.

	Near-Term Urgent Resolution	**Longer-Term Resolution**
High Priority	1 – Environmental Reviews 2 – Standardized Design Approvals 5 – Site License 10 – Meteorology and Weather Data 11 – Geologic and Geotechnical 14 – Operations Staffing 19 – Physical Security	3 – Construction Authorization Upon Docketing 6 – Contested Hearing 7 – Mandatory Hearing 17 – Remote Operations 21 – AA/FFD
Medium to Low Priority	9 – AIA 13 – Fire Brigade 16 – Remote Monitoring 18 – Cyber Security 22 – Radiation Protection 23 – Oversight 25 – Use of Contractors by ML 28 – Features to Preclude Criticality 31 – Used Fuel	4 – ITAAC 8 – Licensing fees 12 – Other External Hazards 15 – Autonomous Operations 20 – Emergency Preparedness 24 – Annual Fees 26 – Loading Fuel at Factory 27 – Testing at the Factory 29 – Transport Modules to Site 30 – Replace Modules at Site

We recognize that implementation of the proposed changes is a large scope of work. Therefore, NEI is willing to work with NRC and industry stakeholders to develop guidance and proposed rule language for topics in support of the development of the proposed approaches. In particular, NEI is already planning to submit the following future guidance documents for NRC endorsement:

1. Environmental Reviews
2. Meteorology and Weather Data
3. Geologic and Geotechnical
4. Aircraft Impact Assessments
5. Fire Brigade
6. Emergency Preparedness

NEI also is willing to consider other guidance documents for NRC endorsement based on discussion with and request by NRC.

As these ideas are relatively new, cover a broad set of topics, and many need near-term clarification to enable new uses of advanced reactors, NEI requests that the NRC establish a series of public workshops in 2024 to enagage all stakeholders in discussing these topics in more detail. The benefits of a series of workshops would be to foster mutual understanding and transparency among all stakeholders, and to produce more timely and well-considered approaches that are effective and efficient for all advanced reactors, and address the unique aspects of RHDRA to enable new business models.

As described above, NEI's members pursuing rapid, high-volume deployable reactors require clarity by the end of 2024 on the feasibility and timeliness of the regulatory enhancements outlined by these proposals. For this reason, we request that NRC provide written feedback by the end of the year.

If you have any questions concerning our input, please contact me, or Marcus Nichol at mrn@nei.org.

Sincerely,

Douglas True
Senior Vice President and Chief Nuclear Officer

Attachments

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Mr. Steve Lynch, NRR/DANU/UARP, NRC
Mr. John Lubinski, NMSS, NRC
Ms. Andrea Veil, NRR, NRC
Ms. Susan Vrahoretis, OGC, NRC
Mr. Russell Chazell, SECY/RAS, NRC
NRC Document Control Desk

PROPOSAL PAPER

Regulation of Rapid High-Volume Deployable Reactors in Remote Applications (RHDRA) and Other Advanced Reactors

Prepared by the Nuclear Energy Institute
July 2024

Acknowledgements

This document was developed by the Nuclear Energy Institute (NEI). NEI acknowledges and appreciates the contributions of our members and other organizations in providing input.

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Other Organizations Consulted: Breakthrough Institute, Electric Power Research Institute, Nuclear Innovation Alliance, Terra Praxis, and U.S. Nuclear Industry Council

EXECUTIVE SUMMARY

With nuclear power on the advent of an unprecedented opportunity, the NRC, industry, and even Congress have identified the need for modernization of regulatory processes. Advanced reactors bring with them very different manufacturing, construction, and operational models, coupled with vastly different business models that will enable and require adaptation of the regulatory processes that have developed to date. Rapid high-volume deployable reactors in remote applications (RHDRA) have low potential radiological consequences that are on the order of research and test reactors, are capable of being fully assembled in the factory and delivered to site ready to operate, and blend simplicity with automatic features that allows a single on-site operator, or no on-site operators with the use of remote operations.

This paper proposes numerous changes to NRC regulations and implementing guidance that would achieve a modern regulatory framework that is more effective and efficient to address the unique considerations of RHDRA, and would also benefit larger advanced (light-water and non-light-water) reactors. These proposals align with and expand upon the NRC's valuable efforts to establish a modern and efficient regulatory framework for new and advanced reactors consistent with the 2019 Nuclear Energy Innovation and Modernization Act (NEIMA). These proposals would also form the basis for risk-informed and performance-based strategies and guidance to license and regulate micro-reactors that meet the requirements in Section 208 of the ADVANCE Act of 2024. Furthermore, these proposals could satisfy, in part, other requirements in the ADVANCE Act that are contained in Sections 206, 505, 506 and 507. Input specific to those and other sections of the ADVANCE Act will be provided separately.

Implementation of the proposed approaches in this paper would enable the NRC to provide reasonable assurance of adequate protection of the public health and safety, and environment in pursuit of the overall goal of the Atomic Energy Act to "make the maximum contribution to the general welfare" … "to the maximum extent consistent with the common defense and security and with the health and safety of the public." There are 31 topic areas included in this paper, for which each separately would significantly improve the effectiveness and efficiency of NRC's regulation of new nuclear reactors, and collectively would enable even greater improvements and facilitate the adoption of nuclear technologies for new applications and business models.

The set of proposed regulatory enhancements would enable more wide-spread adoption of nuclear energy through a more effective and efficient regulatory process that enables shorter deployment timelines. Over time, and through repetitive Nth-of-a-kind (NOAK) use of the process, the NRC could modernize a licensing process that today precludes deployments in less than 49 months (for 12-month safety and envirionmental reviews), and create a licensing process that enables deployments in as few as 6 months within the authorities granted by the existing Atomic Energy Act (AEA). This would occur as the NRC is able to implement the tools discussed in the proposal paper, and as the NRC gains experience in licensing rapid high-volume deployable reactors. This is expected to begin with establishment of regulatory bases over the next 12 months, that enable the use of exemptions and the development of rulemakings to achieve the 3 year timeline required in Section 208 of the ADVANCE Act. With an amendment to the AEA to authorize the use of a general license for rapid high-volume deployable reactors, the NRC could achieve a regulatory framework that enables deployments in a month or less.

The NRC has done a considerable amount of work that encompasses the broad range of advanced reactor technologies and various intended applications of this technology. Much of this work would benefit rapid high-volume deployable reactors, and includes the Part 53 rulemaking and Advanced

Nuclear Reactor Generic Environmental Impact Statement. The NRC has also done a considerable amount of work more specifically applicable with micro-reactors and manufacturing licenses, that has also established a foundation for many of the topics addressed in this paper. This includes NRC SECY-20-0093 and SECY-24-0008. Related to these, NEI has also provided input and proposals on these topics in our 2019 and 2021 papers to the NRC.

This paper identifies a set of 31 regulatory topics, summarized in Table 2-1, that are expected to need alternative regulatory approaches for rapid high-volume deployable reactors in remote applications. While several of these issues have previously been addressed by the NRC and NEI, the more recent micro-reactor market demand signals have resulted in the identification of other issues that must be resolved to ensure line-of-sight to commercial scale deployment of these technologies. Therefore, there is significant scope of regulatory consideration, beyond what has previously been considered, that is needed to potentially enable these business models. Other topics may also benefit from alternative approaches for advanced reactors (e.g., decommissioning, population siting, quality assurance), but they are not included since they were not determined to need alternative approaches to enable rapid high-volume deployable reactors for remote applications. While this paper is exhaustive in the topics considered, other topics could be identified as the business model further develops.

There is no doubt that the idea of deploying reactors within 6 months of an order requires the shattering of old paradigms. To this end, the industry's effort does not start with current approaches and incrementally change them. As outlined in the many attachments, the approach was to start with the endpoint in mind and identify what it would take to safely and securely meet the deployment needs. This meant questioning the basis for current approaches and challenging whether safety and protection of the environment can be assured in entirely new ways.

Fundamentally, there are three changes that are being sought, for which all of the proposed solutions for the 31 identified issues are needed to accomplish:

1) Adapting the regulatory approaches for technologies, like non-power reactors, to advanced reactors that have a similar order of magnitude of potential consequences in order to provide reasonable assurance of adequate protection of the public health and safety, and the environment, and so that licensing and regulation of advanced reactors is efficient and does not unnecessarily limit the use and deployment of nuclear energy, or the benefits of nuclear energy to society;

2) Creating a rapid efficient and repeatable licensing (ReLic) process that can achieve 6 month deployment times by:

    a. completing all, or as much as possible, of the safety and environmental reviews and public engagement processes at one-time prior to the identification of a specific site, and

    b. performing a site license review that only verifies that the site characteristics, which are based on pre-existing generic data as much as possible, conform to the minimum set of site parameters in the envelope established in the one-time up-front reviews; and

3) Establishing performance-based and graded approaches, consistent with SRM-SECY-98-144, including for staffing size appropriate to the functions determined to be dependent upon human

actions, and locations, based upon the design of the advanced reactor (including inherent safety features, advanced technology, and automatic systems).

The proposed approaches have been specifically developed to enable a rapid high-volume deployable reactor (RHDRA) business model that is characterized by two key business case requirements relevant to the NRC regulatory framework:

1) takes no more than 180 days from the date a precise location is identified for a power reactor to the time it is deployed and operating, and

2) the overall licensing and ongoing oversight costs need to be less than 1% of the total capital and operating costs.

NEI identified that enabling alternative business models is an industry priority in our February 12, 2024, letter to the NRC, "NEI Input on Regulatory Priorities for New and Advanced Reactors".[1] In that letter we stated that "*the NRC may need to take more aggressive steps to modernize the regulatory framework to meet the varied carbon-free energy needs of the nation. Some current business plans envision widespread deployment of approved micro-reactors within a matter of six months*." The market potential for nuclear energy in markets that would utilize this type of business model could be in the multiple thousands of operating reactors by 2050. Therefore, enabling these business models is important to meeting the U.S. needs for more nuclear energy to achieve our climate, energy, environmental, economic, and national security goals.

A central goal of the proposed alternative approaches is to enable them to be used for, as broadly as possible, all advanced reactor technologies and business models. This is built upon the establishment of technology-inclusive, performance-based, risk-informed and graded approaches. This goal for broad/general applicability is balanced against the need to develop approaches that specifically enable RHDRA and other advanced reactors in other applications by addressing the unique considerations of those technologies, and concept of deployment and operations. Twenty of the 31 proposed approaches are expected to be applicable to other advanced reactors. However, the approaches proposed are graded such that reactors that meet more stringent conditions are able to realize greater benefits. The outcome of these graded approaches is a consistent level of protection of the public health and safety and the environment, across a wide range of technologies, and concepts of deployment and operations. In this way, the unique aspects of RHDRA and other similar advanced reactors can be most appropriately addressed, while also ensuring maximum applicability to all advanced reactors.

Nearly all of these 31 topics are expected to require changes to the regulations. Due to the broad range of topics and novel approaches being proposed, there are a large number of requirements that would need to be changed, eliminated, or added to modernize the NRC regulatory framework and achieve a more effective and efficient regulatory framework for advanced reactors, including RHDRA and micro-reactors. This paper identifies over 30 regulations, which could represent more than 100 requirements that would require changes to address the set of issues in the paper. Where possible, the detailed proposals in the appendices identify specific requirements that would need to be changed, and in other cases where more regulatory analysis is needed, regulatory changes are identified at the Part or Subpart level. It is important that the alternative regulatory approaches be available for licensing under Parts 50 and 52 and a future Part 53. The NRC could pursue changes to these regulations by incorporating them into existing rulemakings (e.g., Parts 50 and 52 Alignment and Lessons Learned, Part 53, Advanced

[1] ML24043A249

Nuclear Reactor Generic Environmental Impact Statement, and Categorical Exclusions) or through a new rulemaking. There are some topics for which Congressional action is needed to achieve the proposed approaches, or which would enable other options for addressing the topic that are identified but not proposed as the recommended approach.

Implementation of the proposed approaches in this paper would enable a ReLic process for the NRC licensing, from application acceptance to license issuance of 4 months, that in turn would enable RHDRA deployments from site identification to reactor operation of 6 months. The conditions for the technology capabilities and concepts of deployment that would define the characteristics of RHDRA that would be compatible with this ReLic process are discussed in Section 3. Other advanced reactors that do not share all of those characteristics could still see more rapid licensing and deployment timelines that the current NRC process enables through the use of substantial portions of the ReLic process. The proposed approaches would also enable the NRC regulatory framework to be consistent with regulatory costs of 1% or less of the capital and ongoing operating costs for RHDRA and other advanced reactors.

NEI's members pursuing rapid, high-volume deployable reactors require clarity on the scope and pace of regulatory modernization that could be achieved by the end of 2024. This clarity is needed by the market in order to enable investments and customer commitments to deployment. To this end, we seek NRC feedback on whether the NRC agrees that:

1) these topics need to be addressed in order to enable the business model for RHDRA,

2) it is reasonably foreseeable that the identified desired outcomes are achievable and there are no fundamental deficiencies or gaps in the proposed approaches,

3) implementing the proposed approaches would enable deployment timelines of 6 months from site identification to operations and regulatory costs that are less than 1% of total costs,

4) many of the proposed approaches should be applied in a graded approach to also create a more effective and efficient regulatory framework for other advanced reactors, and

5) the NRC supports including these proposed approaches into efforts to implement changes directed by the ADVANCE Act within the next 3 years.

Table of Contents

Table of Figures

Table of Tables

Appendices and Attachments

1 INTRODUCTION

This paper proposes numerous changes to NRC regulations and guidance that would achieve a more modern regulatory framework that is more effective and efficient to address the unique considerations of rapid high-volume deployable reactors in remote applications (RHDRA) and would also benefit other advanced (light-water and non-light-water) reactors. These proposals align with and expand upon the NRC's valuable efforts to establish a modern and efficient regulatory framework for new and advanced reactors consistent with the 2019 Nuclear Energy Innovation and Modernization Act (NEIMA). These proposals would also form the basis for risk-informed and performance-based strategies and guidance to license and regulate micro-reactors according that meet the requirements in Section 208 of the ADVANCE Act of 2024. Furthermore, these proposals could satisfy, in part, other requirements in the ADVANCE Act that are contained in Sections 505, 506 and 507. This section describes the purpose of the document, the relationship to prior work in this area, and the benefits of the outcomes that these proposals are expected to enable.

1.1 Purpose

The purpose of this document is to propose a set of regulatory enhancements that would enable the NRC to provide reasonable assurance of adequate protection of the public health and safety, and the environment in pursuit of the overall goal of the Atomic Energy Act to "make the maximum contribution to the general welfare" … "to the maximum extent consistent with the common defense and security and with the health and safety of the public." If implemented, these proposed approaches would enable more wide-spread adoption of nuclear energy. The topics for which alternative approaches are being proposed, collectively and each separately, would significantly improve the effectiveness and efficiency of NRC's regulation of new nuclear reactors, and enable regulatory improvements that facilitate greater adoption of nuclear technologies for new applications and business models.

The goals of this paper are to:

1. Enable new business models, specifically focusing on applications with technological characteristics and concepts of deployment and operation similar to those for an emerging concept called "Rapid High-Volume Deployable Reactors in Remote Applications (RHDRA)", and

2. Maximize the applicability of proposed approaches to other advanced reactors and business models.

The scope of this report identifies limitations and barriers imposed by the existing regulatory framework (including on-going rulemakings), describe the desired regulatory outcomes, recommend the most suitable regulatory approach (including a basis and regulatory analysis), and identify other options that could be viable but are less desirable. This paper is limited to the set of regulatory policy and technical topics that were identified to need alternative approaches to enable a viable business model for RHDRA. These alternative approaches include needs for rulemakings, policy decisions and/or new guidance. Some alternative approaches may need Congressional action. The set of topics in this paper do not include other topics that may be needed to address other business models. While some of these topics have been addressed by the NRC in other efforts, this paper discusses aspects of those topics, as well as new topics, that have not previously been considered.

Given the urgency and scale at which the market's power needs must be addressed, potential customers in these markets need to obtain clarity that there is a reasonable pathway to modernize the regulatory framework for these technologies and applications in ways that meet the business case requirements (as described in Section 3.2).

It is the intent of this paper to inform on-going work by the NRC to address this class of reactors in developing options for alternative approaches to achieve the goals for regulatory clarity by the end of 2024, and establish these alternative regulatory approaches to enable the business model by 2026.

1.2 Background

NEI identified that enabling alternative business models is an industry priority in our February 12, 2024, letter to the NRC, "NEI Input on Regulatory Priorities for New and Advanced Reactors."[2] In that letter we stated that "*the NRC may need to take more aggressive steps to modernize the regulatory framework to meet the varied carbon-free energy needs of the nation. Some current business plans envision widespread deployment of approved micro-reactors within a matter of six months*."

NEI's proposed approaches in this paper were developed to enable a specific rapid high-volume deployable reactor (RHDRA) business model, while also enabling other business models that were not specifically defined in terms of the interface with the regulatory framework. The RHDRA business model adopted the business requirements identified by Shepherd Power in a letter to the NRC dated February 12, 2024,[3] for the use of reliable and affordable nuclear heat and power to oil and gas operations, and which stated that micro-reactors are the *"best technical option for achieving their decarbonization and, aggregated together, imply a very large and immediate domestic market….the size and importance of this opportunity…cannot be overstated."* The two business case requirements relevant to the NRC regulatory framework that are necessary to enable the business model are: 1) "*takes no more than 180 days from the date a precise location is identified for a microreactor to the time it is deployed and operating"* and 2) *"the overall licensing and ongoing oversight costs need to be less than 1% of the total cost of manufacture and operations."*

The NRC has also done a considerable amount of work that encompass the broad range of advanced reactor technologies and various intended applications of this technology. Much of this work would benefit rapid high-volume deployable reactors. The following is a listing of some of the key areas that address topics discussed in this paper (it is recognized that the NRC has numerous ongoing work related to advanced reactors):[4]

- Part 53 Rulemaking
- Part 50/52 Lessons Learned Rulemaking
- SMR Emergency Preparedness Rulemaking
- Advanced Nuclear Reactor Generic Environmental Impact Statement

[2] ML24043A249
[3] ML24068A021
[4] See NRC's webpage on Generic Activities for Non-LWRs: https://www.nrc.gov/reactors/new-reactors/advanced/modernizing.html, and for LWR SMRs: https://www.nrc.gov/reactors/new-reactors/smr.html

- Categorical Exclusions

There has been considerable work by the NRC to prepare and modernize the regulatory framework to more appropriately address the advanced reactor technologies being developed. Some of the NRC work that is more specifically applicable has been associated with micro-reactors and manufacturing licenses. The following is a listing of some of the key documents from the NRC and NEI that help to address the regulatory needs of this new class of reactors – rapid high-volume deployable reactors.

- NRC SECY-24-0008, "Micro-Reactor Licensing and Deployment Considerations: Fuel Loading and Operational Testing at a Factory" (ML23207A252)
- NRC White Paper, "Micro-reactors licensing strategies" (ML21235A418)
- NEI 2021 Paper, "Manufacturing License Considerations" (ML21197A103)
- NRC SRM-SECY-23-0021, "Proposed Rule: Risk-Informed Technology-Inclusive Regulatory Framework for Advanced Reactors" (ML24064A039)
- NEI Comprehensive Comments on Part 53 (ML22243A257 – 8/31/22) and (ML21309A578 – 11/5/21)
- NRC SECY-20-0093, "Policy and Licensing Considerations Related to Micro-Reactors" (ML20254A363)
- NEI 2019 Paper, "Micro-Reactor Regulatory Issues" (ML19319C497)

This paper identifies a set of 31 regulatory topics that are expected to need alternative regulatory approaches for rapid high-volume deployable reactors in remote applications. Of the roughly 22 regulatory topics identified to date in the above key documents, about 16 are also included in the list of 31 topics. Thus, there are about 15 new topics that have not previously been identified as potentially needing alternative regulatory approaches. Furthermore, of the 16 previously identified topics that are included in this paper, most of those have not sufficiently considered the technology or concepts of deployment and operations for rapid high-volume deployable reactors. Therefore, there is significant scope of regulatory consideration, beyond what has previously been considered, that is needed to potentially enable these business models.

The NRC staff, in the May 14, 2024, public meeting, stated that they have plans to develop a paper addressing the regulatory topics related to the business model for rapid high-volume deployable reactors later this year for the Commission's approval. This paper is expected to address all of the topics the NRC planned 2024 Paper to the Commission, as well as many other topics not expected to be included in that paper.

1.3 Rationale for An Alternative Regulatory Approach

The technology characteristics, concept of deployment and operations, and regulatory framework are interrelated. Thus, the regulatory framework needs to be informed by the capabilities of the design and the activities associated with the deployment and operations for the intended applications. Similarly, the development of the technology capabilities, and the concept of deployment and operation will be informed by the development of the alternative regulatory approach. This interrelationship of technology, business model and regulatory framework are shown in Figure 1-1. As these technologies and concepts are being developed now, there is an urgent need to understand how the regulatory framework needs to be modified to enable the business model.

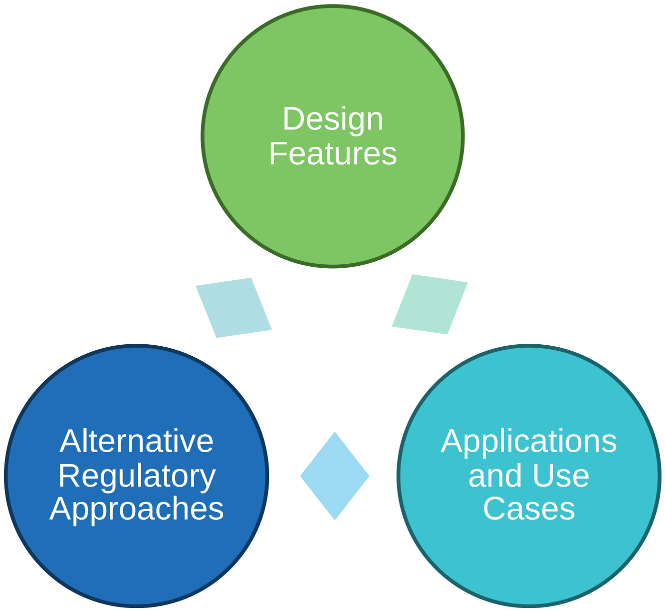

Figure 1-1: Interrelationship of Technology, Business Model and Regulatory Framework

1.3.1 Need for An Alternative Regulatory Approach

The characteristics and safety basis of rapid high-volume deployable reactors are expected to be fundamentally different from those of commercial power reactors, even as compared to advanced small modular reactors. These business models are so new that the current statutes and regulatory requirements, including changes and alternatives that are in process, have not fully considered the technology capabilities or the concepts of deployment and operations. Therefore, it would be appropriate to fully consider these novel aspects with an understanding that a fundamentally different regulatory approach may be appropriate. Such an alternative regulatory approach for rapid high-volume deployable reactors could more effective and efficient in protecting the public health and safety.

The key features of rapid high-volume deployable reactors are their very small inventory of radioactive material and simplicity, as compared to other advanced reactors. They are expected to come in a variety of designs and while there is not a standard set of design features, the following are additional but not exclusive characteristics that may further define RHDRA. (Note that a full description of the technology characteristics is in Section 3).

- Reactors that are fully assembled in factory, and capable of being loaded with fuel at the factory and transported to the operating site while fueled
- Capable of delivery, emplacement, commissioning, and transition to operation on the order of weeks or less;
- Potential radiological consequences to the public, workers and environment that are on the order of non-power reactors

- Operational simplicity with very few active SSCs, instruments or controls

The NRC has made great strides in modernizing its regulatory framework to recognize that the existing frameworks are ill-suited for today's new reactor technology. However, the existing regulatory framework, including on-going work to modernize the framework for advanced reactors, does not currently permit the business model on the required timeframe that would enable hard to abate industries from decarbonizing their energy sources.

The NRC should consider alternative approaches for rapid high-volume deployable reactors that can demonstrate that the potential consequences of accidents, even for the worst-case scenarios in which there are multiple failures of fuel fission product barriers and other systems, structures and components, would not lead to a significant adverse impact on the health or safety of the public.

As discussed in Section 1.2, the NRC has been working to modernize the regulatory framework for advanced reactors, including specific work related to micro-reactor and manufacturing license topics that are relevant to rapid high-volume deployable reactors for remote applications. Also discussed in this paper is the basis for concluding that this prior work, while valuable to this technology, is not sufficiently complete to enable the business model. For rapid high-volume deployable reactors, the existing regulations and proposed rule changes to address advanced reactors, in many cases, would result in excessive regulatory burden that is not necessary to protect the public health and safety. The safety features, and the corresponding simplicity of rapid high-volume deployable reactors, are expected to result in designs with very low potential consequences, which could justify the use of alternative approaches to existing regulations.

1.3.2 Consistent with National Priorities

There is widespread recognition that the U.S. needs more nuclear energy to achieve our climate, energy, environmental, economic, and national security goals.

President Biden's December 2021 Executive Order articulates the need and urgency for accelerating the deployment of advanced nuclear technologies to decarbonize the energy sector. In it, "President Biden has set an ambitious U.S. goal of achieving a carbon pollution-free power sector by 2035 and net zero emissions economy by no later than 2050. As a result of the historic investments in the Inflation Reduction Act and Bipartisan Infrastructure Law as well as other actions the Administration is taking, the United States is on a clear path to achieve this goal, while reducing costs for consumers, lowering harmful pollutants, mitigating climate change, and creating new economic opportunities."[5] Advanced reactors, including rapid high-volume deployable reactors, are needed to decarbonize difficult to abate sectors and use-cases.

In the March 22, 2024, letter to the Secretary of the Department of Defense (DoD),[6] the Senate Select Committee on Intelligence identified the need to bolster the resilience of our critical infrastructure. The letter identified the importance of civil nuclear technology for critical mission demands and increased resilience for U.S. bases. Advanced reactor technologies, including rapid high-volume deployable reactors, are well suited, and perhaps the only technology that can provide the level of resilience needed for defense and commercial critical infrastructure, such as remote industrial or data centers. The

[5] White House Press Release: https://www.whitehouse.gov/briefing-room/statements-releases/2023/04/20/fact-sheet-president-biden-to-catalyze-global-climate-action-through-the-major-economies-forum-on-energy-and-climate/

[6] https://www.warner.senate.gov/public/index.cfm/2024/3/intel-chair-warner-vice-chair-rubio-colleagues-urge-department-of-defense-to-boost-energy-security-of-critical-infrastructure

Committee stressed that "It is critical that the United States lead in the development and deployment of advance nuclear reactors to secure our own critical infrastructure with resilient, continuous power, especially for DoD mission critical operations in remote and austere environments." As DoD is pursuing the use of commercial technology, they are dependent upon this technology being enabled by alternative regulatory approaches that protect the public health and safety more effectively and efficiently.

The Army and Defense Innovation Unity held an information day on June 4, 2024, to announce the launch of an Area of Interest solicitation for a new Army program to deploy micro-reactors at Army installations. In the briefing, the Army stated that they have not decided which regulatory authority they would pursue, either licensing by the NRC or self-regulating under the Army's authority. The ability for the NRC to modernize the regulatory framework to be more effective and efficient for advanced reactors is likely to be a significant fact in that decision.

In the recent DOE Liftoff report for Advanced Nuclear,[7] the Department emphasized that, (2) "This group [capital providers] considers nuclear to be outside of their risk appetite due to perceived technology and regulatory risk…" emphasis added. Furthermore, the DOE Liftoff report identified the following challenge, "The NRC would need to scale its license-application capacity from 0.5 GW per year to 13 GW per year to meet projected demand," and the following potential solution, "The NRC's capacity is determined both by actions taken by the NRC to improve efficiency and increase resources and by activities from applicants to improve and expedite applications interactions."

The industry's recent Advanced Reactor Roadmap[8] reached similar conclusions and recommendations, stating that, "The market need for advanced reactors to enable the United States … to meet their decarbonization goals will result in … a volume of licensing applications that far exceeds the NRC's … current capacity." The Roadmap also identified the following key enabler to regulatory efficiency: "Regulatory reform … would establish regulatory frameworks to facilitate the efficient and timely approval and licensing of innovative and safe designs, … support deployment of the first advanced reactors and fast followers and set the foundation for large-scale deployment in the early 2030s."

The concepts included in this paper are aimed at achieving the outcomes identified by the DOE liftoff and industry Roadmap reports that would enable nuclear technologies to help the nation meet its climate, energy, environmental, economic, and national security goals. This paper supports the resolution of many of the priority issues identified in NEI's February 12, 2024, letter to the NRC, "NEI Input on Regulatory Priorities for New and Advanced Reactors."[9]

1.3.3 Consistent with NRC's Mission and Principles of Good Regulation

Pursuit of more effective and efficient regulation of new classes of reactors, like rapid high-volume deployable reactors, is consistent with the NRC's Mission and Principles of Good Regulation. The Atomic Energy Act established the NRC to regulate radiological hazards to protect the public health and safety in pursuit of the overall goal of the Act to "make the maximum contribution to the general welfare" … "to the maximum extent consistent with the common defense and security and with the health and safety of the public." This establishes a dual-factored mission for the NRC – safety and efficiency. The NRC's

[7] https://liftoff.energy.gov/wp-content/uploads/2023/05/20230320-Liftoff-Advanced-Nuclear-vPUB-0329-Update.pdf
[8] https://publicdownload.epri.com/PublicAttachmentDownload.svc/AttachmentId=83812
[9] ML24043A249

Principles of Good Regulation and numerous Policy Statements have reflected the dual mandate of safety and efficiency.

The NRC's Principles of Good Regulation for Efficiency states, "where several effective alternatives are available, the option which minimizes the use of resources should be adopted." In the application of this principle to advanced reactors, the safety requirements for advanced reactors should be focused on ensuring that advanced reactors meet the underlying intent of the regulations to provide reasonable assurance of adequate protection of the public health and safety. As a result, rapid high-volume deployable reactors would likely not need to meet all of the existing detailed and prescriptive requirements that were developed based on the potential consequences of larger power reactors to ensure public health and safety.

The NRC's Advanced Reactor Policy states that its goal is to encourage advanced reactor designers to consider safety and security in the early stages of design in order to identify potential design features and/or mitigative measures that provide a more robust and effective security posture with less reliance on operational programs. Industry has responded to this goal by developing innovative advanced reactor technologies.

In the Advanced Reactor Policy Statement[10] the Commission stated that it "expects that advanced reactors will provide enhanced margins of safety and/or use simplified, inherent, passive, or other innovative means to accomplish their safety and security functions" and includes a list of over 10 specific features that would enhance safety of advanced reactors. Incorporating even some of those features would result in designs for which many of the NRC's existing regulations would no longer be applicable, because the existing requirements were developed with large LWRs in mind. The Commission recognized this fact and in the Policy Statement stated, "Incorporating the above attributes may promote more efficient and effective design reviews" … "Indeed, the number and nature of the regulatory requirements may depend on the extent to which an individual advanced reactor design incorporates general attributes such as those listed previously." While the NRC has several on-going regulatory initiatives related to advanced reactors, few of these initiatives have fully contemplated the design features and concept of deployment and operations identified in this paper.

1.3.4 Consistent with Congressional Direction

Congress has passed legislation aimed to enable the NRC to modernize the regulatory framework for advanced reactors and enable business models for these technologies. The Nuclear Energy Innovation and Modernization Act (NEIMA) authorized the NRC to develop a technology-inclusive performance-based and risk-informed alternative regulatory framework. The recently enacted ADVANCE Act includes sections specifically related to micro-reactors and the NRC licensing process, and many of the proposed regulatory approaches discussed in this paper to address issues with the current regulatory framework would be options to implement those provision if they become law. There are many other examples of legislation that have been enacted or are being contemplated by Congress, the analysis and discussion of which is beyond the scope of this current paper. However, the key point is that legislation from Congress has directed the NRC to modernize the regulatory framework for advanced reactors, and future legislation may further enable the business models for rapid high-volume deployable and other reactors.

[10] ML082750370

In considering the regulatory framework for rapid high-volume deployable reactors, there may also be statutory requirements identified that would prevent the NRC from implementing a more effective and efficient alternative regulatory approach for this business model. Just as the regulatory framework has not fully considered the technology capabilities, and concept of deployment and operations, so also the statutes, including the Atomic Energy Act, have not fully considered this business model. Therefore, it would not be unreasonable to expect that the statutes, though developed to be flexible and not overly prescriptive to the technology or business model, would not have been able to envision future technology capabilities, and concepts of deployment and operations, that are as fundamentally different from the technology and business models at the time of the enactment of those statutes, and thus may not have provided sufficient flexibility to enable these novel business models.

2 PROPOSED REGULATORY APPROACHES

A key insight from the efforts to develop the proposed approaches is to question past practices and seek to be innovative in developing alternative approaches. There is no doubt that the idea of deploying reactors within 6 months of an order requires the shattering of old paradigms. To this end, the industry's effort does not start with current approaches and incrementally change them. As outlined in the many attachments, the approach was to start with the endpoint in mind and identify what it would take to safely and securely meet the deployment needs. This meant questioning the basis for current approaches and challenging whether safety and protection of the environment can be assured in entirely new ways.

It is noted that the proposed approaches were developed to enable the RHDRA business model of less than 6 months from site identification to operation, and regulatory costs less than 1% of capital and operating costs. However, it is not the only alternative business model that may be pursued for advanced reactors, and as such, the NRC should develop a regulatory framework that is inclusive of all potential advanced reactor technologies, and concepts of deployment and operations. To this end, NEI developed the Concept Paper for the "Regulation of Rapid High-Volume Deployable Reactors in Remote Applications" that we transmitted to the NRC on May 31, 2024. As discussed in that paper, many substantive changes are needed to create processes and alternative regulatory approaches to enable business models for RHDRA that would meet the business case requirements identified for the oil and gas applications, and could also enable business models for other industries that are hard to decarbonize. The market potential for nuclear energy in markets that would utilize this type of business model could be in the multiple thousands of operating reactors by 2050. Therefore, enabling these business models is important to meeting the U.S. needs for more nuclear energy to achieve our climate, energy, environmental, economic, and national security goals.

Efforts subsequent to the transmittal of the May 2024 NEI Concept Paper to develop the identified Topic Areas performed more specific proposed approaches that would address the limitations and barriers created by the current regulatory framework, including on-going rulemakings. These proposed approaches center around several key concepts for any alternative regulatory approach, including: 1) adapting the regulatory approaches for technologies, like non-power reactors, with a similar order of magnitude of potential consequences, 2) establishing a rapid efficient and repeatable licensing (ReLic) process, and 3) developing performance-based acceptance criteria that allow for a graded use of the proposed approaches. This paper presents the outcome of that work, which refines, and supersedes, the concepts introduced in the NEI May 2024 Concept Paper.

The regulatory approach for rapid high-volume deployable reactors should be flexible and accommodate multiple approaches that may be taken by applicants in the licensing process and to demonstrate the safety basis. The most effective way to achieve this is through a regulatory framework that is performance-based with requirements that define the acceptable outcomes in terms of public health and safety, and in ways that are as objectively measurable as possible. There are several methods to do this that have been used successfully for approaches in the NRC current set of regulations, such as consequence-oriented and risk-informed approaches. A graded approach to applying requirements is appropriate, since rapid high-volume deployable reactors may have variations in their safety characteristics, and the alternative regulatory approaches may have applicability to other technologies and concepts of deployment and operations. While the details of the technology characteristics, and concept of deployment and operations, will be needed for the NRC to fully review and approve license applications, the information within this concept document is expected to be sufficient for the NRC to develop an alternative regulatory approach for rapid high-volume deployable reactors.

2.1 Adapting Regulatory Approaches for Technologies with Similar Low Potential Consequences

The technology characteristics and concept of deployment and operations are so fundamentally different from other power reactors that it may be difficult to enable the business model by adapting the current regulatory framework for power reactors and the on-going work related to modernizing the framework for advanced reactors. In fact, the potential consequences and risks to the public health and safety, and the environmental impacts are much more similar to other low risk technologies that the NRC regulates than they are to other power reactors, including even advanced small modular reactors.

Micro-reactors are expected to have source terms that are 100 to 1,000 times smaller than large light-water reactors which are the basis for the current regulatory framework. Micro-reactors are also expected to have source terms that are 20 to 100 times smaller than dry storage casks and other advanced SMRs, which are the basis for most of the NRC regulatory modernization for advanced reactors. The potential consequences of advanced reactors will be similar to those for RTRs rather than to those of large LWRs for which the existing regulations were developed. Figure 2-1 provides a representative comparison of the magnitude of the source terms for these nuclear technologies.

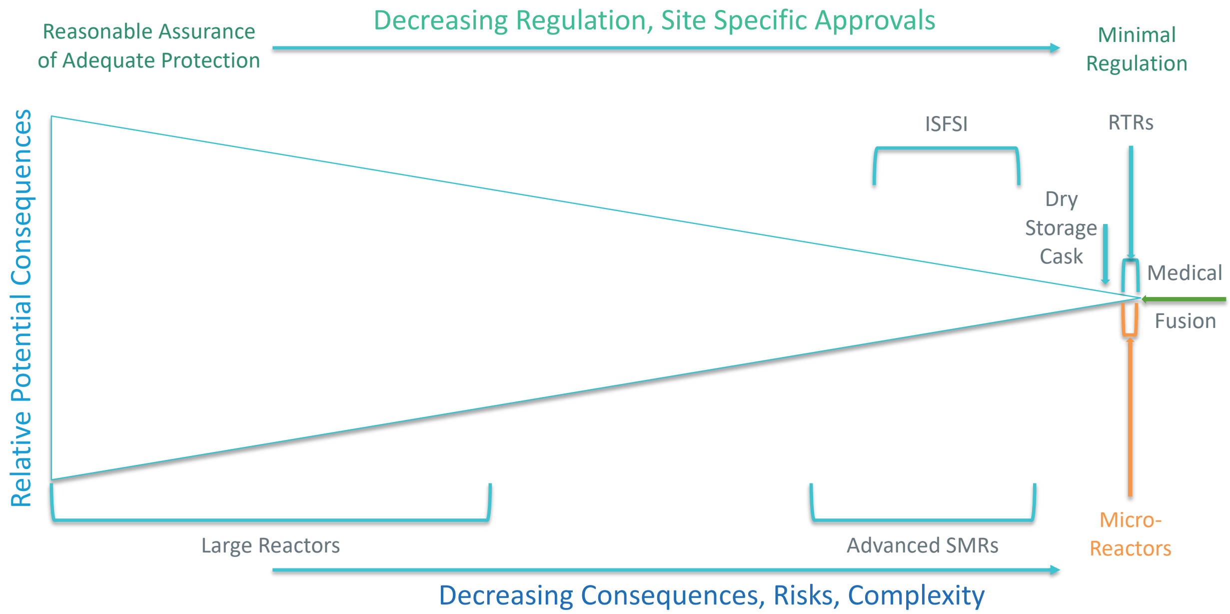

Figure 2-1: Relative Comparison of Potential Radiological Consequences for Selected Nuclear Technologies

<u>Insights from Non-Power Regulation</u>

The size, simplicity, and potential consequences of rapid high-volume deployable reactors are very similar to non-power reactors, also called research and test reactors (RTRs). The regulation of non-power reactors is carried out in accordance with Section 104 of the AEA, using the requirements in 10 CFR 50 (and other parts) and implementing guidance, such as NUREG-1537.

While there are similarities between the potential impact to public health and safety, and environmental impacts between rapid high-volume deployable reactors and RTRs, there are also notable differences between how power reactors and non-power reactors are regulated. The AEA applies a standard of reasonable assurance of adequate protection of the public health and safety, and environment to both. However, the AEA also directs the NRC to "*impose the minimum amount of regulation consistent with its obligations under this Act to promote the common defense and security and to protect the health and safety of the public."* It is important to note that the AEA does not prohibit the NRC from applying the "minimal regulation" standard to other regulated activities, including classes of power reactors that the NRC would determine appropriate. The similarities and differences between non-power reactors, and RHDRA and other similar advanced reactors should be considered in applying or adapting the regulatory framework for non-power reactors to micro-reactors (and other advanced reactor designs with similar safety profiles). These include: acceptable doses, safety features, and operations.

The NRC has already acknowledged that commercial reactors that are similar to non-power reactors should be regulated in a similar manner. In NUREG-1537, the NRC stated:

> "The licensed thermal power levels of non-power reactors are several orders of magnitude lower than current power reactors [large LWRs]. Therefore, the accumulated inventory of radioactive fission products in the fuel (in core) of nonpower reactors is proportionally less and requires less stringent and less prescriptive measures to give equivalent protection to the health

> and safety of the public. Thus, even though many of the regulations of Title 10 apply to both power and non-power reactors, the regulations will be implemented in a different way for each category of reactor consistent with protecting the health and safety of the public, workers, and the environment. Because the potential hazards may also vary widely among non-power reactors, regulations also may be implemented in a different way within the non-power reactor category."

Therefore, it is anticipated that the regulation of advanced reactors, like rapid high-volume deployable reactors, that are around the same order of magnitude lower in potential consequences would be regulated in a proportionally similar manner, with flexibility in the implementation of regulations since designs may vary widely. Attachment A discusses in more detail the regulatory frameworks for non-power reactors and power reactors, including their similarities and differences, and the potential applicability of non-power regulatory approaches for RHDRA and other similar advanced reactors. The following Appendices discuss how non-power regulatory approaches could be adapted for advanced reactors with a similar order of magnitude of potential consequences:

- Appendix 5: Site License Scope and Purpose
- Appendix 9: Aircraft Impact Assessments
- Appendix 10: Meteorology and Weather Data
- Appendix 11: Geologic and Geotechnical
- Appendix 14: Operator On-Site Staffing
- Appendix 19: Physical Security
- Appendix 20: Emergency Preparedness
- Appendix 21: Access Authorization and Fitness for Duty
- Appendix 22: Radiation Protection
- Appendix 23: NRC Oversight and Inspection
- Appendix 24: Annual Fees
- Appendix 27: Operational Testing at the Factory

2.2 Rapid Efficient Repeatable Licensing Process (ReLic)

The NRC's current licensing process will take an applicant approximately 58 months from the time of site identification to operations of the reactor, of which the duration from application submittal to final approval and authorization by the NRC is 34 months.[11] This is more than 10 times the schedule that is needed to enable a business model that depends on a schedule of 6 months from site identification to

[11] This is using the NRC's recent review schedule of 26 months – from docketing to issuance – for the Kairos Hermes, which is about half the time of the NRC's Generic Review Schedules. Note that the NRC review of Kairos Hermes was for a construction permit, and the 34 months for NRC approval and authorization assumes the same schedule for a COL followed immediately by the process to issue a 103.g finding.

operations. Within that 6 months, the regulatory process will need to be no more than 5 months, of which the duration from submittal of the application to the NRC to the final approval and authorization by the NRC must be completed in 4 months or less.

It is clear, it is not possible to achieve a 96% reduction in the current NRC licensing process (a 23-month reduction in the applicant's site characterization and application preparation – going from 24 to 1 month, and a 30-month reduction in the NRC review process – going from 34 to 5 months). More radical thinking, and likely a new process for approving and authorizing the operations are needed to enable the business model for rapid high-volume deployable reactors.

The central concept around rapid efficient licensing (ReLic) for rapid high-volume deployment (RHDRA) is to minimize the scope, content and purpose of the site-specific reviews. This is not suggesting the NRC cut corners, since it is recognized that these reviews must also be effective at providing reasonable assurance of adequate protection of the public health and safety. The concept is in when, who and how the reviews are performed and assembled together as part of demonstrating that the use of an advanced reactor at a particular site provides reasonable assurance of adequate protection of the public health and safety. This new type of site-specific review is enabled by:

1. completing all, or as much as possible, of the safety and environmental reviews and public engagement processes as possible one-time prior to the identification of a specific site, and

2. performing a site license review that only needs to verify that the site characteristics conform to the minimum set of site parameters in the envelope established in the one-time up-front reviews.

Potential cross-cutting fundamental elements (performance-based and graded to safety when possible) of the licensing approach could be:

- **NRC generic approvals on a technology-inclusive basis** – Use of a design that meets the performance-based acceptance criteria established for generic NRC approvals will significantly reduce the scope of the site license review. The NRC has several processes to make generic approvals on a technology-inclusive basis that will be applicable to many designs. While rulemakings are by far the most effective at achieving rapid efficient licensing, they are not the only process available to the NRC. Rulemaking can be used to codify generic decisions, bringing with them the public engagement process, such as the NRC is in the process of doing with the Advanced Nuclear Reactor Generic Environmental Impact Statement. Rulemakings can also be used to establish alternative regulatory approaches, or even eliminate requirements that are not necessary to provide reasonable assurance of adequate protection. (see Appendix 1)

- **NRC approvals with a standardized design** – Use of a standardized design that has been approved by the NRC will significantly reduce the scope of the site license review. The NRC has several processes to approve a standardized design, such as the Standard Design Approval, Design Certification, Manufacturing License, and Part 50 Appendix N. These offer different levels of NRC approvals in terms of scope of the design and finality in the NRC decision. These licensing processes offer graded approaches, in that the more scope and content that is included in these applications, especially for site-characteristics that bound future potential sites, the greater these licensing actions will enable schedule reductions for the site license, and cost reductions for deployment at a high-volume of sites. (see Appendix 2)

- **NRC pre-approvals for a Licensee** – Use of NRC processes to pre-approve a licensee prior to the selection of the site would address matters that are not specific to a site. The NRC must review applications to determine that an applicant is qualified and capable of owning and operating a nuclear reactor. The NRC must also review certain programs in association with the applications to verify compliance with NRC regulations. The more of this non-site-specific site-license information that applicants are able to submit to the NRC, and the more the NRC can review and approve such information ahead of time, the less information that will need to be included in the site-specific review. (see Appendix 5)

- **Use of Pre-Existing Reliable Site Data** – Use of reliable generally available data that already exists will significantly reduce the time it will take to collect site-specific data. The NRC requires several types (e.g., soil, weather, flora and fauna) of site characterization data that must be verified that the site conforms to the conclusions of the safety and environmental analyses. Traditionally, the NRC has required that this data be collected over long periods of time after the site has been selected, typically requiring at least two (2) years from the time the site is selected until the application could be submitted. Clearly a 2-year process, from the point of site selection, that only gets to the point of submitting an application will never enable a business model that requires a 6-month schedule between those two points – even if the NRC's licensing process could be reduced from 34 to 4 months. Reliable data for U.S. sites already exists that could be used in any advanced reactor site license application, review and approval, and for on-going operations when that data may be so required. For example, the National Oceanic and Atmospheric Administration has meteorological data, and the U.S. Geological Survey of the Department of Interior has seismic hazard data and a process to evaluate seismic hazards that is similar to the NRC-endorsed SSHAC process, both of which have this data for sites across the U.S. These are federal agencies directed by Congress to collect and administer this information for use by other federal agencies and others for the benefit of the general public. The NRC has also, in the case of National Metrology Institutes (NMIs) not just in the U.S. but also international, recognized the ability to use their data for safety-related applications and without the need for them to meet Appendix B or be audited by purchasers, because those NMIs are government institutions with proven abilities and disciplines.[12] (see Appendices 10 and 11)

The common theme to each of these fundamental elements to rapid efficient licensing (ReLic) for rapid high-volume deployment (RHDRA) is to move the scope and content of information that has traditionally been in the site license application into licensing processes that can occur one-time prior to the site license application. In doing so, these one-time up-front approvals will establish the minimum set of bounding site parameters that are necessary and sufficient to verify that the site complies to these prior NRC approvals. This enables the NRC's review of the site license application to be a verification of compliance with the site parameter envelope, ensuring that the site license conforms with all the NRC conclusions from prior safety and environmental reviews, along with their commensurate public engagement processes. Figure 2-2 provides a simplified perspective of how a rapid efficient licensing (ReLic) for rapid high-volume deployment (RHDRA) could enable a business model that requires a 6-month schedule from the point of site selection to operations. Figure 2-3 provides a more specific example of how NRC licensing processes could be used to create the ReLic process. Figure 2-4 shows the licensing timelines that the proposed changes to achieve a ReLic process are expected to achieve.

[12] ML15111A477

Implementation of the proposed approaches in this paper would enable a ReLic process for the NRC licensing, from application acceptance to license issuance of 4 months, that in turn would enable RHDRA deployments from site identification to operation of 6 months. The conditions for the technology capabilities and concepts of deployment that would define the characteristics of RHDRA that would be compatible with this ReLic process are discussed in Section 3. Other advanced reactors that do not share all of those characteristics could still see more rapid licensing and deployment timelines than the current NRC process enables through the use of substantial portions of the ReLic process. Section 3.4.2 provides more detailed discussion on the activities and timelines for the ReLic process to achieve a 4 month NRC review schedule, from acceptance of the application to issuance of the license.

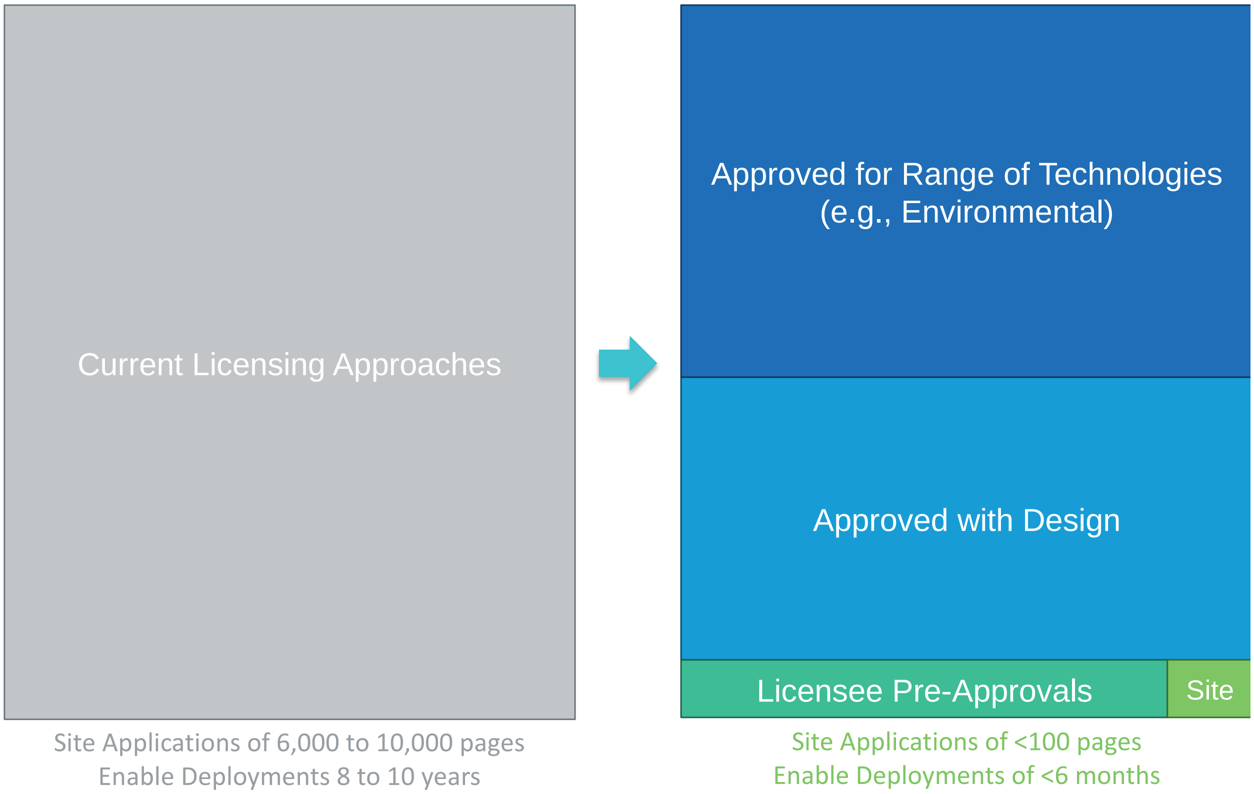

Figure 2-2: Concept for Using Multiple NRC Processes for Rapid Efficient Site Licensing

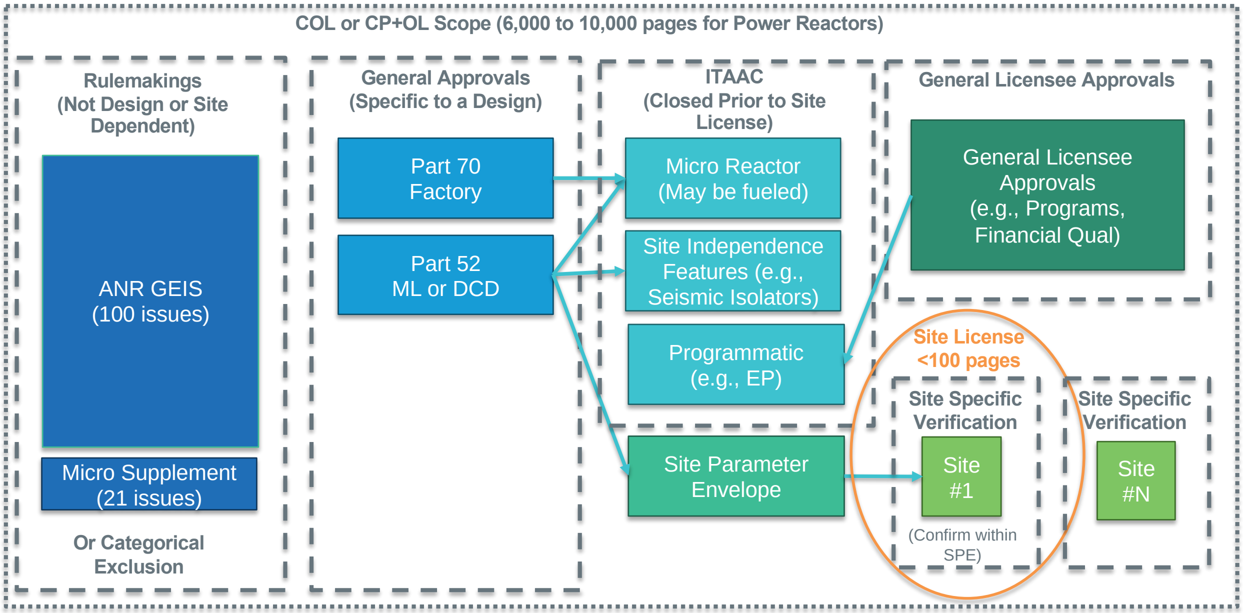

Figure 2-3: Example of NRC Processes that Could Enable Rapid Efficient Licensing of Sites

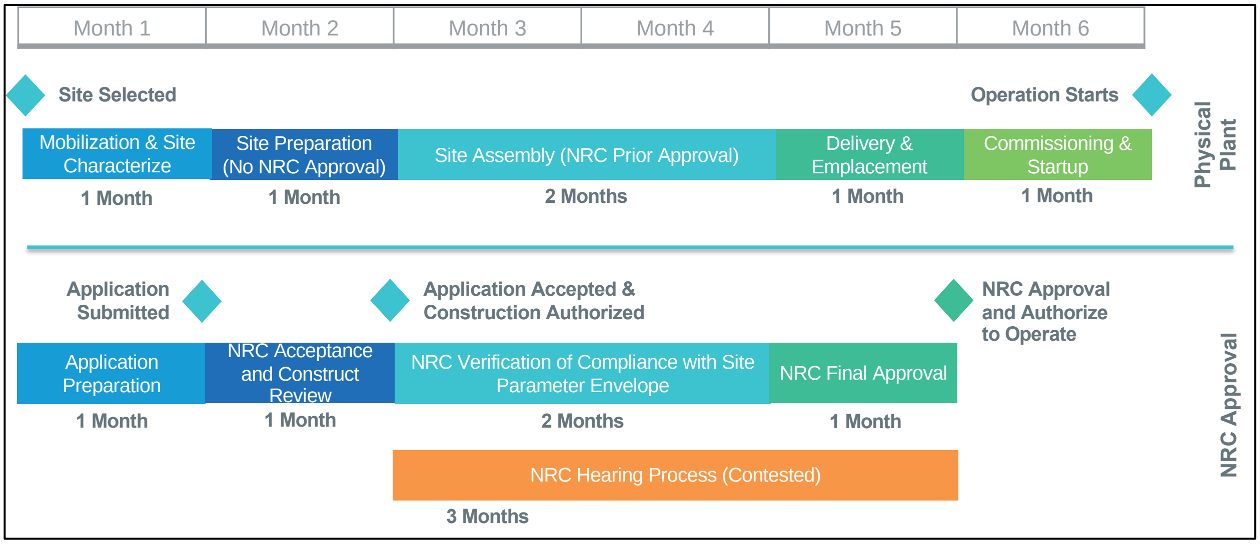

Figure 2-4: Site Selection and Deployment Process

Attachment B discusses the concept of a General License which would be more efficient and effective in regulating nuclear reactors, such as RHDRA, and would be capable of enabling even shorter deployment timeframes that would be needed to support other business models. A general license is not the proposed solution since the ReLic process would enable the business model, and the NRC is not currently authorized to use a general license for nuclear reactors. If or when Congress amends the AEA to authorize and direct the NRC to develop a general licensing approach for certain nuclear reactors, then the NRC would be able to pursue a rulemaking to develop such a general license framework for nuclear reactors.

2.3 Performance-Based and Graded Approaches

This paper is written to enable an emerging business model for rapid high-volume deployable reactors. Most of the individual pieces of these technology capabilities, and concepts of deployment and operations have existed for a while, and in some cases they have existed for decades. However, the combination of all of the technology capabilities and concepts of deployment and operations is unique.

The basis for moving toward performance-based approaches to regulation was established in 1999 through SRM-SECY-98-144, where the Commission directed the staff to develop and implement performance-based and risk-informed regulations, that emphasized the importance of a shared understanding of these terms, and recognized that the transition would be incremental over an unspecified period of time. To that end, the Commission explicitly defined terminology (e.g., performance-based) and contrasted prescriptive requirements against performance-based approaches. The Commission further explained that "a performance-based requirement relies upon measurable (or calculable) outcomes (i.e., performance results) to be met, but provides more flexibility to the licensee as to the means of meeting those outcomes." The benefits of performance-based, rather than prescriptive requirements, is that they focus on actual performance (i.e., desired outcomes) rather than on products (i.e., outputs), and are more clear and inclusive.

For the purposes of this concept paper, it is important to understand how performance-based approaches lead to the specific applicability and the general applicability of the business model discussed in this paper, in this way:

Specific Applicability – This means that it is only designs with a combination of all of the enabling technological capabilities (e.g., passive safety systems, automatic operations, small source terms, small size, transportable and factory manufacturable, etc.), and concepts of deployment and operations, that would be able to fully benefit from the proposed approaches discussed in this paper. For this purpose, these designs have been called "rapid high-volume deployable reactors" in this paper.

General Applicability – This means that any single feature of the proposed approaches discussed in this paper is not dependent upon a design having all of the enabling technological capabilities, and concepts of deployment and operations discussed in this paper. As such, pieces of the concept for an alternative regulatory framework that is specifically developed for rapid high-volume deployable reactors may also be applicable to other advanced reactors.

There is a natural tension between developing a concept around a very specific business model, like rapid high-volume deployable reactors, that has both specific applicability and general applicability. There is a need to be specific in order to fully understand how to develop an effective and efficient alternative regulatory framework for that business model. There is also a need to be general so that the alternative regulatory framework is business-model-inclusive. When the variability among designs is low the tension between the specific and general applicability is not very noticeable, but when variability is high, this tension is apparent. This has been the case for micro-reactors that have found that, even in the development of technology-inclusive Part 53 requirements, those proposed requirements were either not achieving the desired levels of being effective and efficient, or were resulting in the creation of optional requirements that could be more effective and efficient for those designs.

Performance-based requirements, that have outcome-based acceptance criteria, that do not prescribe the methods or features of the solution are essential to creating a technology-inclusive regulatory framework. This paper considers that there are several cross-cutting technical acceptance criteria that generally establish the safety performance for advanced reactors that would be able to use a majority of the concept of an alternative regulatory framework discussed in this paper. This paper further considers that it is possible to develop performance-based acceptance criteria that have a graded approach to safety. In that sense, when possible, identifying different levels of outcomes safety levels or risk-informed terms will increase their general applicability.

This paper recognizes that not all of these cross-cutting acceptance criteria are applicable to every specific regulatory topic area, and as these topic areas are developed it will be helpful for them to identify which of these cross-cutting technical acceptance criteria are applicable to that topic area. This paper also recognizes that as alternative approaches are developed for specific regulatory topic areas (e.g., siting, environmental, security) some of those topics may identify additional issue-specific technical acceptance criteria. Similar to the cross-cutting technical acceptance criteria, performance-based acceptance criteria that have a graded approach to safety will enable them to be more generically applicable.

Potential cross-cutting technical acceptance criteria (performance-based and graded to safety when possible) could be:

- **Off-site doses are small** – Use of a graded approach of acceptance criteria based upon different levels of potential off-site doses would enable this criterion to be broadly applicable. Small off-site doses are expected to be achieved through the use of passive and inherent systems, simplicity and other features that result in higher safety margins and lower risks. Examples of various levels of potential impacts to the public are: [13]
    - **Small Doses** - Site boundary Emergency Planning Zone (EPZ) (Doses are less than the Environmental Protection Agency's Protection Action Guides limits, e.g., 1 rem, at the site boundary). Note that this would result in a site boundary dose of less than 10% of the current requirements of 25 rem upon which the current regulatory framework is established.
    - **Very Small Doses** – Site boundary EPZs that are less than a few hundred meters. Note a site boundary EPZ could be as small as 1% the distance of a 10-mile EPZ for LLWRs upon which the currently regulatory framework was established.
- **Impacts to Land, Water and Atmosphere are small** – Use of a graded approach of acceptance criteria based upon different levels of potential environmental impacts would enable this criterion to be broadly applicable. Examples of various levels of potential impacts to the public are:
    - **Small Impacts** – Physical footprints, water usage and air releases that are on the order of 10% of existing large LWRs. This may be possible for advanced reactors with site boundaries that cover 30 acres or less of land.

[13] Reactors that could meet the criteria for Extremely Small Doses could enable business models and alternative regulatory approaches that go beyond those described in this paper. The AEA identifies in Section 103.f that for reactors where an accident would not result in an unplanned release of quantities of fission products in excess of allowable limits for normal operations, then the NRC is not required to include a condition in the license for immediate notification of the Commission. Note that normal off-site dose release to the public is less than 0.1 rem, which is less than 1% of the accident off-site dose limit of 25 rem dose limit, and a small fraction of the average annual dose of the U.S. public of 620 millirem.

- **Very Small Impacts** – Physical footprints, water usage and air releases that are on the order of 1% of existing large LWRs. This may be possible for advanced reactors with site boundaries that cover several acres or less of land.

- **Independence of Site Conditions** –Use of a graded approach of acceptance criteria based upon different levels of impacts of the site-specific conditions to the safety and environmental reviews would enable this criterion to be broadly applicable. Examples of various levels of potential impacts to the public are:

  - **Small Dependence on Site Conditions** – Bounding analyses with large margins in the safety and environmental conclusions for geotechnical, meteorological, flooding and other external hazards. Bounding analyses would avoid the need for additional analyses using site-specific data for most sites.

  - **Very Small Dependence on Site Conditions** – Use of features to establish a design that is not sensitive to the site-specific characteristics. For example, seismic isolations could create independence between the structure and soil. Similarly, an intermediate loop, between the reactor and the energy supply system, could create independence from the balance of plant such that regardless of what energy production system is connected to the reactor (e.g., electric generator, steam supply, hydrogen) it would be bounded by the safety and environmental conclusions for the design.

This paper makes two assumptions that are not in themselves acceptance criteria for the concept of an alternative regulatory framework, but were made to reduce the scope of regulatory topics that would need to be considered. These are: 1) the site is not located near a population center or densely populated areas (i.e., remote), and 2) there are considerations made for using the reactor for industrial applications (e.g., potential to leverage the industrial facility's infrastructure and workforce).

2.4 Specific Regulatory Issues and Solutions

The proposed solutions and approaches cover 31 issue topical areas that need to be addressed. Of these topics, about half have not been included in NRC efforts related to advanced reactors to-date, and of the topics that the NRC has been working to address for advanced reactors, many of those efforts have not considered the technological capabilities, new business models, concepts of deployment and operations, concepts of alternative regulatory approaches, or the solution ideas included in this paper. Other topics may also benefit from alterantive approaches for rapid high-volume deployable and other advanced reactors (e.g., decommissioning, population siting, quality assurance), but they are not included since they were not determined to need alternative approaches to enable rapid high-volume deployable reactors for remote applications.

Nearly all of these topics are expected to require changes to the regulations. Due to the broad range of topics and novel approaches being proposed, there are a large number of requirements that would need to be changed, eliminated, or added to modernize the NRC regulatory framework and achieve a more effective and efficient regualtory framework for advanced reactors, including RHDRA and other advanced reactors. Where possible, the Appendices identify specific requirements that would need to be changed, and in other cases where more regulatory analysis is needed, regulatory changes are identified at the Part or Subpart level.

2.4.1 Summary of Topic Areas and Functional Groupings

The topic areas are organized into four groupings of similar topics: 1) Licensing Process, 2) Concept of Deployment, 3) Concept of Operations and 4) Total Lifecyle. The set of the 31issue topical areas and their groupings is listed in Table 2-1.

Each topic area includes the following information at a high-level:

- **Priority (High, Medium, Low)** – All topics are very important to a more modern, effective and efficient regulatory framework for advanced reactors, including RHDRA. The priority assigned is relative to other topics included in this paper. High priority are those issues that provide the highest risk to enabling the business model, prevent significant investments needed to pursue the use of these technologies, and/or require a significant departure from prior NRC practices. Medium priorities are issues that are less challenging to overcome, and for which the regulatory risk is still manageable for the level of investments needed to pursue the technologies and business models. Low priorities are topics for which resolution is relatively straightforward, and for which a lack of a generic resolution would still be a manageable regulatory risk to applicants.

- **AR (Applicable, Non-Applicable)** – Identifies whether proposed approaches could be applicable to all advanced reactors, even if the approaches are graded, and are not exclusive to RHDRS.

- **RTR (Applicable, Non-Applicable)** – Identifies whether approaches used for non-power reactors (e.g., NUREG-1537) could be appropriate to apply or adapt to RHDRA and possibly other advanced reactors.

- **GL (Benefit, No-Benefit)** – Identifies whether an ability to use a General License would significantly benefit the pursuit of the proposed solution and regulatory approach toward enabling the business model.

- **AEA (Solution, Option, No-Need)** – Identifies whether a change to the Atomic Energy Act, or other Statutory Requirement is the necessary solution, or whether it is an option that could be beneficial. Solution means it is the proposed approach. Options means it is identified as a viable option, but is not proposed as the solution. No-Need means that it is not identified as a solution or other option.

- **Reg/Policy (Need, No-Need)** – Identifies whether the proposed approach needs changes to the regulations or establishment of a Commission Policy Statement.

Table 2-1: Summary and Functional Grouping of Specific Issue Topics

Topic Area	Priority	AR	RTR	GL	AEA	Reg/Pol
Group 1 (Licensing Process)						
1) Generically Resolved Environmental Considerations	High	Applicable	Non-App	Benefit	Option	Need
2) Design Approval Scope and Authorizations	High	Applicable	Non-App	Benefit	Option	Need
3) Construction Authorization Upon Docketing	High	Applicable	Non-App	Benefit	Option	Need
4) Inspections, Tests, Analyses and Acceptance Criteria	Medium	Applicable	Non-App	Benefit	Option	Need
5) Site License Scope and Purpose	High	Applicable	Applicable	Benefit	Option	Need
6) Streamlined Contested Hearing	High	Applicable	Non-App	Benefit	Option	Need
7) Elimination of Mandatory Hearing	High	Applicable	Non-App	Benefit	Solution	Need
8) Licensing Review Resources and Costs	Medium	Non-App	Non-App	Benefit	Option	No-Need
Group 2 (Concept of Deployment)						
9) Aircraft Impact Considerations	Medium	Non-App	Applicable	No-Benefit	Option	Need
10) Meteorology and Weather Data	High	Applicable	Applicable	No-Benefit	Option	No-Need
11) Geologic and Geotechnical	High	Applicable	Applicable	Benefit	Option	Need
12) Other External Hazards	Low	Non-App	Non-App	No-Benefit	No-Need	No-Need
Group 3 (Concept of Operations)						
13) Fire Brigade	Medium	Applicable	Non-App	No-Benefit	No-Need	No-Need
14) Operations Staffing	High	Applicable	Applicable	No-Benefit	Option	Need

Topic Area	Priority	AR	RTR	GL	AEA	Reg/Pol
15) Autonomous Operations	Medium	Applicable	Non-App	No-Benefit	Option	Need
16) Remote monitoring	Low	Applicable	Non-App	No-Benefit	Option	No-Need
17) Remote operations	Medium	Applicable	Non-App	No-Benefit	Option	Need
18) Cyber security	Low	Applicable	Non-App	No-Benefit	Option	Need
19) Physical Security	High	Applicable	Applicable	No-Benefit	Option	Need
20) Emergency preparedness	Low	Applicable	Applicable	No-Benefit	Option	No-Need
21) FFD/Access Authorization	Medium	Applicable	Applicable	No-Benefit	Option	Need
22) Radiation Protection	Medium	Applicable	Applicable	No-Benefit	Option	No-Need
23) NRC Oversight	Medium	Applicable	Applicable	Benefit	No-Need	Need
24) Annual Fees	Medium	Non-App	Applicable	No-Benefit	Option	Need
Group 4 (Total Lifecycle)						
25) Use of Contractors By Manufacturing Licensees	Medium	Applicable	Non-App	Benefit	No-Need	Need
26) Loading Fuel at Factory	Medium	Non-App	Non-App	Benefit	No-Need	No-Need
27) Testing at the Factory	Medium	Non-App	Applicable	Benefit	No-Need	Need
28) Features to Preclude Criticality	Medium	Non-App	Non-App	Benefit	No-Need	No-Need
29) Transport of Fueled Reactor	Medium	Non-App	Non-App	Benefit	No-Need	Need
30) Replace Modules at Site	Medium	Non-App	Non-App	Benefit	No-Need	No-Need
31) Storing Used Fuel at Site	Medium	Applicable	Non-App	No-Benefit	Option	Need

2.4.2 Detailed Discussions in the Appendices

This section provides an overview of the 31 issue topical areas addressed in this paper, including a discussion on the interconnection of these issues and integrations of the corresponding solutions. Several of these topics have previously been discussed by the NRC in work related to micro-reactors, manufacturing licenses or generally for all advanced reactors. However, this paper identifies additional, previously not considered, aspects of the these topics that merit regulatory consideration to fully enable innovation in advanced reactor technologies and their use in new business models.

Therefore, a fresh regulatory analysis and development of options for alternative approaches is warranted for all of these topics.

Details of these topics are included in the appendices of this paper with preliminary regulatory analyses to support NRC future work and engagement with stakeholders. Specifically, the following information is provided for each of these appendices (i.e., for each Specific Issue Topic):

1. **Issue Introduction**– This includes a description of the topic area, including the challenges with applying the current regulatory framework to RHDRA and other advanced reactors and the desired outcome that would enable more effective and efficient regulatory approaches for advanced reactors, including RHDRA, and enable new business models.

2. **Background** – This includes a discussion of the current regulatory framework, including the statutory requirements (as necessary), the NRC regulations, policy and guidance, and any rulemakings or other changes currently being pursued. The discussion focuses on the limitations of and challenges to applying the existing regulatory framework to RHDRA and other advanced reactors.

3. **Proposed Solution and Approach** – This discusses the proposed solution to the issue and the regulatory approach that would be more effective and efficient for RHDRA and other advanced reactors. The proposed regulatory approach discusses the regulatory changes that are expected to be needed to enable the proposed alternative approach, including statutory requirements (if necessary), the NRC regulations, policy and guidance, and any rulemakings or other changes currently being pursued. Finally, this identifies the acceptance criteria and licensing approaches that would need to be adopted by applicants to use the proposed alternative approach in a technology-inclusive, performance-based, risk-informed and graded approach so as to apply this as broadly as possible to all advanced reactors, but also tailor the approach to the unique aspects of RHDRA and other similar technologies (e.g., micro-reactors).

4. **Other Options for Resolution of the Issue** – This discusses other options that were considered and determined to be viable for addressing the issue, including discussion on why these other options are not proposed as the preferred approach. Typically, these other options are not preferred or recommended because they are less effective and/or efficient than the proposed approach, they would not be as comprehensive in addressing a broader range of advanced reactors, or they would require more time and effort to implement, as compared to the proposed option. The “No Action Alternative” is not discussed as it was determined that for all issue topical areas, “no action” (i.e., the status quo) would not be a viable approach as it does not address the limitations and challenges of the existing regulatory framework that prevents RHDRA and other advanced reactors from meeting the goals of the new business models.

2.4.3 Acceptance Criteria and Licensing Approaches

Acceptance criteria and necessary licensing approaches establish the applicability of each topic area. Each appendix identifies the acceptance criteria and/or licensing approach that is applicable to the use of the proposed alternative approach. The acceptance criteria and licensing approaches identified for each issue topical area generally align across the topics. The following is a discussion of a cross-cutting approach to these conditions that could be useful in creating a holistic and integrated alternative regulatory approach for RHDRA that would benefit other advanced reactors.

In most cases, the acceptance criteria and/or licensing approach identified is expected to be applicable to any advanced reactor technology or business model. For some issue topical areas, a graded approach is used so that meeting more stringent conditions will enable greater benefits in terms of effective and efficient regulation. In this way, the unique aspects of RHDRA and other similar advanced reactors can be most appropriately addressed, while also ensuring maximum applicability to all advanced reactors. Of the 31 topics, about 20 could be used by any advanced reactor and licensing approach, with only 14 having strict criteria that limit any applicability to the RHDRA technology capabilities and concept of deployment and operations described in Section 3.

<u>Acceptance Criteria</u>

The following are the acceptance criteria and applicability to advanced reactor technologies to be able to use the proposed approaches in the following Issue Topical Area Appendices:

- No Acceptance Criteria – Available to Any Advanced Reactor
    - 5 – Site License
    - 6 – Contested Hearing
    - 7 – Mandatory Hearing
    - 12 – Other External Hazards
    - 15 – Autonomous Operations
    - 16 – Remote Monitoring
    - 17 – Remote Operations
    - 31 – Used Fuel
- Graded Acceptance Criteria – Any Advanced Reactor, but Greater Benefits for Meeting More Stringent Criteria
    - 2 – Standardized Design Approvals
    - 4 – ITAAC
    - 14 – Operations Staffing

   - 18 – Cyber Security
   - 19 – Physical Security
   - 25 – ML Holder Use of Contractors
- Acceptance Criteria: Potential Consequences Similar to Non-Power Reactors
   - 9 – AIA
- Acceptance Criteria: Unique to Topic
   - 1 – Environmental Reviews (power and size)
   - 3 – Construction Authorization Upon Docketing (simple and rapid construction or ReLic)
   - 10 - Meteorology and Weather Data (site boundary EPZ)
   - 11 – Geologic and Geotechnical (site boundary EPZ)
   - 13 – Fire Brigade (size and automated features)
   - 20 – Emergency Preparedness (power based)
   - 21 – AA/FFD (Ops model based)
   - 22 – Radiation Protection (Ops model based)
   - 26 – Load Fuel at Factory (able to be transported fueled)
   - 27- Operational Testing at Factory (can transport fueled)
   - 28 – Features to Preclude Criticality (FPC) (can transport fueled and has FPC)
   - 29 – Transport of Fueled Reactor (can transport fueled and has FPC)
   - 30 – Replacing Fueled Reactors at Operating Site (has FPC)
- Dependent Upon Applicability of Other Topics
   - 8 – Licensing fees
   - 23 – Oversight
   - 24 – Annual Fees

Licensing Approach

The following are the licensing approaches, i.e., the use of prior NRC approvals to reduce the licensing timeline, to be able to use the proposed approaches in the Issue Topical Area Appendices:

- Any Licensing Approach – Not Dependent Upon the Licensing Approach
    - 7 – Mandatory Hearing
    - 30 – Replacing Fueled Reactor at Operating Site
- Graded Licensing Approach – Any Licensing Approach, but Greater Benefits for Meeting More Stringent Aspects of the ReLic Licensing Approach
    - 1 – Environmental Reviews
    - 2 – Standardized Design Approvals
    - 4 – ITAAC
    - 6 – Contested Hearing
    - 9 – AIA
    - 10 - Meteorology and Weather Data
    - 11 – Geologic and Geotechnical
    - 12 – Other External Hazards
    - 13 – Fire Brigade
    - 14 – Operations Staffing
    - 15 – Autonomous Operations
    - 16 – Remote Monitoring
    - 17 – Remote Operations
    - 18 – Cyber Security
    - 19 – Physical Security
    - 20 – Emergency Preparedness
    - 21 – AA/FFD
    - 22 – Radiation Protection
    - 31 – Used Fuel
- Licensing Approach: Must use the Full Suite of Tools in the ReLic Licensing Approach
    - 5 – Site License

   - 3 – Construction Authorization Upon Docketing (simple and rapid construction or ReLic)
   - 25 – ML Holder Use of Contractors
- Licensing Approach: Unique to Topic
   - 26 – Load Fuel at Factory (ML with Part 70)
   - 27- Operational Testing at Factory (ML with Part 50)
   - 28 – Features to Preclude Criticality (ML with Part 70 or Part 50)
   - 29 – Transport of Fueled Reactor (ML with Part 71)
- Dependent Upon Applicability of Other Topics
   - 8 – Licensing fees
   - 23 - Oversight
   - 24 – Annual Fees

3 TECHNOLOGIES AND BUSINESS MODELS

A central goal in developing the proposed approaches is to enable them to be used for, as broadly as possible, all advanced reactor technologies and business models. This is built upon the establishment of technology-inclusive, performance-based, risk-informed and graded approaches. This goal for broad/general applicability is balanced against the need to develop approaches that specifically enable RHDRA and other similar advanced reactors by addressing the unique considerations of those technologies, and concept of deployment and operations.

About 20 of the 31 proposed approaches are expected to be applicable to any advanced reactor. However, only one (Mandatory Hearing) is applicable to all advanced reactors equally. For the other 19 topic areas, the approaches are graded such that advanced reactors that meet more stringent conditions are able to realize greater benefits. The ouctome of these graded approaches is a consistent level of protection of the public health and safety, and the environment across a wide range of technologies, and concepts of deployment and operations. In this way, the unique aspects of RHDRA and other similar advanced reactors can be most appropriately addressed, while also ensuring maximum applicability to all advanced reactors.

While this paper is applicable to all advanced reactor technologies and business models, there is a particular focus on the technologies and concepts of deployment and operations that are described as rapid high-volume deployable reactors for remote applications (RHDRA). RHDRA are a subset of the types of advanced reactors being developed, and the intended use cases for the variety of nuclear technologies. Typically, nuclear technologies are categorized by size (e.g., large, small and micro), in terms of thermal power rating, land use, mass and volume dimensions of the reactor system, etc., or by moderator type (e.g., light-water reactors, and non-water cooled – including high temperature gas, liquid metal and molten salt). It is anticipated that rapid high-volume deployable reactors will be a subset of the advanced reactors that are small in size and source term. While many may call these micro-reactors, which the Idaho National Laboratory (INL) taxonomic guide[14] defines as less than 50 MWe in size, there may be some micro-reactors that are not capable of meeting the conditions for rapid high-volume deployment and there may be some designs that are not micro-reactors that could meet those conditions. Similarly, many types of reactors could be used for remote applications, and rapid high-volume reactors could be used for applications that are not in remote locations. Figure 3-1 is a simple depiction of the focused scope of this paper within the broader environment of nuclear reactors.

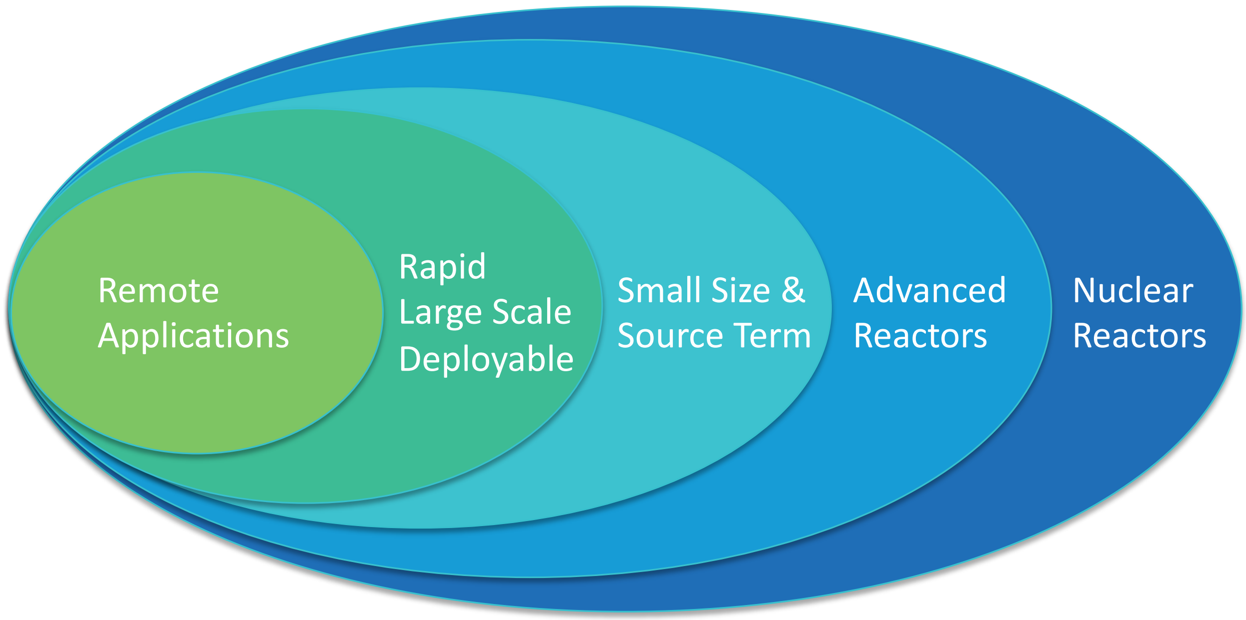

Figure 3-1: Applicability of the Regulatory Approaches for Rapid High-volume Deployable Reactors

The focused scope of rapid high-volume deployable reactors in remote applications is chosen in order to provide a focus for developing alternative regulatory approaches, since it has a well-defined business model, with concept of deployment and operations, that require technological capabilities that can be specified in sufficient detail. A well-defined business model enable the clarity needed to consider alternative regulatory approaches. However, it is important to recognize that these alternatives could be applicable beyond the specific business model discussed within this paper, and the broader applicability should be considered as alternative approaches are developed.

Rapid high-volume deployable reactors are designs that are expected to be able to be deployed in timescales of months (rather than years as is the case for large light-water reactors and other advanced reactors), and in volumes of hundreds to thousands with deployment rates measured in number per days (rather than number per years as is the case for large light-water reactors and other advanced reactors). The technology and business models for these types of designs are rapidly maturing, with many design vendors engaged in preapplication reviews, and the first applications for major licensing actions are expected to be submitted to the U.S. Nuclear Regulatory Commission (NRC) as early as 2024. These technologies are being considered by numerous companies for a range of traditional electricity generation applications and use in industrial applications that also require heat such as oil and gas production and development, mining and extraction, and chemical processing.

[14] https://inldigitallibrary.inl.gov/sites/sti/sti/Sort_64448.pdf

Potential customers in the markets with needs for rapid high-volume deployable reactors have expressed that the NRC licensing processes and impacts of regulation are the chief risks to meeting the business requirements and being a viable alternative for power generation needs. If the NRC licensing and regulatory risks are adequately addressed, then nuclear energy will, for the first time, be a viable option for many new end use cases, in particular for remote industrial applications. Furthermore, in addressing these licensing and regulatory risks in a way that enables the business model for remote applications may also introduce alternative approaches that could help to make the NRC regulatory framework more effective and efficient for other types of designs and use cases.

3.1 Business Model

This section discusses the business model for commercial deployment of this reactor class, which is established to meet the market and customer business case requirements. The business model includes three major components that are interrelated and must be developed in an integrated manner with the objective of achieving the business requirements. These three elements are: 1) the characteristics of the technology, 2) the concept of deployment and operations, and 3) the regulatory paradigm, which includes the regulatory framework and the statutory requirements that the regulatory framework is designed to implement.

The approaches discussed in this section reflect those being developed for a novel business model. The current NRC regulatory framework does not enable this business model, and therefore this paper proposes concepts for an alternative regulatory framework that would enable this business model.

3.2 Market and Customer Business Case Requirements

Many advanced reactors are being designed for rapid high-volume deployment that are well suited to serve the power needs for several markets that currently do not have access to clean, reliable, resilient and affordable energy. Many of these markets are in remote locations, such as upstream oil and gas operations, mining operations, and communities in the arctic and on islands. These locations are characterized by no or limited access to grid-based power supplies, locations away from population centers, limited access to human and technical resources, and challenging logistic considerations for access to and from the end user's energy need.

Rapid high-volume deployable advanced reactors are potential options to power secure micro-grids for critical infrastructure such as defense installations and emergency response facilities, some of which may be in densely populated areas. This paper focuses remote applications, such that potential alternatives to population siting criteria, (e.g., population density distance and population center distance), and considerations for integration with the electric grid, are not considered. Therefore, all of the proposed approaches are also applicable to non-remote applications, although non-remote applications may also have additional considerations such as population siting requirements. Industrial applications are also given special consideration in that the co-location of advanced reactors with industrial facilities that they serve creates new possibilities (e.g., potential to leverage the industrial facility's infrastructure and workforce). Where appropriate, the regulatory approaches discuss the special considerations of co-location with industrial applications. Co-location could either be reactor siting within the footprint of an existing industrial application or locating in a footprint directly adjacent to the application; both arrangements consider the possible impacts between facilities due to proximity. Furthermore, many of the proposed approaches could also be applicable to advanced reactors that follow the traditional deployment models and tend to be larger in size than the reactors that are rapid high-volume deployable, and for those regulatory topics this broader applicability is noted.

Rapid high-volume deployable advanced reactors operate at temperatures that can attractively produce both electricity and usable heat (cogeneration), or can be used exclusively to provide one or the other. The electricity or high-temperature heat from these reactors can also be used to desalinate and purify water, and to generate hydrogen. Heat can be used for industrial applications such as oil refining and chemical processing, and in colder climates, can be used for district heating of homes and businesses. The use of these reactors to produce heat for industrial processes or district heating can improve the utilization of the reactor in applications with variable demand for electricity, thus increasing the market potential for these reactors.

Rapid high-volume deployable advanced reactors are being designed to demonstrate resilience and protection against severe natural phenomena as well as man-made physical and cyber security threats, with the ability to operate in island-mode and to have black-start capabilities, which means they can initiate recovery from a loss of power to the site. These reactors can produce power on-demand, operate independent of weather conditions, and include the ability to automatically vary their power output to match changes in demand. Thus, these reactors are an ideal generation source for uses that need to operate independently from the electric grid to supply highly resilient power for critical loads under normal and emergency conditions.

The market potential for rapid high-volume deployable advanced reactors is very large. While a comprehensive market opportunity study has not been published, some estimate that the market size could be in the several hundreds to tens of thousands (multiple 10,000s) units operational by 2050. Potential customers are looking for energy sources that are reliable, affordable and clean, and advanced nuclear reactors could meet those needs.

In order to achieve the rapid high-volume deployment of advanced reactors to meet the potential demand from these markets and applications, the following business case requirements are of particular focus:

1. Deployment in less than 180 days (6 months) from the time that the site is identified to the time that operations and energy production begins; and

2. Regulatory costs are less than 1% of the total costs, as measured by total up-front capital costs, and annual on-going operations and maintenance (O&M) costs.

While other conditions may exist that enable such a deployment scenario, the business case requirements provide an initial bounding set of constraints within which business, logistic, regulatory, and operational activities must be accomplished.

3.3 Technology Description

Markets and customers that need rapid high-volume deployable energy generation sources have technology options. This section describes the rapid high-volume deployable reactors that and the other technologies that they are considering.

3.3.1 Rapid High-volume Deployable Nuclear Reactors

Rapid high-volume deployable reactors are likely to be very small, in comparison with other advanced reactors. For example, the INL taxonomy defines micro-reactors as less than 50 MWe with some designs being as small as a few megawatts-electric. This power output, a reflection on the potential source term, is 100 to 1,000 times smaller than a typical large light water reactor, and about 10 to 100 times smaller than advanced SMRs. Rapid deployable high-volume reactors are being designed to be small enough to fit on the back of a tractor trailer, potentially including not just the reactor itself, but also the power conversion system. When placed in the operating location, these reactors can be housed inside buildings with footprints measured in thousands of square feet.

Rapid high-volume deployable reactors have a unique combination of design attributes that make this class of reactors differentiated in their concept of deployment and operations. The following are typical characteristics of rapid high-volume deployable reactors, though it is noted that not all reactors have all of these characteristics:

- Substantially lower power rating than that of existing licensed power reactors (e.g., on the order of single or tens of MWe);
- Smaller physical dimensions and weights when assembled;
- Designed for transportability as an integrated system or packages of systems;
- Require minimal assembly at the end-user's operating site;
- Modularized systems and components that can be fabricated, assembled, and tested in factory settings at a high degree of standardization;
- Passive and inherent means of performing safety and protection functions;
- Reduced complexity and improved operability to enable reduced or no human interaction or interventions;
- Smaller site footprints and deployment/operational impacts on the environment;
- Resilience to external hazards that ensures higher reliability in operation and large margins to safety;
- Designed for progressive scale-up in deployments with multiple units at a site possible;
- Capable of delivery, emplacement, commissioning, and transition to operation on the order of weeks or less;
- Reduced or limited hazards that could affect workers, the public and the environment;
- Potential to fuel reactor modules at the factory; and
- Designed for removal of used systems at the end-of-life to reduce or eliminate the need for extended onsite storage.

- Fail-safe to shut down automatically
- Decay heat removal provided entirely by passive and inherent features (e.g., long term passive cooling with natural forces to sufficiently transfer decay heat indefinitely with the loss of any fission product barriers)
- Accident and proliferation resistant fuel with enrichments below 20% U-235
- High fission product retention
- Operator actions are not needed to assure safety of the reactor
- Operational simplicity with very few active SSCs, instruments or controls

Rapid high-volume deployable reactors are unlike current operating nuclear plants or other advanced small modular reactors. In fact, these designs are much more similar – in terms of size and source term – to non-power reactors (also known as research and test reactors) than they are to commercial power reactors. However, unlike the non-power reactors that operate safely today, this class of reactors is being designed with enhancements to further protect the public health and safety based on advancements in technology, and safety and security design approaches.

Nuclear technologies that are very small in size and source term enable new business models in three main ways: (1) they will utilize a high degree of factory construction; (2) the customers for smaller reactors may wish to be only energy users, not energy sellers; and (3) the reduced costs of these reactors allow a vendor to build them before receiving customer orders. Smaller reactors will require little, if any, on-site construction, and in some cases may be transported in a fully assembled configuration. For customers that wish to be only energy users, the advanced reactor developers also may be the reactor owners and operators, supplying energy under power purchase agreement. Having pre-fabricated reactors ready to ship as soon as an order is placed would significantly reduce time to market, a key consideration for many customers.

Advanced reactors can produce power on-demand and operate 24/7, 365 days a year and are being designed to protect against severe natural phenomena as well as man-made physical and cyber security threats, and many are being designed with the ability to operate in island-mode and to have black-start capabilities, which means they can initiate recovery from a loss of power to the site.

The operations and maintenance of advanced reactors are expected to be highly simplified through the use of automatic and/or remote operations/monitoring, the minimization of structures, systems and components (SSCs), and the maximization of the reliance on inherent and passive safety features. Advanced reactors can include the ability to vary their power output to match changes in demand. This attribute makes micro-reactors suitable to serve changing loads and compatible with intermittent sources of energy like renewables.

Novel Manufacturing and Logistics Concepts

Rapid high-volume deployable reactors are being developed to achieve the following general objective:

Prospective Manufacture of Reactor Modules without a Customer Order – In the past, some SMR developers have discussed manufacturing reactor modules prospectively and storing those modules until a specific customer (and hence a host site) is identified. The NRC's current Part 50/52 regulations permit such an approach under an ML, although we encourage the NRC to clarify its position regarding the ability of a DC or SDA holder to prospectively manufacture reactor modules prior to receiving an order from a customer either with a license or that has applied for one (COL or CP).[15] Regardless, this paper discusses options for the Part 53 ML requirements to ensure that an ML is a possible pathway to prospectively manufacture reactor modules up to and including fully assembled reactors.

Fully Assemble an Operable Reactor at the Factory – Some advanced reactor developers, especially micro-reactor developers, will fully assemble the reactor at the factory. In this context, "fully assemble" means the assembly of all the structures, systems and components of an operable reactor module, excluding reactor fuel. If a particular reactor requires a significant amount of on-site construction before the reactor could operate, then it would not meet the definition of "fully assembled." Thus, the developer may become the ML holder and be responsible for the factory fabrication and assembly activities. Alternatively, the developer may contract with an appropriate manufacturer who will manufacture and assemble the reactor, i.e., "build to print." The details of which entity (developer or manufacturer) would be the ML holder would be addressed through contractual arrangements and application to the NRC for the ML. We emphasize that in this scenario, there would be no fuel loaded into the reactor and, in fact, there would not be any fuel at the factory.

This approach would allow the licensee to own or control (e.g., through subcontracts) all necessary facilities for the manufacture and testing (unfueled) of the reactor. (These facilities may or may not be co-located.) Assembly in a factory setting would support conducting ITAAC or ITAAC-like inspections and tests to ensure the reactor has been fabricated and assembled consistent with the license and applicable regulations. Security requirements for these facilities would be consistent with security for commercial manufacturing facilities supporting the nuclear industry. Fitness for duty requirements also would be consistent with those used in commercial manufacturing facilities.

Some designs are being developed with the capabilities to load, remove and reload fuel at the operations site. Designs that are not including the capability to load, remove and reload fuel at the operations site are being developed with the following capabilities.

Fuel a Fully-Assembled Reactor at the Factory – While not feasible for large reactors, fully assembling and fueling a reactor module at the factory is envisioned for a transportable reactor, e.g., a micro reactor, which eliminates onsite fueling. This activity can be performed under a Part 70 *possession license*, which may draw in other requirements, e.g., Parts 26, 30, 40, 70, 73, 74 and 75, etc., under which the primary function is to assure radiological safety and that the reactor is maintained subcritical at all times. Performing reactor fueling at the factory would be more efficient for reactors that are manufactured in large numbers and reduce the burden of doing these activities in numerous remote locations. This activity is separated from critical testing at the factory and transporting a fueled reactor to the operating site (separate activities described below).

Transporting a Fueled Reactor from the Factory – Some companies may wish to transport a fueled reactor to the site at which it will be operated. This will trigger other requirements, including those in 10 CFR Part 71. The developer may wish to transport the fueled reactor by barge, rail, truck, and possibly by air. The transport of a fueled reactor is intended to reduce field fueling activities and risks, and to eliminate or minimize the amount of testing and inspection required at the operating location to

[15] It is noted that the NRC's exception to ASME N-883 may prevent these activities even though they are permitted by regulation. See ML21208A44.

facilitate more rapid reactor deployment. For those situations where the ML holder also is the OL/COL holder, control of the reactor once it is at the approved site (including any storage before installation) would be consistent with the terms of the respective licenses. The OL/COL would govern any interim storage of the reactor on the approved operating site and related security requirements. If the ML holder and OL/COL holder are different entities, then provisions for transferring control of the reactor from the ML holder to the OL/COL holder would be addressed by contractual agreement. The ML holder would be required to ensure the safety and security of the reactor until control of the reactor is transitioned to the OL/COL holder. Any interim storage site, if different from the approved operating site, would require prior approval by the NRC based on relevant safety, security, and environmental considerations.

Defueling and Refurbishing Operated Reactor at a Factory – Some developers (especially those that pursue a multiple location approach) may want to return the reactor to a refurbishment center to enable fuel reloads and reuse of SSCs that have a design life greater than the fuel cycle and remain operable. For example, reactor modules that may be returned to the refurbishment center, refueled and returned to the original operating site or transported to a different operating site. This scenario could also contemplate reactor modules that are leased for use (e.g., for emergency response operations). This scenario raises regulatory issues associated with the transport of a reactor containing used fuel. The refurbishment center may or may not be the original factory at which the reactor was assembled. The refurbishment center likely would remove the used fuel and reload with new fuel. (Note that some designs have fuel that will last 10 to 20 years before refueling is required.) However, there may be some approaches that involve fuel unloading and loading at the operating location. The refurbishment center may also perform routine reactor maintenance, but doing so would be pursuant to the OL/COL, not an ML. For refurbishment centers that remove used fuel, interim storage of used fuel may be necessary, although this would be governed by a Part 72 license and not part of the ML. Finally, the refurbishment center might decommission the reactor. While the refurbishment center concept offers a number of advantages, some organizations may choose a more traditional approach, whereby the reactor would be defueled and decommissioned at the operating site, and the used fuel and defueled reactor would be transported offsite. These options should be available to the OL/COL holder.

Some designs are being developed with the capabilities to perform criticality and power ascension testing at operations site. Designs that are not including the capability to perform criticality and power ascension testing at operations site at the operations site are being developed with the following capabilities. Some designs are also being developed to be relocatable from site to site.

Testing a Fully-Assembled Reactor at the Factory – After fully assembling an operable reactor module at the factory, some developers may wish to perform critical (i.e., zero-power physics) and/or some degree of power ascension testing (also termed operational testing). We distinguish this activity from the above-described activities, which do not include control manipulation and criticality testing. Enabling this type of testing would clearly require significant changes from the existing regulatory framework and facilities, controls, and oversight. In fact, under the current regulatory framework, such activities generally require a utilization facility license, since the criticality prevention requirements for a Part 70 possession license (which governs the licensing of special nuclear material) would specifically preclude this type of testing. Thus, this activity would need the utilization license to either be included with the ML or obtained through a separate and limited Part 53 operating license. Fueling and testing a reactor involves a number of NRC regulations, which may include Parts 26, 30, 40, 55, 70, 73, 74 and 75. The benefit of performing fueled criticality tests at the factory is that such tests could be performed more efficiently for reactors that are manufactured in large numbers, thereby reducing the burden of doing these activities at numerous separate locations. Past precedent for these kinds of activities exists through the use of test reactor or critical experiment licenses.

Testing in a factory setting also would permit addressing ITAAC or ITAAC-like testing and inspection requirements. Performing these ITAAC or ITAAC-like tests and inspections, combined with those that would be conducted in fully assembling the reactor, would reduce the scope of on-site inspection and testing activities. These activities may be needed for the first unit, first several units, or for each unit to address an ITAAC or ITAAC-like testing or inspection requirement. This activity is separated from transporting a fueled reactor to a site (see discussion above), since some developers may wish to do fueled testing at the factory but not transport a fueled reactor (due to the desire to streamline transportation or to keep only a single set of fuel on-site that is used to test multiple reactors). Another option would be to fuel the reactor at the factory but not perform any criticality or power ascension testing, deferring that testing until after the reactor has been installed at the approved site.

Multiple Operating Locations – Developers of advanced reactors that require very little site infrastructure to operate may want the ability to move the reactor to an alternate site one or more times during the lifetime of the reactor: a mobile nuclear power plant versus a stationary power plant. For example, a micro-reactor that could be operated for 60 years might operate at mining site X for 30 years, and then be moved to mining site Y to operate for an additional 30 years. In another case, the micro-reactor might be moved to a new location every 5 years. This “Multiple Location” scenario would incorporate site-specific licensing actions and transportation between sites. Some scenarios that would envision using micro-reactors for multiple operating locations, like emergency response purposes, will likely need even shorter deployment timelines than those considered in this concept paper. This is not intended to be an exhaustive description of other potential deployment models, and it is acknowledged that other use cases, such as in marine environments, are being envisioned by industry.

3.3.2 Alternative Technologies

The market and customers have other options beyond nuclear for electric power, heat generation, and overall reductions in their carbon footprints. These include:

Fossil Fuels – Diesel generators and natural gas plants have traditionally, and currently, been used to provide heat and electricity to remote applications. The challenge with these technologies is the increasing requirements to decarbonize the energy sources by the end-users, coupled with the difficulty and costs of making these sources zero carbon-emitting. Notably, there is some uncertainty regarding the total system costs and effectiveness of abatement technologies such as carbon capture, utilization, and storage. Thus, many of the remote applications are motivated to consider nuclear energy in response to plans to move away from fossil fuel generation. Many end users in the industrial application market have experience with the timeliness and schedule confidence associated with permitting requirements for fossil fuel-based generation sources (e.g., air or water use permits by state and/or federal authorities) that are different than those associated with nuclear power and informed the business requirements defined earlier in this paper.

Renewables – Wind and solar have become some of the lowest cost options in the market, but do not provide the reliability that is needed for remote applications. Adding battery backup (or other energy storage features) and overbuilding capacity to provide the desired levels of reliability appear to be cost prohibitive. Furthermore, the land use needed to achieve the needed reliability appear to also be unfeasible due to constraints on land availability and/or environmental impacts. Geothermal is a promising technology, but is still emerging, with unknown costs and reliability, and geographic limitations on where it could be deployed. While the permitting regime for renewables is different than for fossil fuel-based generation, there are elements of renewable deployment that informed the business requirements defined earlier and could make nuclear energy a more acceptable and attractive solution for their needs.

In comparison with these alternatives, nuclear energy meets more of the market and customer business requirements for be clean, reliable, resilient, safe, timely and cost-effective energy solution.

3.4 Concept of Deployment

The concept of deployment focuses on the timeline for deployment and logistics activities that occur leading to site identification and the subsequent activities leading to commercial operations. This section describes the interfaces of the corresponding NRC licensing process, including the corresponding NRC regulatory costs and timelines.

3.4.1 Deployment Stages and Schedule

The deployment timeline for a rapid high-volume deployable reactor is expected to achieve the 180 day or less business case requirement.

Prior to Site Selection

The rapid high-volume deployment business model is expected to include four major features that will enable a schedule of 180 days or less from the point of site selection to operation. These are:

Fully Manufacturable Reactor – The reactor is capable of being fully manufactured prior to identification of the operating site and submittal of the site license applications. A fully manufactured reactor will utilize the NRC’s Manufacturing License (ML) or Design Certification (DC) processes, and is enabled by designs for which the reactor and primary systems (i.e., nuclear island) are self-contained and able to be transported as a single unit to the site. Some designs may be fueled and made fully operational at the factory, while other designs may be able to be fueled and made operational at the site during the emplacement and commissioning activities. See Section 3.3.1 for more details on the technology description. It is presumed that any manufacturing, assembly, and integration activities to be executed in a factory setting will be completed within an acceptable timeframe to support the logistics for transport and emplacement at the operating site per schedule (i.e., hold points, approvals, etc., fit within or are not constrained by the 180-day deployment target).

Site Independence – The characteristics of these designs that enable rapid deployment are described in Section 3.3.1, and are expected to enable the NRC safety and environmental reviews to be completed prior to the selection of specific sites in a generic manner and to a broadly bounding site parameter envelope. In this way, the NRC review is a confirmation of a specific site utilizing the approved design focused on a verification that the site characteristics conform to the conditions of the approved design, without the introduction of any new or unreviewed safety or environmental considerations.

Use-Case Independence – The characteristics of the design are also expected to enable the NRC safety and environmental reviews to be completed prior to the identification of the specific use-case. A use-case is defined by the type of energy product(s) produced (e.g., electricity, heat, hydrogen, or a combination) and the specific use of those energy products (e.g., oil and gas extraction, mining operations, military installation resilient power). This approach will establish in the design approval the conditions for separating the safety and environmental impacts of the scope that requires NRC approval (i.e., nuclear island) from the scope that does not require NRC approval (i.e., energy island). In this way, the NRC review of the specific use-case in the site license application may be focused on a verification that the site conforms to the conditions of the approved design, without the introduction of any new or unreviewed safety or environmental considerations.

Site Selection Process – The site selection process for the rapid high-volume deployment model is expected to facilitate 1) the fabrication of the fully-manufacturable reactor prior to site selection, and 2) pre-application interactions with the NRC for the site license application. As an example for the oil and gas up-stream extraction use-case, there would be a down-selection from a wide range of potential sites to the specific site over several to many months prior to the site-selection decision. In this example, while it is known that generally there will be future deployments in the Permian Basin the site locations and timing of those locations are not known today. Approximately 18 to 24 months or more prior to site selection, the Sub-Basin (still a large area) will be selected for business operations and at this time the future need for power would be known, such that the ordering of long-lead materials may begin. At least 12 months before the site selection, the Field (a much smaller area) will be selected which will enable collection of site characterization information (e.g., core borings) leading up to a specific site being identified (exact footprint).

This concept of deployment can facilitate pre-application interactions with the NRC, if necessary (e.g., Owner or Field that has not previously been licensed by the NRC). For owners and/or general locations that have previously been licensed (i.e., site characteristics similar to those previously licensed for the design) it is expected that pre-application interactions can be limited to a notification of intent that informs the NRC of the plans for deployment, including the owner, general location, design and schedule so that the NRC can plan resources. Some owners may have a long term plan for rapid high-volume deployments of reactors that they will share with the NRC to facilitate even longer range planning of NRC resources to review multiple site licenses, or possibly even to approve a general area license for which the specific site can be identified and reported to the NRC later as part of a license condition.

<u>After Site Selection</u>

The rapid high-volume deployment business model is expected to include five stages of reactor deployment to the location of operation after the site has been selected that will enable a schedule of 180 days or less from the point of site selection to operation. These are:

Mobilization and Site Characterization (1 month) – Once the site has been selected the owner will immediately begin to mobilize site operations to execute local characterization activities for the site-specific design finalization, and to confirm that the site conditions are in conformance with the conditions of the approved design (ML or DC). Most site characterization data is expected to come from reliable generally and readily available data (e.g., USGS and NOAA) or from other specifically collected data from the site exploration activities that occurred during the site selection process. For industrial sites, such as oil and gas extraction, there may be a significant amount of data from geological investigations for the chosen site that were performed during exploration. Therefore, site characterization, which traditionally has taken 24 months or more, is expected to be possible in 1 month or less for rapid high-volume deployable reactors. The mobilization is also expected to bring equipment to the site that will be used to prepare the site for assembly of the structures.

Site Preparation (1 month) – Site preparation includes any site grading and earth works to prepare the site for the assembly of the site structures. This work would not require NRC prior-approval to perform since it would not have any impact to the NRC safety and environmental considerations in the design approval (ML or DC). Site preparation would include preparing a site assembly lay-down area and the pre-staging of the structural modules and other materials used for the site structures, some of which may be safety-related. This scope is intended to be within the existing definitions of preconstruction.

Site Assembly (2 months) – There are expected to be very few site structures (e.g., concrete pads and buildings) which are also expected to be very simply and modular in nature, such that they could be assembled in 2 months or less. It is expected that the approved design (ML or DC) would have a safety design such that much of the structures would not be safety-related. It is also expected that the NRC approval of the design would approve safety-related site assembly, and delivery and emplacement of the reactor at the site (e.g., a general Limited Work Authorization). In this way, the NRC approved design (ML or DC) would include conditions that the applicant would demonstrate in the site license application, the NRC would verify during the application acceptance review, and the NRC would grant a specific LWA for the site when the application is accepted and docketed.

Delivery and Emplacement (1 month) – After the site structures are assembled, the reactor will be delivered to the site and emplaced in its location. Emplacement includes the separate and integrated systems testing that enables transfer of control from "construction to operations," and the pre-operational testing (hot functional test), which verify that the reactor has been installed correctly and are able to operate according to the NRC design approval (ML or DC). There may be considerable variability in how designs establish their structures and the emplacement of the reactor. Some designs may have an above-ground building with the reactor delivered on a skid that is bolted on a concrete pad, other designs may emplace the reactor below-grade on a pedestal, other designs may deliver a reactor that will remain in the ISO-container in which it was shipped without a surrounding building, and there could be many other variations in the design of the site structures. All designs are expected to deliver the reactor; that includes all systems and components included in the nuclear island in a single truck shipment. Some designs may include the energy island (energy conversion system) and control and monitoring system on the same truck that delivers the reactor, while other designs may have separate modules that are delivered on multiple trucks. While there is room for considerable design variations, in all cases, it is expected that the delivery and emplacement of the reactor will be simple and quick, requiring very little site infrastructure to support lifting, moving and emplacement activities.

Commission and Startup (1 month) – Once the NRC gives final approval and authorization to operate the reactor, the licensee may begin the commissioning and startup of the reactor. These activities focus on fuel loading and start-up testing. Some designs will be delivered with the reactors fueled, and other designs will fuel the reactor on site after emplacement. For designs delivered with fuel loaded, the commissioning activities will include the removal of any components that were installed at the factory to prevent criticality. For designs that are to be fueled at the site, the commissioning activities will include fuel loading. The start-up testing is focused on the testing for nuclear physics and power output, such as criticality, low power and power levels greater than 5% of total rated power. The commissioning will test the operation of the controls (including automatic, and remote monitoring and operation) and protection equipment to verify that they operate consistent with the approved design. Commissioning will also obtain any data needed to calibrate the instrumentation and control system, and verify operations withing the technical specifications. Once the commissioning and startup tests are complete, the reactor may be used for full operations and delivery of the energy products for the intended use-case. While the commissioning and startup traditionally has taken around 6 months, it is expected that rapid high-volume deployable reactors can perform these activities in less than 1 month due to their small size and simplicity.

3.4.2 NRC Licensing

The concept of deployment is dependent upon several milestones in the NRC process for the site license. Currently the NRC licensing process is complex, including many steps and features that would not be necessary for a rapid high-volume deployable reactor. The following are the major considerations of a licensing process for this business model, with the details of the simplification of the NRC licensing process described in Section 2, and several of the identified Regulatory Topics. The following illustrates the licensing process that is expected to be enabled by rapid high-volume deployable reactors, and which will be needed for reactors that could be deployed in the 100s per year, in order to ensure that the NRC reviews are effective and efficient, in that they provide reasonable assurance of adequate protection of the public health and safety while applying resources to the most safety significant activities regulated by the NRC. As technology continues to improve, there is a potential that the use of AI could enable the applicant and NRC to more effectively and efficiently prepare, review and approve applications.

Application Preparation and Pre-Application Engagement (1 month) – The preparation of the application has traditionally taken 12 to 24 months, and is expected to take 1 month or less for rapid high-volume deployable reactors. The major factor for the schedule reduction is that the design approval (ML or DC) is expected to address the safety and environmental considerations, establishing a site parameter envelope for the conditions that must be met by the site. In this manner, the design approval would have already performed the safety and environmental analyses necessary for a site that conforms to the site parameter envelope. Furthermore, these analyses depend on site specific characterization data (such as 2 years of weather data) in order to be completed. Thus, it is the site characterization, and site-specific safety and environmental analyses that require most of the traditional 12 to 24 months. Moving almost all of these activities into the design approval greatly reduces the scope and volume of information in the site-specific application. Most site characterization data is expected to come from reliable generally available data (e.g., USGS and NOAA) or from other specifically collected data from the site exploration activities that occurred during the site selection process. A site license application that focuses on the verification of conformance to the already established site parameter envelope in the design approval will avoid the need for additional site specific safety and environmental analyses. It is expected that pre-application engagement could be completed within this month to facilitate the 4 months or less (possibly as little as 2 months) for the NRC to perform the acceptance review, verification review and issuance of the license. Therefore, the application preparation for rapid high-volume deployable reactors can be completed in less than a month.

NRC Acceptance Review (1 month) – The NRC has established a target for a 3 month application acceptance review, which begins upon NRC receipt of the application and concludes with the NRC acceptance and docketing of the application, and is expected to take 1 month or less (possibly as little as 15 days for applications for a licensee or site previously approved by the NRC) for rapid high-volume deployable reactors.[16] An application for a site license for a rapid high-volume deployable reactor is expected to be focused on the verification of conformance to the site parameter envelope in the design approval. Therefore, it is expected to deviate from the traditional site-specific license applications for

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[16] The NRC may also extend the application acceptance review if supplemental information is needed to perform the review, or reject the application if it is does not meet the acceptance criteria. However, for the purposes of describing the NRC licensing process, it is assumed that the application is complete and meets the NRC's criteria for acceptance.

which the NRC has established a 3 month schedule, since a site license application for a rapid high-volume deployable reactor will 1) have had the safety and environmental considerations previously reviewed and approved by the NRC as part of the design approval (ML or DC), 2) not introduce any new or unreviewed safety or environmental considerations, and (therefore) 3) likely be less than 100 pages, whereas typical applications are 6,000 to over 10,000 pages. The NRC receipt of the application would also initiate the NRC Contested Hearing Process, which given the nature of verification of conformance to the safety and environmental considerations included in the previously approved design, can be expedited and simplified, to enable it to be completed at the same time, or within 7 days after, the NRC Verification Review is completed. As noted above, the applicant will be performing site preparation (not requiring NRC prior approval) during this phase, and the NRC acceptance and docketing of the application will include authorization to perform safety-related assembly, delivery and emplacement (e.g., through a generic Limited Work Authorization included in the design approval).

NRC Verification Review (2 months) – The NRC has established a Generic Review Schedule[17] of 30 months for a Combined Operating License (Part 52), and 36 to 42 months for an Operating License (Part 52). Recently, the NRC completed the Kairos Power Hermes construction permit review (safety and environmental) in 14 months. However, it is expected that the NRC review can be performed in 2 months or less (possibly as little as 20 days for applications for a licensee or site previously approved by the NRC) for site license application that meets the above expectations for a rapid high-volume deployable reactor. This is because the NRC review will not be a traditional safety and environmental review, since those considerations would have been completed with the design approval, but rather the site license review would be a verification that the site conforms to the conditions of the design approval (i.e., the site parameter envelope), the generic environmental approvals (e.g., a Categorical Exclusion or a Generic Environmental Impact Statement), and prior NRC approvals (e.g., in a prior license approval or in Topical Reports) for the licensee qualifications and programs (e.g., Financial Qualification, Quality Assurance Program). It is noted that the applicant will be performing safety-related site assembly, delivery and emplacement of the reactor during the NRC verification review, and the NRC will be providing oversight and inspection of these activities, commensurate with their safety significance.

NRC Final Approval (1 month) – The NRC Final Approval is the approval by the Commission, and the administrative activities, to issue the license. Traditionally this has taken 4 to 6 months, though in some cases it has taken longer. It is expected that a site license application that verified conformance to a prior approved design, such that the site license did not include any additional or new safety and environmental considerations, and would be 10% or less of the volume of a traditional site license application can be performed in 1 month or less (possibly as little as 15 days). It is noted that the issuance of the license 1 month prior to operations will allow sufficient time for the commissioning and startup.

3.4.3 Deployment Costs

The April 2019 NEI report, “Cost Competitiveness of Micro-Reactors for Remote Markets,”[18] establishes a basis for the costs of designs that are expected to be rapid and high-volume deployable. It is noted that an update to that report is on-going to reflect a greater maturity in the technology and other factors (e.g., inflation and recently enacted tax credits) that could show expected costs today are lower than those projected in 2019. Thus, the following discussion on costs is expected to provide a

[17] https://www.nrc.gov/about-nrc/generic-schedules.html
[18] https://www.nei.org/CorporateSite/media/filefolder/resources/reports-and-briefs/Report-Cost-Competitiveness-of-Micro-Reactors-for-Remote-Markets.pdf

reasonable basis for understanding the business need for regulatory costs less than 1% of total costs. In this manner, costs are separated into two categories:

1. Up-Front Capital Costs

2. Annual Operations and Maintenance Costs

Up-Front Capital Costs

Up-Front Capital Costs are the costs associated with the deployment project from project initiation through to completion of construction and initiation of operations, and for which there are associated regulatory costs. These are a one-time cost that are financed through debt and equity and amortized over a portion of the life of the plant. The majority of the capital costs are associated with the manufacturing of the reactor, site assembly, delivery and emplacement of the reactor, and the NRC licensing costs. These are the only costs considered in the referenced 2019 NEI paper, i.e., there could be future capital costs associated with plant modifications or upgrades that are not included because they are negligible in comparison to the up-front capital costs.

The 2019 NEI report provides a simple metric for the up-front capital costs in the form of an overnight capital cost. While this does not include financing costs, it is a reasonable metric to which to compare the expected NRC licensing costs. These costs for the first-of-a-kind are shown as a nominal, with a range between $10,000/kWe and $20,000/kWe, where the kWe is the rated capacity of the reactor. However, costs are expected to reduce rapidly through multiple deployments for a Nth-of-a-kind (NOAK) to as low as $4,000/kWe. Rapid high-volume deployable reactors are expected to come in a variety of sizes, and while this paper does not define a specific size range (since the defining factors are simplicity and safety performance, which cannot be specifically tied to size); however, this paper uses a range of 5 MWe to 30 MWe to estimate costs for illustrative purposes.

The regulatory costs include the direct NRC fees for performing the review, collecting the site data, and preparing the site license application. Based on historical experience, it is expected that the direct NRC fees for performing the review are about 25% to 33% of the total regulatory costs to obtain a site license for a rapid high-volume deployable reactor. Table 3-1 identifies the NRC review costs that would enable the business case for various sizes of rapid high-volume deployable reactors, as measured by the total facility capacity.

Table 3-1: NRC Review Costs that would Enable the Business Model

	5 MWe Facility	15 MWe Facility	30 MWe Facility
Total Up-Front Capital Costs for NOAK	Less than $20,000,000 to up to $75,000,000	Less than $60,000,000 to up to $225,000,000	Less than $120,000,000 to up to $450,000,000
NRC Review Costs that Enable the Business Model	Less than $50,000 to up to $187,000	Less than $150,000 to up to $560,000	Less than $300,000 to up to $1,120,000

This is not to imply that the NRC must conform to these regulatory costs, since we do not wish the NRC to compromise on reasonable assurance of adequate protection of the public health and safety. However, for clarity purposes, it is helpful to have this information in order to assess whether a potential NRC review process for rapid high-volume deployment reactors could meet the business model, in part or in whole. This enables the market and potential customers to determine whether nuclear technologies could meet their needs.

3.5 Concept of Operations

The concept of operations focuses on the activities to operate and maintain the reactor, the NRC oversight and inspection, and the annual O&M costs and the corresponding NRC regulatory costs.

3.5.1 Reactor Operations and Maintenance

There are two primary concepts for the operation and maintenance of the rapid high-volume deployable reactors: 1) operations with on-site staff, and 2) operations with off-site staff located at a remote operations center. For the purposes of this paper, it is assumed that the on-site staff operations model is primarily used by licensees with small fleets of rapid high-volume deployable reactors, with a fleet size of 10 or fewer sites being the example considered in this paper. Similarly, this paper assumes that the operations with off-site staff located at a remote operations center model is primarily used by licensees with large fleets of rapid high-volume deployable reactors, with a fleet size of 100 or more sites being the example considered in this paper.

In reality, the decision by the owner to pursue an on-site or off-site operations model is much more complex than just the number of sites where they are operating rapid high-volume deployable reactors. The decision will also factor in 1) how many reactors are at one site, 2) what is the size of the reactor, which influences 3) the required staffing size to operate the reactor based on a human factors analysis. There may also be other hybrid approaches where there is a mix of on-site and off-site monitoring and control of the reactor, which are not considered here due to the broad variability that these other approaches may take, and because the two approaches discussed here are expected bound of all the potential regulatory considerations.

Therefore, the purpose of the description of the two operations models, on-site or off-site control and monitoring, is to provide a basis for understanding the scope of regulatory topics that need to be addressed for rapid high-volume deployable reactors, and for developing the regulatory approaches for these reactors. The purpose is not to be a guide to an owner for developing a specific operations plan, nor for the NRC to review the operations plan for a specific application.

Automatic and Autonomous Operations

A key feature being designed into rapid high-volume deployable reactors is the ability to leverage automatic normal power control and automatic off-normal safety control. During routine operations, these reactors would control power automatically based on signals from the load center, such that changes in power level will be performed by the reactor's automatic control system. During off-normal events, these reactors would have reactor safety control systems that would return the reactor to a normal operating condition, and when necessary completely shutdown the reactor and place it in a long term steady-state safe configuration. The reactor would be designed to do all of these operational functions automatically, without reliance on the operator to perform any of these functions.

In this case, automatic operations is defined as the reactor responding to changes in externally monitored conditions according to a pre-programmed algorithm. While some designs may seek to incorporate non-human controls that are more similar to autonomous operations, i.e., the reactor could predict future conditions and take actions that are not pre-programmed, such features are not necessary to the rapid high-volume deployable reactor business model.

Role of the Human Operator

Rapid high-volume deployable reactors are being designed with very few or no moving components, and very few operational parameters needed to monitor the condition of the reactor. They are being designed such that the human operators will have access to the real-time status of monitored conditions, and will be able to take actions according to their operating procedures.

It is expected that all designs will have a manual trip function that an operator could quickly activate, although such a feature is expected to provide an additional layer of defense, and is not expected to be essential to demonstrating the safety of the design. Some vendors may design the reactor to have controls that the human operator could use to control the power of the reactor, while other designs may exclude power operation controls.

As these designs will have very little to no reliance on the operator to maintain safety, these operators will not require much training, and the licensing of these operators will be much simpler than it is for today's operating commercial reactor. Furthermore, these operators will be capable of performing other collateral duties (in the case of on-site staffing model), and monitoring a very large number of reactors (in the case of off-site staff at a remote operations center).

Operations of these reactors (either in the on-site or off-site operational models) might have five (5) shifts covering operations 24/7/365. The five (5) shift approach is typical for many of today's operating reactors allowing for 12-hour shifts, with sufficient rotations for time off. However, the five (5) shift model include a rotation about every six (6) weeks for the operations crew (typically 10 to 20 people including Shift Manager, Senior Reactor Operators, Reactor Operators and Non-licensed operators) to attend training. It is expected that due to the simplicity and safety profile of rapid high-volume deployable reactors, including the incorporation of automatic operations features and very little to no reliance on the operator to maintain safety, that operators would not need to be trained every six (6) weeks, but rather once per year. This could enable fewer shifts of a single operator, as each operator is able to spend more of their time at the reactor rather than in training.

Type 1 Operations: With On-Site Staff

Each applicant will need to propose an operations plan with an organization staffing that considers the human factors analysis for controlling and monitoring plant, and performing other required functions to protect the public health and safety. There are likely to be numerous variations in the concept of operations for these types of reactors. The following description is an example of the operations plan that some designs are expected to be able to achieve, subject to demonstrating reasonable assurance of adequate protection and being approved by the NRC.

In the on-site staffing operations model, all operations control is performed at the site. This model could include total or partial on-site monitoring, supplemented by remote off-site monitoring. It is anticipated that some designs will be able to demonstrate that all NRC required functions are capable of being performed by one (1) individual during routine operations and in the case of an off-normal event (e.g., anticipated operational occurrence, accident scenario). This may be supplemented by additional staff during pre-planned non-routine operations, such as a major maintenance activity or in modifications to the facility.

The role of the single on-site operator will enable them to perform collateral duties, such as minor plant maintenance, and security functions. Many designs are being developed for which the single on-site operator would be able to perform all functions regulated by the NRC. These operators might be supplemented by a “home office” staff that performs functions that are not directly related to the operations and maintenance of the facility. The “home office” staff would perform general business functions, such as procurement, accounting, IT and regulatory affairs, and may be sent to specific sites periodically to assist in the non-routine operations that require more than one (1) individual to perform (e.g., major maintenance activity).

Type 2 Operations: With Off-Site Staff Located at a Remote Operations Center

Each applicant will need to propose an operations plan with an organization that considers the human factors analysis for controlling and monitoring plant, and performing other required functions to protect the public health and safety. To-date, there have not been any applications for rapid high-volume deployable reactors submitted to the NRC that have articulated the operations plan for these types of reactors. The following description is an example of the operations plan that some designs are expected to be able to achieve, subject to demonstrating reasonable assurance of adequate protection and being approved by the NRC.

In the off-site staffing operations model, all control and monitoring functions are performed at a remote operations center. Other plant functions, both those required by the NRC such as security and emergency preparedness, and those that are not required by the NRC may also be performed or managed from the remote operations center. As noted below, for some co-located facilities, it is possible that on-site resources from the co-located facility could be leveraged to support these functions (e.g., plant security, fire brigades). Each design will need to establish the exact number of operators at the controls (at the remote operations center). However, as a representative number, most designs are being developed so that a crew of about four (4) people could operate a large fleet of reactors from a remote operations facility. This crew might be comprised of two operators at the controls, one shift manager and one flexible position.

The remote operations center would also include staff that work routine business hours, 8 hours a day 5 days a week, or 10 hours a day 4 days per week. These daytime positions would be responsible for maintaining and administering the NRC required programs, such as QA, Training, Emergency Preparedness, Security and Environmental Monitoring. The daytime positions would also include the licensee's organizational leadership, business functions, such as accounting, engineering, regulatory affairs and other support functions.

Rapid high-volume deployable designs are being developed so that there will not be a need for a human to be stationed on-site. These designs are expected to need a human to visit the site periodically, and to establish Field Technicians as part of their staffing organization. The Field Technicians would provide periodic visual confirmation for the remote monitoring center and periodic tasks that can only be performed on-site. Walk down procedures would define the areas, equipment, controls and monitored parameters that would need to be observed and confirmed. The procedures would also identify any routine or compensatory actions that the Field Technician may need to take, for example testing of certain equipment or cleaning out debris. Each design will also need to establish and obtain NRC approval on the frequency of the site walk-downs, for example whether they would occur in the range of once per week or once per month, which may be dependent upon the simplicity of the design and the extent to which the plant is fully observable from the remote operations center. The field technicians would have the capability to perform non-routine activities as necessary, such as major maintenance on a component. These field technicians could also be sent to visit sites in between the routine walk downs in response to anomalies observed by the remote operations center, for example birds nesting or after a thunderstorm.

Each design will need to establish and obtain NRC approval for a specific organization and staffing plan; however, it is expected that most designs would have an organization size of 80 to 150 FTE for a fleet of around 100 reactors. This would be organized into around 50 to 90 FTE at the remote operations center, and around 30 to 60 FTE Field Technicians.

Co-Located Facilities

Rapid high-volume deployable reactors are expected to be co-located with the end-use applications for which they will provide heat or electricity. Many of these co-located end-use facilities, especially in the case of industrial applications, will have their own infrastructure and staffing. In some cases, the owner of the rapid high-volume deployable reactor will also own the co-located end-use facility, and in other cases there will be a different owner of the co-located end-use facility. In both cases, it may be possible that the infrastructure and the staffing from the co-located end-use facility could be used to support the operations and maintenance of the rapid high-volume deployable reactor (in the case of different owners this could be through a sharing agreement). This is especially true in the case of industrial facilities that have a significant infrastructure and staffing organization.

A simple option for the end-use facility infrastructure and staffing to be used to supplement the rapid high-volume deployable reactor infrastructure and staffing is in the general business functions (see the on-site staffing model). In models where the end-use facility infrastructure and staffing are used to fulfill

NRC requirements (e.g., security fencing, security guards, fire and emergency response), these plans will need to be reviewed and approved by the NRC. They may also require that the end-use facility infrastructure and staffing have some level of NRC oversight.

The details of using end-use facility infrastructure and staffing are beyond the scope of this paper; however, these possibilities are mentioned for regulatory topics where there is a greater potential to credit the end-use facility to meet NRC requirements.

3.5.2 NRC Oversight and Inspection

NRC oversight and inspection of rapid high-volume deployable reactors will cover 1) manufacturing of the reactor, 2) delivery, assembly and emplacement of the reactor at the site, and 3) operations of the reactor. Just as rapid high-volume deployable reactors are very different from currently operation large light-water reactors and other advanced reactors in development, it is also expected that NRC oversight and inspection will be very different for these types of reactors.

Manufacturing and Site Activities

The rapid high-volume deployable reactor is expected to be entirely fabricated and assembled in a manufacturing facility with minimal on-site activities, which are focused on assembly and emplacement. Some licensees will also have a remote operations facility that will need to be constructed; however, the construction of the remote operations center is outside the scope of this paper. NRC's oversight and inspection is expected to be focused at the locations of these activities and at a level of oversight commensurate with the safety related activities being performed.

For high deployment rates, for example 10 reactors manufactured, the NRC may determine that the resources needed to provide oversight and inspections would justify having a full-time inspector located at the reactor manufacturing facility. Similarly, for deployment model for which there is safety-related activities at the site occurring over 4 months, the NRC may determine that an inspector would need to visit the site multiple times to observe these activities. If there are 10 reactors being brought on-line per month (thus 40 reactors in the phase of safety-related site activities) and they are in close proximity to one another, then the NRC may determine that a handful of inspectors could move from site to site to effectively and efficiently provide oversight. If there is a slower deployment rate with locations that are very far from each other, then the NRC may determine that there are not enough economies of scale to have multiple inspectors that move from site to site.

Operations of the Reactor

The NRC currently places resident inspectors at operating reactors to provide oversight. This is for reactors that are very large, with numerous components to control and parameters to monitor, and with significant day to day site activities related to safety. In contrast, the NRC does not utilize resident on-site inspectors for non-power reactors, but inspects them on a periodic basis.

It is expected that rapid high-volume deployable reactors will not need on-site resident inspectors, and that the NRC would periodically inspect sites, and such inspections could be on a sampling basis for a licensee that has a large fleet of sites. The NRC will establish the appropriate frequency for these inspections; however, it is expected that some designs and fleet sizes could justify an NRC inspection frequency of as little as once per year. For licensees that utilize a remote operations center, the NRC is also expected to provide oversight and inspection of the remote operations center. The NRC might determine that an inspector would need to be located at the remote operations center full-time, and that this would reduce the need for site inspections, achieving a more efficient oversight and inspection program.

3.5.3 Operating Costs

The April 2019 NEI report, “Cost Competitiveness of Micro-Reactors for Remote Markets,”[19] establishes a basis for the costs of designs that are expected to be rapid and high-volume deployable. It is noted that an update to that report is on-going to reflect a greater maturity in the technology and other factors (e.g., inflation and recently enacted tax credits) that could show expected costs today are lower than those projected in 2019. Thus, the following discussion on costs is expected to provide a reasonable basis for understanding the business need for regulatory costs less than 1% of total costs. In this manner, costs are separated into two categories:

1. Up-Front Capital Costs
2. Annual Operations and Maintenance (O&M) Costs

<u>Annual Operations and Maintenance Costs</u>

Annual O&M are the costs associated with the operation of the reactor after it is constructed and operations begin, and for which there are associated regulatory costs. These are recurring costs every year, and for which the costs are expected to increase in the future with inflation. Annual O&M costs include property taxes, purchasing of consumables and replacement equipment, general and administrative, personnel and NRC regulatory costs. Staffing is expected to be a small portion of the annual O&M costs. For the purposes of this report, fuel (including used fuel management) and decommissioning funding, which are provided for on an annual basis, are included in the annual O&M costs.

The 2019 NEI report provides a simple metric for the NOAK fixed operations and maintenance costs with a range between $250/kWe and $450/kWe, where the kWe is the rated capacity of the reactor. Fuel and decommissioning costs are reports in $/MWh, and refueling costs are reported in total costs. These costs are combined to form a total annual O&M cost. Rapid high-volume deployable reactors are expected to come in a variety of sizes, and owners may have a variety of sizes of fleets; however, this paper uses a range of 5 MWe to 30 MWe in facility size, and a small fleet that would use the on-site staffing concept and a large fleet that would use a remote operations center.

The regulatory costs include the direct NRC fees for performing oversight and inspections, the NRC annual fee, and licensee support for NRC regulatory engagement. Based on historical experience, it is expected that the NRC fees for regulatory oversight and inspection are to be around 25% to 33%, and NRC annual fees also around 25% to 33% of the total regulatory costs. Table 3-2 identifies the fees (annual and direct for oversight) that the licensee would pay to the NRC that would enable the business case for various sizes of rapid high-volume deployable reactors, as measured by the total facility capacity, and number of reactors in a fleet.

[19] https://www.nei.org/CorporateSite/media/filefolder/resources/reports-and-briefs/Report-Cost-Competitiveness-of-Micro-Reactors-for-Remote-Markets.pdf

Table 3-2: NRC Review Costs that would Enable the Business Model

	Small Fleet On-site Staff Model (e.g., less than 10 sites)	Large Fleet Remote Operations Model (e.g., More than 100 sites)
Example Fleet Size	150 GWe	1,500 GWe
Annual O&M Costs for NOAK	Less than $90,000,000 to up to $120,000,000	Less than $600,000,000 to up to $850,000,000
Anticipated Staffing Size	3 to 5 FTE per site 30 to 50 FTE Total	0 FTE per site 100 to 200 FTE Total
NRC Annual Fees that Enable the Business Model	Less than $30,000 to up to $40,000 per site	Less than $20,000 to up to $30,000 per site
NRC Direct Oversight and Inspection that Enable the Business Model	0.5 to 1 FTE	3 to 5 FTE

This is not to imply that the NRC must conform to these regulatory costs, since we do not wish the NRC to compromise on reasonable assurance of adequate protection of the public health and safety. However, for clarity purposes, it is helpful to have this information in order to assess whether the potential NRC annual fees, and oversight and inspection process for rapid high-volume deployment reactors could meet the business model, in part or in whole. This enables the market and potential customers to determine whether nuclear technologies could meet their needs.

3.6 Total Lifecycle Management

Rapid high-volume deployable reactors are expected to have a novel approach to total lifecycle management. This includes the following:

Manufacturing – The reactor is expected to be fully fabricated at a manufacturing facility with minimal on-site assembly (see Section 3.3.1 on Technology Description).

Refueling – There are multiple concepts of refueling, which align with the concepts of initial fueling during deployment. For designs delivered with the reactor already fueled, they are also being designed to fully replace the reactor and fuel with a replacement reactor that is also fueled. For designs that are fueled on-site, there would be a refueling operations on-site.

Used Fuel Management – Under both scenarios, the reactor is being replaced or there is a refueling operation on-site, the used fuel would be stored on site for a pre-determined time to achieve lower dose and heat rates before being shipped to a used fuel storage location. For reactors that are being replaced without removing the fuel on-site, the used fuel storage location could be co-located with the refurbishment and refueling center.

Decommissioning – The small size of the rapid high-volume deployable reactor enables more streamlined decommissioning of the site. It is expected that the majority, if not all, of the decommissioning will be related to the reactor itself. Since the reactor can be transported by truck or rail, it is expected that it would be packaged and shipped to a decommissioning facility. For reactors that are being replaced without removing the fuel on-site, decommissioning facility could be co-located with the refurbishment and refueling center.

4 ANTICIPATED BENEFITS AND NEXT STEPS

The set of proposed regulatory enhancements are expected to enable more wide-spread adoption of nuclear energy. If implemented, these proposed approaches would enable the NRC to provide reasonable assurance of adequate protection of the public health and safety, and environment in pursuit of the overall goal of the Atomic Energy Act to “make the maximum contribution to the general welfare” … “to the maximum extent consistent with the common defense and security and with the health and safety of the public. Each topic separately would significantly improve the effectiveness and efficiency of NRC’s regulation of new nuclear reactors, and collectively would enable even greater improvements and facilitate the adoption of nuclear technologies for new applications and business models.

The proposed approaches would achieve an effective and efficient regulatory process that would enable shorter deployment times. Over time, and through repetitive nth-a-kind use of the proces, the NRC could modernize a licensing process that today precludes deployments in less than 37 months, and create a licensing process that enables deployments in as few as 6 months within the authorities granted by the Atomic Energy Act (AEA).

The cumulative benefits of the proposed changes in this paper related to establishing a ReLic process would significantly reduce the schedule for deployment as influenced by the NRC regulatory framework. As an example, it is expected that NOAK licensing for a micro-reactor under the current NRC licensing process would not enable deployments in less than 49 months (assuming the NRC could perform the safety and environmental reviews in less than 12 months) – see Figure 4-2. The proposed changes in this paper would result in a 6 month deployment timeline as reflected in Figure 2-4, based upon an NRC licensing process shown in Figure 4-1.

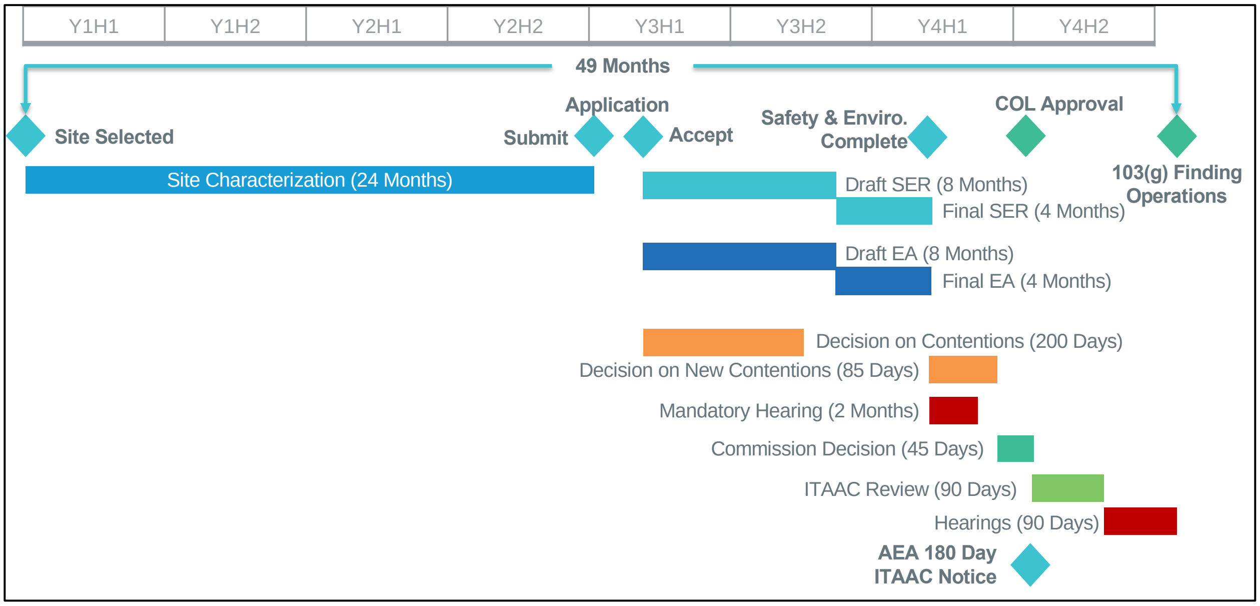

Figure 4-1: NRC Current Licensing Timeline (Expectations for NOAK RHDRA)

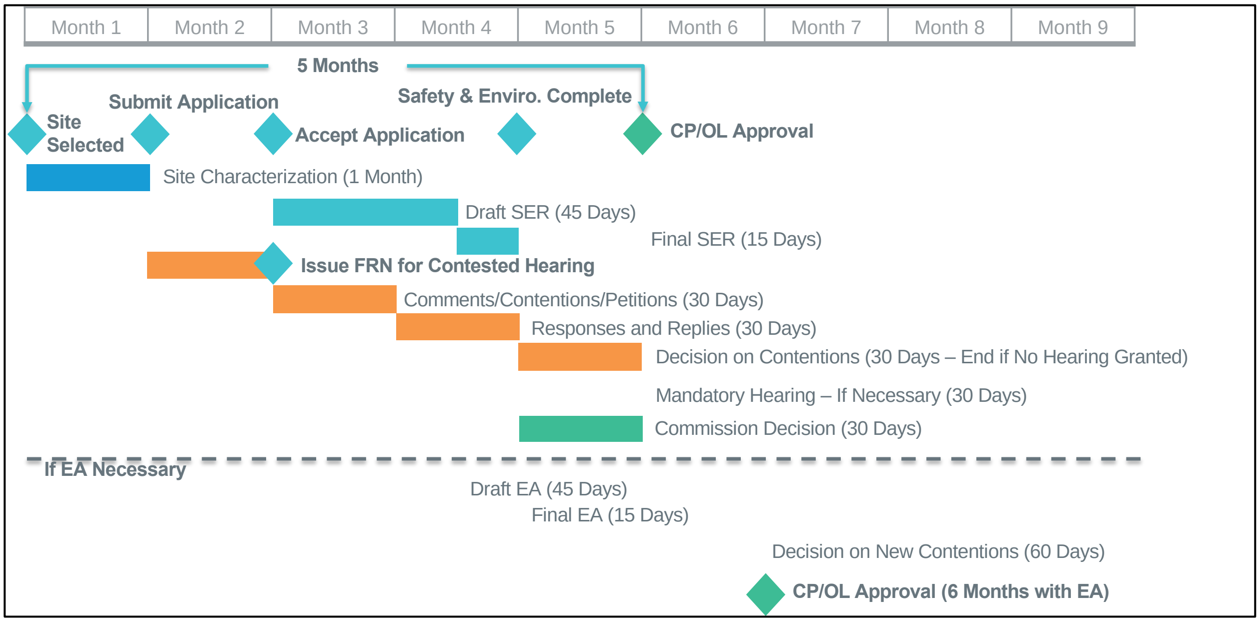

Figure 4-2: NRC Licensing Timeline (Expectations for ReLic Process)

The proposed approaches would also enable the NRC regulatory framework to be consistent with regulatory costs of 1% or less of the capital and ongoing operating costs for RHDRA and other advanced reactors. This would occur as the NRC is able to implement the tools discussed in the proposal paper, and as the NRC gains experience in licensing rapid high-volume deployable reactors. As illustrated in

Figure 4-3, this is expected to begin with development of regulatory bases over the next 12 months, and followed by that rulemakings to achieve the 3 year timeline required in Section 208 of the ADVANCE Act. With an amendment to the AEA to authorize the use of a general license for rapid high-volume deployabl reactors, the NRC could achieve a regulatory frameworkthat enables deployments in a month or less.

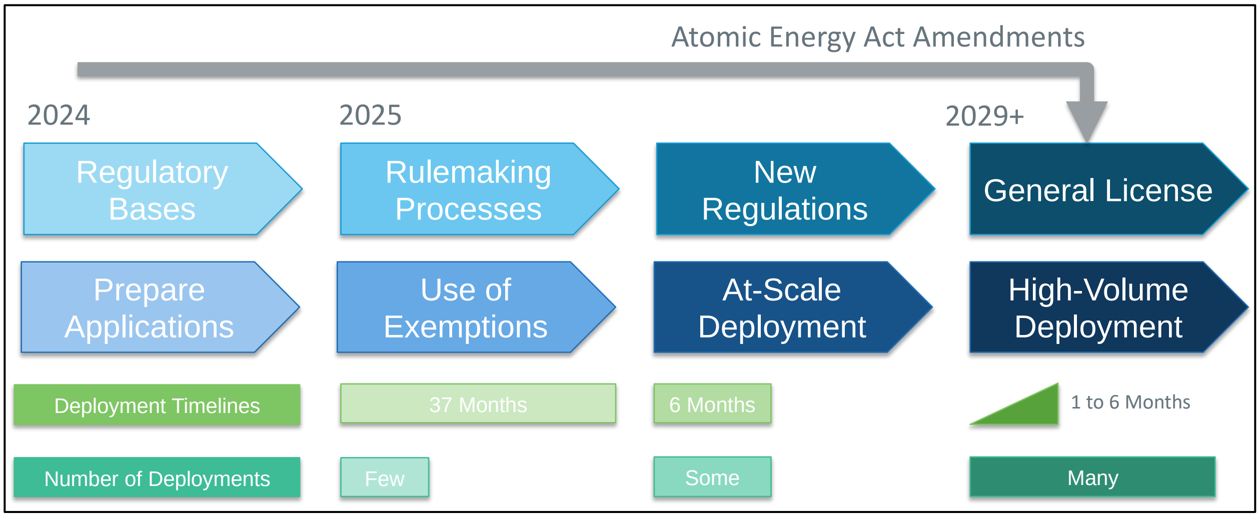

Figure 4-3: Development Timeline for RHDRA Regulatory Framework

4.1 Urgency for Regulatory Clarity

The technology and business models for these types of designs are rapidly maturing and the first applications are expected to be submitted to the U.S. Nuclear Regulatory Commission (NRC) as early as 2024. Lack of clarity on an efficient and effective alternative regulatory framework will impede the work of designers to develop their technologies, and the potential owners to develop their concepts of deployment and operations.

Given the revolutionary changes that are needed to enable a business mode that can achieve a 6-month schedule from site identification to operations, and regulatory costs that are less than 1% of total costs (capital and O&M), these companies have few good choices. They can either develop approaches around the existing regulatory framework, including the in-progress alternatives being developed, or they can develop approaches that are fundamentally different from what the NRC has previously approved or is considering. In the former, they are likely to develop approaches that cannot meet the business requirements and will need to seek alternative technologies, abandoning the potential for these hard to abate industries to reliably and affordably decarbonize their operations. In the latter, they will have to spend tens (10s) of millions of dollars and spend the next few years to develop approaches that they do not know whether the NRC will ever approve.

The difficulty between these two choices is expressed by Shepherd Power that said in the May 14, 2024, NRC public meeting that "*Industrial Customers see licensing & regulatory uncertainty as chief risks,*" so much so that it is "*Impossible to have price and delivery conversations [with customers] based on the current state of regulation.*" This stresses the clear urgency to provide what the market for advanced reactors need, specifically "*sufficient clarity by the end of 2024 on a licensing pathway supporting scale micro-rector deployment*." This clarity could be provided by an NRC plan to pursue alternative regulatory approaches that provide resolution of the topics described in this document and achieve the necessary conditions for regulatory effectiveness and efficiency that enables the business case. To this end, the NRC in the May 14, 2024, public meeting stated that they have plans to develop a paper addressing the regulatory topics related to the rapid high-volume deployable reactor business model later this year for the Commission's approval.

It is the intent of this paper to inform the NRC staff's paper to the Commission, and the Commission's consideration of the regulatory topics for rapid high-volume deployable reactor business. This paper is written to capture the emerging concepts that are being developed into a more detailed and actionable discussion of the issues and corresponding solutions.

As discussed in this paper, there are revolutionary changes that would need to be undertaken in an alternative regulatory framework to enable this business model, and our work to date indicates that this can be done in a way that provides reasonable assurance of adequate protection of the public health and safety. NEI presented an overview of the concepts that are described in detail in this paper. The NRC also agreed with the assessment of achieving the concepts presented in the meeting, saying that it may be hard, but it does not seem untenable.

It is also the intent of this paper to inform other on-going NRC work to prepare the regulatory framework for advanced reactors. As discussed in this paper, many of the concepts can be applied more broadly to other advanced reactors, sometimes directly and sometimes in a graded approach. On-going rulemakings such as Part 53 to create a technology-inclusive, performance-based and risk-informed alternative rule for advanced reactors, according to the requirements of NEIMA, would benefit from considering these emerging concepts for technology capabilities, deployment and operations, and an alternative regulatory framework. Other activities such as the considerations of topics in SECY 24-0008 for micro-reactors would also equally benefit from being informed by these concepts. NRC prompt action in addressing the needs for rapid high-volume deployable reactors will enable market participants to pursue their business goals in the 2026/2027 timeframe.

This paper provides input to the on-going work by the NRC to address this class of reactors in developing options for alternative approaches to achieve the goals for regulatory clarity by the end of 2024, and establish these alternative regulatory approaches to enable the business model by 2026. This paper also provides a foundation for an industry proposal for the regulation of rapid high-volume deployable reactors, that the Nuclear Energy Institute (NEI) anticipates submitting to the NRC around the end of July. NEI anticipates that NRC public workshops to discuss these topics in more detail would foster mutual understanding and transparency to all stakeholders, yielding more timely and well-considered alternative regulatory approaches.

It is recognized that the implementation of the solutions and proposed approaches could take several years to develop the details and promulgate through rulemaking. NRC development of regulatory bases in the near-term would support reducing regulatory uncertainty that is preventing customers from considering RHDRA and other advanced reactors with novel business models, as well as serve as the basis for processing a parallel path of exemptions for near term applications, and rulemaking for longer term applications.

All of the identified issue topical areas will need to be addressed, and other issues may be identified later. However, in alignment with the urgent need for regulatory clarity on the feasiability of achieving the regulatory approaches that enable the business model, we propose a prioritization for clarifying the path forward for higher risk topics. Specifically, NRC should endeavor to clarify by the end of 2024 whether they believe the topics in the High Priority and Near-Term Urgent Resolution topics (clear cells in the table below) could eventually achieve the business requirements, and the plan to achieve the desired outcomes for those topics. NRC should endeavor to clarify by June 2025 whether the other topics (gray cells in the table below) could eventually achieve the business requirements, and the plan to achieve the desired outcomes for those topic. Our assessment of the priority and urgency of achieving clarity is in Table 4-1.

Table 4-1: Prioritization and Urgency of Resolving Specific Issue Topics

	Near-Term Urgent Resolution	**Longer-Term Resolution**
High Priority	1 – Environmental Reviews 2 – Standardized Design Approvals 5 – Site License 10 - Meteorology and Weather Data 11 – Geologic and Geotechnical 14 – Operations Staffing 19 – Physical Security	3 – Construction Authorization Upon Docketing 6 – Contested Hearing 7 – Mandatory Hearing 17 – Remote Operations 21 – AA/FFD
Medium to Low Priority	9 – AIA 13 - Fire Brigade 16 – Remote Monitoring 18 – Cyber Security 22 – Radiation Protection 23 - Oversight 25 – Use of Contractors by ML 28 – Features to Preclude Criticality 31 – Used Fuel	4 – ITAAC 8 – Licensing fees 12 – Other External Hazards 15 – Autonomous Operations 20 – Emergency Preparedness 24 – Annual Fees 26 – Loading Fuel at Factory 27 – Testing at the Factory 29 – Transport Modules to Site 30 – Replace Modules at Site

The focus of addressing these topics and providing regulatory clarity is on whether the stated endpoint (described as desired outcomes) can be achieved, and not in prescribing the steps to reach that endpoint. While it will eventually be necessary to outline the steps to be taken toward these endpoints (e.g., FOAK deployment, additional early deployments, exemptions, rulemakings, etc.), the key issue at hand is whether it is feasible to enable the business models. Unless it is foreseen that the endpoints could reasonably be achieved, there is no purpose in pursuing these alternatives. Furthermore, as long as there is uncertainty whether the endpoints are achievable, then new customers, markets and business models will not be pursued. If the NRC cannot provide the needed clarity that the endpoints are achievable, then these customers and markets have expressed that they will abandon the use of nuclear technologies and will be forced to pursue other technologies that may not be as well suited to providing reliable and affordable energy, or may emit more carbon and have greater impacts on the public health, safety and environment than nuclear technologies.

This paper is written to provide input to the NRC paper by describing the emerging concepts for these alternative business models. NEI and our members are continuing to develop the details of these proposals.

We recognize that implementation of the proposed changes is a large scope of work that will require development of proposed rule language and guidance. Therefore, NEI is willing to develop guidance and proposed rule language for topics in support of the development of the proposed approaches. In particular, NEI is already planning to submit guidance on the following topics in 2025, and is willing to consider development of other guidance as identified by the NRC:

1. Environmental Reviews (Appendix 1)
2. Aircraft Impact Assessments (Appendix 9)
3. Meteorology and Weather Data (Appendix 10)
4. Geologic and Geotechnical (Appendix 11)
5. Fire Brigade (Appendix 13)

4.2 Process for Implementing the Proposed Approaches

It is important that the alternative regulatory approaches be available for licensing under Parts 50 and 52 and a future Part 53. The NRC could pursue changes to these regulations by incorporating them into existing rulemakings (e.g., Parts 50 and 52 Lessons Learned, Part 53, Advanced Nuclear Reactor Generic Environmental Impact Statement, and Categorical Exclusions)[20] or through a new rulemaking.

There may be benefits to near-term Commission policy decisions on whether the NRC should pursue some areas with significant deviation from prior NRC practices. These areas may include:

- Adapting regulatory approaches for non-power reactors, and the corresponding standard of minimal regulation, to commercial power reactors that have similar potential consequences (see Attachment A for insights),
- Establishing a rapid efficient repeatable licensing (ReLic) process that enables prior NRC approvals on safety and environmental matters through generic technology-inclusive rulemakings (E.g., GEIS, CatEx), design approvals (e.g., ML, DC, SDA) and licensee pre-approvals (e.g., financial and technical qualification, plans and programs for operations, security and emergency planning), and NRC reviews of site license applications that focus on verification of compliance with the site parameter envelope established through those prior approvals, (see Attachment B for insights), and
- Allowing operational concepts that would include 1) one on-site individual, and 2) no on-site individual with a staffed remote operations facility, which are enabled through design feactures and technologies like automatic and autonomous operations (see Appendices 14, 15 and 16 for insights).

Notably, there are a few topics for which Congressional action, such as an amendment to the Atomic Energy Act, is needed to achieve the proposed approaches, or which would enable other options for addressing the topic that are identified but not proposed as the recommended approach. To the extent that the NRC agrees that these proposed approaches 1) could be implemented in ways that protect the

[20] NRC-2019-0062; NRC-2024-0091; NRC-2009-0196; NRC-2020-0101; NRC-2018-0300

public health and safety, and the environment, 2) would improve the effectiveness and efficiency of the regulatory framework for advanced reactors, or would enable new business models, and 3) need Congressional action to implement, we request that the NRC make these conclusions known to Congress and request Congressional authorization to pursue those approaches. There are also some topics identified options for which Congressional action could enable more effective and efficient regulation of RHDRA and other advanced reactors, but were not recommended as the preferred approach.

4.2.1 No Rulemaking Needed (Currently Permitted by Regulations)

There were a few topics for which the current regulations are sufficiently technology-inclusive, performance-based, risk-informed and graded to enable the proposed alternative approach. These would still need or may benefit from new or supplemental guidance. However, these topics are such that the NRC staff could pursue the proposed approaches without first seeking approval from the Commission:

- 8 – Licensing fees
- 13 – Fire Brigade
- 16 – Remote Monitoring
- 20 – Emergency Preparedness
- 22 – Radiation Protection
- 26 – Load Fuel at the Factory
- 30 – Replacing Fueled Reactors at Operating Site

4.2.2 Regulatory Changes Needed (Currently Permitted by Statutes)

Each Issue Topical Area Appendix (in Section 3.1, "Changes Needed to Regulations, Policy and Guidance") identifies the regulatory changes needed to achieve the proposed alternative regulatory approach. This includes the NRC regulations, policy and guidance, and any rulemakings or other changes currently being pursued. The following is a high-level summary of those necessary changes to establish regulatory approaches that are more effective and efficient to advanced reactors, including RHDRA.

<u>Changes to Regulations</u>

Due to the broad range of topics and novel approaches being proposed, there are a large number of requirements that would need to be changed, eliminated, or added to modernize the NRC regulatory framework and achieve a more effective and efficient paradigm for advanced reactors, including RHDRA. Where possible, the Appendices identify specific requirements that would need to be changed, and in other cases where more regulatory analysis is needed, regulatory changes are identified at the Part or Subpart level.

It is important that the alternative regulatory approaches be available for licensing under Parts 50, 52 and 53. The following are the NRC regulations that would need to be addressed, as identified in the regulatory analyses performed as part of developing this paper. This list of over 30 regulations could represent more than 100 requirements that would require changes to address the set of issues in this paper):

1. 10 CFR 2.104, “Notice of hearing”
2. Part 26
3. 10 CFR Part 26, Subpart M
4. 10 CFR 50.10(a)
5. 10 CFR 50.35, “Issuance of construction permits*”
6. 10 CFR 50.58, “Hearings and report of the Advisory Committee on Reactor Safeguards”
7. 50.150
8. 10 CFR 50.54(i) to (m)
9. 10 CFR 50.48
10. Appendix R
11. Part 50 - New Regulation – Remote Operations
12. 10 CFR 50.36(c)(ii)(A)(2)(ii)(A)
13. 10 50.67(b)(iii)
14. 10 CFR 50.34
15. 10 CFR 50.54
16. 10 CFR 50.55a(h)
17. 10 CFR 50, Appendix A General Design Criteria (GDC) (e.g., 19)
18. in §50.70(b)(1) and (2
19. 10 CFR 51.105, “Public hearings in proceedings for issuance of construction permits or early site permits; limited work authorizations”
20. 10 CFR Part 51 (Including Appendix O or N)
21. 10 CFR 51.107, “Public hearings in proceedings for issuance of combined licenses; limited work authorizations”
22. 10 CFR 52.103(g)
23. 10 CFR Part 52 (Subpart B)

24. 10 CFR Part 52 (Subpart E)

25. 10 CFR Part 52 (Subpart F)

26. 10 CFR 52.24, "Issuance of an early site permit"

27. 10 CFR 52.97, "Issuance of combined licenses"

28. 10 CFR 52.167(c), "Issuance of manufacturing license"

29. 10 CFR 55

30. 10 CFR 70.23a, "Hearing required for uranium enrichment facility"

31. 10 CFR Part 71

32. Part 72

33. Part 73 (73.55, 73.60 and 73.67) or New Subpart

34. 73.120

35. 73.56

36. 10 CFR Part 140

37. Part 171

It is noted that this list did not consider the changes to regulations that would be necessary if any of the statutory changes identified as Other Options (i.e., not the recommended solutions) are established through legislation.

Rulemakings

The NRC has several options for which to pursue rulemakings. These, if addressing the topics identified for all advanced reactors, and more explicitly the unique features of RHDRA and other similar reactors (e.g., micro-reactors) would meet the goals expressed in NEIMA and the ADVANCE Act for establishing a modern more appropriate regulatory framework for these technologies and concepts of deployment and operations.

Changes to some of these requirements could be implemented through on-going rulemaking activities, most of which the NRC has assigned a "High" Common Prioritization of Rulemaking (CPR) Priority, including.

- Part 53 (NRC-2019-006 and NRC-2024-0091)
- Part 50/52 (NRC-2009-0196)
- ANR GEIS (NRC-2020-0101)

- Categorical Exclusions (NRC-2018-0300)

The NRC could also implement some or all of these changes through a separate rulemaking specific to those considerations.

Potential Policy Statements

Many of the issues and proposed solutions would benefit from clarity in policy statements. While policy for these issues would be established through rulemakings, there are a few areas where clarification of Commission policy could be helpful to inform near-term applicants, as well as provide greater clarity for the pursuit of rulemakings. These are areas where the changes differ significantly from past NRC practices, are fundamental to the success of RHDRA and other advanced reactors, and are being developed by applicants for near-term applications that would be submitted prior to achieving clarity through the rulemaking process.

- Apply of adapting regulatory approaches for non-power reactors (see Attachment A for insights and the related Issue Topical Appendices),
- Establishing a rapid efficient repeatable licensing (ReLic) process that maximizes the use of NRC standardization tools to minimize schedules based on technology characteristices, (see Attachment B for insights and the related Issue Topical Appendices), and
- Allowing operational concepts that would include one or no on-site staff (see Section 3.5.1 and related Issue Topical Appendices).

Guidance

Every topic identified that additional guidance is necessary or would be helpful to provide clarity and minimize regulatory risk. Some topics may need multiple guidance documents due to their scope and/or complexity.

4.2.3 Statutory Changes

The regulatory analyses performed for each topic area reviewed the statutory requirements to determine whether they created any limitations or barriers to pursuing the alternative regulatory approaches.

Necessary Statutory Change – Mandatory Hearing

Appendix 7 discusses and provides that rationale for a change to the AEA to eliminate the mandatory hearing. This appendix also identifies action the NRC can take in the near term to make the mandatory hearing more efficient until the AEA requirement is eliminated. These near-term solutions align with the conclusions of the recent NRC staff consideration on this issue.

Potential Statutory Changes – Contested Hearing

Appendix 6 (in Section 4 in “Other Options for Resolution of the Issue”) discusses and provides the rationale for a change to the AEA to streamline the contested hearing process. Although a statutory change is able to achieve the desired outcomes, and may be necessary if the NRC determines that it is not possible, or chooses not to, make the regulatory changes, this was not determined to be the recommended solution and proposed regulatory approach. The proposed solution for this issue is for the NRC to amend the regulations, within the discretion afforded the NRC in the current statutes, to attempt to achieve the desired business goals.

Potential Statutory Change – General License

Attachment B discusses the concept of a General License (GL) for certain advanced reactors. Several Issue Topical Area Appendices (in Section 4 on "Other Options for Resolution of the Issue") discuss and provide the rationale for a GL process to achieve the desired business goals. Although a statutory change is able to achieve the desired outcomes, and may be necessary if the NRC determines that it is not possible, or chooses not to, make the regulatory changes, this was not determined to be the recommended solution and proposed regulatory approach. The proposed solution for this issue is for the NRC to amend the regulations, within the discretion afforded the NRC in the current statutes, to attempt to achieve the desired business goals. The Issue Topical Area Appendices that would benefit from a General License are:

- Topics Fully Resolved by GL
  - 1 – Environmental Reviews
  - 2 – Standardized Design Approvals
  - 3 – Construction Authorization Upon Docketing
  - 4 – ITAAC
  - 5 – Site License
  - 6 – Contested Hearing
  - 7 – Mandatory Hearing
  - 8 – Licensing Review Resources and Costs
  - 25 – ML Holder Use of Contractors
  - 26 – Load Fuel at Factory
  - 27- Operational Testing at Factory
  - 28 – Features to Preclude Criticality
  - 30 – Replacing Fueled Reactor at Operating Site
- Topics Partially Resolved by GL
  - 11- Geologic and Geotechnical
  - 23 – NRC Oversight

Not Recommended Statutory Change – Minimum Regulation

Attachment A discusses the concept of applying the non-power regulatory framework, which includes the AEA standard for "minimal regulation" (MR), to advanced reactors that have similar low potential consequences (e.g., RHDRA and other similar advanced reactors like micro-reactors. Several Issue Topical Area Appendices (in Section 4 on "Other Options for Resolution of the Issue") identify that a statutory requirement from Section 104 of minimal regulation could achieve the desired outcome of more effective and efficient regulation, similar to that currently applied to non-power reactors, in protecting the public health and safety. Although a statutory change is able to achieve the desired outcomes, and may be necessary if the NRC determines that it is not possible, or chooses not to, make the regulatory changes, this was not determined to be the recommended solution and proposed regulatory approach. The proposed solution for these issues is for the NRC to amend the regulations, within the discretion afforded the NRC in the current statutes, to attempt to achieve the desired business goals. These Issue Topical Area Appendices are:

- Topics Fully Resolved by a MR
  - 9 – AIA
  - 10 – Meteorology
  - 11 – Geotechnical and Geologic
- Topics Partially Resolved by MR
  - 4 – ITAAC
  - 14 – Operations Staffing
  - 15 – Autonomous Operations
  - 16 – Remote Monitoring
  - 17 – Remote Operations
  - 19 – Physical Security
  - 20 – Emergency Preparedness
  - 21 – AA/FFD
  - 22 – Radiation Protection
  - 23 – Oversight
  - 27- Operational Testing at Factory
  - 31 – Used Fuel

Not Recommended Statutory Changes – NRC Fee Structure

A few Appendices (in Section 4 on other options) discuss and provide the rationale for alternative NRC fee structures that would not impose a disproportionate impact on reactors with small power levels (e.g., RHDRA, micro-reactors and other low power reactors) through potential changes to statutory requirements. This was not chosen to be the proposed alternative regulatory approach because it is believed that the NRC could achieve fair and equitable regulatory fee structure for low power reactors within the current AEA statutory requirements. Otherwise, a statutory change is able to achieve the desired outcomes, and may be necessary if the NRC determines that it is not possible, or chooses not to, make the regulatory changes. These issue topical areas are:

- 8 – Licensing fees
- 24 – Annual Fees

Not Recommended Statutory Changes – ITAAC

One Appendix (in Section 4 on other options) discusses and provides the rationale for alterative approaches to ITAAC that would more effective and efficient for reactors with small power levels (e.g., RHDRA, micro-reactors and other low power reactors) through potential changes to statutory requirements. This was not chosen to be the proposed regulatory approach because it is believed that the NRC could achieve resolution within the current AEA statutory requirements. Furthermore, if changes to statutory requirement were needed to address this issue, the option for a General License, which would also require changes to the AEA, was perceived to be a more effective and efficient approach. Nevertheless, a change to the AEA related specifically to ITAAC is able to achieve the desired outcomes, and may be necessary if the NRC determines other options are not possible or less desireable. This issue topical area is:

- 4 – ITAAC

Appendix 1 – Generically Resolved Environmental Considerations

1 ISSUE INTRODUCTION

The NRC's regulations in 10 CFR Part 51 for implementing the National Environmental Policy Act (NEPA) require the agency to prepare an environmental impact statement (EIS) for specific categories of actions, including permits/licenses to construct and operate any nuclear power reactor. The EIS process involves multiple stages, including scoping, development of a draft EIS for public comment and review by other agencies, public meetings, interagency consultations, and preparing responses to public comments for inclusion in the final EIS. Environmental issues also may be the subject of contentions and Commission inquiries as part of the contested and mandatory hearing processes, respectively. As such, the NRC staff estimates that the environmental review process for new reactor applications will take approximately 24-36 months.[1] This review timeline is not compatible with the rapid high-volume deployable reactor in remote locations (RHDRA) business model, which requires reactor deployment in less than 180 days (6 months) from the time that the site is identified to the time that reactor operation begins.

The desired outcome is that the NRC satisfies all NEPA requirements either on a class of reactor basis, e.g., RHDRA and other advanced reactors with similar potential environmental impacts, or on a design-specific basis, so that the site license application and NRC review do not need to include any additional review or hearing scope. The NRC has several options, such as issuing a categorical exclusion for RHDRA, completing a generic EIS (GEIS) that resolves all environmental topics (i.e., the Advanced Nuclear Reactor GEIS scope plus the 21 topics not addressed generically therein), or performing a full EIS with the design approval. Any of these options would need to be completed prior to the identification of the site, and likely require the use of generic bounding analyses, tiering, and incorporation by reference. As discussed below, under the current statutory framework, the optimal approach for RHDRA environmental reviews will likely require the NRC's development and application of categorical exclusions for such a class of reactors. If the NRC can determine that a given RHDRA design would not have a significant impact on the environment when it is sited within a given site parameter envelope, then it should develop a design specific categorical exclusion and associated rulemaking that reflects that determination. No EIS or EA would be necessary for such RHDRA designs. While a GEIS-based approach may be viable and warrants consideration, it poses greater challenges to the 180-day schedule if the need for site-specific review of certain issues cannot be eliminated or greatly reduced.

The NRC also will need to develop an approach that satisfies the Atomic Energy Act (AEA) contested hearing opportunity requirement but still accommodates the goal of site identification to operations in less than 180 days. As discussed in Appendix 6 (Contested Hearing), this likely will require the use of procedural tools like exemptions, hearing orders, and/or rules of particular applicability.

2 BACKGROUND

NEPA is governed by a "rule of reason" and thus requires analyses that are focused on reasonably foreseeable actions and impacts – i.e., those that are likely to occur or are probable – rather than those

[1] NRC's Environmental Review Process, https://www.nrc.gov/reactors/new-reactors/how-we-regulate/regs-guides-comm/erp.html. Consistent with this general estimate, the FEIS supporting issuance of the Clinch River ESP was issued about 32 months from the time of docketing of the application. The Kairos Hermes non-power test reactor construction permit was issued just under 21 months from the time of docketing of the application.

that are merely possible or speculative.[2] This is in keeping with NEPA's original intent to inform agency decisions on federal actions based on an assessment of their likely environmental impacts. Additionally, consistent with Council on Environmental Quality (CEQ) regulations, NEPA documents are intended to "identify and eliminate from detailed study the issues which are not significant or which have been covered by prior environmental review(s)," thereby "narrowing the discussion of these issues in the statement [EIS] to a brief presentation of why they will not have a significant effect on the human environment or providing a reference to their coverage elsewhere."[3] Over time, however, federal agency implementation of NEPA has become unduly complex and time-intensive, with reviews frequently spanning several years or more and requiring massive resource expenditures.

This section describes the relevant NEPA statutory and regulatory requirements, the implementation of those requirements over time, and recent efforts to improve the NEPA process across the federal government and at the NRC.

2.1 Statutory and Regulatory Requirements

2.1.1 Statutory Requirements

Environmental reviews for nuclear power plants are required by NEPA, as that statute requires that all "major federal actions" be assessed to determine the impact of the action on the human environment. NEPA is a procedural statute with two principal aims. Specifically, it requires a federal agency to take a "hard look" at the impacts of a proposed action on the environment before acting and to demonstrate to the public that it has indeed considered environmental concerns in its decision-making process.[4] NEPA directs agencies to perform straightforward and concise environmental reviews that are proportionate to the potential impacts of the actions under review, and the effective conveyance of the relevant decisions to the public in a timely manner.[5]

Contrary to this stated mission, NEPA environmental analyses have become increasingly burdensome both in terms of time and resource expenditures since the statute's adoption in 1970. In 1997, the CEQ aptly observed that agencies were attempting to generate "litigation proof" NEPA reviews, thereby increasing time and costs often with no corresponding increase in review quality. These longstanding concerns about the length and complexity of the NEPA review process prompted Congress to amend NEPA in the Fiscal Responsibility Act of 2023 to improve agency review times.[6]

Different levels of review may be performed to satisfy NEPA requirements depending on the expected environmental impacts of the proposed activity. The different review levels under NEPA relate to the

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[2] *Dep't of Transp. v. Public Citizen*, 541 U.S. 752, 767 (2004) (stating that "inherent in NEPA and its implementing regulations is a 'rule of reason'"); *Potomac Alliance v. NRC*, 682 F.2d 1030, 1035 (D.C. Cir. 1982) ("The starting point in any analysis of an agency's compliance with section 102(2)(C) of NEPA is the 'rule of reason,' under which a federal agency proposing a major action must consider only the reasonably foreseeable environmental effects of the action."); *La. Energy Servs.* (Nat'l Enrichment Facility), CLI-05-20, 62 NRC 523, 536 (2005) (noting that NEPA "does not call for certainty or precision, but an estimate of anticipated (not unduly speculative) impacts").

[3] 40 CFR 1502.4(d)(1),

[4] *Webster v. U.S. Dep't of Agric.* 685 F.3d 411, 417, 424 (4th Cir. 2012) (noting that ensuring informed decisionmaking and public participation are the "dual purposes" of NEPA's "procedural mandates"); *Balt. Gas & Elec. Co. v. Natural Res. Defense Council*, 462 U.S. 87, 97 (1983) (internal citation omitted) (NEPA does not require agencies to "elevate environmental concerns over other appropriate considerations. Rather it require[s] only that the agency take a 'hard look' at the environmental consequences before taking a major action.").

[5] *Citizens Against Burlington, Inc. v. Busey*, 938 F.2d 190, 196 (D.C. Cir. 1991) (noting that "[i]mpacts shall be discussed in proportion to their significance") (citations omitted); 40 CFR 1500.4 ("Agencies shall prepare analytical, concise, and informative environmental documents" by, among other practices, "[u]sing programmatic environmental documents and tiering from documents of broad scope to those of narrower scope, to eliminate repetitive discussions of the same issues").

[6] Fiscal Responsibility Act of 2023, Public Law 118-5, § 321 (Builder Act) (amending 42 U.S.C. 4321 et seq.).

Appendix 1 – Generically Resolved Environmental Considerations

scope and detail of the analysis of the proposed action that must be completed to provide adequate assessment of the potential environmental impacts.

1. The first level of NEPA assessment is categorial exclusion. Specific major federal actions may be "categorically excluded" from more detailed NEPA reviews if an agency demonstrates that the individual and cumulative effects of the activity on the environment will not be significant. These activities are not subject to additional environmental review, but appropriate justification and rulemaking is required before an activity can be defined as "categorically excluded" from future reviews. As the CEQ explained in a 2010 guidance document:

   "Categorical exclusions are not exemptions or waivers of NEPA review; they are simply one type of NEPA review. To establish a categorical exclusion, agencies determine whether a proposed activity is one that, based on experience, normally does not require further environmental review. Once established, categorical exclusions provide an efficient tool to complete the NEPA environmental review process for proposals that normally do not require more resource-intensive EAs or EISs. The use of categorical exclusions can reduce paperwork and delay, so that EAs or EISs are targeted at proposed actions that truly have the potential to cause significant environmental effects. Today, categorical exclusions are the most frequently employed method of complying with NEPA… Appropriate reliance on categorical exclusions provides a reasonable, proportionate and effective analysis for many proposed actions, helping agencies reduce paperwork and delay."[7]

2. The second level of NEPA assessment is an environmental assessment (EA). An EA provides a brief description of the purpose and need for the proposed action, a description of reasonable alternative actions, and an assessment of the environmental impacts of the proposed action and possible alternatives. These reports are generally limited in scope and are based on prior agency experience with the activity. Based on the results of the EA, an agency can either issue a Finding of No Significant Impact (FONSI) or require a more detailed assessment of possible environmental impacts. An agency will issue a FONSI if they find the proposed action will not have any significant impact on the human environment. The FONSI will document the basis for the finding and provide a justification for concluding the NEPA review process. If the agency finds the proposed action will have significant impacts on the human environment or if the impacts on the human environment cannot be conclusively determined, then the agency will prepare a more detailed environmental assessment in the form of an EIS.

3. The EIS is the third and most detailed level of NEPA assessment. An EIS provides a detailed description of the purpose and need for the proposed action, a description of reasonable alternative actions, and a detailed and rigorous assessment of the environmental impacts of a proposed action and the reasonable alternatives. It will also evaluate, when necessary, additional options to mitigate or reduce the proposed action's environmental impacts. An EIS involves a much broader, in-depth analysis that requires significantly more time and resources; mandates greater consultation with other agencies, governments, and stakeholders; and must explore the reasonably foreseeable environmental consequences (including cumulative impacts) associated with the proposed action.

[7] CEQ, Memorandum for Heads of Federal Departments and Agencies. "Establishing, Applying and Revising Categorical Exclusions under the National Environmental Policy Act" (Nov. 23, 2010),

Appendix 1 – Generically Resolved Environmental Considerations

Another option that has been used to improve the efficiency of the NEPA process is the programmatic EIS (PEIS)[8] or generic EIS (GEIS). Such documents "avoid duplicative analysis for individual actions by first considering relevant issues at a broad or programmatic level."[9] A PEIS or GEIS normally does not contain the level of detail on precise project footprints and impacts typical of site-specific EISs, and typically is followed by site-specific environmental analyses of project-specific impacts for projects proposed to be undertaken within the umbrella of the PEIS or GEIS. Subsequent site-specific environmental analyses typically are conducted through a process called tiering, often via a categorical exclusion or an EA/FONSI. While preparation of PEISs/GEISs typically take several years to complete, subsequent analyses of project-specific impacts within the scope of the PEIS/GEIS can be completed in a much shorter period.

Lead agencies are required under NEPA section 102(2)(c) to consult with and obtain comments from any federal agency that has jurisdiction by law or special expertise with regard to any environmental impact involved in the subject matter of an EIS. Thus, while preparing an EIS, the NRC consults and coordinates with various federal, state, and local agencies as well as Tribal entities. These consultations and interagency activities relate to several federal laws and policies, some of which may be implemented by states via federal delegations of regulatory authority. Key examples include the Endangered Species Act, National Historic Preservation Act of 1966, and Clean Water Act of 1972. These interagency activities will also need to be substantially front-loaded and streamlined, to the greatest extent possible.

2.1.2 Regulatory Requirements

Under 10 CFR 51.20(b), any nuclear power reactor or testing facility licensed under Part 50 or Part 52 requires an EIS for construction and operation (i.e., for a CP, OL, or COL). This requirement applies regardless of the reactor size, technology, or proposed facility use case. This and other NRC Part 51 regulations, which have not been substantively updated in many years, do not consider the inherent safety of advanced reactor designs and their environmental benefits, including reduced use of materials and land, use of brownfield sites, reduced source terms, reduced greenhouse gas and air pollutant emissions, and the potential for reduced generation of spent nuclear fuel. Moreover, under current NRC regulations, environmental reviews would need to be performed for each RHDRA deployment site.

Currently, under NEPA and Part 51, the NRC solicits public comments (to which the agency must respond in writing) on the scope of the review and on its draft environmental impact statement (EIS), and holds related public meetings near the proposed site. The NRC also offers members of the public opportunities to request a hearing on the application and to participate in the hearing process through various channels (e.g., as an intervenor/party, interested governmental entity, limited appearance statements). The NRC notifies the public of these various opportunities through a combination of means, including *Federal Register* notices, press releases, newspaper ads and radio scripts, and project-specific webpages. It also coordinates closely with other Federal, State, local, and Tribal governmental

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[8] CEQ regulations define a "programmatic environmental document" as "an environmental impact statement or environmental assessment analyzing all or some of the environmental effects of a policy, program, plan, or group of related actions." CEQ regulations do not reference or define generic environmental impact statement. The NRC, which has issued multiple GEISs, defines a GEIS as an EIS that assesses the scope and impact of environmental effects that are common to many nuclear plant sites. Importantly, the U.S. Supreme Court and other federal courts have affirmed the NRC's use of GEISs. Balt. Gas & Elec. Co. v. NRDC, 462 U.S. 87, 101 (1983) ("The generic method chosen by the agency is clearly an appropriate method of conducting the hard look required by NEPA."). *See also Mass. v. United States*, 522 F.3d 115, 127 (1st Cir. 2008); *Mass. v. NRC*, 708 F.3d 63, 68 (1st Cir. 2013); *NRDC v. NRC*, 823 F.3d, 641, 653 (D.C. Cir. 2016).

[9] 40 CFR 1501.11(a).

entities, and conducts targeted outreach to local communities, including those that may have environmental justice impacts.

10 CFR Part 51 also requires NRC to perform environmental reviews in connection with issuance of Part 52 manufacturing licenses for the design and manufacturing of reactor modules and Part 70 licenses for the possession and use of special nuclear material (which may be necessary for factory fueling/testing of a micro-reactor). Under 10 CFR 51.30(e), the EA for a manufacturing license addresses the consideration of the costs and benefits of severe accident mitigation design alternatives (SAMDA) and the bases for not incorporating SAMDA in the design. The environmental review for the Part 70 license could require an EA or EIS, depending on the environmental impact of the activities requested and authorized by the license. SECY-24-0008 notes that micro-reactor deployment models that include either concurrent or separate requests for a 10 CFR Part 52 manufacturing license and a 10 CFR Part 70 license could raise unique, case-specific environmental review considerations (e.g., consideration of cumulative impacts).

2.2 Efforts to Right-Size NEPA Implementation

2.2.1 Congressional Actions

Congress has recognized the need to improve the efficiency of federal environmental reviews. That need has become more urgent in recent years, as the U.S. Government has sought to foster infrastructure development and support the development of domestic energy resources, including advanced nuclear power. For example, in 2015, Congress enacted the Fixing America's Surface Transportation Act ("FAST Act") to streamline permitting and increase agency accountability.[10] Title 41 of the FAST Act (FAST-41) includes provisions to improve the timeliness, predictability, and transparency of the environmental review and authorization processes for infrastructure projects.[11] The ten "covered project" sectors include renewable energy and conventional energy production.[12]

On June 3, 2023, President Biden signed the Fiscal Responsibility Act of 2023 (FRA). The legislation included important reforms to NEPA, with the objective of expediting the permitting process for infrastructure projects. It also codifies several important NEPA concepts and terms (e.g., "reasonably foreseeable adverse environmental effects" and "reasonable range of alternatives … that are technically and economically feasible and meet the purpose and need of the proposal").

The CEQ recently issued its final "Phase 2" rule, which seeks to implement the FRA amendments to NEPA, improve the efficiency of agency processes, facilitate collaboration, and provide agencies with greater flexibility to prepare environmental analyses in the context of their unique operational needs and statutory obligations.[13] Among other things, the final rule expands the ability of agencies to use categorical exclusions, including by applying or adopting another agency's categorical exclusion, jointly developing a categorical exclusion with another agency, establishing new categorical exclusions based on programmatic EAs or EISs, and expressly permitting the use of "mitigated" categorical exclusions.

[10] Pub. L. No. 114-94, 128 Stat. 1312 (2015). FAST-41 has been codified in Chapter 55 of Title 42 of the US Code (42 USC 4370m–4370m-12).
[11] 42 U.S.C. § 4370m-1(c)(2)(B)(ii)-(iv).
[12] 42 U.S.C. § 4370m(6)(A). FAST-41-covered projects meet the following criteria: (1) they are likely to require an investment of more than $200 million, (2) they are subject to NEPA, and (3) they do not qualify for abbreviated authorization or environmental review processes under any applicable law.
[13] CEQ, National Environmental Policy Act Implementing Regulations Revisions Phase 2; Final Rule, 89 Fed. Reg. 35,442 (May 1, 2024).

Appendix 1 – Generically Resolved Environmental Considerations

On July 9, 2024, President Biden signed into law the Accelerating Deployment of Versatile, Advanced Nuclear for Clean Energy Act (ADVANCE Act), which, among other things, seeks to "[t]o advance the benefits of nuclear energy by enabling efficient, timely, and predictable licensing, regulation, and deployment of nuclear energy technologies." The bill is a compilation of 11 pieces of legislation authored by members of the Energy and Commerce Committee. Several sections warrant mention here:

1. Section 506 (Modernization of nuclear reactor environmental reviews) directs the NRC to submit a report to Congress within 180 days that describes the NRC's current and planned efforts to streamline environmental reviews for nuclear reactor licenses, including through the expanded use of current and new categorical exclusions, environmental assessments, and generic environmental impact statements. The report must also describe how the NRC will implement the Fiscal Responsibility Act of 2023 amendments to NEPA. Section 506 requires the NRC to include a schedule for promulgating a rule for any measures considered by the Commission whose implementation requires rulemaking.

2. Section 208 (Regulatory requirements for micro-reactors) directs the NRC to, within 18 months, develop performance-based and risk-informed guidance and strategies for licensing and regulating micro-reactors, including inspections and oversight, operations and staffing, security and safeguards, risk analysis methods, emergency preparedness, transport of fueled micro-reactors, and siting. In developing these strategies and guidance, the NRC must consider the unique size, source term and design simplicity of micro-reactors to inform the regulations. The NRC also must explore opportunities to consolidate reviews and minimize transition between teams for review, address inefficiencies and redundancies, and create integrated review teams for continuity in the review process. Section 208 further provides that, within three years, the NRC must implement these strategies and guidance within its existing regulatory framework, through the Part 53 licensing framework being developed by the NRC, or through another pending or new rulemaking.

3. Section 206 (Regulatory issues for nuclear facilities at Brownfield sites) directs the NRC to identify and report on regulations, guidance, or policy necessary to license and oversee nuclear facilities at brownfield sites, including sites with retired fossil fuel facilities, and at retired fossil fuel sites where one or more electric generation facilities are retired or scheduled to retire. Section 206 requires the NRC to consider how existing site infrastructure can be reused and how early site permits, plant parameter envelopes, or standardized applications for similar sites may be used for licensing. It further requires the NRC to develop and implement strategies, including through rulemaking, to enable and support licensing of nuclear facilities, considering matters relating to existing emergency planning, environmental data and reviews, decontamination and remediation, community engagement, and historical experience with energy use at the sites.

2.2.2 NRC Actions

Importantly, the NRC already has undertaken multiple initiatives to further streamline and enhance the agency's environmental review process. Through the Environmental Center of Expertise (EnvCOE) in the Office of Nuclear Material Safety and Safeguards, the NRC staff has been implementing process-related improvements in the context of individual licensing actions.[14] Other significant NRC activities include the ongoing development of a GEIS for advanced nuclear reactors (ANR GEIS) that uses a technology-neutral, plant parameter envelope approach; proposed revisions to the NRC's categorical exclusion regulations; issuance of interim staff guidance to assist the NRC staff in determining the scope and scale of environmental reviews of micro-reactor license applications; detailed guidance to optimize applicant and agency pre-application environmental review activities; and additional guidance on project need and purpose statements and the consideration of reasonable alternatives.[15] The NRC staff has also issued a Draft Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) for Kairos Power, LLC's Hermes 2 construction permit application in lieu of an EIS.[16] In addition, on May 30, 2024, the NRC staff issued SECY-24-0046, conveying the results of the staff's review of the FRA amendments to NEPA and its recommendations for future actions to enhance NRC's NEPA-implementing procedures.[17] Those recommended actions include rulemaking, a new policy statement, and updated guidance.

The NRC's draft ANR GEIS is especially germane to the issues discussed in this paper.[18] The GEIS uses a technology-neutral regulatory framework and performance-based values and assumptions (i.e., plant parameter envelope or PPE) to determine those environmental impacts that could result in the same or similar impacts for different advanced reactor designs that fit within the parameters set forth in the GEIS (Category 1 impacts), and those impacts that would require project-specific analysis (Category 2 impacts). The staff also developed a set of site parameters termed the site parameter envelope (SPE) (e.g., site size, size of water bodies supplying water to the reactor, and demographics of the region surrounding the site). The SPE also includes specific assumptions related to the condition of the affected environment, such as the extent and occurrence of wetlands and floodplains, proximity to aquatic features, etc. The GEIS presents generic analyses that evaluate the possible impacts of a reactor that fits within the bounds of the PPE on a site that fits within the bounds of the SPE (see ANR GEIS Appendix G, Table G-1, "Plant Parameter Envelope and Site Parameter Envelope for Advanced Nuclear Reactors").

A license application that references the ANR GEIS will need to demonstrate that its project is bounded by the analysis in the GEIS and that there is no significant new information affecting the evaluation. If the project is bounded by the GEIS and there is no significant new information, the NRC will incorporate by reference the GEIS and no further analysis will be needed. The application will also need to analyze the site-specific resources not resolved generically in the ANR GEIS, and the NRC staff will issue the site-specific supplement to the GEIS that evaluates the impacts to those resources. The draft SEIS would be issued for public comment in accordance with the NRC's current Part 51 procedures. The SEIS would be

[14] Such process improvements include early and more effective use of the pre-application process; an enhanced environmental audit process that includes more timely delivery of NRC questions/audit needs and results in comprehensive audit summary reports; earlier and better-defined site tours; and increased use of requests for confirmation of information in lieu of formal requests for additional information. The NRC also has used customized electronic reading rooms to expedite reviews of environmental documents. EnvCOE staff also are taking specific measures to reduce the length of NRC environmental review documents by reorganizing those documents to avoid redundancy and repetition, and by making increased use of use of tiering and incorporation by reference.

[15] *See* M. O'Neill, "Forging a clear path for advanced reactor licensing in the United States: approaches to streamlining the NRC environmental review process", *Nuclear Law Bulletin*, No. 105 (2021) at 53-69, https://inis.iaea.org/collection/NCLCollectionStore/_Public/52/048/52048856.pdf.

[16] *See* NRC's Notice of Availability and Request for Comment, 89 Fed. Reg. 32,462 (Apr. 26, 2024); ADAMS Accession No. ML24103A002.

[17] SECY-24-0046, "Implementation of the Fiscal Responsibility Act of 2023 National Environmental Policy Act Amendments" (May 30, 2024) (ML24078A013) (package).

[18] In SRM-SECY-21-0098, the Commission directed the NRC staff to revise the rulemaking package and related draft guidance documents to change the applicability of the GEIS from solely "advanced nuclear reactors" to any new nuclear reactor application, provided the application meets the values and the assumptions of the plant parameter envelopes and the site parameter envelopes used to develop the GEIS. It also directed the staff to consider whether to change the title of the GEIS, with associated edits to the rulemaking package and draft guidance documents, to better reflect applicability. For purposes of this paper, we still refer to the New Reactor GEIS as the ANR GEIS.

considered a supplement to the GEIS, and the ANR GEIS and the final SEIS would, together, document the NRC's NEPA review.

The NRC staff has issued a preliminary draft of COL-ISG-030, which outlines an appropriate scope and level of detail for the specific aspects of the staff's environmental review that references generic conclusions in the ANR GEIS. It also has released proposed Revision 4 to RG 4.2, which provides guidance on the content of applicant ERs. The draft RG updates and substantially expands Appendix C to RG 4.2 (which is specific to advanced reactors) and includes detailed guidance for applicants referencing the ANR GEIS in their ERs. Table C-11 of Appendix C lists each of the PPE and SPE values and assumptions, along with guidance related to demonstrating that the value or assumption has been met.

Of the 121 environmental issues identified in the draft ANR GEIS, 100 issues were designated Category 1, 19 issues were designated Category 2, and two issues were not assigned a category designation.[19] The 19 Category 2 issues are listed in Table 1 below.

Table 1 List of Category 2 Issues from NRC's Draft ANR GEIS (NUREG-2249)

Issue	ANR GEIS Section	NRC Explanatory Comments from ANR GEIS Table 4-1
Water Resources – Operation		
Surface Water Quality Degradation Due to Chemical and Thermal Discharges	3.4.2.2.7	The staff determined that a generic analysis to determine operational impacts on surface water quality due to chemical and thermal discharges was not possible because (1) some States may impose effluent constituent limitations more stringent than those required by the EPA, (2) limitations imposed on effluent constituents may vary among States, and (3) the establishment of a mixing zone may be required. Because all of these issues related to degradation of surface water quality from chemical and thermal discharges require consideration of project-specific information, a project-specific assessment should be performed in the SEIS.
Terrestrial Ecology – Construction and Operation		
Important Species and Habitats – Resources Regulated under the Endangered Species Act of 1973 (16 U.S.C. §§ 1531 et seq.)	3.5.2.1.6.1 (Construction)	The NRC staff is unable to determine the significance of potential impacts without consideration of project-specific factors, including the specific species and habitats affected and the types of ecological changes potentially resulting from each specific licensing action.

[19] The two "N/A" issues relate to exposure to electromagnetic fields (EMFs) during reactor construction and operation and do not have a national scientific agreement regarding adverse health effects (i.e., Uncertain Impacts). The draft ANR GEIS states: "Studies of 60 Hz EMFs have not uncovered consistent evidence linking harmful effects with field exposures. Because the state of the science is currently inadequate, no generic conclusion on human health impacts is possible. If, in the future, the Commission finds that a general agreement has been reached by appropriate Federal health agencies that there are adverse health effects from EMFs, the Commission will require applicants to submit project-specific reviews of these health effects as part of their application. Until such time, applicants are not required to submit information about this issue."

Appendix 1 – Generically Resolved Environmental Considerations

Issue	ANR GEIS Section	NRC Explanatory Comments from ANR GEIS Table 4-1
Important Species and Habitats – Resources Regulated under the ESA of 1973	3.5.2.2.10.1 2 (operation)	
Aquatic Ecology – Construction and Operation		
Important Species and Habitats – Resources Regulated under the ESA and Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. §§ 1801 et seq.)	3.6.2.1.4.1 (Construction)	The NRC staff is unable to determine the significance of potential impacts without consideration of project-specific factors, including the specific species and habitats affected and the types of ecological changes potentially resulting from each specific licensing action. Furthermore, the ESA and Magnuson-Stevens Fishery Conservation and Management Act require consultations for each licensing action that may affect regulated resources.
Important Species and Habitats – Resources Regulated under the ESA and Magnuson-Stevens Fishery Conservation and Management Act	3.6.2.2.10.1 (Operation)	
Thermal impacts on aquatic biota	3.6.2.2.7 (Operation)	Staff would have to first review the discharge plume analysis (as described in Section 3.4) and the aquatic biota potentially present before being able to reach a conclusion regarding the possible significance of impacts to that biota.
Other effects of cooling-water discharges on aquatic biota	3.6.2.2.8 (Operation)	
Historic and Cultural Resources – Construction and Operation		
Construction impacts on historic and cultural resources	3.7.2	Impacts on historic and cultural resources are analyzed on a project-specific basis. The NRC will perform National Environmental Policy Act (NEPA) and National Historic Preservation Act (NHPA) Section 106 analysis, in accordance with 36 CFR Part 800, in its preparation of the supplemental environmental impact statement (SEIS). The NHPA Section 106 analysis includes consultation with the State and Tribal Historic Preservation Officers, American Indian Tribes, and other interested parties.
Operation impacts on historic and cultural resources	3.7.2	
Postulated Accidents		
Severe Accidents	3.11.2.3	Based on the analysis in the Final Safety Analysis Report/Preliminary Safety Analysis Report regarding severe accidents, if an ANR design has severe accident progressions with radiological or hazardous chemical releases, then an environmental risk evaluation must be performed.
Environmental Justice – Construction and Operation		

Appendix 1 – Generically Resolved Environmental Considerations

Issue	ANR GEIS Section	NRC Explanatory Comments from ANR GEIS Table 4-1
Construction Environmental Justice Impacts	3.13.2.1	Project-specific analysis would be necessary, including analysis of the presence and size of specific minority or low-income populations, impact pathways derived from the plant design, layout, or site characteristics, or other community characteristics affecting specific minority or low-income populations. In performing its EJ analysis, the NRC staff will be guided by the NRC's "Policy Statement on the Treatment of Environmental Justice Matters in NRC Regulatory and Licensing Actions," which was published in the *Federal Register* on August 24, 2004.
Operation Environmental Justice Impacts	3.13.2.1	
Issues Applying Across All Resources		
Climate Change	1.4.3.2.2	The effects of climate change are location-specific and cannot, therefore, be evaluated generically. For example, while climate change may cause many areas to receive less than average annual precipitation, other areas may see an increase in average annual precipitation. Therefore, applicants and staff would address the effects of climate change in the environmental documents for ANR licensing.
Cumulative Impacts	1.4.2.2.2	Applications must individually consider the cumulative impacts from past, present, and reasonably foreseeable future actions known to occur at specific sites for proposed ANRs, and briefly present those considerations in supplemental NEPA documentation. The staff would explain whether these individualized evaluations of potential cumulative impacts alter any of the generic analyses and conclusions relied upon for Category 1 issues. The individualized cumulative impact analyses may also identify opportunities where staff might rely upon the generic analyses for some Category 1 issues for which certain of the PPE or SPE values and assumptions might be exceeded.
Non-Resource Related Issues		
Purpose and Need	1.4.3.2.3	Must be described in the Environmental Report associated with a given application.
Need for Power	1.4.3.2.3	
Site Alternatives	1.4.3.2.3	
Energy Alternatives	1.4.3.2.3	
System Design Alternatives	1.4.3.2.3	

The NRC historically has issued licenses for land-based reactors at fixed sites. The agency's current approach to site-specific licensing would not support RHDRA due to the time needed for the licensing process (safety and environmental reviews, hearings, etc.). To support timelines of 4 months or less from docketing an application to issuing a site-specific license, the NRC will need to consolidate and

Appendix 1 – Generically Resolved Environmental Considerations

"front load" these components of the licensing process to the maximum extent practicable. The NRC's environmental review would potentially need to cover RHDRA at any site. Relevant to this point, SECY-24-0008 states: "In order to be able to authorize operation of a mobile micro-reactor on an as-needed, where needed basis without preapproved sites, the environmental review would potentially need to cover deployment at any location within the United States. The NRC staff would need to further evaluate the feasibility of performing such a review and possible appropriate ways to meet the NEPA requirements, perhaps through bounding site parameters or other means." As discussed, the NRC's draft ANR GEIS makes use of bounding plant and site parameters and assumptions.

While the ANR GEIS contains only limited references to micro-reactors (which is applicable to RHDRA), it does reference COL-ISG-029, "Environmental Considerations Associated with Micro-reactors," which the NRC staff issued in final form in October 2020. The staff developed COL-ISG-029 to modify existing guidance and provide supplemental guidance to assist the NRC staff and applicants in determining the scope and scale of environmental reviews of micro-reactor applications; highlight unique considerations for micro-reactors in each resource area typically covered in the staff's environmental review; and provide guidance on scaling the analyses (i.e., the level of analysis should be scaled commensurate with the significance of the impact on the resource area being addressed).[20] As the staff notes in Enclosure 1 to SECY-20-0093, "Policy and Licensing Considerations Related to Micro-Reactors" (Oct. 6, 2020), the scaled or graded approach suggests that NRC NEPA review documents for micro-reactors "may not be as long or detailed as EISs prepared for larger reactors, because smaller facilities are likely to have less significant environmental impacts."

COL-ISG-029 reflects the NRC staff's expectation that a micro-reactor will have a small footprint and use limited resources. It further states that if the micro-reactor site disturbs no more than a few acres, then the amount of information and level of data collection needed to characterize the affected resources and the impacts resulting from the footprint of disturbance may be limited. In addition, due to the small facility size, the applicant can potentially select a site that avoids impacts to some resources, such as wetlands, floodplains, sensitive habitats, or historic and cultural resources.[21]

COL-ISG-029 also discusses the role that mitigation measures may play in reducing potential environmental impacts and, accordingly, the scope and scale of NRC's NEPA review. It explains that NRC can rely on "reasonably foreseeable" mitigation measures, which include measures that are: (1) required by NRC as a license condition, (2) required or likely to be required by another regulatory agency (e.g., United States Army Corp of Engineers), or (3) mitigation that the applicant has stated to the NRC (e.g., in the Environmental Report) that it would perform.

COL-ISG-029 also provides resource area-specific guidance that should be useful in implementing the approach suggested; i.e., development of a supplement to the ANR GEIS that generically dispositions as many resource issues as possible, thereby minimizing the scope and scale of any site-specific analysis (if

[20] As COL-ISG-029 notes, "NEPA instructs agencies to discuss environmental issues in accordance with their significance." 10 CFR 51.45(b) directs applicants to take a scaled or graded approach to describing the environmental impacts, noting that "[i]mpacts shall be discussed in proportion to their significance."

[21] COL-ISG-029 also acknowledges that may be possible to site micro-reactors entirely within existing or former industrial areas without requiring the dedication of land otherwise available for non-industrial uses or the disturbance of natural habitats or cultural resources. The discussions of impacts to land use, terrestrial and aquatic ecology, and cultural resources may be simplified for those micro-reactors. However, the ISG notes that may be necessary to consider the possible presence of contaminated soils, groundwater, and other environmental media resulting from former industrial operations at those sites.

not eliminating the need for such analysis altogether). Table 2 below excerpts guidance from COL-ISG-029 that is relevant to the 19 Category 2 issues listed in Table 1 above.

Table 2 COL-ISG-029 Guidance Relevant to ANR GEIS Category 2 Issues

<table>
<tr><th>Issue</th><th>COL-ISG-029 Guidance</th></tr>
<tr><td>Surface Water Quality Degradation Due to Chemical and Thermal Discharges</td><td>If a micro-reactor did not use cooling water it would not require constructing or operating cooling water intake or discharge structures or pipelines. If this is the case, the ER will not need to analyze the associated impacts. A brief evaluation may be sufficient to document that the water demands can be met without noticeably affecting surface and ground water resources. It may also be necessary to briefly document the use of best management practices in accordance with state or local guidelines to minimize potential erosion and sedimentation.</td></tr>
<tr><td>Important Species and Habitats – Resources Regulated under the ESA</td><td>Micro-reactors might affect terrestrial habitat and important species and their habitats. Micro-reactors could be sited to avoid wetlands, riparian habitats, critical habitats, or habitats potentially containing threatened or endangered species. The ER will not have to address potential impacts to terrestrial features that are avoided. Micro-reactors also might not require transmission lines, pipelines, heavy haul roads, or other linear development features. If such linear development is not contemplated, then the ER will not have to consider possible effects on terrestrial habitats distant from the site. It will always be necessary for the NRC staff to consult with the U.S. Fish and Wildlife Service (FWS) to comply with Section 7, “Interagency Cooperation,” of the Endangered Species Act. However, it may be possible to resolve potential concerns from a micro-reactor project affecting little or no terrestrial habitat through informal consultation.</td></tr>
<tr><td>Important Species and Habitats – Resources Regulated under the ESA and Magnuson-Stevens Fishery Conservation and Management Act</td><td rowspan="3">If micro-reactors did not use cooling water it would not require constructing or operating cooling water intake or discharge structures or pipelines; the staff will not have to address such issues as entrainment, impingement, or entrapment of aquatic biota or thermal discharges. If a micro-reactor is sited away from surface waters and associated floodplains and stream valleys, the ER will not need to characterize potential impacts from sedimentation or erosion. Micro-reactors also may not require transmission lines, pipelines, heavy haul roads, or other linear development features. If such linear development is not contemplated, then the ER will not have to consider possible effects on surface water features distant from the site. It will always be necessary for NRC staff to consult with the FWS and National Marine Fisheries Service (NMFS) to comply with Section 7 of the Endangered Species Act. For projects sited in coastal areas or near large rivers, the staff may need to consult with the NMFS as well to comply with the Magnuson-Stevens Act. However, it may be possible to resolve potential concerns from a micro-reactor project affecting little or no aquatic habitat through informal consultation.</td></tr>
<tr><td>Thermal impacts on aquatic biota</td></tr>
<tr><td>Other effects of cooling-water discharges on aquatic biota</td></tr>
</table>

Appendix 1 – Generically Resolved Environmental Considerations

<table>
<tr><th>Issue</th><th>COL-ISG-029 Guidance</th></tr>
<tr><td>Construction impacts on historic and cultural resources</td><td rowspan="2">Applicants for micro-reactors may propose to disturb only a small footprint of land, which may correspond to a small area of potential effects (APE) on historic and cultural resources. Based on the size of the APE, it may be possible to site a micro-reactor to avoid or minimize impacts to historic and cultural resources. However, the process for assessing effects to historic properties and historic and cultural resources, along with the associated consultation under Section 106 of the National Historic Preservation Act of 1966, is the same as for other reactor projects. The implementing regulations at 36 CFR Part 800, “Protection of Historic Properties,” serve as a guide for gathering information and assessing the effects to historic properties. A small APE may expedite the review process. The scope of the impact evaluation depends on the potential presence and significance of resources within the APE. For example, siting on previously disturbed land could potentially reduce the likelihood of discovering archaeological resources.</td></tr>
<tr><td>Operation impacts on historic and cultural resources</td></tr>
<tr><td>Severe Accidents</td><td>A particular micro-reactor design may not have credible severe accidents associated with it. (The NRC staff will determine whether credible severe accidents are associated with a particular micro-reactor design based on the staff’s review of information presented in an applicant’s safety analysis report.) In such a case, the NRC staff will not need to assess the offsite environmental impacts from severe accidents or evaluate the benefits and costs of SAMAs. The ER should provide information, including appropriate references to the accident analysis contained in the safety analysis report, to support the assertion that a SAMA evaluation is not needed. The NRC staff’s EIS must document whether or not the conclusions reached in the safety evaluation report support the applicant’s severe accident analysis. However, if the micro-reactor design has credible severe accidents, a SAMA evaluation will be necessary. The current guidance for SAMAs is based on several documents, including NUREG/BR-0058, “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission,” and NUREG/BR-0184, “Regulatory Analysis Technical Evaluation Handbook,” issued January 1997, with industry guidance for license renewals provided in Nuclear Energy Institute (NEI) 05-01, “Severe Accident Mitigation Alternatives (SAMA) Analysis, Guidance Document,” Revision A, issued November 2005.

If the design includes credible severe accidents, the applicant should perform a SAMA screening, and the NRC staff will determine whether a SAMA evaluation is necessary. In considering the results of the screening, the NRC staff should determine the cost benefit of performing a SAMA evaluation. This screening process should be based on the available risk information from the safety analysis report and apply the cost formulas as a first step rather than a last step, as prescribed under current review practices. If the resulting maximum benefit cost will clearly not exceed the implementation cost of any design alternatives, then the</td></tr>
</table>

Appendix 1 – Generically Resolved Environmental Considerations

Issue	COL-ISG-029 Guidance
	environmental finding of no potentially cost-beneficial SAMAs is reasonable.
Construction Environmental Justice Impacts Operation Environmental Justice Impacts	COL-ISG-029 provides guidance to the socioeconomic impact analysis required under NEPA and does not directly address environmental justice. However, it notes that "[t]he scope [of socioeconomic impact analysis] will depend on the extent of project activities, and the focus of the analyses should consider only those areas affected by the project and the distances at which impacts of building and operating over the expected license term may occur." This suggests that any environmental justice analysis could be similarly scaled, and that individual micro-reactor deployments could be sited to avoid or mitigate any potential adverse impacts on communities with possible environmental justice concerns.
Climate Change	Micro-reactors may have limited potential air emissions and if the project is replacing a carbon dioxide (CO2) emitting generator or is built instead of CO2 emitting generator, then it is expected to have a **net positive potential contribution to mitigating global climate change.** For specific data requirements, the environmental review of potential meteorology and air quality impacts from micro-reactors will likely rely on the same information provided for the safety review and not require additional monitoring data or dispersion modeling. If a micro-reactor operates without cooling towers, then analyses of cooling tower drift, shadowing, fogging, and icing will not be necessary. The applicant should scale, as appropriate, any analysis of atmospheric emissions from construction and operations based on the review procedures in NUREG-1555 to the expected level of emissions. However, the staff may rely on other documents as appropriate for its global climate change review and findings. **If the project will avoid CO2 emissions by replacing a source of power that emits CO2 compared to alternatives, then the staff should estimate the CO2 avoided by generating the electricity from a micro-reactor.** The staff should calculate the operational CO2 emissions from the micro-reactor including emissions from associated auxiliary boilers or emergency generators, if any. The operational CO2 emissions from an alternate generator of the same size as the micro-reactor should be calculated and compared to the operational emissions from the micro-reactor. State the effects of replacing the alternate generator with a micro-reactor on global climate change.
Cumulative Impacts	Micro-reactors may have operational and physical characteristics (e.g., small footprints) that minimize the size of the area affected by the micro-reactor project, thereby more narrowly focusing the scope of the cumulative impact analysis. **If the micro-reactor project does not impact a resource, then the NRC's environmental review will not need to discuss or provide a cumulative impact analysis for that resource.**
Purpose and Need Need for Power Site Alternatives	The NRC staff develops the purpose and need statement, informed by the applicant's objectives as stated in the applicant's ER, and this statement is the basis for the evaluation of the need for the project and for establishing

Appendix 1 – Generically Resolved Environmental Considerations

Issue	COL-ISG-029 Guidance
Energy Alternatives System Design Alternatives	a reasonable set of alternatives to the proposed action. Reasonable alternatives include those that are practical or feasible from the technical and economic standpoint using common sense. A reasonable alternative may be outside an agency's regulatory authority, such as energy alternatives (e.g., coal, wind, solar, natural gas) and would need to be evaluated to determine if it meets the purpose and need statement for the project. However, if the purpose and need statement was to demonstrate a certain advanced reactor technology to generate electricity, alternative energy such as coal, wind, solar or natural gas would not be a reasonable alternative because it does not meet the purpose and need statement. Alternatives that do not meet the purpose and need statement are not considered reasonable alternatives and are not analyzed in detail. **For micro-reactors, the applicant may request licensing for purposes other than or in addition to electric power production, and the NRC staff considers the purpose of the project as identified by the applicant's ER in developing the purpose and need statement in the NRC's EIS.** The applicant should base the discussion of the need for electrical power on the guidance in RG 4.2**. However, a micro-reactor application might include additional purposes, such as generating power in a cogeneration arrangement or exclusively producing specific products (e.g., potable water, hydrogen gas). In each case, the NRC staff will determine the need for the proposed end-user products.** RG 4.2 provides several options to demonstrate the need for power. For instance, if an applicant were to seek a license for the cogeneration of electricity and the desalination of saltwater for human consumption, the applicant would have to establish the need for the electricity in a manner similar to that currently discussed in RG 4.2. Similarly, the plan to produce potable water would trigger a second need analysis to determine whether the relevant service area needs the water that would be produced. This additional need would also trigger a second set of alternative analyses—in this case, for alternative ways to supply the societal need for potable water (e.g., drilling wells, creating reservoirs, or piping in water from where it is more abundant). **Early in the preapplication process, the NRC staff should determine whether the applicant anticipates including purposes for the proposed facility beyond the commercial sale of electricity.**

In SRM-SECY-22-0100, the Commission recently authorized a proposed rule for categorical exclusions from environmental review for certain licensing, regulatory, and administrative actions that individually or cumulatively do not have a significant effect on the human environment. In SECY 22-0100, the staff noted: "The staff identified new categorical exclusions and modified existing categories due to inconsistencies between existing excluded categories. In addition, the staff evaluated all existing categorical exclusions to determine if any are no longer necessary or have proven to no longer meet the criteria for categorical exclusion. The proposed revisions would eliminate the preparation of [EAs] for such actions. The proposed rule would not change requirements for licensees or applicants and would provide for more timely NRC action." Further, the proposed revisions to the categorical exclusion regulations would reduce inefficiencies and inconsistencies in the implementation of the NRC's regulatory program, to "ensure resources are directed to activities that have the potential to significantly affect the environment." Many of these bases are similar to the bases for RHDRA and other similar advanced reactors discussed in this Appendix.

3 PROPOSED SOLUTION AND APPROACH

An alternative approach for the site-specific environmental reviews of RHDRA is needed to achieve the business requirement of less than 6 months from site identification to operations. This approach would be integral to establishing a rapid, efficient licensing (ReLic) process that is based on existing NRC licensing processes in Part 50 and Part 52 (see Appendix 5 – Site License Scope and Purpose). The goals of the approach for RHDRA environmental reviews are to optimize standardization and significantly reduce the scope of the site license review by:

1. Completing all of the environmental review, interagency consultations and public engagement required by NEPA one-time up-front and before sites are identified through one or more of the following: Categorical Exclusion, Generic Environmental Impact Statement, and Rulemakings, to eliminate or greatly reduce the need to consider these during site-specific reviews; and

2. Performing a site-specific license review that only needs to verify that the site characteristics conform to the minimum set of site parameters in the envelope established in the one-time up-front reviews.

Overall, it appears feasible to leverage generic and performance-based environmental review approaches, as well as current NRC guidance documents and procedural tools, to achieve these objectives. Consistent with the ADVANCE Act's directive that the NRC consider the use of categorical exclusions for new nuclear reactor license applications, and as discussed in Section 3.1 below, the NRC should explore the development of a categorical exclusion(s) for RHDRA. In doing so, the NRC should use relevant technical information contained in the ANR GEIS and in EAs and EISs prepared by the DOE and NRC for micro-reactor and advanced reactor projects. It also should consider insights gained from DOE's establishment and application of categorical exclusions for various non-nuclear project types or classes of action in 10 CFR Part 1021, Appendix B, insofar as they may provide useful analogues to the types of categorical exclusions envisioned by the industry for RHDRA.

The ability to use generic environmental reviews to address all environmental considerations stems from several factors:

1. Due to their compact footprint, limited use of natural resources, and relative lack of severe accident risk (i.e., low potential for radioactive releases and associated consequences), the environmental impacts of RHDRA and other similar advanced reactors are expected to be minimal, even if deployed at a "greenfield" site, such that repeated preparation of detailed site-specific EISs or EAs should be unnecessary.

2. The environmental impacts of RHDRA are expected to be much smaller than available alternatives. RHDRA and other similar advanced reactors, due to their size and power level, are

replacements and substitutes for diesel generators, coal plants, and natural gas combined cycle plants. These alternatives are of the same size or greater than the advanced reactor that would be proposed for use. The advanced reactors would also avoid significant amounts of carbon emissions to the air and other potential impacts to land and water (e.g., coal ash or diesel spills). Beyond the direct impacts of the plants, advanced reactors would utilize similar transmission infrastructure, but avoid the need for frequent shipments or the need for pipelines to transport fuel to site.

3. A project that selects an advanced reactor to provide heat and/or power to the site and operations will have done so with considerable thought to the alternatives and decided that advanced reactors are the best (if not only) solution to provide such energy reliably and affordably. The financial qualifications and the technical qualifications that are needed to build and operate the plant are a natural barrier for market adoption and customer selection. Thus, an entity does not enter into an application for a construction permit or operating license lightly, but only after it has determined a need for the energy and that the advanced reactor is by far the best alternative.

4. RHDRA, which are being defined as used for remote applications, are usually paired with an industrial facility or other business operation that needs the power source to be co-located with that facility. While this paper is focused on remote locations, and industrial applications in particular, these siting considerations are applicable to most advanced reactor projects, i.e., the need for the power source to be located proximal to the load center. Thus, there are few alternative locations to site the advanced reactor, except in a limited circumference around the perimeter of the co-located facility. In this manner, all considerations that are hyper-local to the site (e.g., flora and fauna, historical and cultural resources) and can be avoided only to a certain degree would already have been evaluated during siting of the co-located facility. Further, the siting of the advanced reactor will meet state requirements for these hyper-local considerations, following the same process for the siting of the co-located facility. The NRC can appropriately leverage these prior reviews and authorizations in meeting its NEPA obligations.

RHDRA may be constructed in industrial buildings and at previously disturbed sites, where the majority of site work is not related to radiological impacts, and the potential for environmental impacts is small. This greatly reduces the chance that RHDRA would have significant environmental impacts and makes it easier for most (if not all) of the key environmental issues to be evaluated generically, and any required site-specific analyses to be scaled commensurately.

3.1 Use of Categorical Exclusions for RHRDA

The optimal long-term approach for RHDRA environmental reviews likely will involve the use of categorical exclusions. The above-listed considerations reduce the chance that RHDRA would have a significant impact on the environment and makes it easier for a large number, if not all, of the key environmental issues to be evaluated generically. If the NRC is able to determine that a given RHDRA design would not have a significant impact on the environment when it is sited within a given site parameter envelope, then it may consider developing a categorical exclusion and associated rulemaking that reflects this determination and avoids the need for site-specific EAs or EISs.

Appendix 1 – Generically Resolved Environmental Considerations

The CEQ's 2010 guidance on categorical exclusion identifies four methods for substantiating a new or revised categorical exclusion that can be used alone or in combination. Those methods include:

1. Assessing the environmental effects of previously implemented or ongoing actions, including implemented actions that were analyzed in EAs that consistently supported FONSIs, and actions that were implemented in EISs;

2. Using impact demonstration projects to assess the environmental effects of those actions, during which the federal agency may monitor the actual environmental effects of the proposed action during and after implementation;

3. Relying on the expertise, experience, and judgment of agency professional staff and outside experts to assess the potential environmental effects of applying proposed categorical exclusions (including review of relevant scientific analyses); and

4. Benchmarking another agency's experience with a comparable categorical exclusion(s) and the associated administrative record(s).

The NRC could use one or more of these methods to develop categorical exclusions for RHDRA. In this regard, the NRC should consider the approach used by DOE in its NEPA-implementing regulations in 10 CFR Part 1021, Subpart D, Appendix B. Those regulations include useful analogues to the types of categorical exclusions envisioned by the industry for RHDRA. For example, the following categorical exclusions are classes of actions that DOE has determined do not individually or cumulatively have a significant effect on the human environment: small-scale renewable energy research and development and pilot projects (B5.15); solar photovoltaic systems (B5.16); solar thermal systems (B5.17); wind turbines (small scale) (B5.18); ground source heat pumps (B5.19); biomass power plants (B5.20); drop-in hydroelectric systems (B5.24); and small-scale renewable energy research and development and pilot projects in aquatic environments (B5.25). The DOE regulations provide details about the above-listed projects, among others, that would be considered categorically excluded. Many of these projects are of the same scale and size of some proposed advanced reactors (e.g., micro-reactors).

Notably, in a recent rulemaking in which DOE added categorical exclusions for certain energy storage systems and revised categorical exclusions for upgrading and rebuilding powerlines and for solar photovoltaic systems, DOE described its categorical process in detail.[22] As explained therein, in addition to developing a substantiation record to support the establishment or revision of a categorical exclusion, DOE conducts a project-specific environmental review when determining whether one or more categorical exclusions applies to a proposed action. DOE determines on a case-by-case basis that: (1) the proposed action fits within a categorical exclusion listed in Appendix A or B to Subpart D of Part 1021, including, in the case of categorical exclusions listed in Appendix B, the "integral elements" set forth in Appendix B; (2) there are no "extraordinary circumstances" related to the proposal that may affect the significance of the proposed action's environmental impacts and require preparation of an EA or EIS; and (3) the proposal has not been improperly segmented to meet the definition of a categorical exclusion.

The NRC could develop and implement a similar categorical exclusion process for RHDRA to streamline the environmental review process for such projects and avoid the need for an EA or EIS for each site.

[22] DOE, National Environmental Policy Act Implementing Procedures; Final Rule, 89 Fed. Reg. 34,074 (Apr. 30, 2024).

Appendix 1 – Generically Resolved Environmental Considerations

Like DOE, the NRC could retain the ability to prepare an EA or EIS rather than relying on a categorical exclusion, particularly if it determines that extraordinary circumstances are present. The NRC also should modify its Part 51 regulations to be consistent with current CEQ regulations that allow the use of mitigated categorical exclusions.[23] Current 40 CFR 1501.4(b)(1) states: "If an extraordinary circumstance exists, the agency nevertheless may apply the categorical exclusion if the agency conducts an analysis and determines that the proposed action does not in fact have the potential to result in significant effects notwithstanding the extraordinary circumstance, or the agency modifies the action to avoid the potential to result in significant effects." Mitigating circumstances could include such things as design alternatives and best practices that reduce emissions, construction impacts, land disturbances, aesthetic intrusion, etc. The NRC already allows the use of "mitigated FONSIs," a concept that is similar to the mitigated categorical exclusion.[24]

In developing an RHDRA categorical exclusion, the NRC could consider the bounding plant and site parameters and supporting technical analysis presented in the ANR GEIS. The NRC developed the ANR GEIS using technical information and analyses from many sources. Those sources include, among others, 15 new reactor (ESP and COL) EISs prepared between 2005 and 2017, NRC's License Renewal GEIS, other NRC EISs, common elements of state and local land use regulations, and the 2021 *Advanced Nuclear Reactor Plant Parameter Envelope and Guidance* (NRIC-21-ENG-0001; PNNL-30992) jointly prepared by the National Reactor Innovation Center and Pacific Northwest National Laboratory.[25] The PPE/SPE values and assumptions developed by the NRC for each Category 1 issue (but perhaps modified to be better tailored to RHDRA) could provide the criteria or conditions needed to ensure that there is no potential for significant environmental impacts associated with the categorically excluded action(s).

There also is considerable experience available from the research and test reactor fleet to demonstrate that the environmental impact from a micro-reactor is negligible and, in some cases, positive. Moreover, other advanced reactor projects, including micro-reactor projects, have undergone NEPA reviews by DOD, DOE, and the NRC, and those agencies have concluded that the environmental impacts are small. As summarized in a recent Nuclear Innovation Alliance (NIA) report on high-volume licensing:

> "In both the Hermes and Project Pele cases, the EIS for the advanced reactors found the **environmental impacts would be negligible to small for all evaluation categories**. While it is appropriate that a first-of-a-kind project may need to complete an EIS to help assess the environmental impacts, the incredibly small quantitative impacts of these projects suggest that for subsequent projects using a similar design at a similar site an EA may be more appropriate than an EIS and that the EA would likely lead to a FONSI. This conclusion could be extended across different projects with similar characteristics and sites, including reactors with higher power outputs. **The recent experience with NEPA reviews of four advanced reactors (Marvel, MCRE, Hermes, Project Pele) across three federal agencies suggests that use of alternative**

[23] 10 CFR 51.22 and related NRC guidance (NRR Office Instruction LIC-203, Rev. 4) currently do not permit the use of mitigated categorical exclusions. Specifically, 10 CFR 51.22(b) provides that the NRC may apply a categorical exclusion listed in 10 CFR 51.22(c) "[e]xcept in special circumstances."

[24] See NRR Office Instruction LIC-203, Rev. 4, at 7 ("If the EA demonstrates that the proposed action will, or has the potential to, significantly affect the environment, but can be mitigated to the point where the action will no longer have a significant impact, … this scenario may involve the preparation of a 'mitigated' FONSI[].").

[25] *See* ANR GEIS at 1-4, 1-8 to 1-9, G-1.

> **NEPA review processes may be appropriate for the licensing of commercial advanced reactors by the NRC.**[26]

These other NEPA reviews could be useful in developing categorical exclusions for RHDRA. For example, the NRC could benchmark the environmental impacts of the DOD's Project Pele, which is a micro-reactor of similar impacts to RHDRA, to establish a basis for no significant impact considerations. It could also benchmark the experience of other agencies in implementing categorical exclusions for similar impact level activities, such as the DOE actions listed above, and current statutory categorical exclusions for oil and gas activities on public lands.[27] Finally, NRC's initial reviews of pending and future advanced nuclear applications may create precedent-setting analysis that can be incorporated into 10 CFR 51.22.

The foregoing recommendations are focused on the NRC considering how it can exercise more latitude to consider categorical exclusions based on the circumstances of the proposed action. While the development of an RHDRA categorical exclusion would require NRC staff to perform regulatory evaluations, solicit public comment and input, and engage in rulemaking, providing a strong basis for NRC action would address potential challenges that such a change may occasion.

3.2 Use of a GEIS-Based Approach

Until such time as the NRC can develop categorical exclusions, the NRC may need to rely on a GEIS with NEPA compliance provided by site-specific EA/FONSIs tiered off the GEIS. This approach should make the environmental review process for advanced reactors, including RHDRA, substantially more efficient. However, it likely would not achieve the 2-month site-specific environmental review discussed above due to the level of site-specific analysis still required for Category 2 issues and the need to meet other procedural requirements associated with the NEPA process (e.g., scoping, interagency consultation, public meetings, contested hearing opportunity).

As a step toward the 6-month objective, the NRC could develop a supplement to the ANR GEIS that is specific to RHDRA to generically disposition the 19 Category 2 issues and the 2 uncategorized issues in the ANR GEIS as having little to no anticipated impact on the environment.[28] Some of these 19 Category 2 issues appear to be readily conducive to "generic" resolution because they are "Non-Resource Related Issues" – i.e., Purpose and Need, Need for Power, Site Alternatives, Energy Alternatives, and System Design Alternatives. In fact, the NRC staff has developed draft pre-application engagement guidance aimed at optimizing safety and environmental reviews for advanced reactor applications. That guidance recommends that applicants submit white papers on certain key topics and on "any novel approaches to environmental topics," including but not limited to: (1) the purpose and need statement for a project

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[26] NIA, Enabling High Volume Licensing of Advanced Nuclear Energy at 34 (Jan. 2024) (emphasis added), https://nuclearinnovationalliance.org/enabling-high-volume-licensing-advanced-nuclear-energy.

[27] DOE has taken an analogous approach in its current Subpart D regulations, insofar as certain categorical exclusions "include criteria (e.g., acreage, location, and height limitations), **based on DOE and other agency experience and regulatory requirements**, that limit the covered actions to those that normally would not have the potential to cause significant impacts." National Environmental Policy Act Implementing Procedures; Final Rule, 76 Fed. Reg. 63,764 (Oct. 13, 2011) (2011 DOE NEPA Rule) (establishing 20 new categorical exclusions and removing two categorical exclusion categories, one environmental assessment category, and three environmental impact statement categories). The Tennessee Valley Authority (TVA) took this approach when it revised its list of categorical exclusions in 2020*See* TVA, Procedures for Implementing the National Environmental Policy Act; Final Rule, 85 Fed. Reg. 17,434 (Mar. 27, 2020); TVA, Proposed Categorical Exclusions Supporting Documentation (Feb. 2020).

[28] This presumes, of course, that the RHDRA fall within the PPE and SPE, respectively, set forth in the ANR GEIS. This is a reasonable assumption since the ANR GEIS scoping is envisioned to encompass large reactors of 4,500 MW-thermal or more, and the RHDRA are expected to be less than 250 MW-thermal, with most being less than 50 MW-thermal. However, if they do not, then the issues for which the ANR GEIS Category 1 findings do not apply would need to be addressed in the supplement to the ANR GEIS.

that specifies uses other than electricity production; (2) alternatives to the proposed project; (3) information on the proposed facility's water consumption and water availability; and (4) needed authorizations, permits, and licenses for the project, including timelines for obtaining the necessary permits. It appears that much of the information could be developed well in advance of any site-specific application submittal. Information on the RHDRA design (including design alternatives and SAMDAs) should be developed as part of any design certification or manufacturing license application.

Other Category 2 issues may be readily addressed given the smaller site footprints and deployment/operational impacts of RHDRA on the environment. For example, as noted in COL-ISG-029, only brief evaluations may be needed if facility water demands can be met without any significant impacts on surface and ground water resources. Similarly, RHDRA are expected to have a net positive potential contribution to mitigating global climate change by replacing fossil technologies (e.g., diesel generators). Additionally, some potential impacts may be addressed through the use of bounding performance-based assumptions/parameters, and possibly related mitigation measures or best management practices that could be included within an ANR GEIS supplement.

Category 2 issues that involve interagency consultation requirements under other environmental statutes or inherently site-specific analyses (e.g., endangered species, historical and cultural resources, environmental justice) pose greater challenges. As noted in COL-ISG-029, the expected small physical footprints and small environmental impacts of micro-reactors (especially when deployed on previously-disturbed sites) should serve to simplify any necessary evaluations and consultations under the ESA, NHPA, etc. (e.g., by allowing for informal consultations). However, early engagement with the NRC and any relevant federal, state, and Tribal agencies will be needed to address endangered species, historic and cultural resources, and environmental justice issues in the ANR GEIS supplement, such that these issues can be addressed on a generic or programmatic basis for individual RHDRA deployment sites without the need for further interagency consultation or public engagement.

For instance, the NRC could work with the relevant agencies (e.g., Fish and Wildlife Service, federal, state, and tribal historic preservation offices) and state agencies to conduct appropriate programmatic consultations/analyses and develop standardized Best Management Practices (BMPs) and mitigation measures that the RHDRA licensee would need to apply if certain resource conditions occur (e.g., the known or possible presence of a listed endangered species or critical habitat). If the licensee agrees to apply the identified BMPs and mitigation measures during project planning, construction, and operation, as applicable, the analyses presented in the ANR GEIS supplement would serve as the principal means of identifying the nature and magnitude of impacts. The NRC would verify the site-specific license applicant's compliance with the BMP as the principal agency for making such determinations. This would simplify the preparation of site-specific NEPA documentation and would reduce the time needed to complete any site-specific environmental evaluations and interagency consultations, consistent with directives contained in the 2024 ADVANCE Act and 2023 Fiscal Responsibility Act amendments to NEPA.[29]

There is precedent for using such an approach. For example, in the preamble to its April 2024 revisions to its categorical exclusion regulations in 10 CFR Part 1021, DOE noted that it "supports using

[29] For example, Section 506 of the ADVANCE Act directs the NRC to consider opportunities to streamline formal and informal consultations and coordination with other federal, state, and local governmental permitting agencies during environmental reviews of applications. Section 110 (E-NEPA) of the Fiscal Responsibility Act of 2023 directs agencies to explore use of online and digital technologies to "enhance interagency coordination in consultation."

programmatic consultations and similar approaches to improve the efficiency of implementing the Endangered Species Act, the National Historic Preservation Act, and other laws."[30] DOE also provided the following specific example:

> Commenters stated the DOE could encourage programmatic Endangered Species Act Section 7 consultations for specific regions and cited the programmatic biological assessment prepared by DOE's Western Area Power Administration for wind energy development and interconnection requests in the Upper Great Plains Region as a relevant example. DOE responds that the referenced programmatic biological assessment analyzed information and identified a list of conservation measures for 28 species of concern. Western Area Power Administration and the U.S. Fish and Wildlife Service developed a review and approval system based on consistency forms and checklists of conservation measures for each species. If a wind project developer commits to implement the applicable conservation measures, Western Area Power Administration's consultation responsibilities under Section 7 of the Endangered Species Act are concluded when Western Area Power Administration and the U.S. Fish and Wildlife Service review and sign the consistency forms; no separate Section 7 consultation is required unless the particular project involves a listed species, critical habitat, or an effect that was not addressed in the programmatic biological assessment.[31]

Finally, it warrants mention that the NRC staff already is developing procedures to help ensure the timely completion of consultations and interagency coordination when they are conducted in parallel with the staff's NEPA reviews.[32] Additionally, in Enclosure 6 to SECY-24-0046, the staff recommended that rulemaking conducted to comply with the 2023 amendments to NEPA also should consider acceptance review criteria with respect to information that is needed to comply with other statutes. The staff notes, for example, that preparation for NHPA and ESA consultations and outreach to environmental justice communities may occur before application submittal. Therefore, the staff would explore, through the rulemaking process, having the applicant complete preliminary outreach and coordination before submittal of an application. Applicants may also reach out to or identify Tribes and populations to be considered for environmental justice analysis or coordinate with state agencies or federal agencies such as the U.S. Fish and Wildlife Service or the National Oceanic and Atmospheric Administration, as appropriate, to gather needed site information before submitting their application.[33]

Notwithstanding the foregoing recommendations, if all 121 NEPA issues cannot be dispositioned through a GEIS to achieve site-specific environmental reviews within 2 months, and without the need for interagency consultations or public engagement, then the NRC will need to develop a categorical exclusion for those issues, as discussed in Section 3.1.

3.3 Changes Needed to Regulations, Policy and Guidance

The environmental review approach described above could be largely accomplished under the NRC's environmental review framework in 10 CFR Part 51. This presupposes, however, that the NRC publishes

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[30] DOE, National Environmental Policy Act Implementing Procedures; Final Rule, 89 Fed. Reg. 34,074, 34,083 (Apr. 30, 2024).
[31] *Id. See also* DOE, Technical Support Document for Notice of Final Rulemaking, National Environmental Policy Act Implementing Procedures (10 CFR Part 1021) (Apr. 2024), available at https://www.energy.gov/nepa/articles/technical-support-document-final-rule-april-2024 (discussing the use of BMPs and mitigation measures, mitigation implementation tables, mitigation action plans, etc. by various federal agencies).
[32] *See* SECY-24-0046 at 1 & Enclosure 6 at 8.
[33] *See* SECY-24-0046, Enclosure 6 at 7-8.

Appendix 1 – Generically Resolved Environmental Considerations

the ANR GEIS and associated amendments to Part 51 in final form and without major changes. An essential feature of this proposed approach is that the generic disposition of the NEPA requirements (e.g., GEIS, Categorical Exclusion) are codified by rulemaking. The NRC is expected to publish the ANR GEIS, proposed rule, and related draft regulatory guidance (COL-ISG-030, Revision 4 to Regulatory Guide 4.2) by the end of this year. It may be possible to revise those documents such that they encompass RHDRA and other similar advanced reactors.

Developing a technology-inclusive supplement to the ANR GEIS to address the 19 Category 2 and 2 uncategorized issues to minimize the need for site-specific evaluations of RHDRA is a novel approach. Therefore, addressing the remaining issues in a supplement to the ANR GEIS likely will require preapplication engagement with the NRC (and likely other federal and state agencies) and early development of supporting technical information and white papers on the key environmental review topics identified above.

As noted above, if the NRC is able to determine that reactors of a given size and/or design would not have a significant impact on the environment when it is sited within a given site parameter envelope, then it eventually may be able to develop a categorical exclusion. The NRC staff would need to perform appropriate regulatory evaluations, seek public comments, and complete a formal rulemaking process to develop and promulgate performance-based criteria for the use of such a categorical exclusion. Additionally, if the NRC wishes to make greater use of EAs for RHDRA, then it will need to modify 10 CFR Part 51.20(b) to avoid the need for site-specific exemptions (as in the case of the Kairos Hermes 2 construction permit proceeding).

To accomplish the time frame and right-sizing objectives, the NRC also will need to make modifications to the interagency consultation and public participation and hearing processes associated with its site-specific NEPA reviews. Since the Categorical Exclusion and/or GEIS approaches would have fulfilled all NEPA obligations for these activities, they would not be required for site-specific applications. Such modifications could be accomplished through rulemaking or case-specific orders. Under current NRC regulations, licensing proceedings include extensive public participation opportunities, including public meetings near the proposed site to familiarize the public with the safety and environmental aspects of the application, the planned location and type of plant, and the NRC's licensing process. To enable the 180-day schedule, much of this public participation will need to take place in **advance** of the submittal of any site-specific license application, likely as part of the NRC's development of its supplement to the ANR GEIS. However, a contested hearing process that can be completed within three months presents unique legal challenges that may require use of a rule of particular applicability and/or case-specific hearing orders until the NRC can develop an appropriate generic approach.

The NRC also holds public meetings with the applicant during the licensing process to discuss the facility's design and construction and other relevant issues. Additionally, the NRC solicits public comments on the scope of the review and holds related public meetings near the proposed site. It also offers members of the public opportunities to request a contested hearing on the application and to participate in the hearing process through various channels (e.g., as an intervenor/party, interested governmental entity, limited appearance statements). These opportunities could be utilized by the public and other agencies if they believe that the finality of environmental reviews achieved through the GEIS and/or Categorical Exclusions are not applicable to the site-specific application.

3.4 Acceptance Criteria and Licensing Approach

The acceptance criteria will be largely determined by the assumptions and values of the final ANR GEIS, associated Part 51 rule revisions, and related NRC guidance, as adapted for the RHDRA and other similar technologies in an ANR GEIS supplement. As noted in COL-ISG-029, to appropriately scale and expedite the site-specific NEPA review process, it is anticipated that the selected micro-reactor technology will have many, if not all, of the following characteristics:

- occupies only a small area of land, disturbs only previously disturbed lands, or both
- uses zero or only small quantities of resources, such as water or fuel
- releases zero or only small quantities of emissions to the environment
- avoids environmentally sensitive areas such as wetlands and floodplains
- avoids areas with cultural, historic, or environmental justice significance
- avoids habitat for threatened or endangered species
- uses BMPs and mitigation measures to reduce any potential adverse impacts
- involves only low levels of employment for both construction and operation
- uses simpler designs than those for large LWRs, with limited interfaces with the exterior environment

The nearer-term approach described above envisions the NRC's finalization of the ANR GEIS and associated Part 51 rulemaking, and subsequent development of a supplement to the ANR GEIS that is specific to RHDRA and generically dispositions, to the maximum extent possible, the 19 Category 2 issues and 2 uncategorized issues identified in the ANR GEIS. This would limit the need for any detailed site-specific NEPA review at the site license application stage. The NRC's site-specific NEPA review would be largely confirmatory in nature, with the staff verifying that the proposed facility and site meet or are bounded by the relevant values and assumptions in the PPE and SPE that support the generic findings made by the NRC in its GEIS documents, and that there is no new and significant information that would alter the findings. The staff's site-specific NEPA review document, which could be an EA, would tier from the GEIS documents. However, this approach likely would not achieve the 2-month site-specific environmental review discussed above due to the level of site-specific analysis still required for Category 2 issues and the need to meet other NEPA-related procedural requirements.

The optimal long-term approach for RHDRA environmental reviews likely will require the use of categorical exclusions. If the NRC can determine that a given RHDRA design would not have a significant impact on the environment when it is sited within a given site parameter envelope, then it should develop a categorical exclusion and associated rulemaking that reflects this determination. No EIS or EA would be necessary for such RHDRA designs.

4 OTHER OPTIONS FOR RESOLUTION OF THE ISSUE

4.1 Statutory Categorical Exemption

A potential legislative action would be the creation of a statutory exemption (or legislative "categorical exclusion") from compliance with NEPA that is specific to RHDRA licensing. This likely would be a much simpler alternative to the NRC's development of a categorical exclusion through the administrative process, which would require formal rulemaking and supporting technical and regulatory analyses. Congress has previously created statutory exemptions from NEPA review. Such exemptions have been provided in legislation, such as the Stafford Act for certain federal emergency response and assistance activities,[34] as well as in non-emergency contexts, such as for certain activities associated with the exploration or development of oil or gas on public lands.[35] A statutory Categorical Exemption for small advanced reactors, like RHDRA and micro-reactors, could also more broadly address the NEPA requirements for these reactors. Such a statutory exemption could apply to the use of these reactors by federal agencies that have their own obligations under NEPA, such as the Department of Defense (DOD), which is pursuing micro-reactors at Eielson Air Force Base, and a recently launched Army program, and could be applicable for regulation of micro-reactors by DOE and DOD, in addition to NRC.

Relatedly, the CEQ's 2010 guidance on categorical exclusions states: "Other categories of actions may become appropriate for categorical exclusions as a result of mission changes. When agencies acquire new responsibilities through legislation or administrative restructuring, they should propose new categorical exclusions after they, or other agencies, gain sufficient experience with the new activities to make a reasoned determination that any resulting environmental impacts are not significant." Notably, the recently-enacted ADVANCE Act establishes new parameters for the NRC's mission and directs the NRC to consider the expanded use of categorical exclusions to "facilitate efficient, timely, and predictable environmental reviews" of new reactor license applications.

4.2 AEA Change – General License

A general licensing approach would be more efficient and effective in regulating nuclear reactors, such as RHDRA, and would be capable of enabling even shorter deployment timeframes that would be needed to support other business models. Currently, the AEA does not grant the NRC authority to issue general licenses for nuclear reactors, although it does grant authority to the NRC to issue general licenses for other regulated activities. If Congress were to amend the AEA to authorize and direct the NRC to develop a general licensing approach for certain nuclear reactors, and the NRC subsequently pursued a rulemaking to develop such a general license framework for nuclear reactors, this would be a more optimal solution to the issue discussed in this appendix. However, since the NRC could achieve the business requirements with currently granted authorities, and since there is significant uncertainty on whether or when Congress would grant NRC authority for issuing general licenses for reactors, the proposed resolution discussed herein is focused on approaches the NRC can implement without changes to the AEA. This enables the fastest path toward a more effective and efficient regulatory framework for RHDRA and other advanced reactors, and would build the basis of experience that could inform a longer-term General License approach if Congress eventually enables it. More discussion on NRC Regulation Through General Licenses is included in Attachment B.

4.3 Area-Wide Environmental

For some applicants that may seek to deploy tens or hundreds of RHDRA in a general region, an area or region-wide EIS could be another viable option. For example, Shepherd Power's February 2024 letter to the NRC identified the Permian Basin as a potential region for large-scale micro-reactor deployment. This approach could also reference the ANR GEIS to resolve the 100 Category 1 issues. For the remaining

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[34] *See* Robert T. Stafford Disaster Relief and Emergency Assistance Act, Sec. 316 (completely exempting certain activities from NEPA, including actions taken or assistance provided under sections 402 (General Federal Assistance), 403 (Essential Assistance), 407 (Debris Removal) or 502 (Federal Emergency Assistance), and action taken or assistance provided under section 406 of the Stafford Act that has the effect of restoring facilities to conditions that existed before a major disaster or emergency).

[35] *See* Energy Policy Act of 2005, Sec. 390 (establishing a rebuttable presumption that use of a categorical exclusion under NEPA would apply to certain activities conducted pursuant to the Mineral Leasing Act for the purpose of exploration or development of oil or gas).

21 issues, the region would need to be defined so that an area or region-wide EIS could be utilized in concert with the GEIS.

Notably, there is ample federal agency precedent for the preparation of area or region-wide PEISs, including for areas that are larger than the Permian Basin. Some examples are listed below.

- U.S. Department of the Interior, Bureau of Land Management, *Draft Programmatic Environmental Impact Statement for Utility-Scale Solar Energy Development* (DOI-BLM-HQ-3000-2023-0001-RMP-EIS) (Jan. 2024)
- U.S. Department of Energy, Western Area Power Administration and U.S. Department of the Interior, U.S. Fish and Wildlife Service. *Upper Great Plains Wind Energy Final Programmatic Environmental Impact Statement* (DOE/EIS-0408) (May 2015)
- U.S. Department of Energy, *Final Uranium Leasing Program Programmatic Environmental Impact Statement* (DOE/EIS-0472) (Mar. 2014)
- U.S. Department of Energy and U.S. Department of the Interior, Bureau of Land Management, *Programmatic Environmental Impact Statement, Designation of Energy Corridors on Federal Land in the 11 Western States* (DOE/EIS-0386) (Nov. 2008)
- U.S. Department of the Interior, Bureau of Land Management and U.S. Department of Agriculture, U.S. Forest Service, *Final Programmatic Environmental Impact Statement for Geothermal Leasing in the Western United States* (FES 08-44) (Oct. 2008)
- U.S. Department of the Interior, Minerals Management Service, *Final Programmatic Environmental Impact Statement for Alternative Energy Development and Production and Alternate Use of Facilities on the Outer Continental Shelf* (OCS EIS/EA MMS 2007-046) (Oct. 2007)

Further review and analysis of such non-NRC NEPA practices would be needed to determine how a similar approach could best be applied by the NRC in the context of this project. Such an approach might make use of bounding, performance-based values and assumptions and values (like the ANR GEIS itself) and/or identify a representative or reference site(s) (e.g., existing drill sites and potential "greenfield" drill sites) for purposes of analysis. It also could use relevant site-specific information where available. This would greatly reduce the scope and content of any deployment site license application and associated NRC NEPA review document, which could be a concise EIS supplement, or possibly an EA, which would tier from the ANR GEIS supplement prepared for the broader Permian Basin region. This document would confirm that the site-specific impacts are bounded by the NRC's generic, region-wide analysis. This document could be based on a previously-prepared NRC template and prepared in less than four months.

5 ACKNOWLEDGEMENTS

NEI Issue Lead: Martin O'Neill

Appendix 2 – Design Approvals Scope and Authorizations

1 ISSUE INTRODUCTION

The NRC offers several options for obtaining one-time up-front approvals of designs, or portions of designs, that can be referenced in a site license application. However, there are four main challenges with the current regulatory framework for these design approvals:

1. They may not enable all of the safety and environmental considerations of the design and future unknown sites to be addressed such that the design approval applicant can create a site parameter envelope (SPE) that enables the site license application to be focused only on the confirmation of the site's conformance to the SPE,
2. Some do not permit the manufacturing of the reactor or even safety-related components of the reactor without having an identified site or licensee,
3. They do not address all the topics necessary to enable closure of all Inspections, Tests, Analyses and Acceptance Criteria (ITAAC) specific to the reactor module included in the design approval prior to the identification of a specific site that will use the design in a license by the NRC, and emplacing the reactor at the final operation location following NRC issuance of a site-specific license (See Appendix 4), and
4. They do not allow fueling the reactor in the factory, operational testing of the reactor in the factory, and transporting a fueled reactor to the deployment site (See Appendices 26, 27, 28 and 29). However, the staff has put forward the ability to load fuel and perform operational testing at the factory for the Commission to vote on in SECY-24-0008 independently of this effort, and the Commission has directed the staff to work with industry to develop regulatory text for these issues in their Staff Requirements Memorandum (SRM) response to the proposed 10 CFR Part 53 text.

The desired outcome is that the NRC improves the processes to approve standardized designs so that future site licenses incorporating the NRC-approved standardized design would not require NRC review of any new or additional safety and environmental considerations. Rather, the NRC's review would focus solely on verifying that the site conforms to the design's SPE. These NRC approvals of standardized designs would need to be sufficiently comprehensive to enable closing all design-related ITAAC, fueling and operational testing of the reactor in the factory, transportation of a fueled reactor to the operating site, and emplacement of the reactor at the final operation location prior to NRC issuance of a site-specific license. As a result, NRC approval and authorization of the site license (either a concurrent 10 CFR Part 50 Construction Permit (CP) and Operating License (OL) or a concurrent Part 52 Combined License (COL) and 10 CFR 52.103(g) finding) would permit immediate operation of the reactor.

This appendix focuses on use of the design approval to resolve all safety and environmental considerations for both the design and a future operating site. The other requirements are addressed in separate appendices. The use of design approvals to minimize the site license scope is discussed in Appendix 5.

2 BACKGROUND

The purpose of NRC design approval processes is to reduce regulatory risk, shorten the review timeline and lower the costs for site licenses, and to increase design standardization. These benefit not just licensees; they also facilitate more efficient and effective NRC licensing, regulation, and oversight of reactors.

NRC Design Approval Options

The NRC's regulatory frameworks have several options that rapid high-volume deployable reactors in remote applications (RHDRA) and other advanced reactors can utilize to receive standardized approval of their design. These options vary in terms of the scope of design information required and the degree of finality afforded by the NRC's approval. Finality is the fundamental feature that enables the design approval process to be effective and efficient. Without finality from those reviews, as documented in NRC Safety Evaluation Reports (SERs), these processes would be of limited benefit. Finality from these design approvals migrate to the site license application, either a 10 CFR Part 50 CP and OL, or a 10 CFR Part 52 COL.

The two design approval processes that provide the most benefits are Manufacturing Licenses (ML) under 10 CFR Part 52 Subpart F, and Standard Design Certification (DC) under Part 52 Subpart B because these provide finality through rulemaking. Other processes that are available, and which permit portions of the scope of design to be approved are the Standard Design Approval (SDA) under Part 52 Subpart E, Appendix N Standardization in both Parts 50 and 52, and Topical Reports. The NRC has previously discussed that the potential for an approval of a COL or OL to result in finality for the scope of the approved standard design (e.g., concurrent issuance of an SDA).

Of these processes, the ML will be most discussed in this appendix, since it is perceived to be the most capable of achieving the desired outcomes needed to enable the business model for RHDRA due to its focus on both the manufacturing and pre-operations phase. Other advanced reactors that are not seeking 6-month deployment schedules would also benefit from more expansive capabilities to reduce the scope of design and site reviews that have to be repeated for every site, the capability to prospectively manufacture reactors and their components without having a site or licensee identified, and being able to close ITAAC prior to a site license being issued.

A mix of licenses can achieve a scope of similar licensed activities with finality as an ML, but the ideal, streamlined interpretation of ML, a utilization facility license, may be paired with a Part 70 possession license, with ownership transfer including both the reactor and the fuel. NRC regulations in Part 52, Subpart F, provide the requirements and procedures applicable to the Commission issuance of an ML. The requirements in 52.156, 52.157, and 52.158 address the general and technical information that must be part of the application. This information is similar to the required information for a standard design certification, and the review criteria are similar. However, the regulation was developed for light water reactors (LWRs) rather than for non-LWRs or micro-reactors that may be fueled and tested in the factory and transported as a fueled reactor.

In fact, §52.153(a) states "[A] nuclear power reactor manufactured under an ML under this subpart may only be transported to and installed at a site for which either a CP under Part 50 of this chapter or a COL under Subpart C of this part has been issued." This current limitation, expressed differently, is also included in 52.167(c)(1).[1] However, because neither the DC nor SDA minimum requirements address all

[1] Finality of a Standard Design Certification is addressed in §52.63, which states that the Commission may not "modify, rescind, or impose new requirements on certification information…unless the Commission determines by rulemaking that the change is necessary…" Finality for a

Appendix 2 – Design Approvals Scope and Authorizations

NRC safety and environmental considerations for a specific site, they do not provide finality on those topics not directly addressed in the DC or SDA, either directly in the design approval or by incorporating generic approvals on a technology-inclusive basis, that would be needed for NRC review and approval of a site license (e.g., Part 50 CP and OL or Part 52 COL and 103.g finding). Applicants can submit additional information to expand the scope.

The scope of the ML regulations needs to be sufficiently broad to support closing ITAAC at the factory, fueling the reactor in the factory, operational testing of the reactor in the factory, and transportation of a fueled reactor to and from the deployment site. The existing Part 52, Subpart F, and draft proposed Part 53[2] requirements do not address all the issues necessary to support transportation and installation of a fueled reactor at the deployment site and ensuring that the reactor's characteristics are consistent with the draft New Reactor Generic Environmental Impact Statement (New Reactor GEIS) or a final version of that GEIS.

These issues were addressed by NEI in the 2021 White Paper, "Proposed Approach for Manufacturing License Requirements in 10 CFR Part 53," and by the NRC staff in SECY 24-0008. However, SECY 24-0008 did not address whether the ML holder had the authority to close ITAAC at the factory. The NRC staff and industry have developed a mutual understanding of the needed changes to regulations and guidance to support deployment of a manufactured reactor with minimal additional regulatory action needed once the reactor leaves the factory.

Authorization to Manufacture

SDAs are key to enable the RHDRA business model, and other business models that depend on shorter deployment timelines. The licensing and construction of RHDRA is shorter than traditional large LWRs, and potential owners have very short timelines for deploying new reactors once a site is identified. To meet these short timelines, ML and DC holders will likely need to manufacture reactor modules and/or components prior to identification of the site or licensee that will receive them. This can be done without challenging the ability of the NRC to provide reasonable assurance of adequate protection once a design is approved, and for ML and DC holders that have the capabilities, including quality assurance programs, to manufacture reactors and their components.

The ability to prospectively manufacture components before an owner is known is recognized in the ASME Code Case N-883, "Construction of Items Prior to the Establishment of a Section III, Division 1 Owner" May 8, 2024 (ML24128A072). This code case is consistent with the NRC requirements in 10 CFR 50.10(a)(2)(viii), which states, "Construction does not include: Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility." This is part of the scope of work that does not constitute construction, and thus does not

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Standard Design Approval is addressed in §52.145, which states in part in (c), "[E]xcept for information requests seeking to verify compliance with the current licensing basis of the standard design approval, information requests to the holder of a standard design approval must be evaluated before issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information. Each evaluation performed by the NRC staff must be in accordance with 10 CFR 50.54(f) and must be approved by the Executive Director for Operations or his or her designee before issuance of the request. Thus, a change to a DC requires rulemaking while a change to an SDA requires a cost-benefit analysis and approval by the Executive Director for Operations or his or her designee.

[2] In the Commission's Staff Requirements Memorandum on the draft proposed Part 53, SRM-SECY 23-0021, the Commission directed the staff to include factory fuel load provisions in the proposed rule and to work with stakeholders following publication of the proposed rule to develop regulatory text that would allow a holder of a manufacturing license to accomplish operational testing on a fueled manufactured reactor at the factory prior to deliver to the site where it will ultimately be used. That language has not yet been made available.

constitute scope for which a permit or license is required. Therefore, a plain read of the language would be that the NRC's authorization is not needed to make facility components in a factory, whether they have been previously approved through a DC or not. However, the NRC did not accept the provision of Code Case N-883 (CC N-883) that permits the fabrication of components prior to site or licensee identification in the endorsement of it in Regulatory Guide 1.84, Revision 39, "Design, Fabrication, and Materials Code Case Acceptability, ASME Section III." Thus, the NRC is now requiring an Owner (i.e., an NRC site licensee) to fabricate components so that a DC holder or other design authority cannot fabricate a Code item that could be used in a future U.S. facility without additional NRC authorization separate from the already approved design. A reactor and its components could cost billions of dollars for larger advanced reactors and be a risk that is so significant that it can impair the business model for these reactors.

3 PROPOSED SOLUTION AND APPROACH

The proposed alternative regulatory approach is to improve the NRC processes to approve standardized designs so that:

1. All safety and environmental considerations of the design and site are resolved in the design approval, so that future site licenses incorporating the NRC approved standardized design would be focused solely on the verification that the site conforms to the design's SPE. If a design cannot support all considerations to be resolved or the applicant does not seek the resolution of all considerations, then the site license would only require review of the safety and environment considerations related to the scope not included in the original design approval (See Appendix 5),

2. A holder of a standardized design approval or design certification would be permitted to fabricate or manufacture components for a future reactor facility without the need to identify the site or licensee, without the need for any additional NRC authorizations beyond the standard design approval, and without additional requirements imposed on the site license beyond the normal requirements for receipt and use of fabricated components,

3. All ITAAC associated with the fabrication of the design may be closed by the holder of the standardized design approval prior to identification of a site or licensee (See Appendix 4), and

4. A reactor may be fueled in the factory, have operational testing performed in the factory, and transported fueled to the deployment site. The NRC staff provided SECY-24-0008, which discussed these issues, to the Commission, and an affirmative vote of the policy changes would be necessary. (See Appendices 26, 27, 28 and 29 for more information.).

As a fundamental element of a new rapid efficient licensing (ReLic) process, the NRC approval of the standardized design, together with generic approvals on a technology-inclusive basis and licensee pre-approvals, enable a site license process (review and approval, scope, content and purpose) that results in site license applications that are tens of pages and enable an NRC timeline from site license application submittal to approval and authorization to operate in less than 5 months. These NRC approvals of standardized designs would need to be sufficiently comprehensive to enable key requirements for closing all design-related ITAAC, fueling the reactor in the factory, operational testing of the reactor in the factory, transportation of a fueled reactor to the operating site, and emplacement

Appendix 2 – Design Approvals Scope and Authorizations

of the reactor at the final operation location, so that the NRC approval and authorization of the site license (either a concurrent Part 50 CP and OL or a concurrent Part 52 COL and 10 CFR 52.103(g) finding) would permit virtually immediate operation of the reactor when it was emplaced at the licensed site.

Specifically, MLs in Part 52 Subpart F should be clarified or expanded to address the manufacture, fueling in the factory, operational testing, and preparation for transportation of the fueled micro-reactor to the deployment site and transportation of the micro-reactor from the deployment site for refueling, refurbishment, or decommissioning. DCs and SDAs in Part 52 Subparts B and E should permit the manufacturing of components without a site or licensee and standard approval of operational programs. Needed changes to guidance and potential changes to Subpart F, along with specific plans and timelines for bringing about those changes will be identified. The requirements and guidance should ensure that the transported reactor's postulated site parameters used in the design will be enveloped by the site characteristics and that the design will be enveloped by the draft New Reactor GEIS PPE and SPE parameters.

The NRC should enable the ML, DC, SDA, and Appendix Ns to:

1. Establish an SPE for site conditions, including:
    a. Meteorology and Weather Data – See Appendix 10
    b. Geologic and Geotechnical Data – See Appendix 11
    c. Other External Hazards – See Appendix 12
2. Provide pre-approved site-specific design and/or analyses for structures that impact safety. Pre-approved site-specific designs could be included as tables that identify several pre-approved site designs that are suitable based on a set of site conditions identified in the SPE. The site-specific structural analyses, if needed for sites that do not fit in the site parameter for use of a pre-approved site structure design, would include a pre-approved methodology that the site license application could use to minimize the scope of the NRC review. The following are examples of site structures that would be included as pre-approved designs and/or analyses:
    a. Engineered Features to Enable Site Independence (e.g., seismic isolation)
    b. Engineered Features to Enable Nuclear Island Separation (e.g., intermediate loop between Nuclear Island and Energy Island)
    c. Safety Related Site-Specific Structures (e.g., concrete pad, reactor building)
3. Resolve safety and environmental consideration through reference to applicable NRC generic approvals on a technology-inclusive basis, including GEISs, Categorical Exclusions, Rulemakings or other NRC actions that resolve scope of the design approval. This should also permit referencing generic approvals for scope in the site license to minimize the need to address them in every site license application.
4. Provide approval of specified construction activities for site license applications referencing the design, which upon docketing the site license will authorize the site license applicant to conduct the pre-approved construction activities at that site. (See Appendix 3)

3.1 Changes Needed to Regulations, Policy and Guidance

Rulemaking is needed to amend the requirements for standardized design approvals particularly to reduce project timelines. Specifically, changes to Part 52, Subpart B for DC, Subpart E for SDA, and Subpart F for MLs. NRC's most recent proposed 10 CFR Part 53 (see proposed rule date March 2023 – ML21162A095 and ML21162A102) would also need to be revised. These requirements would need to be amended to address loading fuel in the factory and performing operational testing. A favorable Commission vote on SECY-24-0008 would enable important policy changes for the RHDRA business model. SECY-24-0008 also acknowledges an opportunity to conduct operational testing under a 10 CFR 50 CP and OL with a scope more similar to a research and test reactor. These changes would lead to combining Part 70 licenses with the ML, as well as a 10 CFR 50 CP and OL or a Part 52 COL for the operational testing facility. Additionally, changes to §52.167(c) will be needed to provide clear requirements on preparing the micro-reactor for transportation.

3.2 Acceptance Criteria and Licensing Approach

Acceptance Criteria

Any advanced reactor could utilize the proposed approach to add additional capabilities to the SDA processes to further increase the ability to reduce the costs, timelines and risks for site license applications and the NRC review of those applications. However, it is expected that the benefits will be inversely graded, such that as reactors decrease their complexity, size, and potential consequences the benefits of these enhanced standardized design approval processes will increase.

Licensing Approach

Any standardized design approval process (e.g., ML, DC, SDA, Appendix N) can be used to reduce the cost, schedule, and risk of site license reviews. To achieve the timelines for the RHDRA, these reactors will need to include the full scope of the design and site in the standardized design approval.

4 OTHER OPTIONS FOR RESOLUTION OF THE ISSUE

4.1 AEA Change – General License

A general licensing approach would be more efficient and effective in regulating nuclear reactors, such as RHDRA, and would be capable of enabling even shorter deployment timeframes that would be needed to support other business models. Currently, the AEA does not grant the NRC authority to issue general licenses for nuclear reactors, although it does grant authority to the NRC to issue general licenses for other regulated activities. If Congress were to amend the AEA to authorize and direct the NRC to develop a general licensing approach for certain nuclear reactors, and the NRC subsequently pursued a rulemaking to develop such a general license framework for nuclear reactors, this would be a more optimal solution to the issue discussed in this Appendix. However, since the NRC could achieve the business requirements with currently granted authorities, and since there is significant uncertainty on whether or when Congress would grant NRC authority for issuing general licenses for reactors, the proposed resolution discussed herein is focused on approaches the NRC can implement without changes to the AEA. This enables the fastest path toward a more effective and efficient regulatory framework for RHDRA and other advanced reactors, and would build the basis of experience that could inform a longer-term General License approach if Congress eventually enables it. More discussion on NRC Regulation Through General Licenses is included in Attachment B.

5 ACKNOWLEDGEMENTS

NEI Issue Lead: Julianne McCallum

Appendix 3– Construction Authorization Upon Docketing

1 ISSUE INTRODUCTION

The rapid high-volume deployable reactor in remote locations (RHDRA) business model requires, in part, reactor deployment in less than 180 days (6 months) from the time that the site is identified to the time that operations and energy production begins. Current NRC processes for authorizing reactor construction and operation, whether under the Part 50 construction permit (CP)/operating license (OL) or the Part 52 combined license (COL) regulations, will not permit this 180-day schedule. The RHDRA model requires that construction activities (some of which may require prior NRC approval) begin within two months of site identification, coincident with NRC acceptance and docketing of the application. This would not allow the NRC time (beyond the acceptance timeline) to review the application to make a decision to allow construction prior to final approval via a Limited Work Authorization (LWA).

Thus, the NRC will need to establish a process that would authorize, as necessary, certain "construction" activities (as those activities are defined in 10 CFR 50.10 and which now require issuance of a site-specific CP, COL or LWA) concurrent with or prior to the acceptance and docketing of the deployment site license application.[1] This construction authorization process would need to avoid triggering any additional safety assessment, environmental review, or public hearing opportunities. The NRC's current LWA process would not accommodate the 6-month schedule. It requires submittal of a site-specific LWA application contemporaneously with COL application submittal and detailed NRC safety and environmental reviews, as well as a mandatory hearing and a contested hearing opportunity. As such, the current LWA process would be expected to span several years, as reflected in the NRC's 36-month Generic Milestone Schedule for LWAs.[2]

2 BACKGROUND

2.1 History of NRC's Definition of "Construction" in 10 CFR 50.10

Before discussing the specific construction-related requirements imposed by 10 CFR 50.10, it is helpful to understand the origins of that regulation and its evolution. As discussed in the NRC's 2007 LWA Rule, section 50.10 stems from sections 101 and 185 of the Atomic Energy of 1954, as amended (AEA).[3] Section 101 prohibits the manufacture, production, or use of a commercial nuclear power reactor, except where the manufacture, production, or use is conducted under a license issued by the NRC. Although section 101 contains no reference to construction, section 185.a requires that the NRC grant construction permits to applicants for licenses to construct or modify production or utilization facilities. Significantly, "the term construction is **not** defined anywhere in the AEA or in the legislative history of the AEA."[4]

The necessary implication is that "Congress entrusted the agency with the responsibility of determining what activities constitute construction."[5] This discretion is manifest in the history of 10 CFR 50.10. The

[1] As discussed in Section 3.1, to enable this approach for reactors manufactured and/or fabricated under a Part 52 manufacturing license, the NRC also will need to modify and/or grant exemptions from current NRC regulations (10 CFR 52.153(a) and 52.167(c)) stating that a nuclear power reactor manufactured under an ML may only be transported to and installed at a site for which either a CP or COL has been issued.
[2] NRC, "Generic Milestone Schedules of Requested Activities of the Commission," https://www.nrc.gov/about-nrc/generic-schedules.html.
[3] Limited Work Authorizations for Nuclear Power Plants; Final Rule, 72 Fed. Reg. 57,416, 57,425 (Oct. 9, 2007) (2007 LWA Rule).
[4] *Id.* (emphasis added).
[5] *Id.* at 57,427 (citing *Carolina Power and Light Company* (Shearon Harris Nuclear Power Plant, Units 1, 2, 3 and 4), 7 AEC 939 (June 11, 1974)).

Appendix 3– Construction Authorization Upon Docketing

NRC initially developed and codified a definition of "construction" in 10 CFR 50.10(b) in 1960 "[t]o prevent the construction of production or utilization facilities before a construction permit is issued."[6] It modified that definition in 1968 to exclude the "driving of piles" from the definition of construction because the performance of this type of site preparation activity "would not affect the NRC's subsequent decision to grant or deny the construction permit."[7] With the exception of this change, "the NRC's interpretation of the scope of activities requiring a construction permit **under the AEA** has remained largely unchanged."[8]

In 1972, following the enactment of the National Environmental Policy Act of 1969 (NEPA), the NRC made significant modifications to the rule by expanding the definition of construction with the enactment of 10 CFR 50.10(c).[9] Section 50.10(c) expanded the definition of construction to include "any clearing of land, excavation, or other substantial action that would adversely affect the natural environment of a site and construction of non-nuclear facilities (such as turbogenerators and turbine buildings) for use in connection with the facility …." The agency made clear that its "interpretation of its responsibilities under NEPA, **not the AEA**, was the driving factor leading to its adoption of § 50.10(c)."[10]

In 2007, the NRC amended Parts 50 and 52 to revise the requirements for LWAs and site preparation activities at a prospective site of a new commercial nuclear power plant. Although the 2007 LWA Rule maintained the current requirement in 10 CFR 50.10(c) that certain construction activities cannot be performed without prior NRC approval, it significantly narrowed the definition and scope of "construction," thereby permitting a broad range of activities to be performed without any NRC approval. The current rule provides that NRC approval – in the form of an LWA – would be necessary for the driving of piles; subsurface preparation; placement of backfill, concrete, or permanent retaining walls within an excavation, installation of foundations, or in-place assembly, erection, fabrication, or testing. The structures, systems, and components (SSCs) that are within the scope of the definition of construction, set forth in 10 CFR 50.10(a), are **only** those that "have a reasonable nexus to radiological health and safety and/or common defense and security **for which regulatory oversight is necessary and/or most effective in ensuring reasonable assurance of adequate protection** to public health and safety or common defense and security."[11] The scope of SSCs falling within the definition of construction was derived from the scope of SSCs that are included in the program for monitoring the effectiveness of maintenance at large light-water reactors (LWR), as defined in 10 CFR 50.65(b), and supplemented with additional criteria (10 CFR 50.10(a)(1)(v–vii)).[12]

In the 2007 LWA Rule, the Commission took a narrower view of its AEA-derived jurisdiction over certain construction activities. Specifically, it concluded that its jurisdiction does not extend to activities that lack a nexus to radiological health and safety or common defense and security.[13] The Commission also noted that since the 1972 rule change, federal case law has clarified the legal effect of NEPA, establishing that NEPA is a procedural statute that does not expand the substantive authority assigned to the agency by its organic statute.[14] Thus, it concluded that while NEPA may require the NRC to

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[6] *Id.* (citing 25 Fed. Reg. 8712 (Sept. 9, 1960)).
[7] *Id.* (citing 33 Fed. Reg. 2381 (Jan. 31, 1968)).
[8] *Id.* at 57,426 (emphasis in original).
[9] *See* Prohibition of Site Preparation and Related Activities; Final Rule, 37 Fed. Reg. 5745 (Mar. 21, 1972).
[10] 2007 LWA Rule, 72 Fed. Reg. at 57,426 (emphasis added).
[11] *Id.* at 57,426 (emphasis added).
[12] *Id.* at 57,429-30, 57,442.
[13] *Id.* at 57,420.
[14] *Id.* at 57,427.

consider the environmental effects caused by the exercise of its permitting/licensing authority, the statute cannot be construed to expand the Commission's authority over such activities.[15]

Based on the foregoing, it appears that the NRC has ample discretion to permit the conduct of RHRDA-related activities that might meet the definition of "construction" in 10 CFR 50.10 without an LWA. Such "construction" activities (up to but not including loading fuel in a reactor or removing physical features to preclude criticality) do not pose a risk to public health and safety or the common defense and security. Moreover, since the loading of fuel would still require prior NRC approval, at that time, the NRC would be able to perform any review or oversight of the "construction" activities performed without prior NRC approval. Indeed, the NRC's LWA process implicitly recognizes that certain "construction" activities can be performed without prior NRC review and approval of the full application to construct the facility through via a CP or COL.

For advanced reactors with smaller and simpler designs that will be fabricated and assembled in a manufacturing facility under an ML, the scope, scale, and duration of activities to be performed at the deployment site will be substantially smaller than those associated with a large LWR, the construction of which can require five or more years. Further, the NRC should be able to disposition most, if not all, of the safety and environmental considerations in prior approvals; i.e., design approvals (e.g., MLs), licensee prior-approvals, and generic environmental reviews (e.g., Categorical Exclusion, Generic Environmental Impact Statement (GEIS)). Any remaining activities to be conducted at the deployment site may not meet the definition of construction in 10 CFR 50.10(a) or, to the extent they do, may be very limited in number and scope. As discussed below, using generic rulemaking or case-specific procedures, the NRC could exercise its discretion under the AEA to allow such "construction" activities to proceed without prior NRC approval in the form of an LWA.

2.2 Preconstruction Activities Not Requiring Prior NRC Approval

As revised in 2007, NRC regulations afford pre-applicants and applicants the flexibility to conduct "preconstruction" activities before license issuance.[16] NRC regulations permit pre-applicants and applicants to engage in the following preconstruction activities by expressly **excluding** them from the definition of "construction" in 10 CFR 50.10:

(i) Changes for temporary use of the land for public recreational purposes;

(ii) Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;

(iii) Preparation of a site for construction of a facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;

(iv) Erection of fences and other access control measures;

[15] *Id.*

[16] Limited Work Authorizations for Nuclear Power Plants; Final Rule, 72 Fed. Reg. 57,416 (Oct. 9, 2007) (2007 LWA Rule).

Appendix 3– Construction Authorization Upon Docketing

(v) Excavation;

(vi) Erection of support buildings (such as, construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;

(vii) Building of service facilities, such as paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines;

(viii) Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility;

(ix) Manufacture of a nuclear power reactor under a manufacturing license under subpart F of part 52 of this chapter to be installed at the proposed site and to be part of the proposed facility; or

(x) With respect to production or utilization facilities, other than testing facilities and nuclear power plants, required to be licensed under Section 104.a or Section 104.c of the Act, the erection of buildings which will be used for activities other than operation of a facility and which may also be used to house a facility (e.g., the construction of a college laboratory building with space for installation of a training reactor).[17]

As discussed in Regulatory Guide 1.206, Revision 1 (RG 1.206), in accordance with 10 CFR 50.10(a)(2)(ii), the NRC does not consider site investigations that are required by 10 CFR 100.23(c) to be construction. In addition, excavation includes the removal of any soil, rock, gravel, or other material below the final ground elevation to the final parent material, and such activities may be performed without prior NRC approval. However, placing permanent, nonstructural dewatering materials, mud, or engineered backfill in advance of placing the foundation and associated permanent retaining walls for SSCs within the scope of the definition of construction listed below is not an excavation activity and "is considered to fall within the scope of construction" due to its potential to alter the parent material which the excavation occurs (e.g., due to soil compaction, rock grouting). Therefore, the installation of permanent retaining walls within an excavation and the erection of concrete forms for the foundations that will remain in place permanently (even if nonstructural) fall within the definition of construction. Also, the placement of temporary SSCs in the excavation, such as retaining walls, drainage systems, and erosion control barriers, all of which will be removed before fuel load, would be considered preconstruction.

With regard to excavation activities, RG 1.206 further explains that "[c]onstruction includes placing permanent features (e.g., retaining walls and foundations) **within the necessary excavations for SSCs within the definition of construction.**" A necessary excavation is the portion of an excavation that provides sufficient construction access to such SSCs. Site preparation and other activities (e.g., installing

[17] 10 CFR 50.10(a)(2). Those activities that are not considered "construction" are called "preconstruction" and do not require an NRC licensing action. Prior to 2007, NRC regulations had defined "construction" to include many of the above-listed "preconstruction" activities, such that conducting those activities required prior NRC approval (e.g., an exemption). However, in the 2007 LWA Rule, the NRC concluded that "[t]he AEA does not authorize the NRC to require an applicant to obtain permission before undertaking site preparation activities that do not implicate radiological health and safety or common defense and security." 2007 LWA Rule, 72 Fed. Reg. at 57,427. It further concluded that because NEPA is a procedural statute that does not expand the NRC's permitting or licensing authority under the AEA, "the elimination of the blanket inclusion of site preparation activities in the definition of construction under §50.10(c) does not violate NEPA." *Id.*

foundations and support pads) that are performed outside the necessary excavations are considered preconstruction. However, RG 1.206 cautions applicants to "ensure that these preconstruction activities are separate from, and do not result in adverse interactions with, construction-related SSCs, including influence on the stability (static and dynamic) analyses."

2.3 Construction Activities Requiring Prior NRC Approval

10 CFR 50.10(c) provides that no person may begin the construction of a production or utilization facility on a site on which the facility is to be operated until that person has been issued a CP, COL, an early site permit (ESP) authorizing the activities under 10 CFR 50.10(d), or an LWA. As defined in 10 CFR 50.10(a)(1), "[a]ctivities constituting construction are the driving of piles, subsurface preparation, placement of backfill, concrete, or permanent retaining walls within an excavation, installation of foundations, or in-place assembly, erection, fabrication, or testing," and which are for:

(i) Safety-related structures, systems, or components (SSCs) of a facility, as defined in 10 CFR 50.2;

(ii) SSCs relied upon to mitigate accidents or transients or used in plant emergency operating procedures;

(iii) SSCs whose failure could prevent safety-related SSCs from fulfilling their safety-related function;

(iv) SSCs whose failure could cause a reactor scram or actuation of a safety-related system;

(v) SSCs necessary to comply with 10 CFR part 73;

(vi) SSCs necessary to comply with 10 CFR 50.48 and criterion 3 of 10 CFR part 50, appendix A; and

(vii) Onsite emergency facilities necessary to comply with either § 50.160 or § 50.47 and appendix E to this part, as applicable.

RG 1.206 provides additional clarification and guidance, noting that the activities listed below constitute "construction" as defined in 10 CFR 50.10(a)(1):

- installation of the foundation, including related soil compaction
- drainage systems and geofabric
- placement of backfill, concrete (e.g., mudmats), or other materials that will not be removed before placement of the foundation of a structure
- the placement and compaction of a subbase
- installation of reinforcing bars to be incorporated into the foundation of the structure
- erection of concrete forms for the foundations that will remain in place permanently (even if nonstructural)

- placement of concrete or other material constituting the foundation of any SSC within the scope of the definition of construction

- “onsite, in-place” fabrication, erection, integration, or testing activities for any in-scope SCC

- driving piles for SSCs that are described in 10 CFR 50.10(a)(1) (but excludes piles that do not ensure the structural stability or integrity of an SSC within the scope of the definition of “construction”; e.g., piles driven to support the erection of a bridge for a temporary or permanent access road).[18]

RG 1.206 notes that the term “permanent,” in this context, includes “anything that will exist in its **final, in-place plant location after fuel load.**” By contrast, the term “temporary” means anything that will be removed from the excavation before fuel load. It further explains that the terms “onsite, in place, fabrication, erection, integration, or testing” are intended to describe the historical process of constructing a nuclear power plant in its **final, onsite plant location, where components or modules are integrated into the final, in-plant location.** The definition is intended to prevent persons from having to obtain a CP, COL, LWA, or ESP authorizing LWA activities to fabricate, assemble, and test components and modules in a shop building, warehouse, or laydown area, even if located onsite. However, the installation or integration of that SSC into its final plant location would require a CP, COL, LWA, or ESP authorizing LWA activities. Finally, RG 1.206 notes that construction does not include manufacturing a nuclear power reactor under Subpart F of Part 52 if the manufacturing is accomplished onsite, “so long as the manufacturing is not done in place, at the final (permanent) plant location on the site.”

As discussed above, while construction encompasses numerous physical activities (e.g., driving of piles, subsurface preparation, placement of backfill or concrete, installation of foundations), such activities constitute “construction” requiring prior NRC approval only if they meet the criteria set forth in 10 CFR 50.10(a)(1)(i)-(vii). Thus, “SSCs that are not within the scope of construction may be installed before receipt of an LWA, construction permit, or combined license.”[19] During pre-application engagement with the NRC, a reactor developer/prospective site licensee may seek to demonstrate (e.g., through topical reports) that none of the 50.10(a)(1) criteria applies to a given SSC, such that onsite activities related to that SSC do not constitute prohibited “construction.”[20]

2.4 The LWA Process

The LWA process allows COL applicants and applicants for and holders of ESPs to request approval to perform certain limited construction activities before the issuance of a COL.[21] Section 50.10 governs the issuance of LWAs and specifies the information to be included in an LWA application. Section 50.10(f) requires that the LWA application include a safety analysis report (SAR) that describes the activities requested to be performed, along with the information otherwise required by 10 CFR 52.79 for a COL

[18] To “clarify the delineation of preconstruction and construction activities,” RG 1.206 provides a series of specific examples related to the Circulating Water System, Buried Circulating Water System Piping up to the Turbine Building, Circulating Water Intake Structure, Cooling Towers, Turbine Building Structure or Foundation, Temporary or Permanent Features, and Construction Crane Foundations and Support Pads.

[19] 2007 LWA Rule, 72 Fed. Reg. at 57,420 (emphasis added).

[20] *See*, *e.g.*, TerraPower, LLC, “Regulatory Management of Natrium Nuclear Island and Energy Island Design Interfaces,” NATD-LIC-RPRT-0001-A, Revision 0 (Jan. 2024) (ML24011A321).

[21] A COL applicant may submit a request for an LWA either as part of a complete application under 10 CFR 2.101(a)(1)-(4) or as a partial application under 10 CFR 2.101(a)(9) (i.e., “phased COLA”). An ESP applicant may include a request for an LWA as part of a complete ESP application in accordance with 10 CFR 2.101(a)(1)-(a)(4). An ESP holder may submit a request for an LWA as an application for an amendment to the ESP in accordance with 10 CFR 52.39(e).

application or by 10 CFR 52.17 an ESP application. The LWA application also must include an environmental report in accordance with the applicable section(s) of 10 CFR 51.49, "Environmental Report—Limited Work Authorization." Further, the LWA applicant must include a site redress plan that describes the scope of the actions to be taken following suspension of construction activities and addresses the mitigation of impacts resulting from the performance of construction activities.[22] Section C.2.18 of RG 1.206 discusses the required contents of an LWA application in greater detail.

To issue an LWA, the NRC must issue a final environmental impact statement (EIS). The staff also must make positive findings on safety, compliance, and technical qualifications for the LWA activities, and the presiding officer (Atomic Safety Licensing Board or Commission) must make environmental findings and find there are no unresolved safety issues relating to LWA activities that constitute good cause for withholding the LWA. The LWA process also includes a mandatory hearing and a contested hearing opportunity.[23]

3 PROPOSED SOLUTION AND APPROACH

The proposed approach is to change the definition of "construction activities" and "pre-construction activities" in 10 CFR 50.10(a) and (b) to enable RHDRA and other similar advanced reactors to begin any necessary **deployment site** activities (including activities currently defined as "construction" by regulations) without prior NRC approval.[24] This approach is based on the conclusion that the intent and assumptions of those definitions, which were developed for large LWRs, are not applicable to advanced reactors that require very limited on-site work related to permanent SSCs, as compared to fabrication and assembly activities that occur in a factory. A compelling case could be made that the intent of the NRC's delineation between construction and pre-construction activities in 10 CFR 50.10(a) and (b) is not applicable to RHDRA and other similar advanced reactors. In fact, industry is not discussing construction as a concept for RHDRA; rather, we are using terms such as "manufacturing," "installation," "emplacement," and "assembly," since the nature of on-site work related to building a large LWR is very different than that associated with delivering and emplacing manufactured reactor modules at the chosen deployment site(s).

As noted above, while AEA section 185 requires a CP to build a reactor, "the term construction is not defined anywhere in the AEA or in the legislative history of the AEA."[25] Thus, the Commission has defined "construction" via the rulemaking process. Nothing in the AEA precludes the NRC from modifying that definition (as it has done multiple times) or from granting exemptions to 10 CFR 50.10(c), which it also has done.[26]

[22] The primary purpose of the site redress plan is to address activities that were authorized under the LWA (e.g., the placement of piles and installation of foundations), in the event the LWA holder terminates construction, the NRC revokes the LWA, or the underlying COL or CP application is withdrawn or denied.
[23] *See* 10 CFR 2.104, 51.105, 51.107.
[24] As noted above, under 10 CFR 50.10(a)(2)(ix), the manufacture of a nuclear power reactor under a manufacturing license is excluded from the definition of "construction" activities. In its 2007 Final LWA Rule, the Commission clarified that that "under § 50.10(a)(2)(ix), construction does not include manufacturing of a nuclear power reactor under subpart F of part 52, **even if the manufacturing is accomplished onsite**, **so long as the manufacturing is not done in-place, at the final (permanent) plant location on the site**." 2007 Final LWA Rule, 72 Fed. Reg. at 57,433 (emphasis added).
[25] *Id.* at 57,425.
[26] See, e.g., STP Nuclear Operating Company, South Texas Project Nuclear Power Plant, Units 3 and 4; Exemption; 75 Fed. Reg. 69,711 (Nov. 15, 2010) (granting an exemption that would authorize a COL applicant to install two crane foundation retaining walls prior to COL issuance).

Appendix 3– Construction Authorization Upon Docketing

In addition, it is clear from the text of section 50.10(a)(1), its regulatory history, and NRC guidance that the current definition of "construction" – like many Part 50 provisions – was developed with large LWRs in mind.[27] The characteristics and safety basis of rapid high-volume deployable reactors are expected to be fundamentally different from those of large LWRs. Moreover, they are expected to be fabricated and assembled in a manufacturing facility, with minimal on-site activities that are focused on assembly and emplacement. Thus, strict application of "construction" prohibition in 10 CFR 50.10(c) is not necessary to provide reasonable assurance of adequate protection to public health and safety or the common defense and security.

Finally, as the staff has recognized, micro-reactors will have "operational and physical characteristics (e.g., small footprints) that minimize the size of the area affected by the micro-reactor project."[28] Thus, their environmental impacts, including those related to preconstruction and construction activities, are expected to be small and, as necessary, subject to appropriate mitigation and redress measures.

3.1 Changes Needed to Regulations, Policy and Guidance

The proposed approach would require an NRC rulemaking to include in 10 CFR 50.10(a)(2) new criteria to exclude deployment site construction activities for RHDRA and other similar advanced reactors from needing prior NRC approval. Such criteria should be developed through stakeholder engagement; however, a starting point for the criteria could be:

- New 50.10(a)(2)(y): "With respect to a site-specific license application (e.g., ESP, CP, COL) that has been accepted and docketed by the NRC, all site-specific activities (e.g., preparation, installation, emplacement, and assembly activities) described in the application that are bounded by the site parameter envelope and plant parameter envelope associated with designs (e.g., ML, DC, SDA) and environmental reviews (Categorical Exclusion, GEIS) previously approved by the NRC."

- New 50.10(a)(2)(z): "Any and all site work associated with nuclear facilities that are primarily manufactured and/or fabricated in factories and delivered to and emplaced on the site, and for which on-site construction activities can be conducted in less than 12 months from the start of installing foundations to the point of final completion of testing for turnover from construction to operations."

In this proposed approach, the NRC should issue through rulemaking the approval of the standard design that includes the determination that the design achieves one of these criteria, so that it is clear that site license applications referencing the approved design are not subject to undue regulatory risks.

Additionally, the NRC will need to permit the transport of manufactured and/or fabricated reactor modules from the factory to the deployment site once the NRC has accepted and docketed the deployment site license application (e.g., combined CP/OL or COL application). This will require modifications to and/or exemptions from current NRC regulations stating that a nuclear power reactor

[27] As discussed in the 2007 LWA Rule and RG 1.206, the NRC selected the criteria used in the definition of construction to take advantage of the work done during the development and implementation of the Maintenance Rule (10 CFR 50.65). Like the LWA rule, the maintenance rule defines a scope of SSCs that have some nexus to radiological health and safety (safety significance). The NRC selected the maintenance rule criteria for use in the definition of construction, in part because the criteria are well understood and there is good agreement on their implementation, as well as NRC-issued implementation guidance (RG 1.160).

[28] COL-ISG-029, "Environmental Considerations Associated with Micro-reactors" at 11 (Oct. 2020).

manufactured under an ML may only be transported to and installed at a site for which either a CP or COL has been issued.[29]

3.2 Acceptance Criteria and Licensing Approach

The proposed approach establishes two new criteria in 10 CFR 50.10(a)(2) for construction activities that should not require prior NRC approval. The first criterion (y) is related to a particular licensing approach, and the second criterion (z) is related to the technology capabilities and concept of deployment. It is not required that an applicant or design meet both criteria.

The acceptance criterion to use proposed 50.10(a)(2)(y) is that the technology capabilities and concept of deployment allow the NRC to perform up-front reviews and approvals (e.g., via ML, DC, SDA, GEIS, Categorical Exclusion) for the safety and environmental aspects of the site work, such that the on-site construction activities proposed in the site-specific license application (e.g., ESP, CP, COL) would be bounded by the site parameter envelope and plant parameter envelope associated with designs and environmental reviews previously approved by the NRC.

The acceptance criterion to use proposed 50.10(a)(2)(z) is that the technology capabilities and concept of deployment result in the nuclear facility being primarily manufactured and/or fabricated in factories and delivered to and emplaced on site, with on-site construction activities that are conducted in less than 6 months from the start of installing foundations to the point of final completion of testing for turnover from construction to operations. As part of the rulemaking process, the NRC would need to develop an appropriate technical basis for this criterion. For example, reactors for which on-site deployment activities could be conducted within a 12-month time frame would be suitable for generic authorization since such activities are relatively simple and limited in scope as compared to the large LWRs, for which the current criteria in 10 CFR 50.10(a)(1) requiring site specific prior NRC approval were developed and for which construction can require five or more years due to the sheer size of the facility and number of safety-related SSCs. In contrast, and as the Commission noted its 2008 Policy Statement on the Regulation of Advanced Reactors, "advanced reactors will provide enhanced margins of safety and/or use simplified, inherent, passive, or other innovative means to accomplish their safety and security functions."[30]

4 OTHER OPTIONS FOR RESOLUTION OF THE ISSUE

Several other options exist that could be viable in enabling construction activities to occur without the NRC making a specific determination (e.g., through the CP/OL, COL, ESP or LWA) for each site license application. These are listed in order of most comprehensive and simple to implement, to those that would be more complex and include more inherent risk to the applicant.

[29] 10 CFR 52.153(a). *See also* 10 CFR 52.167(c)(1) ("A holder of a manufacturing license may not transport or allow to be removed from the place of manufacture the manufactured reactor except to the site of a licensee with either a construction permit under part 50 of this chapter or a combined license under subpart C of this part. The construction permit or combined license must authorize the construction of a nuclear power facility using the manufactured reactor(s).").

[30] NRC, Policy Statement on the Regulation of Advanced Reactors, 73 Fed. Reg. 60,612, 60,615 (Oct. 14, 2008).

Appendix 3– Construction Authorization Upon Docketing

4.1 AEA Change – General License

A general licensing approach would be more efficient and effective in regulating nuclear reactors such as RHDRA, and would be capable of enabling even shorter deployment timeframes that would be needed to support other business models. Currently, the AEA does not grant the NRC authority to issue general licenses for nuclear reactors, although it does grant authority to the NRC to issue general licenses for other regulated activities. If Congress were to amend the AEA to authorize and direct the NRC to develop a general licensing approach for certain nuclear reactors, and the NRC subsequently pursued a rulemaking to develop such a general license framework for nuclear reactors, this would be a more optimal solution to the issue discussed in this appendix. However, since the NRC could achieve the business requirements with currently granted authorities, and since there is significant uncertainty on whether or when Congress would grant NRC authority for issuing general licenses for reactors, the proposed resolution discussed herein is focused on approaches the NRC can implement without changes to the AEA. This enables the fastest path toward a more effective and efficient regulatory framework for RHDRA and other advanced reactors, and would build the basis of experience that could inform a longer-term General License approach if Congress eventually enables it. More discussion on NRC Regulation Through General Licenses is included in Attachment B.

4.2 Use of Case-Specific Procedures

This approach would use case-specific procedures to conclude that for a particular design, certain activities currently classified as construction activities would not require prior NRC approval for a site license application that references that design.

The NRC approval of the design, e.g., as part of the issuance of an ML, could establish that certain deployment site identified activities in the ML (e.g., pad emplacement), as requested by the applicant and approved by the NRC, do not constitute “construction” activities under the definition in 50.10(a)(1). This process also could be used by site license applications rather than in the design approvals. However, this would further reduce the utility of the option, as it would add time to the site license application, pose risk to the overall use of the design, and increase use of resources from even more repetition.

Below are several options to implement this case-by-case approach. However, none of these processes would address the issue generically and would require each applicant for a reactor design approval to resolve it within their site license application, resulting in significant duplicative work and resources. Moreover, the approaches discussed below (exemptions, hearing orders, and rules of particular applicability) typically require many months, if not years, to complete. Therefore, the use of such processes would require early and substantial pre-application engagement between the applicant and NRC, so that the processes could be completed by the time of site license application docketing or shortly thereafter. The advantage of these options is that they could all be used today without the need for rule changes.

4.2.1 Exemptions

It is expected that NRC-approved RDHRA designs (ML or design certification) will minimize the number of SSCs that are safety-related or otherwise “have a reasonable nexus to radiological health and safety or common defense and security.” Such reactors also are expected to be fully or largely assembled in

Appendix 3– Construction Authorization Upon Docketing

the manufacturing facility, minimizing the amount of on-site construction. If the number of onsite activities constituting "construction" within the meaning of 10 CFR 50.10(a)(1) is limited, then the specific exemption process established by 10 CFR 50.12 may provide a viable alternative process. In fact, section 50.12(b) states: **"Any person may request an exemption permitting the conduct of activities prior to the issuance of a construction permit prohibited by § 50.10."** In addition to determining whether "special circumstances" are present in accordance with 10 CFR 50.12(a)(2), the NRC will "consider and balance" the following factors in deciding whether to grant such an exemption:

(i) Whether conduct of the proposed activities will give rise to a significant adverse impact on the environment and the nature and extent of such impact, if any;

(ii) Whether redress of any adverse environmental impact from conduct of the proposed activities can reasonably be effected should such redress be necessary;

(iii) Whether conduct of the proposed activities would foreclose subsequent adoption of alternatives; and

(iv) The effect of delay in conducting such activities on the public interest, including the power needs to be used by the proposed facility, the availability of alternative sources, if any, to meet those needs on a timely basis and delay costs to the applicant and to consumers.

A compelling case could be made under 10 CFR 50.12(a)(1), (a)(2) and (b), respectively, that the exemption is authorized by law and would not present an undue risk to public health and safety, special circumstances exist, and a balancing of the four listed factors supports issuance of an exemption from 10 CFR 50.10(c). This case would follow the points justifying the proposed approach in Section 3.

Given the large number of potential deployment sites under the RHDRA model, the repeated issuance of site-specific exemptions is not an optimal long-term strategy. In the near term, however, the industry and NRC could take steps to streamline the exemption process to accommodate multiple site license applications. In Appendix B to DANU-ISG-2022-01, "Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications – Roadmap" (Mar. 2024), the NRC staff has provided guidance to help standardize the exemption request and approval processes. This approach would allow the site license applicant to submit the exemption request with its license application, and the NRC to review and approve the request during the 1-month NRC Acceptance Review period. This, in turn, would allow the applicant to proceed with any assembly, delivery, and emplacement activities that might constitute "construction" under current 10 CFR 50.10(a)(1) and otherwise require an LWA, CP, or COL.

4.2.2 Hearing Orders

As the NRC staff has noted in both guidance and correspondence with NEI, there are procedural alternatives to exemptions that the NRC has used successfully in the past to license new technologies.[31] One option is for the applicant to request that the staff develop an **order** (for example, as part of the notice of docketing and opportunity to request a hearing). Given its general supervisory authority over NRC licensing adjudications, the Commission can use case-specific hearing orders to define the applicable license review standards and any special standards or instructions, as the NRC has done

[31] See SECY-0093, "Policy and Licensing Considerations Related to Micro-Reactors" at 5 & Enclosure 2 ("Possible Near-Term Licensing Approaches for Micro-Reactors") (Oct. 6, 2020) (ML20254A363) (package).

previously, for example, in the Louisiana Energy Services, L.P., enrichment facility license proceedings (for the proposed Claiborne Enrichment Center and the National Enrichment Facility).[32]

In this case, the hearing order, which would be issued concurrently with the notice of docketing, potentially could authorize the applicant to undertake limited construction activities before issuance of a combined CP/OL or COL. However, as with an exemption, the legal and technical justification for such an approach would need to be developed during the preapplication phase and require interaction between the NRC staff and the Commission to obtain the latter's approval to use such an approach. One possible approach might be for the NRC to use the exemption process for the first (or first few) deployment sites and then, in subsequent site licensing proceedings, reference the previous exemption(s) as providing the legal and technical bases for a hearing order provision that authorizes the same limited construction activities. This assumes that the same reactor design would be deployed at each site.

4.2.3 Rules of Particular Applicability

An applicant could also request that the NRC develop a rule of particular applicability, which allows for a set of requirements potentially tailored to a specific docket. As the staff has noted, such an approach also could "allow for future efficiency gains if subsequent rulemaking for micro-reactors were desired (as the first rule of particular applicability could lay the groundwork for future applications)."[33] Also, compared to a hearing order, a rule of particular applicability carries a lower risk of litigation because it provides for the public notice-and-comment process associated with a rulemaking. However, this approach is not entirely devoid of risk, insofar as a rule of particular applicability presumably would be implemented as a "non-controversial" direct final rule, as in the case of the SHINE facility example discussed below. If the NRC receives a "significant adverse comment" on the direct final rule, then it will publish a document that withdraws the action and will subsequently address the comments received in a final rule. A significant adverse comment is "a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change."[34]

The NRC used a rule of particular applicability in 2014 in connection with SHINE Medical Technologies, Inc.'s (SHINE) proposed a medical isotope production facility, which included an irradiation facility and a radioisotope production facility housed in a single building.[35] The proposed accelerator-driven subcritical operating assemblies located in the irradiation facility were designed to produce molybdenum-99. For reasons explained in its direct final rule, the NRC concluded that it could not license the irradiation units pursuant to 10 CFR 50.2 as production facilities or utilization facilities. The

[32] See, e.g., Notice of Receipt of Application for License Notice of Availability of Applicant's Environmental Report; Notice of Consideration of Issuance of License; and Notice of Hearing and Commission Order; Louisiana Energy Services, LP.; Claiborne Enrichment Center, 56 Fed. Reg. 23,310 (May 21, 1991); Louisiana Energy Services, L.P. (National Enrichment Facility); Notice of Receipt of Application for License; Notice of Availability of Applicant's Environmental Report; Notice of Consideration of Issuance of License; and Notice of Hearing and Commission Order, 69 Fed. 5873 (Feb. 6, 2004).

[33] See SECY-20-0093, Enclosure 2 at 1.

[34] A comment is significant and adverse if it meets the following criteria: (1) The comment opposes the rule and provides a reason sufficient to require a substantive response in a notice-and-comment process. For example, a substantive response is required when: (a) The comment causes the NRC staff to reevaluate (or reconsider) its position or conduct additional analysis; (b) The comment raises an issue serious enough to warrant a substantive response to clarify or complete the record; or (c) The comment raises a relevant issue that was not previously addressed or considered by the NRC staff. (2) The comment proposes a change or an addition to the rule, and it is apparent that the rule would be ineffective or unacceptable without incorporation of the change or addition. (3) The comment causes the NRC staff to make a change (other than editorial) to the rule.

[35] Definition of a Utilization Facility; Direct Final Rule, 79 Red. Reg. 62,329 (Oct. 17, 2014).

Appendix 3– Construction Authorization Upon Docketing

NRC further concluded, however, that it was within the agency's statutory authority to determine by rule that the SHINE irradiation units are utilization facilities, and that based on the safety considerations associated with operation of the irradiation units, Part 50 was the most appropriate regulatory framework to apply to the licensing of those units. Thus, through a direct final rule, the NRC amended the 10 CFR 50.2 definition of "utilization facility" to include "[a]n accelerator-driven subcritical operating assembly used for the irradiation of materials containing special nuclear material and described in the application assigned docket number 50-608."

In the RHDRA context, the NRC might develop rule of particular applicability for a specific site deployment application that amends 10 CFR 50.10 to identify the specific "construction" activities that the applicant is authorized to perform without an LWA, CP or COL. As noted above, that rule of particular applicability could lay the groundwork for future applications.

5 ACKNOWLEDGEMENTS

NEI Issue Lead: Martin O'Neill

Appendix 4 – Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)

1 ISSUE INTRODUCTION

The rapid high-volume deployable reactor in remote applications (RHDRA) business model requires, in part, reactor deployment in less than 180 days (6 months) from the time that the site is identified to the time that operations begin. According to SECY-24-0008, the Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC) closure process implemented under 10 CFR Part 52 could take at least 6 months.[1] If ITAAC cannot be closed until after the reactor is fully emplaced at the site, this will require at least 11 months from site identification to operation (assuming that the site license process can be completed in the needed maximum of 5 months). Thus, all ITAAC must be closed sufficiently before the reactor is emplaced at a site to enable the 180-day schedule from site identification to operations. However, the NRC does not have a process to enable closure of all ITAAC before reactor emplacement at the final site of operations. The NRC also has not previously considered issuance of the 10 CFR 52.103(g) finding at the same time as the Part 52 combined license (COL) is issued.

The desired outcome, to enable the 180-day schedule, is for the NRC to allow closure of ITAAC as part of the manufacturing license (ML) and Design Certification (DC),[2] or develop another process to approve the standardized design (e.g., at the manufacturing facility) and as part of the licensee's pre-approvals (e.g., emergency preparedness (EP) program). In short, it will be necessary to minimize site-specific ITAAC and/or develop an approach that allows closure of as many site-specific ITAAC as possible prior to emplacement of the reactor, such that a 52.103(g) finding can be made as close to the COL issuance date as possible.

Additionally, the NRC staff will need to identify a process or means by which any section 52.103(a) hearing (on whether the acceptance criteria in the ITAAC have been or will be met) can be completed in a manner that does not adversely impact the 180-day RHDRA deployment schedule.

2 BACKGROUND

The ITAAC requirements allow the NRC to issue an operating license (combined with a construction permit) while retaining the ability to preclude the start of operations until the NRC confirms that the plant was constructed in accordance with the license. This ITAAC process is unique because it is supplementary to the routine construction oversight that the NRC performs for a Part 52 COL (and also performs for a Part 50 OL). It also affords the public an opportunity to request a hearing before the NRC makes a determination on the closure of ITAAC and authorization to load fuel and commence operation. Indeed, the NRC could have established other processes that would have precluded operations if they could not confirm the plant was constructed in accordance with the license; however, those would not have afforded the public an opportunity to seek a hearing.

[1] SECY-24-0008, "Micro-Reactor Licensing and Deployment Considerations: Fuel Loading and Operational Testing at a Factory," Enclosure ("Technical, Licensing, and Policy Considerations for Factory-Fabricated Micro-Reactors") at 3-5 (Feb. 8, 2024) (ML23207A252) (package).

[2] As noted in NEI's Proposal Paper, the industry encourages the NRC to clarify its position regarding the ability of a DC or standard design approval (SDA) holder to prospectively manufacture reactor modules prior to receiving an order from a customer either with a license or that has applied for one (COL or CP). There continues to be some regulatory uncertainty regarding this issue, as highlighted by recent and ongoing industry-NRC interactions concerning the implementation of ASME Code Case N-883, "Construction of Items Prior to the Establishment of a Section III, Division 1 Owner."

Appendix 4 – Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)

These purposes are understandable for the large LWRs for which the ITAAC process was designed, since those reactors historically were licensed years before they began operations. Furthermore, the construction of large LWRs is complex due to their size and significant reliance on active safety systems. In this way, the COL with the ITAAC and 52.103(g) finding still operates as a type of NRC approval to operate. The difference is that with the COL, the NRC reviews and approves all of the design and site considerations in the COL, such that the ITAAC and 52.103(g) finding review and approval are focused on verifying compliance with the parameters established by the COL. Furthermore, because the current regulatory framework for ITAAC was based on large LWRs (for which the NRC anticipated numerous COL applications in 2007), the timelines associated with the various ITAAC notifications and hearing process were based on the estimated construction timeframes associated with large LWRs (e.g., 5 years or more).[3] As discussed below, those timelines are not compatible with the RDHRA business model.

The inclusion of ITAAC in a COL is governed by section 185b of the Atomic Energy Act of 1954, as amended (AEA), and hearings on conformance with the acceptance criteria in the ITAAC are governed by AEA section 189a.(1)(B). Under section 185.b, a COL for a power reactor must contain those ITAAC, including those applicable to emergency planning, that are "necessary and sufficient to provide reasonable assurance that the facility has been constructed and will be operated in conformity with" the license, the AEA, and NRC regulations.[4] Following COL issuance, section 185.b (as implemented through 10 CFR 52.99(e)) requires that the Commission "ensure that the prescribed inspections, tests, and analyses are performed."[5] Finally, before operation of the facility, section 185.b (as implemented through 10 CFR 52.103(g)) requires that the Commission find that the "prescribed acceptance criteria are met."[6] Thus, this Commission finding will not occur until construction is complete, near the date for scheduled initial fuel load, and operation cannot commence until the NRC finds that the acceptance criteria in the ITAAC are met (including those acceptance criteria that are the subject of an ITAAC hearing).[7]

Under NRC regulations, the licensee must submit ITAAC closure notifications (ICN) containing "sufficient information to demonstrate that the prescribed inspections, tests, and analyses have been performed and that the associated acceptance criteria have been met."[8] These notifications alert the NRC to the licensee's completion of the ITAAC and ensure that the NRC has sufficient information to complete all of the activities necessary for the Commission to determine whether all of the ITAAC acceptance criteria have been or will be met. They also ensure that interested persons will have access to information on

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[3] *See generally* Licenses, Certifications, and Approvals for Nuclear Power Plants; Final Rule, 72 Fed. Reg. 49,352 (Aug. 28, 2007) (2007 Final Part 52 Rule). In the regulatory analysis for the 2007 Part 52 Final Rule, the NRC assumed that it would receive 19 COL applications during the next 3 years and 1 COL application per year over the next 17 years for large LWRs. *Id.* at 49,468. *See also* OGC's "Report Summarizing Lessons Learned from the ITAAC Hearing Process for Vogtle Electric Generating Plant, Units 3 and 4" at 1-2, 8(Dec. 18, 2023) (ML23352A124) (acknowledging that NRC's Final ITAAC Hearing Procedures were developed when licensees were pursuing large LWRs with numerous ITAAC, and that nuclear industry nuclear industry is now exploring the use of smaller reactors that have "significantly fewer ITAAC than the recently completed Vogtle reactors" and "very short construction timeframes (from days to a few months, depending on the design)."

[4] 42 USC 2235(b).

[5] *Id.*

[6] *Id.*

[7] As noted above, the NRC's implementation of these AEA ITAAC-related requirements historically has focused on large LWRs. As discussed in SECY-24-0008, the NRC staff has recommended that factory-fabricated reactor modules with physical features to preclude criticality would not be considered "in operation" when loaded with fuel, that operation in these circumstances would begin with removal of those features, and that the removal of those physical features is the best analogue to "initial loading of fuel" for a reactor without such features.

[8] 10 CFR 52.99(c).

Appendix 4 – Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)

both completed and uncompleted ITAAC at a level of detail sufficient to address the AEA section 189.a(1)(B) threshold for requesting a hearing on acceptance criteria.

Section 189a.(1)(B)(i) provides that not less than 180 days before the date scheduled for initial loading of fuel into the reactor, the NRC will publish in the *Federal Register* a notice of intended operation. That notice must provide that any person whose interest may be affected by plant operation may within 60 days request a hearing on whether the facility as constructed complies, or on completion will comply, with the acceptance criteria of the license. Such hearing requests "shall show, *prima facie*, that one or more of the acceptance criteria in the combined license have not been, or will not be met, and the specific operational consequences of nonconformance that would be contrary to providing reasonable assurance of adequate protection of the public health and safety."[9]

Section 189a.(1)(B)(v) directs the Commission, "to the maximum possible extent," to render a decision on issues raised by the hearing request within 180 days of the publication of the notice of intended operation or the anticipated date for initial loading of fuel into the reactor, whichever is later.[10] The Commission, in its discretion, "shall determine appropriate hearing procedures, whether informal or formal adjudicatory," for any ITAAC hearing.[11]

The AEA also allows for interim operation, which is operation of the plant pending the completion of an ITAAC hearing. The potential for interim operation arises if the Commission grants a hearing request that satisfies the requirements of AEA section 189a.(1)(B)(ii). In that circumstance, the AEA provides that the Commission "shall allow operation during an interim period under the combined license" if it determines that "there will be reasonable assurance of adequate protection of the public health and safety during a period of interim operation."[12]

The NRC implements the foregoing statutory requirements through numerous regulations, which are summarized in the table below.

Regulation	Summary of Requirement(s)
§ 52.47(b)(1)	Requires that a **design certification application** contain the proposed ITAAC that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, a facility that incorporates the design certification is built and will operate in conformity with the design certification, the AEA, and NRC rules and regulations.
§ 52.80(a)	Requires that a **COL application** contain the proposed inspections, tests, and analyses, including those applicable to emergency planning, that the licensee must perform, and the acceptance criteria that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, the facility has been constructed and will operate in conformity with the COL, AEA, and NRC rules and regulations.

[9] 42 USC 2239(a)(1)(B)(i)-(ii).

[10] 42 USC 2239(a)(1)(B)(v).

[11] 42 USC 2239(a)(1)(B)(iv).

[12] 42 USC 2239(a)(1)(B)(iii).

Appendix 4 – Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)

Regulation	Summary of Requirement(s)
§ 52.97(a)(2)	Provides that the NRC may find, at the time it issues the COL, that certain acceptance criteria in one or more of the ITAAC in a referenced early site permit or standard design certification have been met. This finding will finally resolve that those acceptance criteria have been met, those acceptance criteria will be deemed to be excluded from the combined license, and findings under 10 CFR 52.103(g) with respect to those acceptance criteria are unnecessary.
§ 52.97(b)	Requires the NRC to identify within the COL the inspections, tests, and analyses, including those applicable to emergency planning, that the licensee must perform, and the acceptance criteria that, if met, are necessary and sufficient to provide reasonable assurance that the facility has been constructed and will be operated in conformity with the license, the AEA, and NRC rules and regulations.
§ 52.99(a)(1)	Requires the licensee to submit to the NRC, no later than 1 year after issuance of the COL or at the start of construction as defined at 10 CFR 50.10(a), whichever is later, its schedule for completing the inspections, tests, or analyses in the ITAAC. Licensees also must submit updates to the ITAAC schedules every 6 months thereafter and, within 1 year of its scheduled date for initial loading of fuel, submit updates to the ITAAC schedule every 30 days until the final notification is provided to NRC under 10 CFR 52.99(c)(1).
§ 52.99(b)	Provides that, with respect to activities subject to an ITAAC, an applicant for a COL may proceed at its own risk with design and procurement activities, and a licensee may proceed at its own risk with design, procurement, construction, and preoperational activities, even though the NRC may not have found that any one of the prescribed acceptance criteria are met.
§ 52.99(c)	Requires licensees to submit several types of ITAAC notifications to the NRC. After an ITAAC is completed, the licensee will submit a 52.99(c)(1) ITAAC closure notification, which must provide sufficient information to demonstrate successful ITAAC completion. Subsequently, if the basis for ITAAC completion is materially altered by new information, 52.99(c)(2) requires the licensee to notify the NRC and to provide sufficient information demonstrating that the ITAAC remains in a successfully completed state. For ITAAC that are not completed as of 225 days before scheduled fuel load, the licensee must submit 52.99(c)(3) uncompleted ITAAC notifications by this date that provide sufficient information to demonstrate that these ITAAC will be completed successfully. Finally, 52.99(c)(4) requires the licensee to notify the NRC when all ITAAC are complete.
§ 52.103(a)	Addresses the role of ITAAC in NRC authorization of operation under a COL, including related notice and hearing opportunity requirements. Requires a licensee to notify the NRC of its scheduled date for initial loading of fuel no later than 270 days before the scheduled date and to notify the NRC of updates to its schedule every 30 days thereafter. At least 180 days before the date scheduled for initial loading of fuel into a plant by a licensee that has been issued a COL, the NRC must publish notice of intended operation in the *Federal Register*. The notice must provide that any person whose interest may be affected by operation of the

Appendix 4 – Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)

Regulation	Summary of Requirement(s)
	plant may, within 60 days, request that the NRC hold a hearing on whether the facility as constructed complies, or on completion will comply, with the acceptance criteria in the COL, except that a hearing shall not be granted for those ITAAC which the Commission found were met under section 52.97(a)(2).
§ 52.103(b)-(e)	Codifies the AEA 189a.(1)(B) requirements for the ITAAC hearing.
§ 52.103(f)	Allows for the filing of petitions with the Secretary of the Commission to modify the terms and conditions of the COL in accordance with 10 CFR 2.206. Before the licensed activity allegedly affected by the petition commences, the Commission must determine whether any immediate action is required. If the petition is granted, then an appropriate order will be issued. Fuel loading and operation under the COL will not be affected by the granting of the petition unless the order is made immediately effective.
§ 52.103(g)	Provides that a licensee shall not operate the facility until the Commission makes a finding that the acceptance criteria in the combined license are met, except for those acceptance criteria that the Commission found were met under section 52.97(a)(2). If the COL is for a modular design, each reactor module may require a separate finding as construction proceeds.
§ 52.158(a)(1)-(3)	Requires that the ML application include ITAAC necessary and sufficient to demonstrate that the manufactured reactor has been manufactured in conformity with the ML, AEA, and NRC regulations, and that the reactor will be operated in conformity with the approved design and any license authorizing operation of the manufactured reactor. If the ML application references a standard design certification, the ITAAC contained in the certified design must apply to those portions of the facility design which are covered by the design certification. Such application may include a notification that a required inspection, test, or analysis in the design certification ITAAC has been successfully completed and that the corresponding acceptance criterion has been met.
§ 2.105(b)(3)	Sets forth the required contents of the notice of intended operation under section 52.103(a).
§ 2.309(f)(1)(vii)	Codifies the *prima facie* showing requirement of AEA section 189a.(1)(B)(ii) in the NRC's contention admissibility standards. Also allows a petitioner to claim that a licensee's 52.99(c) ITAAC notification is incomplete, and that this incompleteness prevents the petitioner from making the necessary *prima facie* showing.
§ 2.310(j)	Permits the Commission to direct that the ITAAC hearing be conducted in accordance with other procedures designated by the Commission. NRC has developed generalized ITAAC hearing procedures that can be adapted to individual proceedings via case-specific orders. The procedures include pre-approved templates for case-specific orders with procedures for the hearing. *See* Final Procedures for Conducting Hearings on Conformance With the Acceptance Criteria in Combined Licenses, 81 Fed. Reg. 43,266 (July 1, 2016) (Final ITAAC Hearing Procedures).

Appendix 4 – Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)

Regulation	Summary of Requirement(s)
§ 2.340(c), (f), (j)	After the completion of an ITAAC hearing, the presiding officer will issue an initial decision on whether the acceptance criteria have been or will be met. An initial decision finding that acceptance criteria in a COL have been met is immediately effective upon issuance unless the presiding officer finds that good cause has been shown by a party why the initial decision should not become immediately effective. The Commission or its delegate (i.e., the NRC staff) will make the 10 CFR 52.103(g) finding within 10 days from the date of issuance of the initial decision if the conditions in 10 CFR 2.309(j)(1)-(3) are met.
§ 2.341(a)	Prohibits parties from seeking further Commission review of a Commission decision allowing interim operation under 52.103(c).

3 PROPOSED SOLUTION AND APPROACH

The proposed approach is for the NRC to establish processes that enable the following:

1. The full scope of ITAAC that will be applicable to a COL application are established in the prior NRC standardized design approvals (e.g., ML or DC) and the licensee's pre-approvals (e.g., Operational Programs, such as EP);[13]

2. The full scope of the ITAAC (in the prior NRC approvals referenced by the COL application) can be closed either prior to the identification of the site (e.g., if design provisions make the reactor facility fully independent of the site and external hazards) or once the site is identified;

3. The ITAAC closure verification process and NRC's 52.103(g) finding can commence upon the docketing of the COL application and be completed in parallel with the COL review (i.e., for the RHDRA deployment model this would be in 2 months or less), and

4. The hearing associated with the ITAAC and 52.103(g) finding can be combined with the hearing process for the COL and performed in parallel with the process for the NRC to verify ITAAC closure.

Intuitively, it seems that ITAAC related to the fabricated scope of the design could be readily closed in the factory. Further, ITAAC related to programs, such as EP, appear conducive to closure through pre-approval of programs, although some ITAAC may be focused on meeting acceptance criteria that may be demonstrated by implementation of approved programs. It is less clear how ITAAC related to site-specific design features could be closed prior to or just after identification of the site. For RHDRA that require site-specific ITAAC, the use of the standardized design to address all safety and environmental considerations related to the site will be important (see Appendix 2). In this way, the standardized design approval could include the ITAAC that requires site-specific information to be closed through the

[13] If a COL references an ML or DC, the ML-ITAAC or DC-ITAAC become part of the COL. In addition, there may be site-specific COL-ITAAC included in the COL so that the COL contains all the necessary ITAAC.

Appendix 4 – Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)

deployment site licensing process to verify compliance with the design's site parameter envelope (see Appendix 5).

Even with this rapid efficient licensing (ReLic) approach, and RHDRA that require minimal work related to structures and emplacement of the reactor, there could still be one or a few ITAAC for safety-related structures. If such ITAAC cannot be closed until after the site work and emplacement related to the structures is completed (which is expected to be about 4 months after the site license application is filed), then the NRC would need to establish a process that allows it to verify closure of the ITAAC, conclude the hearing process for the 52.103(g) finding, and issue the 52.103(g) finding in only a few days. It may be feasible for the NRC to establish such a process given that there would only be one or a few ITAAC to close under this very short schedule.

Another option is that for ITAAC related to a safety-related feature of a site structure that can be fabricated prior to site identification, NRC could allow closure of the ITAAC as part of the component's fabrication under the ML or DC. Thus, the ITAAC would already be closed when the site license application is submitted. The fabricated component would need to be substantially significant to the safety function of the structure, and NRC would rely on its regular construction oversight and inspection processes, and licensee programs (e.g., QA), to provide reasonable assurance that the fabricated component with ITAAC is installed properly and the reactor is emplaced in the structure properly.

Seismic isolators are an example of such a component that could meet the conditions for allowing ITAAC to be associated only with pre-fabricated components of the site structures. Specifically, seismic isolators can be pre-fabricated so that the ITAAC can be closed at the factory before site identification, and they are substantially significant to the safety function of the structure because they can provide independence between the soil motion and the seismically-induced loads experienced by the reactor. Moreover, the NRC's routine construction oversight and inspection processes, and the licensee's programs, would be well suited to confirming that the safety-related functions of the site structures have been constructed in accordance with the license, the AEA, and NRC rules and regulations. Consistent with the proposed approach for the standardized design approvals in Appendix 2, the design approval could include pre-approval of the site structure design in a way that allows multiple designs of the site structure depending on the site-specific conditions. For example, the design approval could include a table with different combinations of soil conditions and hazard levels, each of which has a specific seismic isolator design. Once the site conditions and hazard are known (see Appendix 11 on Geologic and Geotechnical Site Characterization), the seismic isolator that fits the site could be selected for use, as determined by the design's site parameter envelope. Conformance of the site to the site parameter envelope would then be confirmed as part of the site license approval process.

Given that the key ITAAC-related requirements are set forth in the AEA and codified in NRC regulations, meeting the goal of site identification to operations in less than 6 months poses some practical and legal challenges. However, in SECY-24-0008 and recent guidance documents, the NRC staff has identified some potential strategies for meeting that objective. The NRC staff also has indicated that it will consider proposed modifications to its ITAAC hearing procedures to better tailor the ITAAC hearing process to the characteristics of, and licensing strategies for, micro-reactors.

Based on recent NRC staff policy papers and guidance documents, it appears that completion of ITAAC at the manufacturing facility is feasible, even under NRC's current regulations. In SECY-24-0008, the NRC staff recognized that manufacturing, assembly, and fuel loading of a micro-reactor module in a

Appendix 4 – Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)

manufacturing facility are key elements of some business models. In fact, one of the staff's proposals in that paper would change the historical definition of when a reactor is considered to be "in operation." The proposed change would allow the ML holder to load fuel into a factory-fabricated microreactor at the fabrication facility without also having to obtain a CP and OL under Part 50 or a COL under Part 52. It also would require the ML holder to obtain a license under Part 70 to receive title to own, acquire, deliver, receive, possess, use, and transfer SNM to facilitate fuel loading at the factory. However, as discussed in SECY-24-0008, operational testing of a factory-fabricated micro-reactor at the factory would require the ML and Part 70 Category II SNM license holder to also obtain a CP and OL or a COL.[14]

Under such a business model, the reactor manufacturing site COL may contain ITAAC that are redundant to ITAAC included in the reactor deployment site COL. Accordingly, such a model could involve completion of ITAAC that ordinarily would be included in the deployment site COL at the manufacturing facility under the manufacturing site COL. Given that a COL application referencing a design certification or an ML must include the ITAAC stated in the design certification or ML, the holder of the deployment site COL would need to ensure that all ITAAC have been completed, including those performed at the manufacturing facility.

The NRC also should establish clear requirements and/or guidance allowing an ML holder to both perform and close-out ITAAC at the factory, even if the ML holder does not receive an OL or COL to perform operational testing at the factory. These ITAAC closures could then be included in the notifications of closed ITAAC when a COL referencing an ML design is issued. In fact, in its 2007 Part 52 rulemaking, the Commission considered establishing "a regulatory structure for further extending the scope of NRC review and issue finality to the manufacturing process itself."[15] The Commission declined to do so due to the lack of interest (at that time) by any entity in obtaining an ML. However, the Commission noted that it "would address these issues in a timely fashion if raised in a rulemaking petition which demonstrated near-term interest in an application for a manufacturing license."[16]

Notably, during the rulemaking process, the Commission identified two potential approaches or models. One approach was "an analogue to the subpart C of Part 52 combined license process, whereby the NRC would review and approve manufacturing ITAAC to be included in the manufacturing license."[17] Namely, during the manufacturing of each reactor, the NRC would verify at the manufacturing location whether the ITAAC have been conducted and the acceptance criteria met. An NRC finding of successful completion of all the ITAAC would preclude any further inspection of the acceptability of the manufacture of the reactor at the site where the manufactured reactor is to be permanently sited and operated. The NRC's inspections and findings for the COL or OL would be limited to whether the reactor had been emplaced in undamaged condition (or damage had been appropriately repaired) and all interface requirements specified in the manufacturing license had been met.[18]

Although Commission action on SECY-24-0008 is pending, NRC staff guidance recently issued as part of the Advanced Reactor Content of Application Project (ARCAP) provides insight into how ITAAC completion could be implemented to facilitate the rapid, high-volume deployment of RHDRA. DANU-

[14] *See* SECY-24-0008 at 16-19.
[15] 2007 Final Part 52 Rule, 72 Fed. Reg. at 49,356.
[16] *Id.*
[17] *Id.*
[18] *Id.* The other approach considered by the NRC was a combination of the approval processes used by the Federal Communications Commission (FCC) and Federal Aviation Administration (FAA) in approving the manufacture of electronic devices and airplanes and involved the construction and testing of a prototype of the reactor. *See id.*

Appendix 4 – Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)

ISG-2022-06, Chapter 12, "Post-Manufacturing and Construction Inspection, Testing, and Analysis Program" (Mar. 2024) (ML23277A144), provides guidance on the post-manufacturing and construction inspection testing and analysis program (PITAP) for non-LWR applicants. This guidance addresses "the integration of post-manufacturing and postconstruction quality assurance (QA), the initial test program, and ITAAC for CP, OL, DC, ML, and COL applications, as applicable."[19] It also contains "post fuel load" guidance applicable to OLs and COLs.[20] The ISG explains that:

- The PITAP is generally divided into two phases. Phase 1 is the preoperational phase (prior to initial fuel loading), and Phase 2 is initial startup testing (initial fuel loading and initial power ascension). The COL, DC, and ML application under Part 52 should describe the Phase 1 inspection, test, and verification programs and the Phase 2 test programs, as well as the scope, objectives, and programmatic controls associated with the test programs.

- Under 10 CFR Part 52, applicants must include ITAAC as part of their PITAPs to meet the requirements of 10 CFR 52.47(b)(1), 52.80(a), or 52.158(a), as applicable. The ITAAC will be included as license conditions in any COL issued to assure that the facility has been constructed in accordance with the approved design.

- For an ML application, 10 CFR 52.157(f)(27) requires that the ML applicant provide the necessary parameters to be used in developing plans for preoperational testing and initial operation. In addition, 10 CFR 52.157(f)(17) requires a description of the QA program applied to the design, and to be applied to the manufacture of, the structures, systems, and components of the reactor in accordance with Appendix B to 10 CFR Part 50.

- For COLs referencing an ML, much of the post-manufacturing inspection and testing to resolve ITAAC may be performed at the manufacturer's facility and not at the COL final site. The COL holder has the responsibility of verifying the ITAAC are complete. The COL holder could rely on testing performed at the manufacturing facility to verify ITAAC completion.

- An ML holder also may seek a CP and OL or COL to conduct some or all of the PITAP in the factory before delivery to the deployment site. In these cases, the OL or COL for the factory testing would specify the portions of the PITAP that would be conducted in the factory. The OL or COL for the deployment site would specify what remaining tests must be conducted at the deployment site. The ML itself may need to include terms or conditions to ensure that all aspects of the PITAP are covered in the licenses authorizing operation.

While DANU-ISG-2022-06 suggests that some ITAAC completion at the COL deployment site is possible, it supports the view that completion of ITAAC at the manufacturing facility could achieve closure of ITAAC at the time of deployment site COL issuance. To that end, during the preapplication process, the ML applicant and NRC staff could explore options for maximizing the extent to which ITAAC may be performed at the manufacturer's facility; completing any necessary installation activities at the

[19] DANU-ISG-2022-06 at 2.

[20] *Id.*

Appendix 4 – Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)

deployment site without the use of ITAAC (e.g., under an NRC-approved QA program); and obtaining NRC pre-approvals of key licensee programs (e.g., emergency preparedness) to avoid related ITAAC.[21]

As SECY-24-0008 notes, "[w]here the fabricator has a final design already approved by the NRC with maximum standardization (such as in a manufacturing license), the scope of review for licensing could be considerably narrowed."[22] As a result, the NRC staff would be able to complete its licensing review expeditiously, such that any remaining ITAAC could be closed within the 6-month schedule from site identification to operations.

The NRC will also need to develop an alternative approach to meeting the ITAAC hearing requirement set forth on AEA section 189a.(1)(B) and 10 CFR 52.103(a) to enable the 6-month schedule. The ITAAC hearing requirement is tied to the NRC's publication of the notice of intended operation in the *Federal Register*. As explained in SECY-24-0008, "[t]he NRC could not publish this notice before combined license issuance because AEA section 189a.(1)(B)(i)-(ii) provides that the hearing opportunity is on conformance with the acceptance criteria **in the combined license**."[23] Section 189a.(1)(B)(i) further provides that such notice must be published at least 180 days before the date scheduled for initial loading of fuel into a plant by the COL licensee, and that the period for requesting such a hearing is 60 days.

As SECY-24-0008 notes, in the absence of any ITAAC hearing request, the NRC staff should be able to make its section 52.103(g) finding quickly:

> "During the 60-day opportunity to request a hearing, the licensee would presumably complete construction of the reactor, provide the appropriate notifications related to ITAAC required by 10 CFR 52.99(c), and notify the NRC of its update to the date scheduled for initial fuel load in accordance with 10 CFR 52.103(a). If the NRC staff is able to conclude that all acceptance criteria are met by the close of the 60-day period for requesting a hearing and no hearing was requested, the NRC staff would aim to make the 10 CFR 52.103(g) finding shortly thereafter, possibly within 5 days. This could result in a deployment timeframe of as little as about 80 days after combined license issuance, which may be driven primarily by the statutory requirement in AEA section 189a.(1)(B)(i) that the notice of intended operation "provide that any person whose interest may be affected by operation of the plant, may within 60 days request the Commission to hold a hearing …."[24]

The submittal of a hearing request, however, would extend the minimum timeframe in accordance with NRC's Final ITAAC Hearing Procedures (81 Fed. Reg. 43,266). That is, the 52.103(g) finding might be issued (1) after the Commission's decision on the hearing request if the request is denied; (2) after a decision allowing interim operation if the hearing request is granted and the requirements for interim operation are met; or (3) after the presiding officer has issued a decision on the merits after an evidentiary hearing.[25]

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[21] For example, the use of seismic isolation would put the critical safety features on the seismic isolator and remove it from the concrete pad, fasteners to embed the reactor to the site infrastructure, or any surrounding buildings. In this way, it may be possible to associate any remaining site-specific ITAAC with the seismic isolators and to close those ITAAC at the factory.

[22] SECY-24-0008 at 21.

[23] SECY-24-0008, Enclosure at 4 (emphasis in original).

[24] *Id.*

[25] *Id.*

Appendix 4 – Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)

If a hearing is requested, then NRC's Final ITAAC Hearing Procedures allow the licensee and the NRC staff 25 days to answer the hearing request, and establish a milestone of 30 days after the answers for a Commission ruling on the hearing request. If the Commission does not grant a hearing request, this still would add 55 days to the minimum deployment timeframe compared to the scenario in which no hearing request is filed (135 days total). If the Commission does grant the hearing request, then the minimum timeframe could be extended by an additional 70 to 94 days (205 to 229 days total), which would exceed the 180-day timeframe for site identification to RHDRA operation.

As a practical matter, given the much smaller number of ITAAC expected for a RHDRA (relative to a large LWR), and the anticipated ability of the licensee to effectively complete those ITAAC, the likelihood that any hearing request is granted may be low. The AEA and 10 CFR 52.103(b) impose a high threshold for granting a hearing. The requestor must make a *prima facie* showing that: (1) one or more of the acceptance criteria of the ITAAC in the COL have not been, or will not be, met; and (2) the specific operational consequences of nonconformance that would be contrary to providing reasonable assurance of adequate protection of the public health and safety.

SECY-24-0008, in any case, identifies some potential ways to mitigate this hearing-related schedule risk. First, it notes that the Commission may allow interim operation during any hearing. Section 52.103(c) unequivocally states: "If the Commission grants the request, the Commission, acting as the presiding officer, shall determine whether during a period of interim operation there will be reasonable assurance of adequate protection to the public health and safety." The comparatively low safety risks posed by a RHDRA seem conducive to making such a determination.[26]

Additionally, SECY-24-0008 notes that schedule delays could be avoided or substantially reduced in several ways. As discussed above, the NRC must provide the ITAAC hearing opportunity at least 180 days before the scheduled initial fuel load. Manufacturers may seek to accelerate the timeframes for authorization to load fuel under a Part 52 COL by submitting the notifications and schedules related to ITAAC completion required by 10 CFR 52.99 as early as possible for each factory-fabricated module.[27] Because RHDRA modules may be fabricated in much less than 180 days, this could allow noticing of intended operation and the related hearing opportunity before the start of fabrication of a module. Further, as a practical matter, the NRC would consider such a contraction in the licensee's schedule as

[26] As noted in the table above, under 10 CFR 52.103(f), members of the public may petition the Commission to modify the terms and conditions of Part 52 COLs in accordance with 10 CFR 2.206. According to SECY-17-0007 and the Commission's related SRM, the time for filing 52.103(f) petitions begins at COL issuance and ends with the Commission's 52.103(g) finding, which allows the licensee to begin operating the reactor. The 52.103(f) process addresses whether the terms and conditions of the license should be modified for operational safety, not whether the acceptance criteria in the ITAAC are met. The Commission will consider the NRC staff's recommendation in deciding whether to grant or deny the petition. If the petition is granted, the Commission will issue an appropriate order, but fuel loading and operation will not be affected unless the order is made immediately effective. If NRC's review of a petition is pending when the licensee is about to begin a licensed operational activity (e.g., fuel loading, low-power testing) that is allegedly affected by the petition, then 10 CFR 52.103(f) requires that NRC determine whether any immediate action is necessary before that activity begins.

[27] SECY-24-0008 at 16. On this point, SECY-24-0008 (Enclosure at 4) notes that a licensee could provide the 10 CFR 52.103(a) notification of its scheduled date for initial fuel load and either an ITAAC closure notification or an uncompleted ITAAC notification under 10 CFR 52.99 for all ITAAC immediately upon receipt of the COL. If fuel is loaded at the manufacturing facility, then the site deployment licensee would not be able to notify the NRC "of its scheduled date for initial loading of fuel" as required by 10 CFR 52.103(a) because the manufacturer would be loading fuel at its site under its license rather than the licensee for the deployment site loading fuel at the deployment site under its license. In that circumstance, however, the site licensee could alternatively provide a schedule for the removal of the features to preclude criticality proposed by the NRC staff in SECY-24-0008. If the COL applicant intends to do this, then it should inform the NRC staff of its intention in the COL application or by other means so that the NRC can make necessary arrangements to prepare the notice of intended operation.

Appendix 4 – Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)

part of its process for making the 10 CFR 52.103(g) finding and the adequate protection determination for interim operation.[28]

Another possibility is that the ITAAC closure and hearing processes for each reactor could be coordinated for both the factory and deployment site if the deployment site COL is issued before operational testing at the factory.[29] The review process also could be made more efficient if the fabricator applies for an ML and a COL together, and COLs are issued simultaneously for each reactor to be manufactured.[30]

Finally, the NRC also should consider rulemaking to revise the notification and hearing processes (including the associated schedules) for ITAAC closure, given that the current processes are based on large LWR construction estimates that are not relevant factory-fabricated reactors. In this regard, while AEA section 189a.(1)(B) mandates a hearing opportunity on ITAAC completion, it provides the NRC with broad discretion to determine appropriate hearing procedures. Thus, NRC has the flexibility to develop alternative ITAAC hearing procedures for RHDRA that could include less formal processes and a much more condensed hearing schedule, such that any ITAAC hearing does not become critical path. SECY-24-0008 notes that the NRC staff intends to further assess the Final ITAAC Hearing Procedures and current Part 2 requirements based on (1) Commission direction on the options presented in SECY-24-0008 for features to preclude criticality, fuel loading, and operational testing; (2) the characteristics of factory-fabricated micro-reactors; and (3) stakeholder input. Notably, the staff states that it may "propose an update to the final ITAAC hearing procedures for Commission consideration and consider rulemaking options, as appropriate, **to better tailor microreactor hearing processes to the characteristics of, and licensing strategies for, micro-reactors**."[31]

These staff statements are consistent those made by the NRC's Office of the General Counsel (OGC) in its "Report Summarizing Lessons Learned from the ITAAC Hearing Process for Vogtle Electric Generating Plant, Units 3 and 4" (Dec. 18, 2023) (ML23352A124) (OGC ITAAC Hearing Report). That report states:

> "Also, the NRC staff acknowledges that the Final ITAAC Hearing Procedures were developed in consideration of large light-water reactors with numerous ITAAC (e.g., the Vogtle Unit 3 license had 875 ITAAC when the procedures were developed). The nuclear industry is now exploring the use of smaller reactors with significantly fewer ITAAC, including microreactors with thermal outputs hundreds of times smaller than Vogtle Units 3 and 4. Further, factory-fabricated microreactors might have very short construction timeframes (from days to a few months, depending on the design). Also, current rulemaking processes might result in a need to revise the ITAAC hearing procedures; these include the 10 C.F.R. Part 53 rulemaking and the rulemaking to align the 10 C.F.R. Parts 50 and 52 licensing processes and apply lessons learned from new reactor licensing."[32]

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[28] SECY-24-0008, Enclosure at 3.

[29] SECY-24-0008 at 21.

[30] *Id.*

[31] SECY-24-0008, Enclosure at 5 (emphasis added).

[32] OGC ITAAC Hearing Report at 8.

OGC thus acknowledged that "there may be occasion in the future, when more information is available, to consider such changes."[33]

3.1 Changes Needed to Regulations, Policy and Guidance

Although certain ITAAC-related requirements are imposed by statute, the NRC should pursue rulemaking for the ITAAC requirements to the maximum extent permitted by statute. Moreover, as discussed above, the NRC staff already has noted in current guidance that "**[f]or COLs referencing a ML, much of the post-manufacturing inspection and testing to resolve ITAAC may be performed at the manufacturer's facility and not at the COL final site**."[34] This is a significant acknowledgment that suggests that further guidance on this approach to ITAAC completion would be implemented under current NRC regulations may be warranted.

As a policy matter, SECY-24-0008 identifies for Commission consideration several potential strategies to "shorten the timeframe for deployment of a factory-fabricated micro-reactor under a combined license" and avoid ITAAC hearing-related delays.[35] Those strategies include maximizing standardization, accelerating the timeframe for authorization to load fuel under a COL, publishing the notice of intended operation as early as possible, and coordinating the ITAAC closure and hearing processes for the factory and deployment sites by issuing the deployment site COL before operational testing at the factory. Assuming the Commission's future SRM on SECY-24-0008 permits such approaches, the industry and NRC should consider developing additional guidance to implement these strategies, consistent with the RHDRA concept.

Importantly, AEA section 189a.(1)(B)(iv) gives the Commission discretion to determine "appropriate hearing procedures" for any ITAAC hearing, and the NRC staff has expressed its intent to assess whether its current ITAAC hearing procedures can be streamlined for micro-reactors, which will have significantly fewer ITAAC than a large LWR like Vogle Unit 3 or 4. Thus, to ensure that any ITAAC hearings for RHDRA are completed expeditiously, it appears that both Commission policy guidance and NRC rulemaking (generic rulemaking and/or a rule of particular applicability) may be warranted. As discussed in the NRC's Final ITAAC Hearing Procedures, the Commission also may use case-specific orders to impose case-specific hearing procedures.

As noted above, it is conceivable, if not likely, that the number of ITAAC hearing requests granted for RHDRA applications will prove to be small in practice. Nonetheless, an alternative hearing process appears necessary given the NRC's current use of Subpart L procedures (which it uses for most licensing proceedings) for ITAAC hearings. Subpart L includes the use of mandatory disclosures, pre-filed written testimony (initial and rebuttal), questioning by the presiding officer at an oral hearing, post-hearing findings, and issuance of a hearing decision. These procedures are too time-intensive to enable the 180-day schedule needed for rapid efficient licensing of RHDRA (notwithstanding the potential for interim operation under 10 CFR 52.103). Thus, the NRC should consider an ITAAC hearing process that relies on limited and simplified written filings (not formal written testimony) that are submitted on a much more expedited schedule, and which either eliminates or substantially truncates any mandatory disclosure and oral hearing requirements. Some of OGC's streamlining proposals in SECY-24-0032, "Revisiting the

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[33] *Id.*

[34] DANU-ISG-2022-06 at 7 (emphasis added).

[35] SECY-24-0008, Enclosure at 4.

Mandatory Hearing Process at the U.S. Nuclear Regulatory Commission" (Apr. 12, 2024) (ML24103A090), may serve as useful analogues in the ITAAC hearing context.

It bears mention that the industry previously has recommended, and the NRC has rejected, the possible use of 10 CFR Part 2, Subpart N procedures for ITAAC hearings. In the final rule promulgating Subpart N, the Commission explained that Subpart N is intended to be a "'fast track' process for the expeditious resolution of issues in cases where the contentions are few and not particularly complex, and therefore may be efficiently addressed in a short hearing using simple procedures and oral presentations."[36] In addition, the Subpart N procedures were developed to permit a quick, relatively informal proceeding where the presiding officer could easily make an oral decision from the bench, or in a short time after conclusion of the oral phase of the hearing. To date, the Commission and OGC have cited a lack of "sufficient experience to conclude that the issues to be resolved in an ITAAC hearing will be simple enough to profitably employ the procedures of subpart N and forego the advantages accruing from written testimony and statements of position."[37] As discussed above, however, the need to rapidly license RHDRA in large volumes should compel NRC's reassessment of that position and the development of ITAAC hearing procedures that are tailored to such reactors.

Finally, the NRC should consider revisiting the industry's prior recommendation that the NRC establish a process for invoking the Administrative Procedure Act (APA) exception in 5 USC 554(a)(3) to avoid holding a hearing where the decision "rest[s] solely on inspections, tests, or elections." In its 2016 Final ITAAC Hearing Procedures, the NRC rejected this recommendation as impractical, although it acknowledged that "it may be legally possible to apply the APA exception to some ITAAC in an ITAAC hearing (depending on the wording of the ITAAC and other relevant circumstances)."[38] The anticipated limited number and scope of ITAAC for RHDRA may warrant NRC reconsideration of this position as an alternative means of avoiding ITAAC hearing delays.

3.2 Acceptance Criteria and Licensing Approach

3.2.1 Acceptance Criteria

Any advanced reactor could benefit from a more streamlined ITAAC process in which ITAAC could be closed as part of a component's fabrication under the ML or DC and prior to site identification, especially where that component is a safety-related feature of a site-specific structure. However, the maximum benefits that would be needed to meet the deployment timelines for RHDRA are expected to include technical features that meet the following conditions:

- The design enables all ITAAC related to site structures to be associated only with pre-fabricated components of those structures, alleviating the need for ITAAC to be associated with components that must be completed on-site. For example, the use of seismic isolators that would be substantially significant to the safety function of the structure could enable the site structure ITAAC to be solely associated with the seismic isolators. If the seismic isolator design is

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[36] Changes to Adjudicatory Process; Final Rule, 69 Fed. Reg. 2182, 2214 (Jan. 14, 2004). As the NRC has noted, in their current form, even the Subpart N procedures might not offer a significant schedule advantage relative to the Subpart L procedures. As such, some alternative process appears necessary to enable the 180-day timeline for site identification to RHDRA operation in cases where an ITAAC hearing is requested and granted.

[37] Final ITAAC Hearing Procedures, 81 Fed. Reg. at 43,282.

[38] *Id.* at 43,273.

approved in the standard design approval, then the ITAAC could be closed at the factory prior to site identification. Verification of proper installation of the seismic isolators and other components of the site structure would be performed through the NRC's routine construction oversight and inspection processes, and the licensee's programs, such as QA, which are well suited to confirm that the safety-related functions of the site structures have been constructed in accordance with the license, AEA, and NRC requirements.

- The reactor designer/manufacturer limits the number of proposed ITAAC to the maximum extent practicable by identifying only those ITAAC that are needed to provide reasonable assurance that the RHDRA has been manufactured and installed and will be operated in conformity with the relevant licenses, AEA, and NRC rules and regulations. This includes maximizing the extent to which (1) any installation and testing activities at the deployment site can be completed without the use of ITAAC, and (2) the ML holder can obtain NRC pre-approvals (e.g., as topical reports) of programmatic and operational information (e.g., QA, security, EP, operator licensing, technical specifications, plant operations and maintenance organizations) that might otherwise require an ITAAC and closure thereof by the site COL licensee.

- To reduce the scope of on-site inspection and testing activities, the reactor is assembled and tested in a factory setting to support conducting ITAAC or ITAAC-like inspections and tests to ensure the reactor has been fabricated and assembled consistent with the license and applicable NRC regulations. This would allow completion of ITAAC that ordinarily would be included in the deployment site COL at the manufacturing facility under the manufacturing site COL.

- The holder of the deployment site COL ensures that all ITAAC (including those performed at the manufacturing facility) are completed as expeditiously as possible.

- To avoid ITAAC hearing delays, manufacturers should seek to accelerate the timeframes for authorization to load fuel under a Part 52 COL by submitting notifications and schedules related to ITAAC completion as early as possible. The NRC, in turn, should publish the notice of intended operation as soon as possible. The ITAAC closure and hearing processes for each reactor also should be coordinated for the factory and deployment sites to the greatest extent possible.

- The NRC establishes (via rulemaking and/or case-specific orders) simplified ITAAC hearing procedures that ensure completion of any ITAAC hearing (if one is requested and granted) on an expedited basis (i.e., no more than 2-3 months).

3.2.2 Licensing Approach

Any licensing process could be used to benefit from a more streamlined ITAAC process that allows for more ITAAC closure in the factory, through licensee pre-approvals and prior to site identification. However, to maximize benefits of such a streamlined process, and to meet the deployment timelines for RHDRA, the ReLic process would need to be used.

4 OTHER OPTIONS FOR RESOLUTION OF THE ISSUE

Appendix 4 – Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)

4.1 AEA Change – ITAAC Provisions

Given that the ITAAC requirements are explicitly statutory in nature, any alternative approaches likely would be legislative in nature. For example, the industry and/or NRC could propose targeted legislative amendments to the AEA to remove a class of commercial power reactors, e.g., RHDRA (which would need to be defined), from the scope of the ITAAC and ITAAC hearing requirements in sections 185 and 189, respectively. Changes to the AEA for ITAAC would have broader benefits to all advanced reactors, as compared to the other options for AEA changes.

4.2 AEA Change – General License

A general licensing approach would be more efficient and effective in regulating nuclear reactors, such as RHDRA, and would be capable of enabling even shorter deployment timeframes that would be needed to support other business models. Currently, the AEA does not grant the NRC authority to issue general licenses for nuclear reactors, although it does grant authority to the NRC to issue general licenses for other regulated activities. If Congress were to amend the AEA to authorize and direct the NRC to develop a general licensing approach for certain nuclear reactors, and the NRC subsequently pursued a rulemaking to develop such a general license framework for nuclear reactors, this would be a more optimal solution to the issue discussed in this appendix. However, since the NRC could achieve the business requirements with currently granted authorities, and since there is significant uncertainty on whether or when Congress would grant NRC authority for issuing general licenses for reactors, the proposed resolution discussed herein is focused on approaches the NRC can implement without changes to the AEA. This enables the fastest path toward a more effective and efficient regulatory framework for RHDRA and other advanced reactors, and would build the basis of experience that could inform a longer-term General License approach if Congress eventually enables it. More discussion on NRC Regulation Through General Licenses is included in Attachment B.

5 ACKNOWLEDGEMENTS

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Appendix 5 – Site License Scope and Purpose

1 ISSUE INTRODUCTION

The NRC's current site-specific approach to safety and environmental reviews and issuing either an operating license (OL) under 10 CFR Part 50 or a combined license (COL) and subsequent section 52.103(g) finding under 10 CFR Part 52 requires several years to complete. Thus, it will not support either the 6-month proposed rapid high-volume deployable reactor in remote locations (RHDRA) deployment schedule or the less-than one percent of overall O&M cost target for managing regulatory matters, as a multi-year review process inherently involves substantial resources to complete. The NRC therefore will need to establish a licensing process that minimizes the scope and content of the site license application to the maximum extent practicable. This is not to suggest that NRC reviews should be less rigorous, as they must provide reasonable assurance of adequate protection of public health and safety. Rather, this paper discussed how the NRC may adapt and optimize its licensing processes to complete its site-specific licensing reviews in a timeframe that supports the RHDRA business model.

A new approach to site-specific licensing is needed that addresses as much of the required scope and content as possible through licensing processes that occur one-time prior to the site license application (e.g., generic technology-inclusive approvals, approvals with the design, and licensee pre-approvals). Under this approach, the site license's main purpose would be to verify the site's conformance to the site parameter envelope (SPE) established by those prior approvals. This process would enable the concurrent issuance of a construction permit (CP) and OL under Part 50, or a COL and 10 CFR 52.103(g) finding, within 5 months from application submittal to license issuance.

The most effective way to achieve this objective is through a regulatory framework that is performance-based, with requirements that define the acceptable outcomes in terms of public health and safety and in ways that are as objectively measurable as possible. The approach described herein would be to model the licensing for site deployment of RHDRA after 10 CFR Part 72, where, for purposes of this concept, the reactor is analogous to a spent fuel storage cask and the deployment site is analogous to an Independent Spent Fuel Storage Installation (ISFSI). Recognizing the important similarities and differences between the technical attributes and the requirements of Parts 50/52 and Part 72, this paper focuses primarily on identifying a near-term pragmatic solution that fits within the statutory constraints established by the Atomic Energy Act of 1954, as amended (AEA). As such, the primary approach described below more closely aligns with a Part 72 specific license process. An alternative approach that tracks the Part 72 general license process (but requires changes to the AEA) is described in Section 4, "Other Options for Resolution of the Issue."

2 BACKGROUND

The technology characteristics and concept of deployment and operations for RHDRA are so fundamentally different from other power reactors that the business model for RHDRA needs to be addressed uniquely. That is, the RHDRA business model cannot be enabled solely by adapting the current regulatory framework for power reactors and the NRC's ongoing work to modernize the licensing framework for advanced reactor designs. Specifically, the ability of RHDRA to achieve high degrees of design standardization[1], and to bound a large range of potential sites, enables these reactors to achieve finality on all safety considerations before site identification for most potential deployment locations. Coupled with this, their small potential impacts to land, water, air, and ecological resources enable these reactors to achieve finality on all environmental considerations prior to site identification. Importantly, the potential public health and safety risks and environmental impacts of RHDRA operation are much more akin to those of other low-risk technologies regulated by the NRC than they are to other power reactors. RHDRA are expected to have source terms that are 100 to 1,000 times smaller than the large light-water reactor (LWR) source terms on which the NRC's current power reactor regulatory framework is based. In fact, a more appropriate comparison for the source term of a RHDRA is a typical spent fuel dry storage system (DSS). RHDRA are expected to have source terms that are 20 to 100 times smaller than a DSS.

Further, the sizes and source terms of RHDRA will be more like those of research and test reactors (RTR) than the large LWRs for which current NRC regulations governing production and utilization facilities were developed. Other Appendices and Attachment A address the similarities of RHDRA risks to those of RTRs, as well as concepts for aligning RHDRA licensing with the processes used for RTRs. This paper exclusively addresses site deployment of NRC-licensed RHDRA designs.

2.1 NRC Power Reactor Site-Specific Licensing

The NRC has two processes by which to issue a site license, Part 50 and Part 52. Both are available for the licensing of RHDRA sites. The purpose of this section is to describe how these processes currently work. The NRC has established Generic Milestone Schedules for various requested activities of the Commission on its website.[2] These Generic Milestone Schedules are based upon applications that may incorporate by reference content for which finality has been achieved through prior NRC review and approval, but which still include considerable new safety and environmental information that the NRC must review on a case-specific basis.

The Part 50 and 52 licensing processes permit the incorporation by reference of scope of the application that was previously reviewed and approved by the NRC. Part 50 OL and Part 52 COL applications may reference or otherwise leverage design approvals, such as Manufacturing Licenses (ML), Design Certifications (DC) and Standard Design Approvals (SDA), Part 50/52 Appendix N approvals,[3] Generic Environmental Impact Statements (GEIS), and Topical Reports (TR), all of which provide varying degrees of finality. In this manner, the site license application reviews would only focus on verifying that the site license conforms to those prior approvals, including any conditions established for verifying conformance. If the site license conforms to those prior approvals, the site license application review within that prior approved scope of the application would be substantially streamlined.

It is important to note that the NRC's schedules do not include the minimum 24 months for an applicant to collect data to satisfy the NRC's current requirements and guidance for site characterization.

[1] As defined by the NRC staff in its draft "Micro-reactors Licensing Strategies" white paper, the term "standardization" refers to "a micro-reactor design that could be deployed to the majority of sites in the U.S. without the need for site-specific features where the majority of safety issues could be resolved as part of a design certification and/or manufacturing license."

[2] *See* NRC, "Generic Milestone Schedules of Requested Activities of the Commission," https://www.nrc.gov/about-nrc/generic-schedules.html.

[3] 10 CFR Part 50 and 10 CFR Part 52 (Appendix N in both Parts) contain requirements and provisions applicable to situations in which applications are filed by one or more applicants for licenses to construct and operate nuclear power reactors of essentially the same design (common design) to be located at different sites.

Appendix 5 – Site License Scope and Purpose

Reducing the site characterization schedule is addressed in Appendix 10 (Meteorology and Weather Data) and Appendix 11 (Geologic and Geotechnical Site Characterization).

2.1.1 Part 50 Site Licensing

The NRC issues operating licenses (OLs) for specific sites pursuant to 10 CFR 50.50, "Issuance of licenses and construction permits." Traditionally, the NRC will first issue a construction permit (CP) for a site, and once construction of the facility is substantially complete, it will issue the operating license. The NRC's Generic Milestone Schedule for CPs is 36 months, and for OLs it is 42 months for LWRs and 36 months for non-power and non-LWR reactors. If these licensing actions are pursued sequentially, it would take 96 to 102 months to complete the licensing process from the time of site identification to operations (this includes the 24 months for site characterization).

The NRC has the authority to issue a CP and an OL concurrently, thereby reducing the NRC Generic Milestone Schedule to 60 to 66 months. The NRC considered this issue when it first promulgated Part 52 in 1988. In the Statement of Considerations for the 1998 final rule, the NRC rejected commenters' assertion that "section 185 of the Atomic Energy Act mandates a two-step licensing process."[4] The Commission examined the plain language of AEA sections 161.h and 185 and their legislative history. It concluded that "[a] closer look at section 161h and 185 shows that section 161h clearly gives the Commission authority to combine a construction permit and operating license in a single license and that section 185 is not inconsistent with section 161b."[5] As the Commission further explained:

> "To be sure, [section 185] speaks in terms of a construction permit's being issued first, and then a license (presumably an operating license). **However, the contrast between the two licenses is not fundamental to the section.** The substance of the section is clearly indicated by the title of the section and by the list of findings the Commission must make. The section may be paraphrased thus: A construction permit is not a grant of authority to operate once construction is complete; before operation begins, the original application must be brought up to date, and the Commission must make certain affirmative findings. **Thus, the critical matter is not the separation of the two licenses, but the need for specific findings before operation.**
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> . . .
>
> By speaking of a separate issuance of a license after completion of construction, section 185 simply conforms itself to the simplest case, in which the licenses are in their elementary, uncombined states, and avoids having to make an already long section longer in order to acknowledge the case which section 161h makes possible. Moreover, section 185 acknowledges section 161h implicitly when it speaks not of a separate application for an operating license but simply of an updating of the original application."[6]

[4] Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Reactors, Final Rule; 54 Fed. Reg. 15,372, 15,379 (Apr. 18, 1989).
[5] *Id.*
[6] *Id.* (emphasis added).

Appendix 5 – Site License Scope and Purpose

The Commission also noted that "[t]his interpretation of section 185 is confirmed by the legislative history of the section."[7]

At the proposed rule stage, the NRC explained that the two-step process "was structured to allow licensing decisions to be made while design work was still in progress and to focus on case-specific reviews of individual plant and site consideration."[8] However, with the industry's maturation, it is now "possible to describe and evaluate plant designs on a generic basis, to have designs essentially complete in scope and level of detail prior to construction, and to propose and evaluate plant sites without plant design details," thereby making it possible to combine the construction permit proceeding with much of the operating license proceeding into a single proceeding.[9]

Although it provides guidance on the conduct of licensing reviews for non-power reactor license applications, NUREG-1537 provides insight into how a CP and OL could be concurrently pursued under Part 50. NUREG-1537 states:

> "The regulations (see 10 CFR 2.105(c)) do not preclude, and the NRC prefers a joint application for a construction permit and operating license for the initial licensing of a research reactor facility. If well planned, the final facility design and the final SAR descriptions, analyses and conclusions will not be significantly changed from those in the initial application, and a one-step licensing procedure can be undertaken. To initiate this process, the application should request both a construction permit and an operating license to be issued when construction and operating readiness are acceptable to NRC. The submitted SAR should be complete, appropriate, and acceptable for both permits. **This allows a joint notice-of-intent to be published in the *Federal Register* at the construction permit stage that includes issuance of the operating license without further prior notice when appropriate. The joint application and joint notice procedure streamlines the licensing process.** If a final SAR is submitted which documents changes made during construction, it shall demonstrate that the facility design and the safety conclusions of the previous SAR documents are unchanged." NUREG-1537 also discusses how a non-power reactor could submit a single Safety Analysis Report (SAR), fulfilling the requirement for a preliminary SAR (PSAR) for the construction permit application and final SAR (FSAR) for the operating license application."[10]

2.1.2 Part 52 Site Licensing

The NRC issues COLs for specific sites under Subpart C of 10 CFR 52. Traditionally, the NRC will first issue a COL for a site that permits construction. After construction is completed and the NRC verifies that all Inspections, Tests and Analyses, and Acceptance Criteria (ITAAC) are met, the NRC permits operations after it authorizes fuel loading through a 10 CFR 52.103(g) finding. The NRC's Generic Milestone Schedule for COLs is 36 months for applications referencing a DC (both LWRs and non-LWRs), 42 for LWRs and 36 months for non-LWRs (both not referencing a DC). In SECY-24-0008, the NRC staff indicated that they could issue a 52.103(g) finding in several months after the COL is issued for micro-

[7] *Id.*

[8] Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Reactors; Proposed Rule, 53 Fed. Reg. 32,060, 32,065 (Aug. 23, 1988).

[9] *Id.*

[10] NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors – Standard Review Plan and Acceptance Criteria" at xv (Feb. 1996) (emphasis added).

reactors that have completed all of the ITAAC, but the exact timing would be affected by the filing and the nature of the NRC's disposition of any ITAAC hearing requests.[11] If these licensing activities are pursued sequentially, it would take 66 to 72 months to complete the licensing process from the time of site identification to operations (this includes the 24 months for site characterization).

To date, the NRC has not concurrently issued a COL and 10 CFR 52.103(g) finding. In SECY-24-0008, the NRC indicated that notification requirements for ITAAC and the 52.103(g) finding process, including hearings, are major challenges to achieving the potential 6-month schedule for a 52.103(g) finding after issuing a COL.[12] These notification requirements would also challenge the NRC's ability to concurrently issue a COL and 52.103(g) finding for applications for which all ITAAC can be closed prior to the issuance of the COL, or even prior to the NRC acceptance of the COL application (which is addressed in Appendix 4).

2.2 NRC Part 72 Licensing Process

The NRC's two Part 72 ISFSI licensing processes can serve as models for a more streamlined licensing process for RHDRA. This section describes the Part 72 specific license process (Section 2.2.1) to provide a "baseline" for the analysis of near-term efficiency improvements for micro-reactor deployment. Section 2.2.2 describes the Part 72 general license process, as it provides a model on which a future general license process for micro-reactors could be based.

2.2.1 The Part 72 Specific License Process

The Part 72 specific license process is like most other NRC specific licensing processes that apply to one facility on one site. It involves the preparation of a license application (LA) that includes a Safety Analysis Report (SAR), which describes the design, operation, and maintenance of the ISFSI facility and the dry storage system (DSS) design to be used at the ISFSI to store the spent nuclear fuel. Importantly, this type of "blank-sheet" SAR also includes detailed site characterization information for the proposed ISFSI site (used for establishing the design bases as well as in the Environmental Report (ER) submitted with the LA), descriptions of the analyses for postulated off-normal and accident events involving the DSS, operating organization, and information on other topics.

The format and content of the specific license ISFSI SAR is based on NUREG-2215, "Standard Review Plan for Dry Spent Fuel Storage Facilities and Systems" (Apr. 2020), which includes 17 chapters that address the NRC's major areas of review, including relevant regulatory requirements, staff positions, industry codes and standards, acceptance criteria, and other information. In addition to the SAR, a Part 72 ISFSI specific license application also must include proposed program description documents that govern various elements of ISFSI operation and management and other information, including:

- General and Financial Information (10 CFR 72.22)
- Technical Specifications (10 CFR 72.26)

[11] *See* SECY-24-0008, Enclosure 1 at 4-5.

[12] *See id.* at 3 ("For large light-water reactors, the timeframes for licensee notifications and Commission actions required by AEA section 189 and Subpart C of 10 CFR Part 52 fit within the overall construction schedule, which is usually several years. For factory-fabricated micro-reactors with much shorter deployment schedule goals, these timeframes could result in delays in entering the reactor into operation.").

- Applicant's Technical Qualifications (10 CFR 72.28)
- Decommissioning Plan (10 CFR 72.30)
- Emergency Plan (10 CFR 72.32)
- Environmental Report (10 CFR 72.34)
- Quality Assurance (QA) Program (10 CFR 72, Subpart G)
- Security Plan (10 CFR 72, Subpart H)

After completing its technical and environmental reviews, the NRC staff will issue a Safety Evaluation Report (SER) and an Environmental Impact Statement (EIS) for the facility. If the NRC approves the application, then it issues a specific license to operate the facility.

2.2.2 The Part 72 General License Process

The NRC created the Part 72 general license process in response to congressional direction contained in the 1987 amendments to the Nuclear Waste Policy Act.[13] Congress's intent was to allow reactor operator licensees to leverage existing programs for reactor operation to operate an ISFSI on site without additional NRC site-specific approvals. NRC regulations in 10 CFR 72, Subpart K grant the general license to Part 50 and 52 licensees (10 CFR 72.210) and establish conditions for the general license in 10 CFR 72.212. These license conditions provide, in part, that a Part 72 general licensee may store only spent fuel that it is authorized to possess at the site under the specific Part 50/52 license, and that the general licensee must use a DSS design certified by the NRC and for which a Part 72 Certificate of Compliance (CoC) has been issued.

The DSS designer submits an application, including a SAR, for design approval. The DSS SAR includes details on the cask design, operation, and safety analyses, as well as the allowed contents and how to load and operate the DSS. Upon approving the application, the NRC issues a Part 72 CoC and lists the DSS design in 10 CFR 72.214. Once a CoC is issued, any Part 72 general license may use the DSS design.[14]

[13] *See* Nuclear Waste Policy Act of 1982 (NWPA), Public Law 97-425; 96 Stat. 2201, Sec. 218(a) ("The Secretary shall establish a demonstration program, in cooperation with the private sector, for the dry storage of spent nuclear fuel at civilian nuclear power reactor sites, with the objective of establishing one or more technologies that the Commission may, by rule, **approve for use at the sites of civilian nuclear power reactors without, to the maximum extent practicable, the need for additional site-specific approvals by the Commission**.") (emphasis added). *See also* Sec. 133 ("The Commission shall, by rule, establish procedures for the licensing of any technology approved by the Commission . . . or [sic] use at the site of any civilian nuclear power reactor.").

[14] Part 72 specific licensees may also use a certified DSS design by incorporating the design by reference in its license application. If they choose to do so, 10 CFR 72.46(e) provides that "the scope of any public hearing held to consider the application will not include any cask design issues."

Appendix 5 – Site License Scope and Purpose

The Part 72 general licensee must notify the NRC of its intent to operate an ISFSI under the general license and must create (but not submit to the NRC) a 10 CFR 72.212 Report ("212 Report") before beginning ISFSI operation.[15] The purpose of the 212 Report is for the general licensee to[16]:

1. Describe licensee compliance with the DSS CoC,

2. Describe the design and analysis of the ISFSI storage pad,

3. Summarize the offsite dose analysis showing expected annual doses from normal ISFSI operation and anticipated occurrences will be less than the limits in 10 CFR 72.104,

4. Describe how the generic cask design criteria (e.g., seismic, temperature, wind, etc.) bound the reactor site where the ISFSI will be constructed and operated, and

5. Determine if an amendment to the facility license is required to operate the ISFSI under the Part 72 general license.

While not required to be included in the 212 Report, other conditions of the general license in 10 CFR 72.212 require certain operational programs to be reviewed and revised as necessary to include ISFSI operations.[17] Other Part 72 regulations apply equally to both specific and general licensees (e.g., operator training, facility decommissioning, reporting, SNM accounting, facility change control, etc.).

The NRC's role in the Part 72 general license process is limited to approving the DSS designs and inspecting ISFSI construction and operation. There is no process analogous to ITAAC in the Part 72 general license process.

3 PROPOSED SOLUTION AND APPROACH

An alternative approach for the site-specific licensing of RHDRA is needed to achieve the business requirement of less than 6 months from site identification to operations. This approach would be focused on establishing a rapid, efficient licensing (ReLic) process that would be based on existing NRC licensing processes in Part 50 and Part 52. The goals of the approach are to optimize standardization and significantly reduce the scope of the site license review by:

1. completing all, or as much as possible, of the safety and environmental reviews and public engagement processes one-time prior to the identification of a specific site, and

2. performing a site-specific license review that only needs to verify that the site characteristics conform to the minimum set of site parameters in the envelope established in the one-time up-front reviews.

[15] As germane to later discussion, the Part 72 general license is not legally effective until the licensee begins loading spent fuel into the DSS. However, by virtue of the general licensee also having a Part 50 or 52 specific license, the NRC has inspection and enforcement jurisdiction at the site.

[16] *See* 10 CFR 72.212(b)(5), (b)(6), and (b)(8).

[17] *See* 10 CFR 72.212(b)(9) and (b)(10).

Appendix 5 – Site License Scope and Purpose

The RHDRA simplified specific license (SSL) approach proposed in this paper is based on an adaptation and simplified version of the 10 CFR Part 72 ISFSI specific licensing process, incorporating concepts of the Part 72 ISFSI General License process where they can be accommodated by existing Part 50 licensing tools (e.g., GEIS and Topical Reports).

3.1 Scope and Content of the ReLic Process

The RHDRA deployment SSL concept is based upon the use of the following types of NRC approvals that can achieve finality prior to the identification of a specific site:

- NRC generic approvals on a technology-inclusive basis (e.g., GEIS or rulemakings)
- NRC approvals with a standard design (e.g., ML, DC, SDA, Appendix N)
- NRC pre-approvals for a licensee (e.g., Topical Reports for programs)

Other Appendices address the NRC prior approvals in the areas of Environmental (Appendix 1), Design approvals (Appendix 2), ITAAC (Appendix 3) and Hearings (Appendices 6 and 7). For the purposes of this Appendix, it is assumed that the site-specific license application references, and is using, a RHDRA with an approved Part 52 ML that includes NRC approval of the reactor design (either directly or via a design certification). It further presumes that owner-operator requirements, including operational programs, are reviewed by the NRC at the design stage to the maximum extent practicable. This may be accomplished either as part of the design approval (to the extent allowed under Commission policy), through topical reports (TRs), or through a design-centered review approach.[18] The owner-operator would commit to these generically approved requirements in its license application. Section 3.2 provides additional details regarding this approach. As shown in the figure below, enhanced standardization of the design, coupled with use of licensee pre-approvals and other technology-inclusive generic approvals for which finality is provided, can significantly reduce the scope of the information required to be submitted by a COL applicant and reviewed by the NRC staff.

[18] Under a design-centered review approach, the NRC staff would review operational matters for the first micro-reactor application of a particular design, and the review would be applied to subsequent applications that use the same approach to operational matters as the first application.

Appendix 5 – Site License Scope and Purpose

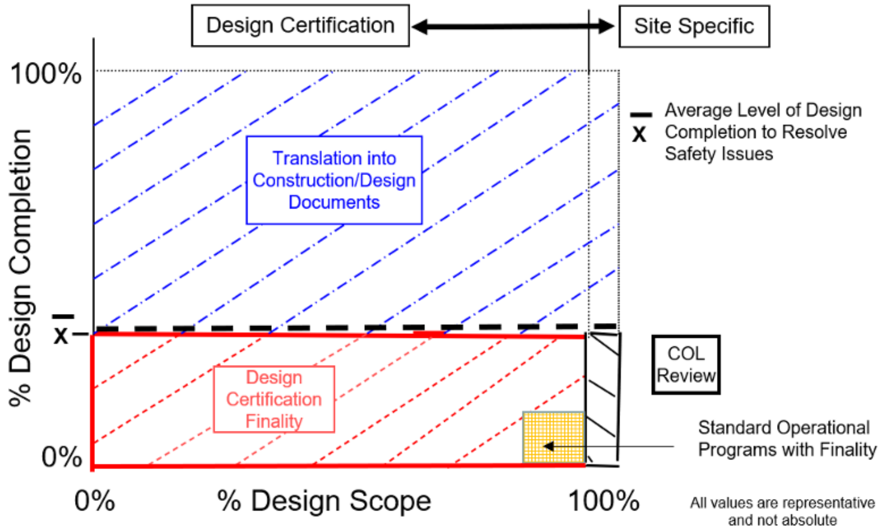

Figure 3 COL application referencing a certified design with enhanced standardization and finality for operational programs

This paper is also based on a RHDRA for which site-specific license reviews need only to verify that the site characteristics conform to the minimum set of site parameters in the envelope established in the one-time, up-front reviews.[19] The following is expected to be the scope of the SSL:

1. Describe site compliance with prior NRC approvals:
    a. Prior design approvals (e.g., ML)
    b. Prior environmental reviews (e.g., CatEx or GEIS-based)
    c. Licensee pre-approvals (e.g. TRs)
    d. Other technology-inclusive generical approvals (if not already included in the ML or NRC environmental review)
    e. Closure of ITAAC (if using Part 52)
2. Describe the applicable site parameter envelope:
    a. Meteorology and Weather Data (see Appendix 10)
    b. Geologic and Geotechnical Data (see Appendix 11)
    c. Other External Hazards (see Appendix 12)
3. Describe any site-specific design and analyses for structures that impact safety:
    a. Engineered Features to Enable Site Independence (e.g., seismic isolation)

[19] RHDRA that achieve finality on less scope may need to include that scope in the SSL.

b. Engineered Features to Enable Nuclear Island Separation (e.g., intermediate loop between Nuclear Island and Energy Island)

c. Safety Related Site-Specific Structures (e.g., concrete pad, reactor building)

4. Describe how the site parameter envelope (e.g., seismic, temperature, wind, etc.) bound the site where the reactor will be emplaced and operated

5. Summarize the offsite dose analysis showing expected annual doses from normal operation, and anticipated occurrences will be less than the NRC limits.

3.2 ReLic Administrative Process

The ReLic process may use either Parts 50 or 52 licensing processes. For Part 50, the NRC should allow concurrent issuance of a CP and OL. As discussed above, this approach is authorized by AEA sections 161.h and 185 and permitted for use by RTRs in NUREG-1537.

For Part 52, the NRC should allow concurrent issuance of COL and 10 CFR 52.103(g).

For both processes, the NRC will need to be able to issue pre-approvals for entities that intend to become future site-specific licensees for a production or utilization facility. The scope of these licensee pre-approvals should include requirements related to the licensed entity that can be reviewed and approved without knowledge of a specific site. These include:

- General Licensee/Financial Information (10 CFR 50.33)
- Applicant’s Technical Qualifications (10 CFR 50.34)
- QA Program (10 CFR Part 50, Appendix B)
- Operations Staffing (10 CFR 50.54 and 50.120) – See Appendix 14
- Security Plan (10 CFR 73.55) – See Appendix 19
- Emergency Plan (10 CFR 50.160) – See Appendix 20
- Access Authorization/Fitness for Duty (10 CFR 73.56 and 10 CFR Part 26) – See Appendix 21
- Radiation Protection Program (10 CFR 20.1101) – See Appendix 22

The applicant should use Topical Reports, or other similar processes, to submit information in these areas to obtain an NRC review, approval, and finality. Future SSL applications would incorporate these by reference and the NRC review would be focused on verifying, to the extent necessary, that the specific site conforms to the conditions of the site parameter envelope.

The design approval would include, to the maximum extent practicable, all programmatic controls and operational programs, as applicable, in the ML as generic requirements for any SSL application. The potential SSL holder would obtain approval for future sites in a series of topical reports. For example,

Appendix 5 – Site License Scope and Purpose

TRs would be submitted for QA, security, emergency planning, operator licensing, technical specifications, plant operations and maintenance organizations, and any other set of requirements that are appropriate for the NRC to approve for a prospective owner-operator.

The NRC would issue an SER for each TR to be incorporated by reference into each SSL application, including any limits and conditions on the TR that the SSL applicant must meet. A TR (or NRC-endorsed industry guidance document) would also be submitted to identify the process for preparing and submitting an SSL application. It would include LA format and content guidance, including guidance on the extent to which each SSL applicant would need to address necessarily site-specific items. The goal would be to limit the list of site-specific items to those that have not achieved finality.

In keeping with the goal of standardization, each TR should be written with maximum flexibility, so that each SSL applicant can adopt the approved TRs as written. The details of program implementation would be contained in site implementing procedures. (While outside the NRC approval process, the site implementing procedures could be generically written by the ML holder.)

The deployment site license applicant (and future licensee) would submit site characterization data that are expected to come from reliable generally and readily available data (e.g., USGS and NOAA) or from other specifically collected data from the site exploration activities that occurred during the site selection process. The bases for this approach are discussed in Appendices 10 (Meteorology and Weather Data), 11 (Geologic and Geotechnical Site Characterization), and 12 (Other External Hazards).

Appendix 1 discusses how the NRC could meet its environmental review obligations under the National Environmental Policy Act (NEPA) and 10 CFR Part 51. As discussed therein, the optimal long-term licensing approach for RHDRA environmental reviews likely will involve the use of categorical exclusions. If NRC can determine that a given RHDRA design would not individually or cumulatively have a significant effect on the human environment when reactors of that design are sited within a given site parameter envelope, then it may develop a categorical exclusion and associated rulemaking that reflect this determination and avoid the need for site-specific environmental impact statements or environmental assessments for that specific reactor design.

As a nearer-term option, Appendix 1 envisions the NRC's finalization of the Generic Environmental Impact Statement (GEIS) for Advanced Nuclear Reactors (ANR GEIS) and associated Part 51 rulemaking, and subsequent development of a supplement to the ANR GEIS that is specific to RHDRA. That supplement would generically disposition, to the maximum extent possible, the Category 2 (site-specific) issues identified in the ANR GEIS. This would limit, if not eliminate, the need for detailed site-specific NEPA review at the site-specific application stage. The NRC's site-specific NEPA review would be largely confirmatory in nature, with the staff verifying that the proposed facility and site meet or are bounded by the relevant values and assumptions (i.e., plant parameter envelope and site parameter envelope) in the GEIS documents, and that there is no new and significant information that would alter the staff's generic findings.[20] The staff's site-specific NEPA review document would tier from the GEIS

[20] This is consistent with the approach described by the NRC staff in its Micro-reactors Licensing Strategies white paper, which notes that "[t]he environmental review could be streamlined by adopting the ANR GEIS, which will reduce the effort required for environmental review to the extent that the ANR GEIS parameters bound the plant and site, and absent any new and significant information."

documents.[21] However, given that some level of site-specific analysis still may be required for Category 2 issues, and the need to meet other procedural requirements associated with the NEPA process, this approach likely would not meet the 180-day RHDRA licensing timeline.

The ultimate goal of the SSL application would be to reduce the scope of the NRC's review as much as possible, such that it is principally a verification review that can be performed in two months or less. To a large degree, the LA would be a series of commitments to adhere to the ML conditions and TRs, with site implementing procedures containing the details. A good template or model for this approach is a typical QA program submitted to the NRC for approval. Such programs are largely commitments to have controls in place to implement each of the 18 QA criteria in the NRC's regulations. The SSL LA approach would be similar, with commitments to the approved TRs, as well as commitments to implement the terms and conditions in the ML and its SAR pertaining to operations, maintenance, etc.

3.3 Changes Needed to Regulations, Policy and Guidance

It is possible to establish the alternative licensing approach for RHDRA with minimal rulemaking by affirming that the concurrent issuance of a Part 50 CP and OL, as currently permitted for RTRs in NUREG-1537) can also be used for power reactors. As noted, there is no statutory barrier to this approach. More complex rulemaking would be needed to permit concurrent issuance of a Part 52 COL and 10 CFR 52.103(g) finding.

For both the Part 50 and 52 licensing processC, the NRC would need a rulemaking to remove the restriction in 10 CFR 52.153(a) and 10 CFR 52.167(c)(1) on the deployment of manufactured reactors to sites for which either a Part 50 CP or Part 52 COL has been issued. The requirement would need to be modified to permit emplacement of a RHDRA to a site for which the NRC has docketed an SSL application. Additionally, Part 52 would need to be modified to recognize the SSL concept in a new appendix or subpart that is appropriately connected to other parts of Part 52.

For either of these approaches, it is possible that the NRC may prefer to issue a new Policy Statement, or update its 1987 Policy Statement on Nuclear Power Plant Standardization (52 Fed. Reg. 34884), to enable and establish the framework for a ReLic process.

New NRC and industry guidance would be needed to clarify the ReLic process. Such guidance should provide ML applicants and owner-operators with consistent recommendations for LA format and content, and current NRC guidance would need to be modified to address the SSL licensing process.

3.4 Acceptance Criteria and Licensing Approach

3.4.1 Acceptance Criteria

There are no acceptance criteria per se for a RHDRA or other advanced reactor to be able to use a ReLic process as described in this Appendix. However, it is acknowledged that to achieve the standardization

[21] Tiering refers to the process by which an environmental document may rely on an existing and broader or more general environmental document. See 40 CFR 1501.11(b). As noted in 10 CFR Part 51, Appendix A, the techniques of tiering and incorporation by reference described respectively in the Council of Environmental Quality's (CEQ) NEPA regulations may be used as appropriate to aid in the presentation of issues, eliminate repetition or reduce the size of an environmental impact statement.

that is necessary to enable the ReLic process, the design will likely need to be simple and have low potential consequences to bound future sites without the need for site specific design changes.

3.4.2 Licensing Approach

For RHDRA that need to achieve a 180-day or less timeline from site identification to operation, it is expected that they will need to meet specific conditions that enable the full benefits of the ReLic process. These specific conditions are defined in this paper and are in the following categories:

- NRC generic approvals on a technology-inclusive basis (e.g., GEIS or rulemakings)
- NRC approvals with a standard design (e.g., ML, DC, SDA, Appendix N)
- NRC pre-approvals for a licensee (e.g., Topical Reports for programs)

With the intended goal of:

1. completing all, or as much as possible, of the safety and environmental reviews and public engagement processes as possible one-time prior to the identification of a specific site, and
2. performing a site-specific license review that only needs to verify that the site characteristics conform to the minimum set of site parameters in the envelope established in the one-time up-front reviews.

For other advanced reactors that would only meet some of these conditions, they could also benefit from the ReLic process but may not be able to achieve the 6-month timelines. For advanced reactors that seek timelines from site identification to operations on the order of 180 days or less, it is likely that they would need the AEA changes as discussed for this option in Section 4.

4 OTHER OPTIONS FOR RESOLUTION OF THE ISSUE

4.1 AEA Change – General License

A general licensing approach would be more efficient and effective in regulating nuclear reactors, such as RHDRA, and would be capable of enabling even shorter deployment timeframes that would be needed to support other business models. Currently, the AEA does not grant the NRC authority to issue general licenses for nuclear reactors, although it does grant authority to the NRC to issue general licenses for other regulated activities. If Congress were to amend the AEA to authorize and direct the NRC to develop a general licensing approach for certain nuclear reactors, and the NRC subsequently pursued a rulemaking to develop such a general license framework for nuclear reactors, this would be a more optimal solution to the issue discussed in this appendix. However, since the NRC could achieve the business requirements with currently granted authorities, and since there is significant uncertainty on whether or when Congress would grant NRC authority for issuing general licenses for reactors, the proposed resolution discussed herein is focused on approaches the NRC can implement without changes to the AEA. This enables the fastest path toward a more effective and efficient regulatory framework for RHDRA and other advanced reactors, and would build the basis of experience that could inform a longer term General License approach if Congress eventually enables it. More discussion on NRC Regulation Through General Licenses is included in Attachment B.

4.2 AEA Change – Minimal Regulation

The technical and safety bases for power reactors with potential consequences on the order of magnitude of non-power reactors should be sufficient to enable the NRC to adapt the non-power reactor requirements and implementation guidance for those qualifying power reactors. Adaption of the non-power reactor regulatory framework, as discussed in this Appendix, should achieve a similar level of regulation that accounts for the safety and operational characteristics of the qualifying power reactors that will tailor requirements and applicability to the technology. An AEA change to direct the NRC to regulate power reactors with potential consequences that are on the same order of magnitude as non-power reactors, e.g., with minimal regulation or under Section 104, is an option that was identified. However, such a change does not appear necessary, since the AEA provides sufficient authority to the NRC to regulate power reactors commensurate with their potential impacts, and is capable within the current AEA provisions to apply regulatory approaches to qualifying power reactors that are similar to those used today for non-power reactors. More discussion on NRC Regulation of Non-Power Reactors is included in Attachment A.

5 ACKNOWLEDGEMENTS

NEI Issue Lead: Martin O’Neill

Appendix 6 – Simplification of Procedures for "Contested" Hearings

1 ISSUE INTRODUCTION

The Atomic Energy Act of 1954, as amended (AEA) and the Administrative Procedure Act (APA) include provisions that govern the NRC's process for engaging the public in licensing actions. The NRC's reactor licensing process includes an opportunity for members of the public to request a hearing prior to NRC issuance of a license or permit. The NRC currently uses a trial-like process for these "contested hearings" that takes many months – if not years – to complete. The contested hearing process was originally developed in the 1950s by the Atomic Energy Commission (AEC), the NRC's predecessor agency, against a unique historical backdrop that prompted the AEC to construe the AEA as requiring formal or "on-the-record" hearings. The NRC, importantly, no longer adheres to that reading of the AEA. Moreover, the hearing process was developed to support the initial licensing of the large light-water reactor (LWR) operating fleet. Although the NRC has sought to "deformalize" the contested hearing process, it remains procedurally complex and LWR-centric. As such, the process has not been adapted to support the licensing of rapid high-volume deployable reactors (RHDRA) and other similar advanced reactor technologies, the business models for which mandate short licensing and deployment schedules.

The desired outcome is a significant reduction in the complexity and duration of the NRC's contested hearing process, such that this process can be completed within several weeks to no more than three months of an applicant's submittal of a deployment site license application to the NRC. This outcome is necessary to enable the business model for a 180-day or less timeline from site identification to the commencement of RHDRA operations.

2 BACKGROUND

2.1 Statutory Requirements Applicable to NRC Hearings – the AEA and APA

Section 189.a(1)(A) of the AEA provides, in relevant part, that in any proceeding for the granting, suspending, revoking, or amending of any license or construction permit, the NRC "shall grant a hearing upon the **request** of any person whose interest **may** be affected by the proceeding, and shall admit any such person as a party to such proceeding."[1] These hearings, when granted, are referred to as "contested" or "adversarial" hearings. Importantly, "neither the AEA nor [the National Environmental Policy Act (NEPA)] guarantees an absolute right to a hearing and neither dictates how the Commission should determine who receives a hearing."[2] As noted, the AEA mandates granting a hearing only when a person "whose interest may be affected by the proceeding" makes an acceptable "request" for a hearing; i.e., participation in the contested hearing process "is not automatic."[3] These two threshold requirements to obtaining a contested hearing, which NRC has implemented in 10 CFR Part 2, its Rules of Practice and Procedure, are known as the "standing" and "contention admissibility" requirements, respectively.[4] Further, as discussed below, while AEA section 189.a requires the NRC to offer an opportunity to request a hearing, it does not specify the hearing procedures to be used by the agency.

[1] 42 USC 2239(a)(1)(A) (emphasis added).
[2] *Natural Resources Defense Council v. NRC*, 823 F.3d 641, 652 (DC Cir. 2016).
[3] *AmerGen Energy Co., LLC* (Oyster Creek Nuclear Generating Station), CLI-08-28, 68 NRC 658, 677 (2008).
[4] *See* 10 CFR 2.309, "Hearing requests, petitions to intervene, requirements for standing, and contentions."

Appendix 6 – Simplification of Procedures for "Contested" Hearings

Section 181 of the AEA states that "[t]he provisions of the Administrative Procedure Act . . . shall apply to all agency action taken under this Act."[5] The APA specifies minimum procedures for hearings when another statute or legal authority mandates a hearing opportunity.[6] Thus, "[t]he APA lays out only the most skeletal framework for conducting agency adjudications, **leaving broad discretion to the affected agencies in formulating detailed procedural rules**."[7]

Under the APA, hearings "required by statute to be determined **on the record** after opportunity for an agency hearing" are governed by sections 554, 556 and 557 of that statute.[8] Those provisions establish a process for formal "on-the-record" hearings, including witness testimony, cross-examination and independent presiding officers.[9] If hearings are not required to be "on the record," then the procedures of sections 556 and 557 are not triggered; the only section of the APA applicable to the proceedings is section 555, titled "Ancillary matters."[10] Section 555(b) entitles a party to be represented by a lawyer; section 555(c) entitles people who have submitted data or evidence to retain copies of their submissions; and section 555(e) requires agencies to give prompt notice when they deny a petition made in connection with a proceeding and to give a brief statement of the grounds for denial.[11]

As the Commission has noted: "By its terms, Section 181 merely states that the APA applies; nowhere does Section 181 explicitly state that adjudications required by the AEA are to be considered 'on-the-record' adjudications for purposes of applying the APA. The APA itself does not specify what adjudications must be 'on-the-record.'"[12] AEA Section 189.a, in turn, contains no reference to "on the record" hearings or to APA section 554.[13] (In contrast, AEA section 193, which applies to uranium enrichment facilities, explicitly refers to "on the record" hearings.) As a result, the Commission has long construed section 189.a as **not** requiring on-the-record hearings for reactor proceedings.[14] As the Commission explained in a 2004 rulemaking revising its Part 2 hearing procedures:

> "The key statutory provision, Section 189.a. of the AEA, declares only that "a hearing" (or an opportunity for a hearing) is required for certain types of agency actions. It does not state that such hearings are to be on-the-record proceedings. Furthermore, the legislative history for the AEA provides no clear guidance whether Congress intended agency hearings to be formal, on-the-record hearings. As a legal matter, where Congress provides for "a hearing," and does not specify that the adjudicatory hearings are to be "on-the-record," or conducted as an adjudication under 5 U.S.C. 554, 556 and 557 of the APA, it is presumed that informal hearings

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[5] 42 USC 2231.

[6] *See Am. Trucking Ass'ns, Inc. v. United States*, 627 F.2d 1313, 1321 (DC Cir. 1980) ("The Administrative Procedure Act … prescribe[s] certain procedures that must be followed by the [agency]; beyond that, procedural regulations are generally within the discretion of the agency."); Koch Jr., C. and R. Murphy (2019), *Administrative Law and Practice, 3d*, Thomson West, sec. 2:33 ("The APA merely requires that a licensing hearing be completed in an expeditious and judicious manner. The nature of the hearing itself is determined by other statutes.").

[7] *Citizens Awareness Network v. United States*, 391 F.3d 338, 349 (1st Cir. 2005) (citing *Am. Trucking Ass'ns, Inc.,* 627 F.2d at 1321 (noting that "operating procedures … are uniquely within the expertise of the agency") (emphasis added).

[8] *See* 5 USC 554(a), "Adjudications;" 5 USC 556, "Hearings; presiding employees; powers and duties; burden of proof; evidence; record as basis of decision;" 5 USC 557, "Initial decisions; conclusiveness; review by agency; submissions by parties; contents of decisions; record."

[9] While the APA itself does not use the term "informal adjudication," that term is used as a residual category that includes all agency actions that are not rulemaking and that need not be conducted through "on the record" hearings described in APA section 554. *See* 5 USC 551(6), (7), "Definitions;" *Izaak Walton League of America v. Marsh*, 655 F.2d 346, 362 n. 37 (DC Cir. 1981).

[10] *Citizens Awareness Network*, 391 F.3d at 356.

[11] *Id.* at 356-57. Additionally, subsections (c) and (d) require that process, subpoenas, and other investigative demands be made in accordance with law. These "informal" hearings must also comply with basic due process requirements. *Id.* at 357.

[12] Changes to Adjudicatory Process, 69 Fed. Reg. 2182, 2205 n.13 (Jan. 14, 2004) (2004 Part 2 Rule).

[13] *See Union of Concerned Scientists v. NRC,* 920 F.2d 50, 53 (DC Cir. 1990) (noting that AEA section 189.a "nowhere describes the content of a hearing or prescribes the manner in which this 'hearing' is to be run").

[14] 2004 Part 2 Rule, 69 Fed. Reg. at 2192 ("[T]he Commission continues to believe that formal, on-the record hearings are not required by the AEA, except for the initial licensing of the construction and operation of a uranium enrichment facility under Section 193 of the AEA.").

> are sufficient. *United States* v. *Allegheny-Ludlum Steel Corp.,* 406 U.S. 742, 757 (1972), citing *Siegel* v. *AEC,* 400 F.2d 778, 785 (D.C. Cir. 1968); *United States* v. *Fla. E. Coast Ry. Co.,* 410 U.S. 224 (1973). Significantly, these Supreme Court decisions occurred more than fifteen years after the period where the Atomic Energy Commission (AEC) first enunciated its position on the hearing requirements in Section 189.a."[15]

When, as in AEA section 189.a(1)(A), a statute requires a hearing opportunity but does not describe the hearing content or procedures,[16] an agency has discretion to structure its procedures as it deems necessary to carry out its responsibilities, including "in the interests of speed and efficiency." [17] Moreover, "the courts are obliged to defer to the operating procedures employed by an agency when the governing statute requires only that a hearing be held."[18]

In *Citizens Awareness Network*, a case that arose from a challenge to the NRC's 2004 Part 2 Rule, the U.S. Court of Appeals for the First Circuit underscored the "broad authority" of the NRC to formulate its procedural rules:

> "[A]gencies have broad authority to formulate their own procedures – and **the NRC's authority in this respect has been termed particularly great**. A necessary corollary of this authority is the freedom to experiment with different procedural formats. Consequently, tinkering with rules is by no means a forbidden activity. … In this case, the NRC has determined that its existing rules of practice lead to hearings that are cumbersome, unnecessarily protracted, and wasteful of the resources of the parties and the Commission. **This determination warrants a high degree of deference**."[19]

Importantly, the court explained that agencies can revise their rules in response to subsequent legal or factual developments: "An agency's rules, once adopted, are not frozen in place. The opposite is true: an agency may alter its rules in light of its accumulated experience in administering them."[20] An agency must, however, "offer a reasoned explanation for the change . . . to demonstrate that the agency fully considered its new course."[21] "It is enough that the agency reasonably determines that existing processes are unsatisfactory and takes steps that are fairly targeted at improving the situation."[22]

2.2 NRC's Adjudicatory Hearing Procedures in 10 CFR Part 2

The NRC has implemented the section 189.a(1)(A) hearing requirement through its in regulations in 10 CFR Part 2. Consistent with the principles discussed above, the NRC has modified those regulations multiple times based on its accumulated experience, largely with the aim of making the contested hearing process "more effective and efficient."[23] As discussed below, however, while the NRC has achieved greater efficiencies in the hearing process, it still remains fairly complex and time and

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[15] 2004 Part 2 Rule, 69 Fed. Reg. at 2183.
[16] *Union of Concerned Scientists*, 920 F.2d at 53.
[17] *See*, *e.g., Union of Concerned Scientists v. NRC*, 735 F.2d 1437, 1448 (DC Cir. 1984) ("[W]e find that [AEA] section 189(a)'s hearing requirement does not unduly limit the Commission's wide discretion to structure its licensing hearings in the interests of speed and efficiency.").
[18] *Kelley v. Selin*, 42 F.3d 1501, 1511 (6th Cir. 1995) (quoting *Union of Concerned Scientists*, 920 F.2d at 54) (internal quotation marks omitted); *see also Vt. Yankee Nuclear Power Corp. v. Natural Resources Defense Council,* 435 US 519, 535-49 (1978).
[19] *Citizens Awareness Network*, 391 F.3d at 352 (citations omitted; emphasis added).
[20] *Id.* at 351 (citation omitted).
[21] *Id.*
[22] *Id*. at 352.
[23] 2004 Part 2 Rule, 69 Fed. Reg. at 2182, 2190.

resource-intensive, especially relative to other agencies' hearing processes. This section summarizes the evolution of the NRC's contested hearing procedures.

2.2.1 NRC's Early Use of Formal (On-the-Record) Hearing Procedures

Until the early 1980s, the NRC used formal adjudicatory procedures of the type described in APA sections 554, 556, and 557. The AEC originally interpreted section 189.a(1)(A) of the AEA as requiring on-the-record hearings in accordance with the APA. These hearings closely resembled federal court trials and proved to be very lengthy, with some lasting many years. In its 2004 Part 2 Rule, the Commission summarized the AEC's rationale as follows:

> The AEC of the 1950s asserted that formal hearings were required by Section 189.a. At that time, the AEC saw benefits in a highly formal process, resembling a judicial trial, for deciding applications to construct and operate nuclear power plants. It was thought that the panoply of features attending a trial – parties, sworn testimony, and cross-examination – would lead to a more satisfactory resolution of the complex issues affecting the public health and safety and would build public confidence in the AEC's decisions and thus in the safety of nuclear power plants licensed by the AEC. One study concluded that the use of formal hearings developed in order to address concerns that the pressures of promotion by the AEC could have an undue influence on the AEC's assessment of safety issues. By use of an expanded hearing process, the Commission could more fully defend the objectivity of its licensing actions. *See* William H. Berman and Lee M. Hydeman, The Atomic Energy Commission and Regulating Nuclear Facilities (1961), reprinted in 2 Improving the AEC Regulatory Process, Joint Comm. on Atomic Energy, 87th Cong., at 488 (1st Sess. 1961). **Thus, notwithstanding the lack of explicit language in the statute or clear direction in the legislative history for the 1954 AEA regarding the use of formal, on-the-record hearings, AEC took the official position that on-the-record hearings were not merely permissible under the AEA but required**.[24]

2.2.2 NRC's Reassessment of the Hearing Process

The agency's interpretation of section 189.a(1)(A) and its views on the benefits of on-the-record hearings evolved over time. In 1982, the NRC relaxed its approach for certain types of licensing proceedings, deciding that formal hearings are not necessary in materials licensing cases.[25] That decision was affirmed by the U.S. Court of Appeals for the Seventh Circuit.[26] Nevertheless, the Commission retained the full range of trial-like procedures for reactor licensing cases. The Seventh Circuit's finding that formal hearings were not required for materials licenses "opened the door considerably wider for the argument that formal hearings are not necessarily required in reactor licensing cases either, as the provision of the Atomic Energy Act that establishes the basic statutory entitlement to a 'hearing' does not distinguish between reactor licenses and materials licenses."[27]

The passage of time brought further changes. Confronted with an impending deluge of license renewal applications, the NRC began to reassess its adjudicatory processes, focusing especially on the procedures used in reactor licensing cases. The Commission's issuance of its *Policy on Conduct of*

[24] *Id.* at 2183 (emphasis added).
[25] 2004 Part 2 Rule, 69 Fed. Reg. at 2182; *Kerr McGee Corp.* (West Chicago Rare Earths Facility), CLI–82–2, 15 NRC 232 (1982).
[26] *City of West Chicago v. NRC*, 701 F.2d 632 (7th Cir. 1983).
[27] 2004 Part 2 Rule, 69 Fed. Reg. at 2185.

Adjudicatory Proceedings in 1998 marked the inception of this process.[28] The 1998 policy statement reiterated the NRC’s commitment to expeditious adjudication and urged Atomic Safety and Licensing Board (ASLB) panels to use innovative case-management techniques to improve hearing efficiency.

In late 1998, the NRC’s Office of the General Counsel (OGC) reexamined the NRC’s adjudicatory practices as conducted under the AEA and NRC regulations, as well as APA requirements and the practices of other agencies and the federal courts. That effort, which sought to identify options for improving the NRC's hearing processes, culminated in the issuance of SECY-99-006, “Re-examination of the NRC Hearing Process” (Jan. 8, 1999). OGC concluded that except for a very limited set of hearings (i.e., those associated with the licensing of uranium enrichment facilities), “the AEA did not mandate the use of a ‘formal, on-the-record’ hearing within the meaning of the APA, 5 U.S.C. 554, 556, and 557, and that the Commission enjoyed substantial latitude in devising suitable hearing processes that would accommodate the rights of participants.”[29] Later that year, the NRC conducted a public workshop on its hearing procedures.[30] These activities paved the way for the NRC’s publication of a 2001 proposed rule in which the agency recommended significant revisions to its hearing procedures to “make the NRC's hearing process more effective and efficient.”[31]

2.2.3 NRC’s 2004 Final Part 2 Rule

On January 14, 2004, the NRC published its final rule. In the accompanying Statement of Considerations, the Commission reiterated its view that reactor licensing hearings need not use formal procedures, as well as its “intent to expand the use of more informal procedures to improve the effectiveness and efficiency of the NRC's hearing processes.”[32] As noted above, the 2004 final rule was affirmed upon judicial review by the U.S. Court of Appeals for the First Circuit in the *Citizens Awareness Network* case.

The 2004 Part 2 Rule established three primary hearing tracks supplemented with additional hearing tracks tailored to the kind of proceedings and issues that may be addressed in such proceedings. The primary hearing tracks are: (1) Subpart G (10 CFR 2.700 to 2.713), containing the full panoply of formal, trial-type procedures;[33] (2) Subpart L (10 CFR 2.1200 to 2.1213), establishing a set of more informal hearing processes; and (3) Subpart K (10 CFR 2.1101 to 2.1119), containing specialized hearing track for contested proceedings on licenses or license amendments to expand spent fuel storage capacity at a civilian nuclear power plant site. All NRC hearing tracks are used in conjunction with Subpart C (10 CFR 2.300 to 2.390), which contains the Rules of General Applicability for considering hearing requests, petitions to intervene and proffered contentions, for determining the appropriate hearing procedures to use for a particular proceeding, and for establishing the general powers and duties of presiding officers for the NRC hearing process.[34]

Under the new rules – which remain in effect today – reactor licensing hearings generally are to be conducted using the “more informal hearing procedures” contained in the substantially revised Subpart

[28] *Statement of Policy on the Conduct of Adjudicatory Proceedings*, CLI-98-12, 48 NRC 18 (1998), published at 63 Fed. Reg. 41,872 (Aug. 5, 1998).
[29] 2004 Part 2 Rule, 69 Fed. at 2183.
[30] *Id.* at 2187-88.
[31] Changes to Adjudicatory Process; Proposed Rule, 66 Fed. Reg. 19,610 (Apr. 16, 2001).
[32] 2004 Part 2 Rule, 69 Fed. at 2191.
[33] The Subpart G procedures, which are used in the types of proceedings specifically identified in 10 CFR 2.310 (“Selection of hearing procedures”) and 10 CFR 2.700 (“Scope of Subpart G”), retain the use of traditional discovery devices (e.g., requests for document production, interrogatories, and depositions) and permit direct and cross-examination of witnesses by the parties at the evidentiary hearing.
[34] *See* 2004 Part 2 Rule, 69 Fed. Reg. at 2191-93.

L of 10 CFR Part 2.[35] In lieu of traditional discovery, Subpart L requires the NRC Staff to compile and update a “hearing file,” and the applicant and intervenor(s) to make initial and periodic “mandatory disclosures” of documents relevant to the admitted contentions. Subpart L hearings can be either an oral hearing or a hearing consisting of written comments (if the parties unanimously agree to the latter). Although the hearings are usually oral, they are preceded by the parties’ submittal of substantial written evidence, including direct and rebuttal testimony, exhibits, and statements of position. With limited exceptions, only the presiding officer cross-examines witnesses, but the parties may submit suggested questions before the hearing. The parties also file extensive post-hearing briefs and proposed findings of fact and conclusions of law to assist the presiding officer in preparing its decision on the merits. Thus, while the current Subpart L procedures are less elaborate than their precursors, they remain complex and, in fact, meet the APA requirements for an “on the record” or “formal” hearing.[36]

In the 2004 Part 2 Rule, the NRC also retained or added several specialized hearing tracks, the following of which warrant mention here.

Subpart M – In 1998, the NRC adopted Subpart M (10 CFR 2.1300 to 2.1331) mandating the use of a streamlined license transfer process with informal hearings, rather than formal adjudicatory hearings.[37] These rules cover any direct or indirect license transfer for which NRC approval is required. Oral hearings are the default format, unless the parties unanimously agree to request a hearing consisting only of written comments. Parties in oral hearings may file initial written statements of position and testimony, written responses and rebuttal testimony, affidavits, and proposed questions with the Commission, which serves as the Presiding Officer (not the ASLB). Subpart M also contains a generic “no significant hazards consideration” determination with respect to license amendments related to license transfers and provided the NRC staff with the authority to approve license transfers even while intervention petitions or hearings were pending before the Commission.[38]

Subpart N – Newly added in 2004, Subpart N (10 CFR 2.1400 to 2.1407) is a “fast track” process for “the expeditious resolution of issues in cases where the contentions are few and not particularly complex, and therefore may be efficiently addressed in a short hearing using simple procedures and oral presentations.” With certain exceptions (e.g., uranium enrichment facility and HLW geologic repository licensing proceedings), Subpart N procedures may be used by direction of the Commission if the proceeding is expected to take no more than two days to complete, or if all parties agree to the use of the “fast-track” procedures. Subpart N hearings include an expedited oral hearing and oral motions, and strict limits on written submissions and responses thereto.

Subpart O – Also added in 2004, Subpart O (10 CFR 2.5300 to 2.1509) contains the NRC’s procedures for conducting simplified, non-adversarial “legislative-style” hearings to assist the Commission in obtaining information and varying policy perspectives on specific subjects identified by the Commission. Subpart O may be used, in the Commission's sole discretion, in design certification rulemakings under 10 CFR Part 52, and in situations where the Commission has determined, under 10 CFR 2.335(d), that a legislative hearing would assist it in resolving a rule waiver petition filed under 10 CFR 2.335(b).

[35] *Id.* at 2185.
[36] *Citizens Awareness Network*, 391 F.3d at 351 (“we find that the new [NRC] rules meet the APA requirements for on-the-record adjudications”).
[37] *See* Final Rule, Streamlined Hearing Process for NRC Approval of License Transfers, 63 Fed. Reg. 66,721, 66,722 (Dec. 3, 1998).
[38] 10 CFR 2.1315(a).

2.2.4 Post-2004 Revisions to Part 2

Since issuing the 2004 rule, the NRC has made some additional modifications to its Part 2 hearing regulations. In 2005, the NRC amended its regulations to (1) adopt model milestones for the conduct of NRC adjudicatory proceedings, (2) require a presiding officer to refer to the model milestones as a starting point for establishing a hearing schedule in an adjudicatory proceeding, and (3) manage the case in accordance with that schedule.[39] The Model Milestones are contained in Appendix B to 10 CFR Part 2 and contain milestone schedules for an enforcement action conducted under Subpart G and licensing hearings conducted under Subparts L, M, and N.

In 2012, the NRC again revised its Part 2 rules to further "promote fairness, efficiency, and openness in NRC adjudicatory proceedings."[40] Among other things, the NRC revised the 10 CFR 2.309 standards for hearing requests, intervention petitions, and motions for leave to file new or amended contentions filed after the section 2.309(b) filing deadline. It also adopted revised mandatory disclosure and discovery provisions that limit the NRC staff's mandatory disclosure obligations to documents related to the admitted contentions and that alter the timeline applicable to all parties' mandatory disclosures.

2.2.5 The 2016 ITAAC Hearing Procedures

In 2016, the NRC issued finalized generic procedures for conducting hearings on whether acceptance criteria in combined licenses (COL) issued under 10 CFR Part 52 are met.[41] These acceptance criteria are part of the inspections, tests, analyses, and acceptance criteria (ITAAC) included in the COL for a nuclear reactor. Reactor operation may commence only after the NRC finds that these acceptance criteria are met, and AEA section 189a.(1)(B) provides a hearing opportunity on whether the acceptance criteria in the ITAAC are satisfied. These procedures, which are intended to provide an expedited and streamlined hearing process, are based on the Subpart L process and thus involve written testimony and position statements with subsequent questioning by the presiding officer at an oral hearing.

3 PROPOSED SOLUTION AND APPROACH

The proposed approach is to significantly streamline the contested hearing process for RHDRA and other advanced reactors. The goals of the streamlined contested hearing process are to:

1. Use an informal adjudicatory hearing process that is substantially simpler and faster than the current Subpart L process and based exclusively on written submissions.

2. Establish condition-based timelines for the contested hearing process so that the process can be completed in approximately three months from the date the NRC publishes its notice of acceptance of the application for docketing and notice of opportunity to request a hearing in the *Federal Register*. As a starting point for such an expedited hearing process, the NRC could evaluate the approaches used in Subparts K, M, and N of 10 CFR Part 2, the 2016 Final ITAAC Hearing Procedures, as well as those recommended by OGC in SECY-24-0032 for streamlining

[39] *See* Model Milestones For NRC Adjudicatory Proceedings; Final Rule, 70 Fed. Reg. 20,457 (Apr. 20, 2005).
[40] Amendments to Adjudicatory Process Rules and Related Requirements; Final Rule, 77 Fed. Reg. 46,562 (Aug. 3, 2012).
[41] Final Procedures for Conducting Hearings on Conformance With the Acceptance Criteria in Combined Licenses; Final Rule, 81 Fed. Reg. 43266 (July 1, 2016) (2016 Final ITAAC Hearing Procedures).

Appendix 6 – Simplification of Procedures for "Contested" Hearings

the mandatory hearing process, and modify them as necessary to achieve the 3-month schedule. Such modifications might include, but are not limited to:

a. Issuing a notice of acceptance of the application for docketing and notice of opportunity to file comments or request a hearing within thirty days of NRC's receiving the RHDRA simplified specific license (SSL) application, which, based on the rapid efficient licensing (ReLic) process for RHDRA discussed in the Proposal Paper and other Appendices, would reference prior NRC approvals and thus be much shorter in length.[42] Consistent with current NRC requirements, the notice would, among other things, clearly describe the proposed action and the nature, scope, and timing of the associated opportunity to file comments or request a hearing on the application.[43]

b. Given the substantially narrower scope and smaller size of the SSL application, establishing a much shorter period for filing any hearing requests (e.g., 30 days in lieu of the 60 days provided under current NRC regulations), applicant/staff responses to those hearing requests, and petitioner replies.

c. Establishing strict criteria for admitting contentions for SSL applications, perhaps analogous to those for contentions in the 10 CFR 52.103 hearing process related to ITAAC closure (see Appendix 4). For example, contentions could be limited to whether the applicant has provided sufficient information for the NRC to verify that the site characteristics conform to the minimum set of site parameters in the envelope(s) established through prior NRC approvals (e.g., Manufacturing Licenses, Design Certifications, Standard Design Approvals, Generic Environmental Impact Statements and supplements thereto, and Topical Reports), and that there are no new or unreviewed safety or environmental considerations that could materially impact the NRC's safety and environmental findings under the AEA and NEPA, respectively.

d. Using an expedited notice-and-comment-type hearing process. As noted, upon accepting the application for docketing, the NRC would issue a *Federal Register* notice to inform the public of its docketing decision and the opportunity to provide comments on the application or request a hearing on the papers, and specify the due date for any comments or hearing requests/petitions to intervene (e.g., within 30 days). The notice would inform the public of the written-only hearing format and explain how members of the public may access the application and any related materials, as well as written materials that are developed during the proceeding (e.g., via a specific ADAMS docket number or the NRC's Electronic Hearing Docket (EHD)). As a general matter, absent leave of the presiding officer for good cause shown, there would be no mandatory disclosures or other discovery; i.e., the hearing participants would rely on the NRC's designated document database (e.g., ADAMS, EHD) for the proceeding.

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[42] Appendix 5 (Site License Scope and Purpose) describes a proposed simplified specific license (SSL) approach that is based upon is based upon the use of the following types of NRC approvals that can achieve finality prior to the identification of a specific site: NRC generic approvals on a technology-inclusive basis (e.g., Generic Environmental Impact Statement (GEIS), Categorical Exclusions, rulemakings); NRC approvals with a standard design (e.g., Manufacturing Licenses, Design Certifications, Standard Design Approvals, Appendix N (which allows concurrent NRC reviews of applications using a common design)); and NRC pre-approvals for a licensee (e.g., Topical Reports for programs).

[43] Members of the public could be given the option of filing comments on the SSL application in lieu of requesting a hearing and seeking to intervene in the proceeding. The NRC could include responses to any public comments in its safety and/or environmental review documents for the application, as applicable.

Appendix 6 – Simplification of Procedures for "Contested" Hearings

The parties would submit written materials using established filing methods (e.g., NRC's E-Filing system). Any hearing request/petition to intervene would need to address the petitioner's standing to seek a hearing, identify its specific legal and/or factual contentions (consistent with the limited proceeding scope described in paragraph 2.c above), and include all supporting materials (including any affidavits or declarations). The applicant and NRC staff would be given an opportunity to file written responses (e.g., within 20 days of the hearing request). In addition to responding to a petitioner's arguments on standing and contention admissibility, the applicant would address the merits of the petitioner's claims, including identifying or supplying any information that it believes would resolve the petitioner's specific concerns. Any NRC staff response similarly would respond to the petitioner's procedural and substantive arguments, and also could include the results of the staff's confirmatory safety and environmental reviews.[44] It also could address the staff's decision to authorize any safety-related delivery, assembly, and emplacement activities (see Appendix 3) described in the application that are bounded by the site parameter envelope and plant parameter envelope associated with prior design approvals (e.g., ML, DC, SDA) and environmental reviews. The petitioner could file a reply within 7-10 days of the applicant's and staff's responses and explain whether its concerns have been addressed and notify the presiding officer accordingly.

If the petitioner's concerns are not fully resolved by the applicant's and staff's filings, the presiding officer, which likely would be the Commission, an ASLB, or an individual administrative judge, would evaluate and disposition the hearing requests/petitions to intervene and contentions based on the parties' written filings. The presiding officer's decision would address whether the hearing requests/petitions to intervene and contentions satisfied applicable procedural requirements and, if so, would address the merits of any admitted contentions based on the petitioner's initial and reply filings and the applicant's/NRC staff's responses. Thus, absent a request from or leave of the presiding officer for good cause shown, there would be no supplemental written filings, oral argument, or oral evidentiary hearing.

e. Establishing a specific milestone schedule for RHDRA SSL proceedings (as shown in Figure 4-2 of the Proposal Paper) that includes a strict overall completion deadline of three months (90 days) from the date the NRC publishes in the *Federal Register* its notice of acceptance of the application for docketing and notice of opportunity to file comments or request a hearing. As noted, this schedule would require condensed timeframes for the filing of hearing requests and responses/replies and the presiding officer's decision (which, as noted above, would concurrently address petitioner's compliance with applicable procedural requirements and the merits of its claims). Finally, consistent with current NRC regulations, any presiding officer decision authorizing approval of the licensing action would be immediately effective, such that any opportunity for reconsideration and/or appeal of the presiding officer's decision would not automatically stay the effectiveness of that decision. Any such review of the

[44] As shown in the proposed schedule illustrated in Figure 4-2: NRC Licensing Timeline (Expectations for ReLic Process) of the Proposal Paper, the NRC staff would issue its draft safety evaluation report (SER) and environmental review document (e.g., environmental assessment (EA) if a categorical exclusion is not applied) within 45 days of the NRC staff's acceptance of the SSL application for docketing, and the final versions of those documents with 60 days of docketing of the application.

presiding officer's decision also would need to be completed expeditiously, ideally in parallel with the 30-day NRC Final Approval phase described in the Proposal Paper.

The industry recognizes that the hearing approach described above for RHDRA differs from the NRC's current Part 2 hearing format and milestone schedule for reactor licensing proceedings, which, as discussed above, were developed for the licensing of large LWRs that have very different safety profiles, physical footprints, and construction/operation timelines than RHDRA. License applications for large LWRs are substantially more complex and voluminous (thousands of pages) than RHDRA SSL applications. The latter are expected to be less than 100 pages and focused on providing the information needed by the NRC to verify that the deployment site conforms to the conditions of the design approval (i.e., the site parameter envelope), the generic environmental approvals (e.g., a Categorical Exclusion or a Generic Environmental Impact Statement), and prior NRC approvals (e.g., in a prior license approval or in Topical Reports) for the licensee qualifications and programs (e.g., Financial Qualification, Quality Assurance Program). Thus, unlike the NRC's review of a conventional large LWR license application, which involves *de novo* technical evaluation of numerous safety and environmental issues, the NRC's review of a RHDRA SSL application will be fundamentally confirmatory in nature.

The written-only format and expedited hearing schedule described above make practical sense in the RHDRA context and are permissible under the relevant statutes – i.e., AEA, APA, and NEPA. Consistent with the legal principles and precedent discussed in Section 2, the Commission has noted that the AEA gives it "exceptionally wide latitude in designing its own proceedings" and "broad power to organize its licensing process efficiently," especially in "[t]he absence of statutory procedural requirements."[45] In addition, it is well-established that the Commission has the authority to define the scope of any hearing on the license application.[46] Notably, in SECY-24-0032, OGC cited the NRC's "considerable discretion" in establishing hearing procedures under AEA section 189.a and noted that:

> "For hearings not required by statute to be conducted "on the record," such as those under AEA § 189a., there is no APA requirement for an oral evidentiary hearing. For hearings required to be "on the record," the APA includes an exception to the general requirement of an oral evidentiary hearing that allows agencies to "adopt procedures" for hearings on "applications for initial licenses" that provide "for the submission of all or part of the evidence in written form," so long as "a party will not be prejudiced thereby." 5 U.S.C. § 556(d)."[47]

The written-only format also is consistent with the practices of other federal agencies, which do not routinely offer oral evidentiary hearings on contested issues. For example, the Federal Energy Regulatory Commission (FERC) routinely holds paper hearings on contested matters. Both FERC and the

[45] *Duke Cogema Stone & Webster* (Savannah River Mixed Oxide Fuel Fabrication), CLI-02-07, 55 NRC 205, 215 (2002); see also *Siegel v. AEC*, 400 F.2d 778, 783 (D.C. Cir. 1968) (explaining that "flexibility was a peculiar desideratum" of the AEA's proponents, and that "Congress agreed by enacting a regulatory scheme which is virtually unique in the degree to which broad responsibility is reposed in the administrating agency, free of close prescription in its charter as to how it shall proceed in achieving the statutory objectives'"); *Ohio ex rel. Celebrezze v. NRC*, 868 F.2d 810, 813 (6th Cir. 1989) (reiterating the court's statements in *Siegel* regarding the Commission's uniquely broad statutory authority).

[46] *See*, *e.g.*, *Massachusetts v. NRC*, 924 F.2d 311, 331 (D.C. Cir. 1991) (quoting *Union of Concerned Scientists*, 735 at 1446) (noting "the NRC's 'great discretion to decide what matters are relevant to its licensing decision"); *Deukmejian v. NRC*, 751 F.2d 1287 (D.C. Cir. 1984) (noting that "the Commission has broad authority to decide what matters are relevant to its licensing decision"); *Duke Power Co.* (Catawba Nuclear Station, Units 1 and 2) ALAB-825, 22 NRC 785 (1985) ("The various hearing notices are the means by which the Commission identifies the subject matters of the hearings . . . .").

[47] SECY-24-0032 at 5 n.15.

federal courts have concluded that such hearings are sufficient where the paper record provides a sufficient basis for resolving the relevant issues.[48]

The Commission also has discretion to determine who serves as the presiding officer in a contested hearing. The relevant provision of the APA does not mandate the use of administrative law judges (ALJs) in informal adjudications. Specifically, section 3105 of the APA states that "[e]ach agency shall appoint as many administrative law judges as are necessary for proceedings required to be conducted in accordance with **sections 556 and 557** of this title." As discussed in Section 2.1, APA sections 556 and 557 apply only to formal or on-the-record adjudications.

Section 191 of the AEA authorizes the Commission to use ASLBs as an alternative to ALJs in agency hearings. On its face, however, section 191 does not require the Commission to use an ASLB in all contested hearings. It provides that "the Commission is authorized to establish one or more [ASLBs] ... to conduct such hearings as the Commission may direct and make such intermediate or final decisions as the Commission may authorize with respect to the granting, suspending, revoking or amending of any license or authorization under the provisions of this Act ...."). Notably, 10 CFR 2.4 defines "presiding officer" as "the Commission, an administrative law judge, an administrative judge, an [ASLB], or other person designated in accordance with the provisions of this part, presiding over the conduct of a hearing conducted under the provisions of this part. Further, section 2.313(a) provides that "[t]he Commission may provide in the notice of hearing that one or more members of the Commission, an administrative law judge, an administrative judge, an [ASLB], or a named officer who has been delegated final authority in the matter, shall be the presiding officer."[49]

Finally, it bears emphasis that when viewed holistically, the proposed rapid efficient licensing process for RHDRA allows for ample public participation. For example, any necessary rulemakings (e.g., for a Design Certification or the GEIS) would allow for public comments and judicial review of the final rule. In addition, any license applications associated with a RHDRA manufacturing facility that are necessary to carry out NRC-regulated activities at the facility (e.g., under a Part 52 Manufacturing License, Part 52 COL, Part 50 OL, or Part 70 license) would include a contested hearing opportunity and other vehicles for public participation. Thus, any generic and facility-specific prior approvals on which a RHDRA SSL applicant might rely upon and reference in its application would have included appropriate opportunities for public participation.

3.1 Changes Needed to Regulations, Policy and Guidance

The proposed solution will require a rulemaking to make changes to the NRC's Part 2 regulations within the NRC's substantial discretion under the AEA and APA to develop a much-simplified contested hearing process by either modifying existing processes for use in this context (e.g., Part 2, Appendix N), or developing a new process to govern these proceedings – either within Part 2 or as a stand-alone set of procedures (e.g., like the NRC did for ITAAC hearings). This is necessary to establish a stable and efficient

[48] *See, e.g. Moreau v. FERC*, 982 F.2d 556, 568 (DC Cir. 1993); *Transcontinental Gas Pipeline Co*., 158 FERC 61125 at 8 (3 Feb. 2017) ("Although our regulations provide for a hearing, neither section 7 of the [Natural Gas Act] nor our regulations require that such hearing be a trial-type evidentiary hearing. When, as is usually the case, the written record provides a sufficient basis for resolving the relevant issues, it is our practice to provide for a paper hearing.") (citing *Minisink Residents for Environmental Preservation and Safety v. FERC*, 762 F.3d 97, 114 (DC Cir. 2014) (stating "FERC's choice whether to hold an evidentiary hearing is generally discretionary.")).

[49] Thus, the AEA and NRC regulations provide the Commission with the flexibility to delegate the presiding officer role in informal adjudications to a senior agency official (e.g., an official who is in the Office of the Executive Director for Operations (OEDO) or who reports to the EDO), subject to the *ex parte* communications and separation of functions provisions in 10 CFR 2.347 and 2.348, respectively.

process that can be consistently applied across licensing actions, and which is informed by stakeholder and public input via the rulemaking process. In doing so, the NRC can balance the need for efficient and timely decisions on any contested matters with the need to allow public participation and develop an adequate record to support the agency's decisions. The NRC also may consider any potential impacts of the simplified contested hearing process on the nature and timing of judicial review of its decisions.

3.2 Acceptance Criteria and Licensing Approach

3.2.1 Acceptance Criteria

As noted above, the contested hearing process for RHDRA deployment site license applications that substantially rely on prior NRC approvals must be completed in three months or less. It is conceivable that this simplified and expedited contested hearing process could be used, or adapted for use, in other advanced reactor licensing proceedings.

3.2.2 Licensing Approach

The rapid efficient licensing process for RHDRA should be used to minimize the scope, content and purpose of the site-specific reviews. This type of site-specific review would enable completion of all, or as much as possible, of the safety and environmental reviews and public engagement processes one-time prior to the identification of a specific site. Where the entire site-specific review is not possible before site identification, performing a site license review that only needs to verify that the site characteristics conform to the minimum set of site parameters in the envelope established in the one-time up-front reviews is recommended.

This would include use of a standardized design approved by the NRC. Such processes include Standard Design Approval, Design Certification, Manufacturing License, COL and subsequent COLs, and Part 50 Appendix N (common design reviews for multiple sites). These NRC approvals differ in terms of scope of the design approved by the NRC and the finality afforded by the NRC's approval.

4 OTHER OPTIONS FOR RESOLUTION OF THE ISSUE

4.1 Amendment to the AEA

Direction from Congress via an amendment to the AEA would require the NRC to change its current process to expedite the conduct of contested hearings RHDRA and other similar advanced reactor applications. Notably, the proposed "Efficient Nuclear Licensing Hearings Act" (H.R. 6464) would amend AEA section 189.a(1) to require the Commission to use "informal adjudicatory procedures" for any hearing held under that section. If enacted, this legislation could provide helpful direction to the NRC regarding the development of a simplified contested hearing process for RHDRA, as well as other commercial reactors. This proposed change also could disposition any remaining questions about whether the AEA requires "on the record" hearings subject to the more stringent procedural requirements of sections 554 and 556-557 of the APA for reactor licensing proceedings.

4.2 General License

A general licensing approach would be more efficient and effective in regulating nuclear reactors, such as RHDRA, and would be capable of enabling even shorter deployment timeframes that would be needed to support other business models. Currently, the AEA does not grant the NRC authority to issue general licenses for nuclear reactors, although it does grant authority to the NRC to issue general licenses for other regulated activities. If Congress were to amend the AEA to authorize and direct the NRC to develop a general licensing approach for certain nuclear reactors, and the NRC subsequently pursued a rulemaking to develop such a general license framework for nuclear reactors, this would be a more optimal solution to the issue discussed in this appendix. However, since the NRC could achieve the business requirements with currently granted authorities, and since there is significant uncertainty on whether or when Congress would grant NRC authority for issuing general licenses for reactors, the proposed resolution discussed herein is focused on approaches the NRC can implement without changes to the AEA. This enables the fastest path toward a more effective and efficient regulatory framework for RHDRA and other advanced reactors, and would build the basis of experience that could inform a longer term General License approach if Congress eventually enables it. More discussion on NRC Regulation Through General Licenses is included in Attachment B.

4.3 Case-Specific Hearing Orders

The NRC staff has noted in recent policy papers and regulatory guidance that there are case-specific procedural options that the NRC has used successfully in the past to license new technologies.[50] One option is for the applicant to request that the staff develop an order (for example, as part of the notice of docketing and opportunity to request a hearing). Given its general supervisory authority over NRC licensing adjudications, the Commission can use case-specific hearing orders to define the applicable license review standards and any special standards or instructions. The Commission has issued a number of hearing orders over the years in different types of licensing proceedings, including early initial license renewal proceedings (e.g., Calvert Cliffs, Turkey Point),[51] the mixed oxide fuel (MOX) fabrication facility licensing proceeding,[52] and five uranium enrichment facility licensing proceedings.[53]

In the uranium enrichment facility proceedings, the Commission provided explicit procedural and substantive guidance aimed at expediting the conduct of those proceedings. For example, the Commission delineated the specific matters of fact and law to be decided in the proceedings; reserved certain rulings for the Commission (e.g., rulings on standing and the admissibility of environmental justice contentions); identified applicable legal precedent from prior proceedings; endorsed NRC staff

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[50] *See* SECY-24-0008, "Micro-Reactor Licensing and Deployment Considerations: Fuel Loading and Operational Testing at a Factory" at 15, 20, 24 (Jan. 24, 2024) (ML23207A250); SECY-20-0093, "Policy and Licensing Considerations Related to Micro-Reactors" at 5 (Oct. 6, 2020) (ML20129J985) & Enclosure 2, "Possible Near-Term Licensing Approaches for Micro-Reactors" (ML20254A366); DANU-ISG-2022-01, "Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications – Roadmap," Appendices A & B (Mar. 31, 2024) (ML23277A139).

[51] *See Balt. Gas & Elec. Co.* (Calvert Cliffs Nuclear Power Plant, Units 1 and 2), CLI-98-14, 48 NRC 39, 41*, motion to vacate denied,* CLI-98-15, 48 NRC 45 (1998), *aff'd sub nom. Nat'l Whistleblower Ctr. v. NRC*, 208 F.3d 256 (D.C. Cir. 2000), *cert. denied*, 531 U.S. 1070 (2001) (providing guidance to the ASLB on the scope of the proceeding as well as discovery management and a proposed schedule); *Fla. Power & Light Co.* (Turkey Point Nuclear Generating Plant, Units 3 and 4), CLI-00-23, 52 NRC 327, 329 (2000) (same).

[52] *Duke Cogema Stone & Webster* (Savannah River Mixed Oxide Fuel Fabrication Facility), CLI-01-13, 53 NRC 478, 484-86 (2001) (providing guidance on the scope of the proceeding and a proposed schedule).

[53] See Notice of Receipt of Application for License Notice of Availability of Applicant's Environmental Report; Notice of Consideration of Issuance of License; and Notice of Hearing and Commission Order for the following proceedings: *Louisiana Energy Services, LP*. (Claiborne Enrichment Center), 56 Fed. Reg. 23,310 (May 21, 1991); *Louisiana Energy Services, L.P.* (National Enrichment Facility), 69 Fed. 5873 (Feb. 6, 2004); *USEC, Inc.* (American Centrifuge Plant); 69 Fed. 61,411 (Oct. 18, 2004); *Areva Enrichment Services, LLC* (Eagle Rock Enrichment Facility), 74 Fed. Reg. 38052 (July 30, 2009); and *GE-Hitachi Global Laser Enrichment LLC* (GLE Commercial Facility), 75 Fed. Reg. 1819 (Jan. 13, 2010).

use of environmental impact statements prepared by the Department of Energy; directed the presiding officer to certify novel legal and policy issues to the Commission for resolution; provided substantive legal guidance on key topics (e.g., depleted uranium disposition, financial qualifications, foreign ownership); and directed the ASLB and parties to develop a hearing schedule based on very specific procedural milestones incorporated by the Commission into the hearing orders.

5 ACKNOWLEDGEMENTS

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Appendix 7 – Elimination of Mandatory (Uncontested) Hearings

1 ISSUE INTRODUCTION

The Atomic Energy Act of 1954, as amended (AEA), requires the NRC to hold mandatory uncontested hearings for the issuance of construction permits (CP), combined licenses (COL), early site permits (ESP), and limited work authorizations (LWA). These hearings take place after issuance of the NRC staff's final safety and environmental documents and, historically, have taken 4-7 months to complete. This timeline is not compatible with the rapid high-volume deployable reactor in remote locations (RHDRA) business model, which requires reactor deployment in less than 180 days (6 months) from the time that the site is identified to the time that reactor operation begins.

The desired outcome is the elimination of the mandatory hearing for all Part 50, Part 52 and future Part 53 applications. These hearings have outlived their intended and useful purpose. The NRC also has expressed support for amending the AEA to eliminate the mandatory hearing requirement, and there are bills circulating in Congress that, if enacted, would eliminate the requirement.

2 BACKGROUND

Sections 189a.(1)(A) and 185b. of the AEA, and related NRC regulations[1] require NRC to hold a mandatory uncontested hearing for issuance of CPs, COLs, ESPs, and LWAs. The Commission has long interpreted the purposes of these hearings to be "sufficiency reviews" intended to assess the adequacy of, but not replicate, the NRC staff's review of an application. Only the applicant and NRC staff are parties to the mandatory hearing. The Commission has also permitted interested states, local government bodies, and federally recognized Indian Tribes the opportunity to submit written statements as part of the mandatory hearing process.[2]

Even as amended in 1954, the AEA contained no mandatory hearing requirement.[3] Rather, the 1954 Act required that the Atomic Energy Commission (AEC)[4] provide an **opportunity** for a hearing on an application for a CP or facility license.[5] If a person requested a hearing and demonstrated an interest that might be affected by the proceeding, then that person was admitted as a party to the licensing proceeding.

Several years later, the Staff of the Joint Committee on Atomic Energy (JCAE) studied AEC reactor licensing procedures and organization considering various developments since the AEA's enactment. Notably, the AEC had issued three CPs for power reactors without any public hearing or notice of intent prior to issuance.[6] The AEC issued the permits on the basis of reactor safety evaluations that were not publicly disclosed and, in one case, over the objections of the AEC's Advisory Committee on Reactor Safeguards (ACRS).[7] These AEC practices raised issues of "public and congressional confidence in the agency, the need for separation of prosecutorial and quasi-judicial functions, and the need for a quasi-

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[1] *See, e.g.*, 10 CFR 2.104, 50.35, 50.58, 51.105, 51.107, 52.24, 52.97, 70.23a.
[2] *See* NRC, "Internal Commission Procedures," Chapt. VI at 13 (Aug. 16, 2016), available at https://www.nrc.gov/about-nrc/policy-making/internal.html.
[3] *Exelon Generation Company, LLC* (ESP Permit for Clinton ESP Site), CLI-05-17 62 NRC 134, (2005).
[4] The AEC was the predecessor to the NRC.
[5] *See* 42 U.S.C. § 2239a.
[6] *See* Staff of J. Comm. on Atomic Energy, 85th Cong., A Study of AEC Procedures and Organization in the Licensing of Reactor Facilities, at 8 (J. Comm. Print 1957) ("1957 JCAE Study"). *See also* Clinton, CLI-05-17, 62 NRC at 134.
[7] *Id*.

judicial body independent of the portion of the AEC that itself operated or promoted reactors."[8] To enhance opportunities for public involvement,[9] Congress amended AEA Section 189a. in 1957 to require a hearing for every CP or facility license.[10]

Historically, the mandatory hearing process has added approximately 4-7 months on back end of the licensing proceeding.[11] **Notably, because the mandatory hearing occurs after the staff issues its final safety and environmental documents, it drives the critical path for issuance of the license.** For mandatory hearings conducted by the Commission, the current objective is to issue adjudicatory decisions no later than 4 months after the final safety evaluation report (FSER) and final environmental impact statement (FEIS) or environmental assessment) (EA) are both publicly issued.[12] Thus, left "as is," the time required to conduct the mandatory hearing alone would consume all, or a substantial portion of, the 180-day deployment goal.

Recently, NRC's Office of the General Counsel (OGC) recommended that the Commission reform the mandatory hearing process.[13] OGC discussed several options to substantially revise and simplify the mandatory hearing process. OGC recommended that the Commission adopt the following approaches (referred to as Options 1 and 5 in SECY-24-0032):

> First-of-a-Kind Technology or First Facility at a Particular Site (Option1): The Commission would retain its role as presiding officer and continue to conduct mandatory hearings under a simplified process that would be limited to presentation of written evidence, without an oral hearing. The total timeframe for this process – from issuance of the FSER and FEIS or EA to issuance of a final decision – is estimated to be roughly **two months.**
>
> Nth-of-a-Kind Technology or Facilities at a Particular Site (Option 5): The Commission would delegate authority to conduct mandatory hearings to the Executive Director for Operations (EDO) or another senior agency official. This process would be modeled after the Management Review Board (MRB) process that the NRC staff uses to assess Agreement State programs under the Integrated Materials Performance Evaluation Program (IMPEP), and the hearing itself would be conducted via a public meeting. The total timeframe for MRB-like process – from issuance of the FSER and FEIS or EA to issuance of a final decision –is estimated to be roughly **2 to 2.5 months.**

On July 18, 2024, the Commission issued its Staff Requirements Memorandum (SRM) for SECY-24-0032. The Commission approved the use of the simplified hearing procedures outlined by OGC as Option 1 (i.e., written materials without an oral hearing), with the Commission serving as the presiding officer for

[8] *Id*.

[9] The legislative history of the 1957 AEA amendments reflected JCAE comments that full, free, and frank public discussion of the hazards involved in any particular reactor was the most certain way of assuring that reactors will be safe and that the public will be apprised of their safety. Although the AEC Chairman expressed an aversion to a requirement that the Commission conduct a hearing prior to issuance of every license, Congress imposed that requirement in the 1957 AEA amendments. Rep. No. 85-296 (1957), *reprinted in* 1957 U.S.C.C.A.N. 1803.

[10] The 1957 amendments to AEA Section 189a added the following sentence: "The Commission shall hold a hearing after thirty days' notice and publication once in the Federal Register, on each application under section 103 or 104b. for a license for a facility, and on any application under 104c. for a license for a testing facility." Pub. L. No. 85-256, § 7, 71 Stat. 576, 579 (1957).

[11] *See* Idaho National Laboratory, "Recommendations to Improve the Nuclear Regulatory Commission Reactor Licensing and Approval Process," INL/RPT-23-72206, Rev. 0 (April 2023).

[12] "Internal Commission Procedures," Chapt. VI at 15. In a COL proceeding, if an associated design certification rulemaking is still pending as of that date, the Commission will issue a decision immediately after affirming the final rule for the referenced design. *Id.*

[13] "Revisiting the Mandatory Hearing Process at the U.S. Nuclear Regulatory Commission," SECY-24-0032 (April 12, 2024).

all proceedings falling under the provisions of AEA section 189a., regardless of whether the application is considered first-of-a-kind.[14] Thus, the Commission did not adopt Option 5 for nth-of-a-kind applications. The SRM further states that the Commission's decision in mandatory hearings will take the form of a streamlined Commission Legal Issuance (i.e., a memorandum and order in the style of an adjudicatory decision) focused on novel issues and site-specific considerations. SRM-SECY-24-0032 contains the following additional directives:

- The staff should continue to submit an information paper as currently contemplated by the NRC's Internal Commission Procedures.
- The Office of Commission Appellate Adjudication (OCAA) should maintain its role in support of the Commission's mandatory hearing review, including the provision of adjudicatory technical support, if needed.
- After completing two mandatory hearings under the revised procedures, OGC, in consultation with the Office of the Secretary and OCAA, should propose limited scope changes to the section on mandatory hearings in Chapter IV of the Internal Procedures to implement this approach. OGC also should conduct a lessons-learned review after the completion of two mandatory hearings held under the new process to determine further efficiencies.
- OGC should consider potential rulemaking changes consistent with the SRM as part of its regular internal evaluation of 10 CFR Part 2. Any recommendations associated with provisions that impact the procedures for mandatory hearings should be provided to the Commission for consideration as part of a rulemaking plan

The revised mandatory hearing process adopted by the Commission will substantially shorten the duration of mandatory hearings. **However, as noted, this process is still expected to require approximately two months – one-third of the 180-day deployment goal.**

3 PROPOSED SOLUTION AND APPROACH

The proposed approach is to eliminate the mandatory hearing through an amendment to the AEA.

The mandatory hearing no longer serves its original purpose. While the relevant portions of AEA Section 189a have not changed since 1962, the NRC's organizational structure and reactor licensing process have changed dramatically. The concern of the JCAE 50 years ago regarding the "independence" of the NRC's licensing review has been addressed, through separation of the AEC's regulatory function from its promotional function. In 1975, Congress created the NRC as an independent agency whose sole function is "regulatory." Additionally, the creation of the NRC eliminated the structural conflict of interest that prompted the 1962 establishment of the Atomic Safety and Licensing Board as a separate, quasi-judicial

[14] The Commission's direction in SRM-SECY-24-0032 is immediately effective and supersedes and replaces existing delegations and Commission policy for mandatory hearings associated with (1) Staff Requirements – SECY-15-0088 – Selection of Presiding Officer for Mandatory Hearings Associated with Early Site Permit Applications and Construction Permit Applications for Medical Isotope Production and Utilization Facilities (ML15238B093); and (2) Staff Requirements – SECY-21-0107 – Selection of Presiding Officer for Mandatory Hearings Associated with Construction Permit Applications (ML22083A045).

body. The emergence of the NRC as an independent regulatory entity also made largely redundant the Licensing Board's original role as an independent reviewer and decision maker on uncontested issues.

Also, in marked contrast to the regulatory and political environment that led to the 1957 amendments to the AEA, the entire NRC licensing process is now transparent to the public. Applicants seeking approval to construct and operate new reactors must file their application and supporting documents on a public docket. Members of the public can raise issues of concern regarding NRC license applications and intervene in NRC licensing proceedings. Interactions and meetings with the NRC are also open to the public. Most portions of license applications, as well as NRC licensing documents documenting the agency's review of those applications (e.g., FSER and FEIS) are available to the public as well.

Moreover, the passage of NEPA in 1969 gave members of the public a platform to raise issues surrounding the environmental impacts of reactors and requires the Commission to respond in writing to those public comments. Applicants' environmental analyses and the NRC's corresponding environmental review documents are publicly available.

The NRC previously has supported elimination of the mandatory hearing, and the policy justification for doing so is well developed.[15] For example, in 2008 the Commission provided a draft bill and legislative memorandum to Congress that proposed to eliminate the mandatory hearing.[16] More recently, in his July 2023 testimony before the House Energy and Commerce Committee, the NRC's Executive Director for Operations acknowledged the 2008 NRC proposal and stated that eliminating the hearing would not affect the public's ability to participate in the licensing process or the NRC's safety conclusions.

3.1 Changes Needed to Regulations, Policy and Guidance

Sections 189.a(1)(A) and 185.b of the AEA should be revised to eliminate the mandatory hearing requirement.

A bill entitled the "Efficient Nuclear Licensing Hearings Act" has been circulated in both the House and Senate. This bill would, in part, amend AEA sections 189a and 185b to eliminate the mandatory hearing requirement. The amendments proposed in this bill would not be limited to micro-reactors but would eliminate the mandatory hearing for all commercial reactors licensed under sections 103 or 104b of the AEA, as well as proceedings for the licensing of uranium enrichment facilities.

Assuming the existing process for the conduct of mandatory hearings remains in place, amending the AEA to eliminate these hearings would save **4-7 months** at the back end of the current licensing process (i.e., time between issuance of the FSER and FEIS or EA, and an agency decision to issue the license). If the recommendations provided in SECY-24-0032 are adopted by the Commission, elimination of the mandatory hearing process would save from **2 to 2.5 months** at the back end of the hearing process.

[15] *See, e.g.*, M. Bowen, R.T. Ponangi, S.G. Burns, "Improving the Efficiency of NRC Power Reactor Licensing: The 1957 Mandatory Hearing Reconsidered," Nov. 2023 (https://www.energypolicy.columbia.edu/wp-content/uploads/2023/11/NRCLicensing-CGEP_Report_112123.pdf).

[16] Letter to Speaker Nancy Pelosi from NRC chairman Dale Klein, June 9, 2008, https://www.nrc.gov/reading-rm/doc-collections/congress-docs/correspondence/2008/pelosi-06-09-2008.pdf.

If the AEA amendments discussed above were implemented, conforming changes to several sections of the NRC's implementing regulations would be necessary. For example, conforming changes to the following regulations would be required:

- 10 CFR 2.104, "Notice of hearing"
- 10 CFR 50.35, "Issuance of construction permits*"
- 10 CFR 50.58, "Hearings and report of the Advisory Committee on Reactor Safeguards"
- 10 CFR 51.105, "Public hearings in proceedings for issuance of construction permits or early site permits; limited work authorizations"
- 10 CFR 51.107, "Public hearings in proceedings for issuance of combined licenses; limited work authorizations"
- 10 CFR 52.24, "Issuance of an early site permit"
- 10 CFR 52.97, "Issuance of combined licenses"
- 10 CFR 70.23a, "Hearing required for uranium enrichment facility"

3.2 Acceptance Criteria and Licensing Approach

Any licensing action would benefit from the elimination of the mandatory hearing, including all new reactor licensing. No specific acceptance criteria or particular licensing approaches are necessary because the requirement would longer exist.

4 OTHER OPTIONS FOR RESOLUTION OF THE ISSUE

4.1 AEA Change – General License

A general licensing approach would be more efficient and effective in regulating nuclear reactors, such as RHDRA, and would be capable of enabling even shorter deployment timeframes that would be needed to support other business models. Currently, the AEA does not grant the NRC authority to issue general licenses for nuclear reactors, although it does grant authority to the NRC to issue general licenses for other regulated activities. If Congress were to amend the AEA to authorize and direct the NRC to develop a general licensing approach for certain nuclear reactors, and the NRC subsequently pursued a rulemaking to develop such a general license framework for nuclear reactors, this would be a more optimal solution to the issue discussed in this appendix. However, since the NRC could achieve the business requirements with currently granted authorities, and since there is significant uncertainty on whether or when Congress would grant NRC authority for issuing general licenses for reactors, the proposed resolution discussed herein is focused on approaches the NRC can implement without changes to the AEA. This enables the fastest path toward a more effective and efficient regulatory framework for RHDRA and other advanced reactors, and would build the basis of experience that could inform a longer term General License approach if Congress eventually enables it. More discussion on NRC Regulation Through General Licenses is included in Attachment B.

4.2 Additional Process Improvements

The Commission's adoption of the revised mandatory hearing process in SRM-SECY-24-0032 will substantially shorten the duration of the mandatory hearing. However, that action alone will not enable the RHDRA business model, because the mandatory hearing process is still expected to require at least two months based on current staff estimates. It is conceivable that OGC could identify further efficiencies as part of the future lessons-learned review required by the Commission in its SRM. For example, the OGC recommendation was based upon all licensing decisions, as discussed in Appendix 5 and other appendices, the proposed ReLic process would result in a very small scope for the site license review and that scope would focus on the verification of compliance with prior NRC approvals, rather than on new safety and environmental considerations. For these reviews, the NRC would need to achieve a 30 day or less Mandatory Hearing process in order to enable deployments of 180 days or less.

5 ACKNOWLEDGEMENTS

NEI Issue Lead: Jerry Bonanno and Martin O'Neill

Appendix 8 – Licensing Review Resources and Costs

1 ISSUE INTRODUCTION

NRC reviews for site license applications (e.g., Part 52 combined license, or the combination of the Part 52 construction permit and operating license) have typically been about 89,000 person-hours ($30 million) for applications that are around 6,000 to 10,000 pages.[1] Resources and costs of this magnitude are cost-prohibitive for NRC reviews of site operating license applications for rapid high-volume deployable reactors for remote applications (RHDRA). For RHDRAs, it is envisioned that after the NRC issues generic technology-inclusive approvals (e.g., Generic Environmental Impact Statement or Categorical Exclusion), design approvals (e.g., Manufacturing License, Design Certification, Standard Design Approval), and site operating licensee pre-approvals (e.g., technical and financial qualifications, plans and programs such as operations and emergency preparedness), the site license applications would be submitted for each operating site that would be on the order of a few 10s of pages in length. In order to enable the business model and meet the business case requirement that the regulatory costs are less than 1% of the total capital costs, NRC reviews for site license applications would need to be less than 500 person-hours ($150,000). It is expected that if the NRC establishes a rapid efficient licensing (ReLic) process, this will enable site license applications that are on the order of a few 10s of pages and NRC reviews that are less than 500 person-hours. The ReLic process would enable the scope and content of the site license to be minimized by moving as much as possible from what has traditionally been in the site license application into licensing processes that can occur one-time prior to the site license application (e.g., generic technology-inclusive approvals, approvals with the design, and licensee pre-approvals), and the purpose of the site license to be a verification of conformance to the site parameter envelope established by those prior approvals (see Appendix 5 on Site License). The process would enable the NRC review of a construction permit (CP) and operating license (OL) under Part 50, or a combined operating license (COL) and 103(g) finding under Part 52, in two months or less. Accounting for the receipt review, hearing process and NRC final approval and issuance of the site licence, the ReLic process would enable an NRC licensing process of four months or less from the time the site license application is submitted by the applicant to the time the NRC issues the site operating license with all approvals and authorizations to commence operations. Details of how the ReLic process would work are discussed in Section 2.2.4 of the main body of the paper, and in Appendices 1, 2, 5, 6 and 7.

2 BACKGROUND

The NRC is statutorily required to recover fees for services, such as the licensing of commercial power reactors. The NRC establishes the fees for NRC site operating license applications in 10 CFR Part 170, which designates the hourly rate at which the NRC charges for these reviews. The NRC's total costs for the site operating license review is the number of review hours times the hourly rate and can include costs for using contractors. The NRC published in January 2023 resource and cost estimates for new reactor licensing actions, including the number of staff hours and contractor costs for COLs in the range of 44,269 to 178,160 staff hours, with total costs in the range of $15M to $60M.[2] This paper is focused

[1] The most recent NRC experience for advanced reactors established review resources estimates of 18,000 person hours and $6 million for Kairos Hermes, and 27,000 person hours and $13 million for TerraPower Natrium. Note that these were only the construction permit application reviews, and the NRC has typically utilized more resources for the operating license reviews. Therefore, the recent NRC experience is consistent with the historical experience.

[2] https://www.nrc.gov/docs/ML2301/ML23018A174.pdf

on the number of hours of the NRC review and does not evaluate the basis for the hourly rate or the considerations for the use of contractors.

Current requirements in 10 CFR Part 50 and in 10 CFR Part 52 on the content of applications to construct and operate a nuclear power reactor are extensive and address a broad range of topics, both technical and programmatic. Examples of the technical topics include site characterization and safety assessment demonstrating compliance with dose criteria, an evaluation and analysis of the reactor structures, systems and components, description of the design bases and principal design criteria and how they are met. In addition to the reactor-related technical topics, Part 51 of the regulations requires an environmental evaluation. Reviewing the applicant's Environmental Report and preparing the NRC's Environmental Impact Statement or Environmental Assessment is a significant effort (see Appendix 1 on Environmental Reviews).

Programmatic topics requiring operational programs include Quality Assurance, Radiation Protection, Emergency Preparedness, Physical Security, Safeguards Contingency Plan, Fire Protection, and Fitness for Duty and Access Authorization and are typically reviewed on a site by site basis. While the operational programs are often addressed through Topical Reports, the review of this material contributes to the volume of material to be reviewed (traditionally around 6,000 to 10,000 pages) and the person-hours required (traditionally around 89,000 person-hours). In addition to the material submitted to address the technical and programmatic topics, the NRC must address any contested hearings and the mandatory hearing (see Appendices 6 and 7 on Contested and Mandatory Hearings).

3 PROPOSED SOLUTION AND APPROACH

The proposed approach is for the site license application to use the ReLic process, and for the NRC to streamline licensing reviews and approvals for site license applications that focus on verifying compliance with prior NRC approvals. Achieving the desired outcomes of site license applications that are on the order of a few 10s of pages, NRC reviews that are less than 500 person-hours, and the concurrent issuance of a CP and OL under Part 50, or a concurrent COL and 103(g) finding under Part 52, within 4 months from application submittal to issuance will require significant change to existing requirements and processes. This requires implementing the proposals in Appendix 5 on Site Licenses, and other related appendices (e.g., for environmental reviews and design approvals).

The overarching approach proposed in this paper is to focus the site license application on verification of conformance to the site parameter envelope established through prior review and approval of site safety and environmental considerations, and on any remaining safety or environmental considerations that were not able to be reviewed and approved in prior approvals and are essential to assuring public health and safety. To the maximum extent possible, the required site license application content should be structured to support a review based on verifying conformance with established performance goals. For example, rather than reviewing the details of site characterization information, the review would consist of "verifying conformance of the site license application to the site parameter envelope in the combined license or manufacturing license application (or potentially other design approvals such as a design certification or standard design approval), and any licensing conditions from other generic approvals, such as environmental impact statements and licensee programs." The emphasis is on "verifying conformance" and avoiding the need to review new or unaddressed safety or environmental considerations rather than individual subject reviews.

Appendix 8 – Licensing Review Resources and Costs

The approaches being taken in addressing other topics in this report, i.e., Generically Resolved Environmental Conditions, Design Approval Scope and Authorizations, Site License Scope and Purpose, Streamlined Contested Hearings, Eliminating Mandatory Hearing, Inspections, Tests, Analyses and Inspection Criteria (ITAAC), Aircraft Impact Considerations, and the full range of Site Characterization topics, such as Meteorology and Geotechnical, will all contribute to reducing the site license application content and enabling efficient review hours, review costs, and review time. This will correspondingly reduce the NRC staff effort required to review the application and simultaneously (1) ensure that the NRC has sufficient resources to support high-volume licensing activities and (2) drive down the overall costs to an applicant that employs reactor technology with relatively low potential consequences

3.1 Changes Needed to Regulations, Policy and Guidance

No changes are needed to the regulations specific to the NRC review fees; however, numerous regulation changes related to other appendices (e.g., Appendix 5 Site License Scope and Purpose) will enable the efficiencies described here. NRC review guidance would be helpful in establishing the NRC's expectations for developing site operating license applications that can focus on verification of conformance to the site parameter envelope to enable applications on the order of a few 10s of pages. It is possible that an NRC Policy Statement would be needed to enable a ReLic process.

The descriptions of the other topics mentioned above have all addressed the changes to regulations, policy, and guidance, and in some cases the need for legislative changes. Those changes would lead to site license application content for construction permits and operating licenses in Part 50, and for combined licenses and ITAAC Closures in Part 52, that are structured to support a review based on verifying conformance of the site license application to the site parameter envelope in the manufacturing license and other generic approvals, such as environmental impact statements and licensee programs. It is expected that site license application content that is focused on verifying conformance to site parameter envelope, and which avoids the need to review new or unaddressed safety or environmental considerations, should result in site license applications that are on the order of a few 10s of pages.

For such conformance verification types of review, the NRC's existing guidance for applications in the Standard Review Plan (SRP) for the Review of Safety Analysis Reports for Nuclear Power Plants, NUREG-0800, and the NRC's Advanced Reactor Content of Application (ARCAP) will not be relevant, as all or as much as possible of this content would have been reviewed and approved as part of prior up-front approvals through the design, licensee pre-approvals and on a generic technology basis. Therefore, guidance for contents of applications that are focused on verification of compliance with prior NRC approvals would be helpful.

Addressing operational program content in Topical Reports is a common practice. However, the proposed alternative regulatory approach would expand the use of Topical Reports to address more of the required application content and associated NRC reviews earlier in the process (assuming they have not been addressed in a previously approved license application), so that they are not on the critical path for deployment. Developing the Topical Reports to rely on "verification compliance" to the extent possible and making the reports risk-informed and performance-based will help focus the content on the most critical aspects of the subject. This will reduce report volume as well as review time and cost.

3.2 Acceptance Criteria and Licensing Approach

The descriptions of the other topics mentioned above have all addressed the applicable acceptance criteria and licensing approaches.

Achieving the desired outcomes for these other topics will enable site license applications that are focused on verifying conformance to a site parameter envelope and are a few 10s of pages.

Acceptance Criteria

The NRC may identify additional acceptance criteria and elements of the licensing approach in order to enable NRC reviews for site license applications that are less than 500 person-hours ($150,000). For example, the NRC may identify, through internal office instructions for this type of review, expectations for pre-submittal notification by the applicant in cases where large volumes of site license applications (e.g., 10s per month) may be expected. The NRC may also identify the benefit for extending the use of core teams that reviewed a given design, including safety, environmental and legal, to also perform the review of the site license applications referencing their prior work, or for an expedited management approval process.

Licensing Approach

This proposed approach is based upon use of the ReLic process to address all, or as much as possible, of the design and site safety and environmental considerations in prior one-time approvals. These include generic technology-inclusive approvals (e.g., Generic Environmental Impact Statement or Categorical Exclusion), design approvals (e.g., Manufacturing License, Design Certification, Standard Design Approval), and site operating licensee pre-approvals (e.g., technical and financial qualifications, plans and programs such as operations and emergency preparedness). The maximum efficiencies in NRC licensing review resources and costs would be achieved by addressing all safety and environmental considerations before the site license application. It is just as beneficial to apply this framework to site operating license applications that address many but not all of the safety and environmental considerations in prior NRC approvals. While applications that necessitate more than a verification of compliance with prior NRC approvals may not achieve the targeted 500 person-hours review, they would realize substantial streamlining and commensurate benefits in terms of the resources and costs of those reviews.

4 OTHER OPTIONS FOR RESOLUTION OF THE ISSUE

4.1 AEA Change – General License

A general licensing approach would be more efficient and effective in regulating nuclear reactors such as RHDRA, and would be capable of enabling even shorter deployment timeframes that would be needed to support other business models. Currently, the AEA does not grant the NRC authority to issue general licenses for nuclear reactors, although it does grant authority to the NRC to issue general licenses for other regulated activities. If Congress were to amend the AEA to authorize and direct the NRC to develop a general licensing approach for certain nuclear reactors, and the NRC subsequently pursued a rulemaking to develop such a general license framework for nuclear reactors, this would be a more optimal solution to the issue discussed in this appendix. However, since the NRC could achieve the business requirements with currently granted authorities, and since there is significant uncertainty on whether or when Congress would grant NRC authority for issuing general licenses for reactors, the proposed resolution discussed herein is focused on approaches the NRC can implement without changes to the AEA. This enables the fastest path toward a more effective and efficient regulatory framework for RHDRA and other advanced reactors, and would build the basis of experience that could inform a longer term General License approach if Congress eventually enables it. More discussion on NRC Regulation Through General Licenses is included in Attachment B.

4.2 AEA Change – NRC Fee Structure

Another alternative approach would build on reactor project funding approaches used in some other countries. Specifically, Congress would appropriate the funds for the NRC license review fees that are not recoverable from applicants for nuclear technologies like rapid high-volume deployment for remote industrial applications. This approach would recognize that the NRC regulatory framework is unable to achieve license review costs that enable business models needed to meet national environmental, energy, economic and national security goals by using nuclear technologies for these use cases; even in cases where the safety and environmental considerations are pre-approved one-time prior to the site operating license application through the use of the generic technology-inclusive, standardized design, and site licensee qualifications/programs to the maximum extent possible to reduce the scope of the site license review and to focus it only on verification of conformance to the site parameter envelope.

5 ACKNOWLEDGEMENTS

NEI Issue Lead: Marc Nichol, NEI

Appendix 9 – Aircraft Impact Assessments

1 ISSUE INTRODUCTION

The 10 CFR Part 50.150 Aircraft Impact Assessment (AIA) Rule requires applicants to perform a design-specific assessment of the effects on the facility of the impact of a large, commercial aircraft. Using realistic analyses, applicants should identify and incorporate into the design those design features and functional capabilities to show that, with reduced use of operator actions: 1) the reactor core remains cooled, or the containment remains intact; and 2) spent fuel cooling or spent fuel pool integrity is maintained.

The rule is based on application to large light water reactor (LWR) technology, where it is assumed that an aircraft could impact the reactor in ways that result in off-site dose releases. For reactors below a certain size, there would be an extremely low probability that an aircraft could impact the reactor building, and in some cases it may be impossible even for highly skilled pilots to impact. A primary driver for the current approaches to designing nuclear reactors to withstand an aircraft impact is the fact that the consequences of such an impact could pose a hazard to public health and safety. For advanced reactors that are very small, it is expected that the unmitigated consequences of an aircraft impact on such a reactor would not lead to a significant adverse impact on the health or safety of the public. This rationale is driven by the low radionuclide inventories associated with these designs, and limited potential for fuel damage. For these reactors, the existing AIA regulations would result in unnecessary regulatory burden based on each applicant's calculated low-risk likelihood and a lack of identified consequences.

The desired outcome is for the NRC to define a class of reactors such that it is highly unlikely that an aircraft could impact the reactor and/or damage fuel in a way that results in a significant radiological release. The NRC could develop performance-based criteria related to footprint, radiological inventory, thermal power level, or some combination thereof that would serve as the basis for exempting plant designs from compliance with 10 CFR 50.150 in the near-term and eventually serve as a basis for a Rulemaking. Such a class of reactors would provide reasonable assurance of adequate protection of the public health and safety without the need to meet 10 CFR Part 50.150 or consider the consequences of an aircraft impact, and without the need to design, analyze or provide other means of defense-in-depth against such a threat. The NRC's determination could be made in part on the basis that there is no credible means for aircraft impact or in the event a plane did impact the plant, off-site dose rates would be so low that public health and safety would be ensured.

2 BACKGROUND

Following the events of September 11, 2001, the NRC began consideration of a commercial aircraft threat against nuclear power plants, ultimately deciding to establish requirements for nuclear power plants (which at that time were only large LWRs) to analyze an aircraft impact and to incorporate design features based on the analysis that would minimize the consequences. The overall purpose of the AIA requirements is to ensure that commercial aircraft cannot be used as a security threat against nuclear power plants and impose an undue risk to the public.

Appendix 9 – Aircraft Impact Assessments

10 CFR 50.150 (AIA Rule) requires:

> "Assessment. Each applicant listed in paragraph (a)(3) shall perform a design-specific assessment of the effects on the facility of the impact of a large, commercial aircraft. Using realistic analyses, the applicant shall identify and incorporate into the design those design features and functional capabilities to show that, with reduced use of operator actions:
>
> (i) The reactor core remains cooled, or the containment remains intact; and
>
> (ii) spent fuel cooling or spent fuel pool integrity is maintained."

Within this rule are the implicit assumptions that:

1. There is a reasonable threat of malevolent use of a commercial aircraft to target a nuclear facility,

2. The characteristics of the aircraft are such that they pose a security threat to the nuclear facility,

3. The aircraft could hit the nuclear facility, including consideration of the flight skills of a malevolent actor, and

4. Such an impact of the aircraft on the nuclear facility would cause damage that potentially leads to off-site radiological consequences in excess of NRC limits.

Regarding non-LWRs, the AIA Statements of Consideration[1] states:

> The acceptance criteria in paragraph (a)(1) focus on the functions of core cooling capability, containment, spent fuel cooling capability, and spent fuel impact. These four functions are applicable to light water reactors (LWRs), and each may not be applicable to non-LWR reactor designs, or may have to be supplemented by other key functions. When reviewing non-LWR designs, the NRC will evaluate the applicability of the acceptance criteria set forth in the aircraft impact rule and the possible need for other criteria. If necessary, the NRC will issue exemptions and impose supplemental criteria to be used in the aircraft impact assessment for such non-LWR designs. The NRC believes this regulatory approach is preferable to excluding non-LWRs from the applicability of the aircraft rule, because such an exclusion could be interpreted in an erroneous manner as reflecting the NRC's belief that non-LWRs need not be designed against large, commercial aircraft impacts.

In SECY-20-0093, the Staff considerations for aircraft impact assessments for micro-reactors are captured as follows (emphasis added):

> **From a consequence perspective, the staff expects micro-reactors to more closely resemble nonpower reactors than large LWRs**. Further, the site footprint of micro-reactors is likely to be substantially smaller than that of the existing power reactor fleet and the new reactors

[1] Federal Register Vol. 74, No. 112, Friday, June 12, 2009)

Appendix 9 – Aircraft Impact Assessments

> envisioned when the NRC promulgated the aircraft impact rule. Some micro-reactors might also be located underground, which could prevent a large commercial aircraft from striking safety-significant portions of a facility. **A holistic risk-informed consideration of design-specific features, including the potential consequences of an aircraft impact, could provide a basis for meeting the underlying purpose of the rule and would be consistent with the Statements of Consideration, which stated that the NRC may need to issue exemptions and impose supplemental criteria for aircraft impact assessments of non-LWRs.** Provided a micro-reactor applicant can make a case for demonstrating compliance with the rule, the staff expects that existing regulatory processes are sufficient to address micro-reactor applications in the near term. **In the longer term, the staff will address this topic within the NEIMA-directed rulemaking for a technology-inclusive framework for advanced reactors.**

The NRC therefore acknowledges the uniqueness of rapid high-volume deployable reactors in remote applications (RHDRA) and other advanced reactors regarding key safety functions related to acceptance criteria for the AIA Rule. The NRC has established through these statements that the AIA Rule requires exemptions or rulemaking for micro-reactors to address supplemental criteria.

In SECY-20-0093: Enclosure 1, the NRC noted the following applicability for the AIA for micro-reactors:

> "In accordance with 10 CFR 50.150(a)(3), the aircraft impact assessment rule is applicable only to power reactors licensed after July 13, 2009 and does not apply to nonpower reactors. In the Statements of Consideration for the aircraft impact assessment rule, the Commission stated that core cooling, containment, spent fuel pool capability, and spent fuel pool integrity functions are applicable to LWRs, and each may not be applicable to non-LWR designs or may have to be supplemented by other key functions for non-LWR designs (Volume 74 of the Federal Register, page 28131 (74 FR 28131) (2009))."

The key output of the AIA Rule is to ensure the plant design incorporates features to minimize the consequences of aircraft impact. This is achieved through realistic assessment of design response to an aircraft impact and to identify and incorporate design enhancements. Such design enhancements often include structural damage resistance and strengthening, functional and physical diversity of systems, and relocation of equipment. Given the inherent safety characteristics of micro-reactors, these designs typically convey small footprints, limited interior physical space, and limited diversity of redundant and back-up systems for micro-reactors. Therefore, assessing for and implementing such design enhancements needed for compliance with the AIA Rule is not likely feasible for micro-reactors. The underlying goal of the AIA Rule to provide reasonable assurance of adequate protection to public health, safety, and the environment is the surrogate acceptance criterion against which any assessment for micro-reactors should be measured. Enhanced protection of a micro-reactor to aircraft impact is unnecessary to protect public health and safety, and will make deployment unfeasible, adding cost, design, size, manufacturing, shipping, and operational challenges that significantly hamper micro-reactor technology deployment.

Current treatment of the assessment is that the aircraft impact assessment is subject to inspection by the NRC and is not subjected to a contention submitted as part of a petition to intervene under 10 CFR 2.309. Given the expected reduced scope of the aircraft impact assessment for micro-reactors, the requirement for NRC inspection should be reconsidered to reduce unnecessary burden on both the applicant and the NRC. Issue resolution should also be streamlined to reduce regulatory burden. While the aircraft impact assessment historically has contained Safeguards Information (SGI), it may be possible to categorize the micro-reactor assessment as security-related information withheld under 10 CFR 2.390, and not SGI, depending on the assessment methodology adopted and endorsed. For example, use of maximum radiological releases already documented in the licensing basis and conservative estimates of the impact zones of an aircraft crash may justify the classification of non-SGI for the assessment.

The terrorist attacks on September 11, 2001, were a turning point in the U.S. security posture for commercial aviation. Prior to that date, anyone could walk up to a departure gate without a ticket for an actual flight, and there was very minimal security screening at the airport. From 1973 to 2001, aircraft hijackings occurred in the range of 20 to 40 per year. Since 2001, the Transportation Security Administration has provided strict security screening and implementing controls on allowed and banned items. The U.S. maintains a no-fly database and strict monitoring of individuals of concern. Aircraft have been installed with cockpit doors to protect against hijackers. Air crews undergo counter terrorist training. TSA continues to make improvements to flight security and prevent terrorist activity in commercial airlines.[2] Hijackings today are very rare, and of those that have occurred, most are not in the U.S. Reduction in fatalities, which is a measure of whether a hijacker can actually use the plane as a weapon, is even more dramatic. The FAA reports that there are over 16 million flights and 1 billion passengers in the U.S. each year.[3] There have been no successful hijackings in the U.S. since 2001, and although official statistics of attempted incidences in the U.S. are lacking, there are very few reported attempts documented in literature, and of those reported, the incidences appear to be on small aircraft by single individuals, appear to be unplanned, and were subdued by flight crew. NEI acknowledges that the NRC gets their periodic threat briefs from DHS and other organizations to inform the appropriateness of the DBT, including the likelihood of an intentional aircraft impact.

3 PROPOSED SOLUTION AND APPROACH

The proposed approach is to define a class of reactors that do not need to consider the potential for aircraft impacts because it is highly unlikely that an aircraft could impact the reactor (e.g., based upon the footprint or being underground), or the potential consequences would be well below acceptable limits (e.g., based on accident analyses or radiological content). Such a class of reactors would provide reasonable assurance of adequate protection of the public health and safety without the need to meet 10 CFR Part 50.150 or consider the consequences of an aircraft impact, and without the need to design, analyze or provide other means of defense-in-depth against such a threat.

NRC statements discussed above demonstrate the consideration, albeit at a high level, of the applicability of the rule to reactors with characteristics like research and test reactors (RTRs). Aircraft impact assessment is not required for RTRs and no equivalent AIA Rule exists for this class of reactors. RTRs have a relatively low source term and are considered unattractive targets for adversaries due to the much smaller potential radiological consequences of such an event. Therefore, it should be considered that 10 CFR 50.150 may not be applicable to a similar class of power reactors. In this manner, the regulatory framework for research and test reactors (RTRs) could be adapted to a class of

[2] https://www.tsa.gov/timeline
[3] https://www.faa.gov/air_traffic/by_the_numbers

power reactors which have similar characteristics including low likelihood of a strike and low potential consequences.

3.1 Changes Needed to Regulations, Policy and Guidance

The proposed approach is expected to require rulemaking. The NRC should amend 50.150 to exclude the proposed class of reactors or establish criteria to determine whether the rule applies to a particular class of reactors. While the acceptance criteria for exemption from 50.150 stated below are performance-based, it is recognized that these could be cumbersome to establish in rule language, and there may be advantages to establishing acceptance criteria in the rule based on power level or alternatively through regulatory guidance.

In the near-term, the NRC should develop the regulatory basis with performance-based acceptance criteria and graded requirements for when the AIA regulations are not applicable to support the use of exemptions to 50.150. The regulatory basis for exemptions would facilitate more streamlined and timely rulemakings to be codified. Both the near-term and longer-term changes would also need guidance documents developed specifically for automatic/autonomous operations.

In line with SECY-20-0093 and NEIMA, NRC should promulgate a rulemaking to establish exceptions and supplemental acceptance criteria for reactors which have small radionuclide inventories such that a potential aircraft impact is unlikely to pose a hazard to the public health and safety. This would meet the intent of 10 CFR Part 50.150 to provide reasonable assurance of adequate protection to public health and safety from the consequences of an aircraft impact. To some extent this can be inferred from the draft language in Part 53:

> “(j)(1) Design features must be provided and related functional design criteria defined such that, with limited use of operator actions, one or more physical barriers are maintained to limit the release of radionuclides from reactor systems, waste stores, or other significant inventories of radioactive materials assuming the impact of a large, commercial aircraft.”

The draft rule language uses “significant inventories of radioactive materials” which aligns with the proposal that micro-reactors with an insignificant inventory of radioactive materials may be exempted from the rule.

Regarding the establishment of acceptance criteria of the rule, in the AIA Statements of Consideration, the NRC response to a commenter as follows:

> The NRC agrees with the commenters’ recommendations for alternative acceptance criteria and agrees that 10 CFR part 100 dose limits should not be used for the purpose of this rule. The NRC decided not to adopt an additional acceptance criterion based on 10 CFR part 100 dose limits in the final rule for the reasons outlined by the commenters, namely, that the 10 CFR part 100 limits are limits that the NRC uses to judge compliance with design basis requirements.

The NRC response can be interpreted that the NRC declined to use limits in 10 CFR Part 100 as success criteria because they would impose unnecessary burden as aircraft impact is a beyond-design-basis event. Due to the low inventory of radionuclides in micro-reactors, it is likely that Part 100 limits would be met. Reactors that could meet 10 CFR 100 dose limits with a maximum hypothetical accident approach should therefore be exempted from 10 CFR 50.150. Another criteria implied by SECY-20-0093 is hittability. If the reactor is underground, or sufficiently small to be unattractive as a target, then hittability may be used as criteria for exemption from 10 CFR 50.150.

3.2 Acceptance Criteria and Licensing Approach

Acceptance Criteria:

The definition of the class of reactors considered should be revised to make clear that RHDRA and certain other reactor types are exempt from the requirement to consider aircraft impact. One possible approach is to define a sufficiently small potential consequences, for example a site boundary emergency planning zone of a few hundred meters or less. Alternatively, radionuclide inventory, or accident source term could be used, although the disadvantage is that these may be calculated with conservative assumptions, to define the reactor class as one that would inherently protect the health and safety of the public. Calculations to establish appropriate limits on radionuclide inventory or accident source term could be performed generically but would likely need to be protected from public release to not compromise security. The calculation could provide the basis for exempting a class of reactors.

Because the RHDRA are similar to nonpower reactors, such as RTRs, an exemption is reasonable. RTRs do not have to comply with the AIA Rule and do not execute aircraft impact analysis. Risk-informed considerations should include the following key points to justify the exemption for micro-reactors:

- **Reduced likelihood of a strike** – The small footprint and low hittability will result in a much more difficult target to strike compared to a traditional LWR. Above-grade structures are expected to be a single story. This results in a much lower likelihood of a successful strike on the micro-reactor. The likelihood of impact would need to consider the number and spacing of reactors. For example, a single reactor would be difficult to hit, whereas 10 closely spaced reactors would be easier.

- **Low radiological consequence** – The much smaller source terms result in much smaller emergency planning zones (EPZs). The potential impact to the health and safety of the public is greatly reduced.

- **Less attractive target** – The two previous bullets result in the micro-reactors being a less attractive target for attack. The success of attack and potential consequences are greatly reduced, which act as inherent disincentives to adversaries.

Licensing Approach:

Any licensing approach would be feasible with the proposal to eliminate the need for RHDRA and other similar reactors to consider AIA. Applicants would be expected to demonstrate that their proposed designs meet acceptance criteria.

4 OTHER OPTIONS FOR RESOLUTION OF THE ISSUE

If the NRC does not conclude that a class of reactors can be defined to be exempt from the rule, then the NRC could endorse an update to NEI 07-13 in RG 1.217. Longer-term rulemaking to make 10 CFR 50.150 technology inclusive could be conducted. Alternative acceptance criteria could be based on:

1. Hittability – a small or subterranean target may justify exemption from the rule.
2. Source Term (or inventory as a surrogate) – An assessment of potential source terms from an aircraft impact may provide sufficient justification that the health and safety of the public will be maintained.
3. Functional Containment – An assessment that the safety-related radionuclide barrier in advanced fuel types is maintained following an aircraft impact.

This approach is also consistent with the proposed Part 53 rulemaking since the source term criteria would align with the rule language around "significant inventories of radioactive material" and the functional containment criteria would align with "related functional design criteria defined such that, with limited use of operator actions, one or more physical barriers are maintained to limit the release of radionuclides."

The following are alternative approaches to meeting the requirements.

<u>10 CFR 50.150(a)(1) *Assessment requirements*.</u>

Based upon bounding accident consequence analyses or aircraft impact consequence analysis, the design would demonstrate the ability to meet supplemental acceptance criteria. The use of realistic analyses should be maintained and may include radiological release calculations performed as part of other licensing requirements. These calculations may not impose or be dependent upon design features that are solely needed for aircraft impact considerations. This identifies how the design meets the acceptance criteria. The reduced use of operator action requirement should be maintained, as it is expected that some micro-reactor designs will not have onsite personnel. The acceptance criteria of (a)(1)(i) must have supplemental acceptance criteria established. This is discussed further in Section 3.2.

<u>10 CFR 50.150(a)(2) *Aircraft characteristics.*</u>

The aircraft characteristics may be modified for smaller reactors. The lower profile and smaller cross-section of the micro-reactors compared to traditional LWRs would require the aircraft to have a much lower approach elevation and lower velocities representative of an aircraft landing sequence. This provides justification to establish an adjusted/reduced loading function for micro-reactors. Terminology in this part of the AIA Rule may be adjusted accordingly.

<u>10 CFR 50.150(a)(3) *Applicability*.</u>

The applicability of the Rule can be generally retained. Current aircraft impact assessments are performed early in the initial licensing cycle, for example with design certification or construction permit. Furthermore, performing the assessment to meet the Rule for standard plant designs should still be applicable to micro-reactors, with consideration in a similar manner to reactor and unit design as well

Appendix 9 – Aircraft Impact Assessments

as including site characteristics. While the Rule does not explicitly require so, generic site considerations should continue to be included in the assessments on a generic basis as much as possible to avoid future site-specific re-assessments.

10 CFR 50.150(b) *Content of application.*

This section is applicable to micro-reactors and can be retained.

10 CFR 50.150(c) *Control of changes*.

This section should continue to control changes to the micro-reactor design in the context of aircraft impact.

The aircraft threat response requirements of 10 CFR 50.54(hh)(1) should be maintained as generally applicable to micro-reactors with no exceptions anticipated. However, it must be acknowledged that a micro-reactor site may have no personnel on the site, rendering some requirements not applicable.

The AIA Statements of Consideration, regarding new nuclear power reactors, states:

> This final rule is based on the premise that it is desirable for newly-constructed power reactors to be designed to withstand the effects of an aircraft impact through design features or functional capabilities that reduce or eliminate the need for operator actions.

The intention of withstanding the effects of an aircraft impact can be interpreted as being able to avoid an unmitigated release to the public.

The supplemental acceptance criteria proposed for AIA must be reflective of the micro-reactor design characteristics. The acceptance criterion of maintaining core cooling is a key safety function for LWRs and may not be required for non-LWRs. Also, micro-reactors are not expected to have spent fuel pools onsite.

Suggested supplemental acceptance criteria may include the following as an alternative or supplement to the existing criteria:

- A functional containment (or at least one fission product barrier) is maintained.
    - The intent of this is acceptance criteria is to demonstrate that a release would be mitigated. Key safety functions for non-LWRs may include controlling reactivity and radionuclide retention in TRISO fuel.

OR

- Dose to the public for an unmitigated release does not exceed design basis (or beyond design basis) limits.
    - The intent of this acceptance criteria is to show that the bounding release of an aircraft impact would be bounded by other design basis or beyond design basis events. 10 CFR 100 or 10 CFR 50.34 may be applicable in this case.

OR

- The hittable cross-section of buildings of concern below a threshold such that the likelihood of an aircraft impact is very low.
    - The definition of "very low" and calculation methodology would be established through implementing guidance.

An alternative implementation of the AIA Rule must include defined supplemental acceptance criteria and commensurate assessment methodology through revision of NEI 07-13 and then endorsement through a revision to Regulatory Guide 1.217.

5 ACKNOWLEDGEMENTS

NEI Issue Lead: Jon Facemire

Appendix 10 – Meteorology and Weather Data

1 ISSUE INTRODUCTION

The NRC currently requires commercial power reactor applicants for Construction Permits, Early Site Permits, Operating Licenses and Combined Licenses to collect meteorological and weather data. This data collection is expected to be performed over one to two (or preferably three) years and include wind speed/direction, temperature, humidity, and precipitation data measured by an on-site meteorological tower, depending on the type of license application under consideration.

The guidance to collect two (preferably three) years of site-specific data using meteorological towers does not support the business model for rapid high-volume deployable reactors in remote applications (RHDRA) that requires no more than six months from site identification to operation and regulatory costs less than 1% of total costs. This accelerated time frame makes adoption of an alternative methodology for meteorological data collection a necessity.

The desired outcome is an alternative methodology for meteorological data collection that allows the use of reliable, pre-existing, and readily available data (e.g., from the National Oceanic and Atmospheric Administration-National Centers for Environmental Information (NOAA-NCEI), state/federal environmental protection agencies or other local sources) to meet applicable operating dose and emergency planning requirements. In cases where these data either do not exist, or are not sufficient to meet the requirements, they may be supplemented by locally-measured data from commercially available meteorological equipment.

2 BACKGROUND

Meteorological and weather data are important to understanding the potential radiological consequences of accidental releases of radiological material and to establishing the design basis hazards. As these parameters (e.g., wind speed, precipitation) vary from site to site and can change the potential off-site dose consequences of a postulated radiological release, they are important for determining whether a design and its associated site location will be able to meet the NRC established dose limits.

These data support dispersion calculations for main control room (MCR) dose (GDC 19), offsite dose (10 CFR 20, 50, 52); occupational dose (10 CFR 20); design-basis hazard characterization (10 CFR 50, 52); environmental impacts (10 CFR 51); and emergency planning (10 CFR 50.47). Importantly, as discussed below, the requirements related to meteorological and weather data focus on the need to have the data for use in certain analyses, emergency response and in establishing the design basis. The requirements are generally aligned with the concept of realistic meteorological and weather data and are not focused on overly precise (in terms of specificity in the location of the meteorological data collection instruments) or bounding data.

Currently, the only NRC-endorsed guidance for meteorological monitoring programs is RG 1.23 R1, published in March 2007. It also provides endorsement and clarifications for use of industry standards,

Appendix 10 – Meteorology and Weather Data

such as ANSI/ANS 3.11-2005, "Determining Meteorological Information at Nuclear Facilities." For new power reactors, this guidance addresses the following regulatory requirements:

- 10 CFR 100.20(c)(2) requires consideration of the meteorological characteristics of the site necessary for safety analysis or that may have an impact upon plant design in determining the acceptability of a site for a nuclear power plant.

- 10 CFR 100.21(c) requires the evaluation of site atmospheric dispersion characteristics and the establishment of dispersion parameters such that (1) radiological effluent release limits associated with normal operation from the type of facility proposed to be located at the site can be met for any individual located off site, and (2) radiological dose consequences of postulated accidents meet the prescribed dose limits at the exclusion area and low-population zone distances set forth in 10 CFR 50.34(a)(1).

- 10 CFR 51 requires that basic meteorological information must be available for use in assessing (1) the environmental effects of radiological and non-radiological emissions and effluents resulting from the construction or operation of a nuclear power plant and (2) the benefits of design alternatives.

- 10 CFR Part 51 also requires a realistic assessment by both the applicant and the regulatory staff of non-radiological environmental effects, such as fogging, icing, and salt drift from cooling towers or ponds, to aid in evaluating the environmental impact of a nuclear power plant in accordance with Subpart A to 10 CFR Part 51.

- General Design Criterion (GDC) 19 requires that a control room be provided from which actions can be taken to operate the nuclear power unit safely under normal conditions and to maintain it in a safe condition under accident conditions. Atmospheric dispersion estimates are significant inputs in assessments performed to demonstrate compliance with this requirement. Per 10 CFR 50 Appendix A, the GDCs establish minimum requirements for the Principal Design Criteria (PDC) for water-cooled reactors. They serve as guidance for non-water-cooled reactors. RG 1.232 provides guidance on developing PDCs for non-LWR technologies and proposes the same criterion be applied to these designs, including performance requirements for adequate habitability under normal and accident conditions.

- 10 CFR 50.47 requires emergency preparedness in accordance with 10 CFR 50 Appendix E. RG 1.23 was last updated in 2007 and the last periodic review was published prior to the 10 CFR 50.160 rulemaking. Updated guidance on collection of meteorological data should address means of complying with the more performance-based regulations in 10 CFR 50.160.

- 10 CFR 50 Appendix I provides numerical guidance for the design objectives of equipment intended to control releases of radioactive material in effluents from nuclear power reactors. Knowledge of meteorological conditions in the vicinity of the reactor is important to provide the basis for estimating maximum potential annual radiation doses resulting from radioactive materials released in gaseous effluents.

- The requirement for an on-site meteorological tower as described in RG 1.23 is codified in 10 CFR 50 Appendix E for emergency preparedness (EP) to accurately describe radionuclide dispersion during accident conditions. However, a recent rulemaking in 10 CFR 50.160 provides a performance-based alternative to 10 CFR 50 Appendix E.

RG 1.23 provides guidance on the construction of meteorological towers and collection of meteorological data to support a broad array of licensing requirements. The guidance recommends at least 12 months of on-site meteorological data for a Construction Permit (CP) and 24 months for an Early Site Permit (ESP), Operating License (OL) or combined license (COL) with a preference of three years of data. Siting, procuring, and erecting a 60-m tower can easily take a year. That is additional time that factors into a project schedule before data collection begins. To procure, install, and operate a meteorological tower can easily cost several million dollars, which would far exceed the business requirement of regulatory costs less than 1% of total costs, since the weather data needed for purposes other than meeting NRC requirements could be obtained from pre-existing sources.

RG 1.23 identifies the following parameters to be measured by an on-site meteorological tower:

- Wind speed and direction
- Vertical temperature difference (delta-T)
- Dry bulb temperature
- Precipitation
- Atmospheric moisture (humidity or dew point)

A meteorological tower instrumented according to RG 1.23 records wind speed, wind direction, and temperature at several vertical levels, typically 10 and 60 m above ground level (AGL). The vertical temperature difference, delta-T (measured between 10 and 60 m AGL), is used to determine the Pasquill stability class[1] per RG 1.23, Table 1, which becomes a key input for many dispersion calculations. For comparison, airports use automated weather observing systems to measure horizontal visibility, wind speed/direction, cloud cover/height, dry bulb temperature, humidity and precipitation. Wind speed/direction are measured at only one vertical level, typically 10 m AGL.[2]

Airports generally do not measure parameters at multiple levels, so delta-T measurements are not available from airports. However, Turner (1964) described a methodology for estimating the Pasquill stability class from wind speed and cloud cover/height measured at airports.[3] A comparison of short-term atmospheric dispersion estimates based on Pasquill stability derived from airport data and Pasquill stability from 10 – 60 m delta-T found comparable results.[4] This demonstrates that Pasquill stability class derived from measurements at a representative airport are a suitable substitute for Pasquill

[1] The Pasquill stability scheme characterizes atmospheric stability in terms of discrete levels (classes) ranging from class A (extremely unstable) to class G (extremely stable).

[2] NCEI, 2001. Data file "anem_elev_inf" referenced in Data Documentation for Data Set 6421 (DSI-6421) Enhanced Hourly Wind Station Data for the Contiguous United States. Version 1.1. National Centers for Environmental Information, Asheville, North Carolina. December 6, 2001.

[3] Turner, D. 1964. "A Diffusion Model for an Urban Area. Monthly Weather Review," Vol 3, pp. 83-91. February 1964.

[4] Mitchell, A.E., 1983. "A Comparison of Short-Term Dispersion Estimates Resulting from Various Atmospheric Stability Classification Methods." Atmospheric Environment, Vol. 16, No. 4, pp 765-773.

stability derived from 10 – 60 m delta-T measurements. Such alternative methodologies may support developing initial values of stability to support the siting and licensing processes for a project.

The U.S. Environmental Protection Agency (US EPA) used the Pasquill-Gifford-Turner method to determine atmospheric stability from airport meteorological data in its regulatory air quality models for approximately 40 years until 2005 when AERMOD (**A**merican Meteorological Society/**E**PA **R**egulatory **M**odel) was formally adopted as the US EPA's preferred dispersion model for many regulatory applications.[5] AERMOD uses a more advanced methodology that treats atmospheric stability as a continuum instead of discrete stability classes like those based on Turner (1964) or RG 1.23. However, the US EPA still uses the Pasquill stability class based on Turner's methodology to estimate atmospheric stability classes in its Clean Air Act Assessment Package - 1988 (CAP88-PC) air dispersion model that estimates dose and risk from radionuclide emissions.[6] CAP88-PC uses a built-in database of historical meteorological data from airports.[7]

Since RG 1.23 R1 was issued in 2007, various state environmental agencies, such as Texas and North Carolina,[8,9] have developed site-specific meteorological data sets using airport data that (non-nuclear) industries use for air dispersion analyses in their construction permit applications. Environmental agencies follow a rigorous process for selecting a representative meteorological data set for a site[10] and evaluating data completeness.[11] Starting in 2011 these data sets incorporated 1-minute average wind data from airports to produce high-resolution wind speed/direction data sets (hourly-averaged wind direction to the nearest 1 degree and wind speed to the nearest 0.1 m/s).[12] The US EPA made this change to improve air dispersion modeling involving periods with low wind speeds and variable wind directions.[13] This change also brought the wind data speed/direction resolution from airports[14] in line with the wind direction and speed data resolution requirements of RG 1.23.

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[5] The US EPA relied upon the Industrial Source Complex (ISC) model and its predecessors for ambient air quality modeling until the agency formally adopted its next-generation AERMOD modeling system in November 2005. ISC used atmospheric stability based on methodology of Turner (1964). AERMOD uses an entirely different technique that still uses airport meteorological data from a single vertical level.

[6] U.S. Environmental Protection Agency. CAP-88-PC (Clean Air Assessment Package – 1988) computer program. Available from https://www.epa.gov/radiation/cap88-pc

[7] U.S. Environmental Protection Agency. "CAP-88-PC Version 4.1 User Guide." Page 50.

[8] Texas Commission for Environmental Quality (TCEQ), 2024. https://www.epa.gov/scram/meteorological-processors-and-accessory-programs)

[9] North Carolina Department of Environmental Quality (NCDEQ), 2024. Meteorological Data. Available from: https://www.epa.gov/scram/meteorological-processors-and-accessory-programs)

[10] Example in: Texas Commission for Environmental Quality (TCEQ), 2024. "Technical Basis for AERMOD Meteorological Data Sets." Available from: https://www.tceq.texas.gov/permitting/air/modeling/aermod-datasets.html.

[11] The US EPA requires 90% data completion for use in modeling per US EPA, 2000: "Meteorological Monitoring Guidance for Regulatory Modeling Applications." EPA-454/R-99-005. February 2000. Section 5.3.2. This matches the data completion requirement in RG 1.23.

[12] U.S. Environmental Protection Agency, 2023. AERMINUTE User's Guide. EPA-454/B-23-007. U.S. Environmental Protection Agency Office of Air Quality Planning and Standards Air Quality Assessment Division Air Quality Modeling Group. Research Triangle Park, North Carolina October 2023. Available from: https://www.epa.gov/scram/meteorological-processors-and-accessory-programs

[13] *Ibid*, page 1.

[14] Before this change in 2011, wind direction data from automated weather observing systems for input in air dispersion models were only available to the nearest 10 degrees.

There is precedent for using airport data as an alternative to on-site meteorological data for reactor siting. Section 2.4.1 of NUREG/CR-2239 states the following regarding the use of on-site meteorological data:[15]

> "Data from reactor sites, however, are often of poor quality. Some site meteorological files do not include observations of precipitation and there are often 'gaps' in the recordings. For this study, meteorological records from 29 National Weather Service (NWS) stations were used with the site wind rose."

Section 2.4.1 of NUREG/CR-2239 later states:

> "NWS data have several potential advantages over reactor site data in that they are generally of higher quality, are readily available, contain more detailed observations, and are of durations up to 30 years."

This discussion has focused on airport data because there are several thousand airports in the United States and airport data are widely available. However, there are other public data sources that may be potentially used. These include meteorological instrumentation networks (mesonets) that are being developed by various organizations. Mesonets in Oklahoma, North Dakota, and New Mexico are examples.[16,17,18]

The approach to documenting site characteristics for a non-power reactor differs from that for a power reactor. Regarding non-power reactors, Section 2.3.2 of NUREG-1537 allows an on-site measurements program or an alternative source of meteorological data (e.g., National Weather Service station). This guidance does not establish the need to collect data for two to three years using on-site meteorological towers, but rather permits use of publicly available reliable weather data. Further, Section 2.3.1 of NUREG-1537 requests the applicant describe the general climate of the region, historical weather, and local meteorology. The parameters include prevailing air-flow patterns (wind direction and speed); temperature and humidity; precipitation; and seasonal and annual frequencies of severe weather phenomena. In practice these parameters come from publicly available summaries of data collected at airports and other weather observing facilities.[19,20] Therefore, the NRC accepts data from the National Weather Service or other nearby sources. The NRC does not establish requirements or expectations that this data be collected at a site specifically for the purposes of the license application, nor does it require or expect that any data the applicant chooses to collect and use to support analyses or design bases be from meteorological towers or according to Appendix B quality programs.

3 PROPOSED SOLUTION AND APPROACH

The proposed approach is the use of pre-existing data from the National Oceanic and Atmospheric Administration (NOAA), National Weather Service or other nearby sources to support analyses and

[15] NUREG/CR-2239: "Technical Guidance for Siting Criteria Development." December 1982.

[16] Data from the Oklahoma mesonet are available from: https://www.mesonet.org/

[17] Data from the North Dakota mesonet are available from: https://ndawn.ndsu.nodak.edu/

[18] Data from the New Mexico mesonet are available from: https://weather.nmsu.edu/

[19] A typical example of a summary of airport data is provided here: https://www.ncdc.noaa.gov/IPS/static/images/lcdsample.pdf

[20] A typical example of a summary of meteorological data from various observing facilities is provided here: https://www.ncdc.noaa.gov/IPS/static/images/sample3.pdf

Appendix 10 – Meteorology and Weather Data

design bases for all new reactor site license applications (e.g., CP, ESP, OL, COL). If pre-existing data is incomplete, then the proposed approach would permit the collection of locally-measured data from commercially available meteorological equipment, to the extent needed to supplement pre-existing data. The proposed approach would permit the resolution of all safety and environmental considerations related to meteorological and weather data, and the establishment of a site parameter envelope in the design approval (e.g., Manufacturing License (ML), Design Certification (DC), Standard Design Approval (SDA)) and generic environmental decisions (e.g., GEIS, CatEx), so that the site specific license application would only need to focus on verifying that the data related to the site complies with the site parameter envelope.

The proposed approach to use pre-existing data would enable the establishment of meteorological and weather conditions in days or weeks, rather than two to three years as currently required today. It would also enable reduced costs that are small fractions of the several millions of dollars required to procure, install and operate an on-site meteorological tower.

The use of meteorological and weather data from pre-existing sources is appropriate for all new reactors.

First, meteorological data from airports are readily available from NOAA-NCEI.[21] The data are subject to various quality control procedures before publication.[22] Airport meteorological data have been used in recent NRC submittals for an RTR and medical isotope production facilities. Abilene Christian University (ACU) submitted a Preliminary Safety Analysis Report (PSAR) to support construction of a molten salt RTR on the ACU campus in Abilene, Texas.[23] The PSAR used the US EPA CAP88-PC model with data from the nearby Abilene airport.[24] Further, the NRC recently issued construction permits for two radioisotope production facilities at SHINE (Janesville, Wisconsin) and Northwest Medical Isotopes (Columbia, Missouri). Permit applications for both facilities used meteorological data from airports to represent local meteorological conditions.[25,26]

High-resolution airport meteorological data sets from environmental agencies would be especially useful since they have the benefit of having undergone a rigorous technical review by an environmental agency which found a set of data to be representative of a site. For RHDRA deployments involving multiple units in proximity to each other, meteorological data from the same airport could be used, streamlining the safety and environmental review process.

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[21] NOAA-NCEI Weather and Climate Quick Links. Website: https://www.ncdc.noaa.gov/data-access/quick-links#dsi-3505

[22] Del Greco et al., 2006. S. A. Del Greco and collaborators, Surface Data Integration at NOAA's National Climatic Data Center: Data Format, Processing, QC and Product Generation, 86th AMS Annual Meeting, 29 January - 2 February 2006.

[23] Abilene Christian University. Nuclear Energy Experimental Testing (NEXT). Preliminary Safety Analysis Report. Revision 0. August 2022. Available from NRC ADAMS database. Succession number: ML22227A203.

[24] *Ibid*. Section 19.4.9.2.2.2.

[25] SHINE Medical Technologies. Preliminary Safety Analysis Report, Rev. 0. August 2015. Available from NRC ADAMS database. Accession number: ML15258A370. Section 2.3.2.5.

[26] Northwest Medical Isotopes Construction Permit Application for Radioisotope Production Facility. Chapter 2.0 Site Characteristics. NWMI-2013-021, Rev. 0. January 2015. Available from NRC ADAMS database. Accession number: ML15210A113.

Appendix 10 – Meteorology and Weather Data

Second, there is NRC precedent for accepting reliable data from other sources with technical capabilities. In a letter to NEI dated April 30, 2015,[27] the NRC reaffirmed and extended its prior determination that safety-related calibration and testing services from international National Metrology Institutes do not require compliance with Appendix B QA or purchaser audit/survey requirements. The NRC recognized that these services are performed by organizations with proven capabilities in relevant disciplines. The NRC's affirmation and extension of this position, originally established in August 24, 1983, between the NRC and the Bingham-Willamette Company provides a useful model for accepting data from sources that have recognized proven capabilities, without the need to question the pedigree of that data. Regarding meteorological data, NOAA-NCEI, or a state/federal environmental agency would certainly have proven capabilities for managing meteorological data collection.

NOAA data is high-quality, broadly applicable, and can accurately model dispersion as demonstrated for other regulatory purposes and in NRC precedent. For these reasons, it is justifiable to use publicly available meteorological data to support all advanced reactors, and not only RHDRA and micro-reactors. Regulation previously required met towers under 10 CFR 50 Part E, but 10 CFR 50 .160 allows for performance-based radionuclide release assessment and monitoring which should be available for all new reactors, but certainly for all reactors meeting the criteria for an EPZ within the site boundary. Emergency preparedness is discussed more comprehensively in Appendix 20.

While the use of reliable pre-existing data should not depend on the safety profile of the reactor, it is recognized that the consideration of potential consequences and accidental offsite doses could be a factor considered by the NRC in allowing the use of commercially available instrumentation. The need to use meteorological towers to collect local data may be appropriate for large LWRs, but such data are not necessary for advanced reactors to provide reasonable assurance of adequate protection of the public health and safety, and the environment Large LWRs have significantly larger source terms and require containment structures and emergency planning to ensure adequate protection of public health and safety. In contrast, most advanced reactors are expected to achieve maximum doses during design basis and beyond design basis events at the site boundary under the EPA PAG (e.g., 1 rem or less). Therefore, the sensitivity of meteorological and weather data to the calculated doses to the public is significantly less than it is for LLWRs for which the NRC establishes the expectations for this data for power reactors. While RHDRA and micro-reactors are expected to meet similar potential consequences, albeit with site boundaries that are smaller than larger advanced reactors, the differences as it relates to the importance of the meteorological and weather data are not significant.

3.1 Changes Needed to Regulations, Policy and Guidance

The proposed approach appears to be consistent with current NRC requirements and thus would not require rulemaking. However, because the NRC guidance in RG 1.23 is overly prescriptive and not commensurate with the lower hazards posed by micro-reactor designs, either RG 1.23 would need to be revised or a new guidance for meteorological and weather data for new reactors would need to be created. The revised or new guidance should permit the use of pre-existing data sets from NOAA, the National Weather Service, state agencies, airports, other existing government, or commercial sources as is allowed for other NRC-regulated facilities. The guidance should specifically endorse the use of data from currently known government and commercial sources with recognized proven capabilities and

[27] Roach, E.H. to Marcus Nichol, Nuclear Energy Institute, Quality Assurance Program Requirements for National Metrology Institutes as Suppliers of Primary Reference Standards and Calibration, April 30, 2015. Available from NRC ADAMS database. Accession number ML15111A477

provide guidance for applicants to demonstrate the acceptable use of other government and commercial sources as they become available.

3.2 Acceptance Criteria and Licensing Approach

Acceptance Criteria

The proposed approach for using meteorological and weather data depends on two acceptance criteria:

1. Use of pre-existing data from government or commercial sources would be appropriate if previously accepted by NRC in guidance, or otherwise demonstrated to be from sources with recognized proven capabilities

2. Use of commercially available instrumentation to collect local site data (if needed to complete pre-existing data) would be appropriate for an advanced reactor design that enables a site boundary EPZ

Licensing Approach

Any licensing approach can use pre-existing data or data from commercially available instruments to establish design basis values for wind speed and precipitation as well as dispersion factors for use in normal effluent and accident calculations. To achieve the deployment timelines of RHDRA for meteorology and weather data, the rapid efficient repeatable licensing (ReLic) process should be used to minimize the scope, content and purpose of the site-specific reviews. This type of site-specific review would enable completion of all, or as much as possible, of the safety and environmental reviews and public engagement processes as possible one-time prior to the identification of a specific site. Where the entire site-specific review is not possible before site identification, performing a site license review that only needs to verify that the site characteristics conform to the minimum set of site parameters in the envelope established in the one-time up-front reviews is recommended.

This would include use of a standardized design that has been approved by the NRC. Possible approval processes include Standard Design Approval, Design Certification, Manufacturing License, COLA and subsequent COLAs. These offer different levels of NRC approvals in terms of scope of the design and finality of the NRC's decision. It is expected that the NRC review, relative to analyses and design bases supported by meteorological and weather data, would be performed during the design approval, and would establish a site parameter envelope for the data to be determined for each specific site.

The site license application would then demonstrate that the data for the site is bounded by the site parameter envelope.

4 OTHER OPTIONS FOR RESOLUTION OF THE ISSUE

4.1 AEA Change – Minimal Regulation

The technical and safety bases for power reactors with potential consequences on the order of magnitude of non-power reactors should be sufficient to enable the NRC to adapt the non-power reactor requirements and implementation guidance for those qualifying power reactors. Adaption of the non-power reactor regulatory framework, as discussed in this appendix, should achieve a similar level of regulation that accounts for the safety and operational characteristics of the qualifying power reactors that will tailor requirements and applicability to the technology. An AEA change to direct the NRC to regulate power reactors with potential consequences that are on the same order of magnitude as non-power reactors, e.g., with minimal regulation or under Section 104, is an option that was identified. However, such a change does not appear necessary, since the AEA provides sufficient authority to the NRC to regulate power reactors commensurate with their potential impacts, and is capable within the current AEA provisions to apply regulatory approaches to qualifying power reactors that are similar to those used today for non-power reactors. More discussion on NRC Regulation of Non-Power Reactors is included in Attachment A.

4.2 Bounding Design Analyses

Another approach is to calculate radiological source inventory with recognized conservative assumptions to bound estimated radiological impacts. If the radiological source terms are sufficiently small, the site EPZ would be potentially within the site boundary, there would no longer a need for modeling atmospheric dispersion and diffusion out to 10 miles per current practice under 10 CFR 50.47. The specific design would become largely independent of site-specific meteorological conditions.

Meteorological data from alternative sources could also be used to develop design conditions, including precipitation and wind loads. A facility would be designed against a bounding set of external hazards such that the worst-case meteorological event (e.g., maximum precipitation rate, tornado wind loading) would not impact the safety of the facility.

While this option would enable the timely and efficient licensing of advanced reactors, it could also result in overly conservative designs, and could impose unnecessary regulatory burden.

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Appendix 11 – Geologic and Geotechnical

1 ISSUE INTRODUCTION

Site geological, geophysical, seismological, and geotechnical investigations that support site characterization (herein referred to as site geo-characterization) for proposed nuclear power plants (NPPs) are costly and time consuming, requiring significant investigation work for a Site Region (200 miles), Site Vicinity (25 miles), Site Area (5 miles) and Site Location (1 km). Site Area and Site Location investigations in particular require collaborative scientific endeavors plus physical borings and other surface and subsurface explorations for the purposes of site seismic characterization, that can incur timelines of years and cost tens of millions of dollars. The extent of such site-specific work includes scope that is considered unnecessary for rapid high-volume deployable reactors in remote applications (RHDRA) to demonstrate reasonable assurance of adequate protection to the public and environment for low-consequence facilities. This current regulatory framework is unable to meet the business case requirements of 180 days from site selection to operation and <1% of total capital costs, and is not consistent with advanced reactor-specific consequences.

The desired outcome is an alternative methodology for site geo-characterization that is commensurate with the potential consequences of advanced reactors and enables rapid and confirmatory comparison to a site parameter envelope used for site-independent design such as for RHDRA. Within that methodology, the site seismic characterization would allow use of reliable pre-existing seismic hazard data catalogued for locations across the United States. The United States Geological Survey's (USGS) National Seismic Hazard Model (NSHM) provides readily available national seismic hazard data that can be used to characterize site-specific seismic vibratory hazards without performing a unique evaluation. The site seismic characterization would consider local site effects (e.g., soil amplification) by way of the site classification approach embodied within the USGS NSHM which can be implemented with more streamlined site investigation work complementing that performed for assessing other non-vibratory seismic hazards (e.g., liquefaction, slope stability. Additional seismic design strategy options, such as use of seismic isolation, could further support the application of site-independent seismic design confirmed by site seismic characterization via the NSHM. Site seismic characterization in this way allows the other non-seismic aspects of site geo-characterization to rely on commercial best practices and focus on collection of other geologic and material property data needed for demonstrating site suitability and for the engineering analyses, design, and construction of a plant. The specific elements of site geo-characterization necessary for confirmatory demonstration within a site parameter envelope would be identified during technology review of the site-independent design considering the design's relative radiological inventory and consequence of failure.

2 BACKGROUND

Site geo-characteristics are unique and affect NPP siting and corresponding design. Understanding the geo-characteristics of a site is necessary to identify geo-hazards which can influence the potential offsite dose consequence for an NPP. Furthermore, an analysis of site geo-characteristics is essential to demonstrating that an NPP design can adequately prevent and mitigate the effects of those geo-hazards to meet NRC established dose limits. Earthquakes are one important category of geo-hazard, including both ground deformation (surface faulting, liquefaction, landslide, and settlement) and ground shaking (vibration) considerations. Other non-seismic geo-hazards include soil and rock stability, total and relative settlement, and subsurface discontinuities (e.g., cavernous rocks and karst). Criteria for geological and seismic siting for NPPs are prescribed in 10 CFR 100.23, with particular emphasis on site

Appendix 11 – Geologic and Geotechnical

geo-characterization for seismic factors. Criteria for earthquake engineering of NPPs accounting for site geo-characteristics are prescribed in 10 CFR 50 Appendix S. Together, these criteria require that: (a) a site investigation be performed as part of developing a Safe Shutdown Earthquake (SSE) ground motion, and to collect engineering properties for evaluating a site and engineering solutions for seismic and other geologic effects; and (b) that an NPP be designed so that certain structures, systems, and components (SSCs) necessary to assure certain safety functions are designed to remain functional should the SSE occur. NRC Regulatory Guides (RG) provide guidance about how these criteria can be met for NPPs.

<u>Site Geo-Characterization</u>

RG 1.208, "Performance-Based Approach to Define Site Specific Earthquake Ground Motion," provides a set of guidance to determine a site-specific performance-based ground motion response spectra (GMRS) towards defining a plant SSE that satisfies requirements of 10 CFR 100.23 and 10 CFR 50 Appendix S. RG 1.208 has guidance for the incremental steps of performing site geo-characterization investigations specific to seismic-related hazards, identifying seismic sources (e.g., faults), developing a probabilistic seismic hazard analysis (PSHA), and accounting for local site effects (e.g., soil amplification). The guidance in RG 1.208 is aligned for PSHA steps developed using the NRC's Senior Seismic Hazard Analysis Committee (SSHAC) guidelines to capture the center, body, and range of the informed technical community. GMRS developed in accordance with RG 1.208 are performance-based in the sense that the resulting GMRS targets 1E-5 mean annual probability of exceedance (frequency) of the onset of significant inelastic deformation. A site-specific GMRS is calculated based on frequency-dependent interpolation between 1E-4 and 1E-5 annual exceedance frequency (AEF) uniform hazard response spectra (UHRS), where the specific interpolation depends on the slope of the hazard between these two AEFs. The GMRS defined in this way achieves the 1E-5 target performance goal by crediting that the seismic demand and structural capacity evaluation to achieve two minimum performance goals: less than about a 1% probability of unacceptable performance for design ground motion, and less than about a 10% probability of unacceptable performance for 1.5x the design ground motion. A seismic target performance goal of 1E-5 per year and defined based on onset of significant inelastic deformation is less suitable for a micro-reactor that has small off-site dose potential and small impact to land, water, and atmosphere.

RG 1.132, "Geologic and Geotechnical Site Characterization Investigations for Nuclear Power Plants," provides guidance on field investigations for determining site geo-characteristics for engineering analysis and design of NPPs. RG 1.132 describes the types of data to be acquired for site geo-characterization and acceptable means of acquiring such data. Certain specifics of field investigation programs to collect surface and sub-surface properties are described, including core borings and geophysical investigations. While RG 1.132 acknowledges the role of professional judgement in selecting the appropriate scope, extent, and details of site investigations for nuclear power plants to provide a strong basis for site suitability determination and foundation design and construction, it is also significantly influenced by the detailed site investigation activities involved in site geo-characterization suitable for a detailed site-specific seismic hazard analysis described in RG 1.208.

RG 1.138, "Laboratory Investigations of Soils and Rocks for Engineering Analysis and Design of Nuclear Power Plants," describes laboratory investigation and testing practices for determining soil and rock properties and characteristics needed for engineering analysis and design of foundations and earthworks for NPPs. RG 1.138 complements RG 1.132 for overall site geo-characterization of a site.

Appendix 11 – Geologic and Geotechnical

RG 1.198, "Procedures and Criteria for Assessing Seismic Soil Liquefaction at Nuclear Power Plant Sites," provides guidance on evaluating the potential for earthquake-induced instability of soils resulting from liquefaction and subsurface strength degradation. Additional site geo-characterization guidance is provided that supplements that in RG 1.132 and RG 1.138 for collecting and analyzing field and laboratory investigation data specific to liquefaction potential.

Site geo-characterization for seismic hazards performed according to the guidance described above, especially that necessary to perform a PSHA in accordance with RG 1.208 incorporating detailed site investigation data collected in accordance with RG 1.132, can be the biggest cost and schedule driver for overall site geo-characterization for NPPs. Guidance for seismic characterization of NPP sites in the cited RGs is not graded according to radiological inventory, dose consequence of failure, or presence of inherent safety features. Rather, RG 1.208 assumes the same seismic performance target of 1E-5 annual frequency of exceeding onset of significant inelastic deformation for GMRS (and thus SSE) development for NPPs of all types and sizes. Therefore, the refined process for seismic characterization including treatment of uncertainties and variabilities required to meet RG 1.208 applies even when flexibility permitted by RG 1.132 for non-seismic geo-characterization would otherwise apply.

Notably, seismic site geo-characterization guidance is different for non-power reactors than for NPPs. Although non-power reactors must comply with the same Part 50 requirements related to geology, seismology and geotechnical engineering that apply to power reactors, implementation guidance differs from power reactors. The approach to implement these requirements for non-power reactors is discussed in Sections 2.5 and 3.4 of NUREG-1537. Importantly, this guidance acknowledges that the "*degree of detail and extent of the [geology, seismology, and geotechnical engineering] considerations should be commensurate with the potential consequences of seismological disturbance, both to the reactor facility and to the public from radioactive releases*," and permits data "*obtained from sources of adequate credibility and is consistent with other available data, such as data from the USGS.*" Specifically, the guidance requests the applicant sufficiently characterize the geologic features underlying and in the surrounding region and seismic activity affecting the site to support development of applicable design criteria for the reactor structures. The NRC does not establish guidance that this site geo-characterization data be collected specifically for the purposes of the license application, nor does it define guidance for the specific means or extent of any data the applicant chooses to collect and use to support analyses or design bases. Notably, test reactors are also subject to 10 CFR 100 (Subpart A) Appendix A for geologic and seismic siting criteria, as opposed to power reactor applicants on or after January 10, 1997, that are subject to geologic and seismic siting criteria in 10 CFR 100.23 instead.

<u>Seismic Design</u>

Once the site geo-characterization establishes the general suitability for siting an NPP and the site's seismic hazard (including definition of a design basis earthquake such as SSE), the site properties are used to perform engineering analysis and design of the NPP. Criteria in 10 CFR Part 50 Appendix S require that certain SSCs necessary for safety remain functional and within applicable stress, strain and deformation limits as demonstrated through design, testing, or qualification methods, and that the seismic evaluation account for soil-structure interaction (SSI) effects from vibratory motion. Implementing guidance is contained in various locations, including but not limited to NRC RGs, ISGs, and SRPs too numerable to identify each here. Although the focus of this paper is on site geo-characterization rather than SSC design, certain seismic design related details affect how site-specific conditions are demonstrated to be covered by an NPP design.

SSI considerations are expected to be accounted for in the seismic demands used for design, testing, and qualification of SSCs needing to remain functional during and/or following an SSE. SSI analysis produces seismic demands for structures in terms of forces, moments, stresses, and deformations; and seismic demands for components and systems generally in terms of in-structure response spectra (ISRS). Consideration of site-specific SSI effects uses engineering properties from site geo-characterization plus pre- and post-processing analysis steps to ensure sufficient compatibility with treatment of site effects in the PSHA and accounting for inherent uncertainty and variability. Seismic qualification of equipment and components such as in accordance with NRC RG 1.100 imply use of site-specific SSI analysis for generation of ISRS that form the Required Response Spectra (RRS) of minimum component capacity. Where seismic demands are not produced by detailed site-specific SSI analysis, such as for Part 52 NPP applications, the seismic demands are compared to the results of a detailed site-specific SSI analysis to demonstrate that they are bounding. This reliance on site-specific SSI exacerbates the time and resources required for demonstrating an NPP design is suitable for a given site, on top of that required for site geo-characterization described above. Additionally, the relative sensitivity of seismic demands to detailed site-specific SSI analysis performed in accordance with NRC guidance can lead to excessive design conservatisms when seeking a standard NPP design.

Two new RGs related to NPP seismic design are under development. DG 1410 (proposed new RG 1.251), "Technology Inclusive, Risk Informed, and Performance Based Methodology for Seismic Design of Commercial Nuclear Plants," is to provide an alternative design pathway for seismic design as part of an advanced reactor license application, in which the seismic performance of each SSC is considered separately, accounting for SSCs contribution to safety and risks. DG 1307 (proposed new RG 1.252), "Seismically Isolated Nuclear Power Plants," is to provide an acceptable approach to incorporate seismic isolation systems for isolation of NPP structures. Both DGs follow a risk-informed performance-based approach for seismic design and seismic safety. Both DGs were prepared in support of ongoing rulemaking of proposed Part 53, but may be published as guidance for interim applicants pursuing Part 50 and Part 52, acknowledging that exemptions from certain requirements of 10 CFR 50 Appendix S may be required to implement portions of these DGs.

Regarding non-power reactors, guidance for seismic design criteria is described in Section 3.4 of NUREG-1537. This guidance specifies that "seismic design for non-power reactors should, at a minimum, be consistent with local building codes and other applicable standards" which notably relies on the USGS NSHM. Additionally, the guidance for seismic design emphasizes providing reasonable assurance of dose consequences from a seismic event within acceptable limits specified elsewhere. The guidance cross-references to 10 CFR 100 requirements for test reactors. Limited information is provided regarding seismic design implementation considerations that would be found acceptable by NRC reviewers.

3 PROPOSED SOLUTION AND APPROACH

The proposed approach outlined below would enable rapid and confirmatory comparison of site-specific geo-characterization to a site parameter envelope used to design and license a new reactor. A central tenet of the approach is that the site confirmation can be performed without requiring a detailed site-specific evaluation to license the construction of a standard design at a specific site. The proposed approach could apply to all new reactor site license applications (e.g., CP, ESP, COL) having sufficiently low frequency of dose release (e.g., low seismic hazard and/or high design robustness) and/or low dose consequence of seismic failure (e.g., small radiological inventory and/or limited dose exposure) but is described here most specifically to RHDRA.

Appendix 11 – Geologic and Geotechnical

The proposed approach would establish the site's Safe Shutdown Earthquake (SSE) based on the United States National Seismic Hazard Model (NSHM) developed and published by the United States Geological Survey (USGS) of the U.S. Department of Interior. Accordingly, the site geo-characterization would focus on collecting sufficient surface and subsurface geophysical and geotechnical information for two primary objectives: (1) to classify a site according to a USGS site classification that feeds into querying the NSHM at the site location; and (2) to permit adequate engineering solutions to actual or potential geological and geotechnical effects at the site. The classification of a site would use site characterization techniques aligned with variables employed by the NSHM, namely the average shear-wave velocity of the upper 30m of site subsurface conditions, which may make use of existing site characterization data where available. The site data needed to support engineering design solutions are influenced by the nature of the reactor design, its relative sensitivity to site conditions, and the range of such conditions that a site may potentially exhibit. Both objectives are enabled by the development and approval of a standard design using the manufacturing license pathway. Approval of the design as part of the manufacturing license review process would be used to evaluate the relative safety of the design and define the site parameter envelope for which such safety is demonstrated.

The proposed approach would permit the use of a relatively limited geophysical and geotechnical exploration program following commercial best practices to establish the site classification for defining the SSE. Then, a small sample size of additional geotechnical explorations such as core borings, also obtained using commercial best practices, would be used to supplement pre-existing data to satisfy other site geo-characterization needs besides seismic site classification. The proposed approach would permit the resolution of all safety and environmental considerations related to seismic analyses and design such that the site specific license application would only need to focus on verifying that the data related to the site complies with the site parameter envelope that was previously established in the design approval (e.g., ML, DC, SDA) and in the generic environmental decisions (e.g., GEIS, CatEx).

Enabling rapid and confirmatory site-specific geo-characterization without requiring detailed site-specific analysis will require more than capturing site effects in accordance with USGS NSHM site classification methods. The proposed methodology requires that the design is demonstrated to be adequate for a bounding site parameter envelope corresponding to the deployment location. Such demonstration must consider SSI effects to be compliant with Part 50 Appendix S, or other more technology-inclusive requirements for earthquake engineering (if applicable). This could be accomplished generically by demonstrating that a design is insensitive to SSI effects, or by directly considering SSI effects in a simplified manner analogous to the site classification process. The former could be feasible for small and lightweight reactor designs that inherently have minimal inertial and kinematic SSI effects for a wide range of soil conditions, or for reactor designs employing seismic isolation that filter site-specific ground motions to a pre-defined seismic isolation system vibration frequency decoupled from SSI effects. The latter could be feasible if bounding and demonstrably conservative SSI effects are considered, including the treatment of uncertainties, for the range of site conditions captured within the site parameter envelope. In both cases, the proposed approach would evaluate the site suitability based on the confirmatory site geo-characterization and not on site-specific analyses.

The proposed use of the USGS NSHM to define an SSE is most appropriate for NPPs that can achieve adequate seismic safety by designing for an SSE with an annual frequency of exceedance of 1E-4 or greater, because that is the range of return period for which the USGS NSHM is designed to be used in model building codes such as are adopted for design of other conventional and hazardous facilities. This

Appendix 11 – Geologic and Geotechnical

includes use of the site classification procedure embodied within the NSHM to capture site response effects, which relies on relatively limited site geotechnical investigation as compared with RG 1.208 and RG 1.132.

This use of the USGS data and process, and a more limited and flexible site geo-characterization program, is appropriate for all advanced reactors with sufficient seismic safety, and not just for reactors like RHDRA that would have potential consequences similar to RTRs. Seismic safety in this context could be characterized by one or more features. First, sites with low seismic hazard have lower likelihood of damaging ground motions occurring, especially if designed to a larger ground motion such as the minimum 0.1g PGA of Part 50 Appendix S, thereby reducing the frequency of seismic induced consequence. Second, designs with high seismic robustness have lower likelihood of seismic damage for a given ground motion level, also reducing the frequency of seismic induced consequence. Third, designs with low radiological inventory and/or significant mitigation features have lower dose consequence from seismic induced damage. Safety inherent in advanced reactors with the second and/or third feature can be demonstrated via one or more methods like those afforded to RTRs.

The consideration of potential consequences and accidental offsite doses is an important factor in allowing the use of data from pre-existing sources and typical commercial geo-characterization practice. Use of the SSHAC process and rigorous site response analysis reliant on extensive core borings and other geo-characterization may be appropriate for large LWRs, but it is an unnecessary regulatory burden for advanced reactors to provide reasonable assurance of adequate protection of the public health and safety, and the environment. Large LWRs have significantly larger source terms and require containment structures and emergency planning to ensure adequate protection of public health and safety. In contrast, most advanced reactors are expected to achieve maximum doses during design basis and beyond design basis events at the site boundary under the EPA PAG (e.g., 1 rem or less). Therefore the magnitude and sensitivity of the seismic hazard and soil data to the calculated doses to the public are significantly less than for LLWRs. While RHDRA and micro-reactors are expected to meet similar potential consequences, albeit with site boundaries that are smaller than larger advanced reactors, the differences as it relates to the importance of the geotechnical data are not significant.

The USGS NSHM data and process are readily available and used ubiquitously for establishing design basis ground motions with an annual exceedance frequency of 1E-4 or higher, even for critical infrastructure that have higher risks and potential consequences to the public health, safety, and the environment than many advanced reactors under design. For example, the USGS NSHM underpins the seismic hazard used for all buildings and structures designed to the International Building Code (IBC), including hospitals, first responder infrastructure and other essential facilities, and facilities that manufacture, process, handle, store, use, or dispose of hazardous (toxic, highly toxic, or explosive) substances. This also includes the Unified Facilities Criteria (UFC) that adopts IBC for use in design and construction for the U.S. Department of Defense. The USGS NSHM is also used for design and evaluation of U.S. Army Corps of Engineers facilities such as dams and levees with significant consequence of seismic induced failure, and for transportation infrastructure like bridges and tunnels in accordance with American Association of State Highway and Transportation Officials (AASHTO) design specifications.

As described above, it is justifiable to perform rapid and confirmatory comparison of site-specific geo-characterization, including seismic considerations, to a site parameter envelope used for design, without requiring detailed site-specific analysis. The USGS NSHM tool is capable of defining seismic ground motions, and its site classification approach can capture site effects on ground motions. Such an approach should be adapted for use by all advanced reactors with sufficient seismic safety, including RHDRA.

RTR Guidance

For RHDRA and other advanced reactors with similar potential consequences, the use of site geo-characterization for research and test reactors, including seismic hazards, such as described in NUREG-1537 could be used as an alternative to the more extensive guidance of RG 1.132 and RG 1.208. This approach would provide flexibility to incorporate limited seismic-induced dose consequences to specific site conditions and inherent reactor design features into the site geo-characterization criteria. However, the limited level of specificity leaves room for applicant and regulatory reviewer interpretation that diminishes confidence in its ability to support the business model with clearly defined confirmatory site geo-characterization steps.

3.1 Changes Needed to Regulations, Policy and Guidance

The proposed approach appears to be compliant with existing NRC requirements and would require minimal rulemaking. However, because the NRC guidance in this area is overly prescriptive and does not provide a graded approach appropriate for advanced reactors, either the existing guidance should be revised or new guidance to support site geo-characterization including seismic hazard for advanced reactors should be developed. The guidance should permit the use of the pre-existing USGS NSHM similar to other critical infrastructure and essential facilities, including its site classification approach that relies on relatively limited site geo-characterization data available from other government or commercial sources. The guidance should also establish a process for applicants to demonstrate the sufficiency of a design based on a site parameter envelope without requiring separate detailed site-specific analysis.

10 CFR 100

No changes identified. However, use of the words “suitable,” “appropriate,” and “pertinent” in 10 CFR 100.23 underscore the importance of establishing regulatory guidance that reduces applicant risk in the use of professional judgement to define site investigations for evaluating geologic and seismic siting criteria. Changes may be necessary in Part 100 for RHDRA or other advanced reactors with potential consequences on the order of RTRs if the NRC determines that they should have similar requirements (e.g., the applicability of Subpart A instead of Subpart B, exclusion of the Part 50 Appendix S requirements, or a new alternative set of requirements).

10 CFR 50 Appendix S

The definition of SSCs required to withstand the effects of the SSE or ground surface deformation should be revised to reflect a technology-neutral position with flexibility in defining required safety functions, and allow limiting these SSCs to those that are relied upon in the response during, and immediately following, an SSE.

10 CFR Part 53

The draft proposed Part 53 rulemaking incorporated some of the proposed approaches but may need additional enhancements as it progresses through the rulemaking process. 10 CFR 53.4733 provides

Appendix 11 – Geologic and Geotechnical

alternatives to the Appendix S seismic design criteria. This provides some flexibility by allowing different Design Basis Ground Motions (DBGM) informed by the Principal Design Criteria instead of requiring all Safety Related SSCs to withstand the SSE. However, the presumption for site characterization in line with RG 1.208 and RG 1.132 remains.

The following specific changes to existing guidance are identified to provide more details about the positions that are needed in guidance:

RG 1.208 and RG 1.132

RG 1.208 should be updated to include an alternative definition of GMRS with a different seismic target performance goal depending on the consequence of seismic failure. Where a higher seismic target performance goal than currently in RG 1.208 is justified based on plant safety and/or consequence, the alternative guidance should also permit alternative seismic hazard analysis implementation that enables reliance on the NSHM developed and published by USGS. The NSHM was developed for building codes concerned with AEF of 1E-4 and above. As described in ASCE/SEI 43-19, and using the same two capacity performance goals as currently in RG 1.208, an analogue to GMRS consistent with seismic target performance goal of 1E-4 per year could be calculated based on an interpolation of 1E-3 and 1E-4 AEF UHRS, which is within the return periods of primary consideration in the NSHM.

RG 1.208 should also be updated to allow investigations for site geo-characterization that parallel best practices used routinely for other critical facilities where the NSHM is justified for use in development of the design basis ground motions. In these cases, the extent of investigations described in detailed guidance in Appendix C of RG 1.208 may not be warranted. Rather, the types of site geo-characterization such as is required to comply with the International Building Code may be adequate to demonstrate the applicability of the NSHM for use at a given site and support the necessary engineering design of the facility. This includes the site classification approach embodied in the NSHM to capture local site effects on seismic response spectra.

Updates or alternatives to RG 1.208 would require an update or alternatives to RG 1.132, owing to the close interrelationship of RG 1.208 and RG 1.132.

RG 1.132 should be updated to reflect the proposed alternative to RG 1.208 described above, namely leveraging commercial best practices for geotechnical investigations and use of the NSHM for providing seismic hazard, while retaining the flexibility to tailor the investigation considering the specific site conditions and foundation requirements of the safety-related structures. This is particularly true related to Section 4, “Detailed Site Investigations.”

Additionally, RG 1.132 should be updated to remove prescriptive requirements in favor of additional flexibility to accommodate the potential for rapid high-volume deployable reactors that may be inherently insensitive to certain postulated subsurface performance characteristics that a detailed site investigation seeks to characterize for subsequent engineering analysis. For example, use of a single geophysics test method may be adequate to demonstrate that a site shear wave velocity profile falls comfortably within the site classifications considered in a reactor design site parameter envelope without requiring multiple geophysics methods to characterize uncertainty. Where requirements of RG 1.132 are tailored to quantifying or reducing uncertainty associated with subsurface conditions, an alternative should be provided that allows adequately conservative interpretation of less information accounting for that uncertainty as opposed to requiring collection of more information.

RG 1.138

No specific changes identified. However, supplemental guidance may be warranted depending on the type of soil and rock laboratory investigations that are identified to be most applicable to the site suitability confirmation of deployable reactors analogous to updates in RG 1.132 described above.

RG 1.100

No specific changes identified. However, clarifications to the seismic qualification methods and standards included in RG 1.100 may be beneficial regarding seismic equipment demands and RRS compatible with the SSE as defined according to the alternative regulatory approach described herein such as noted updates to RG 1.208.

DG 1410

DG 1410 (future RG 1.251) should be updated for applicability to Part 50 and 52 applications and issued for use to provide options for NPP applicants using risk-informed and performance-based bases for defining appropriate seismic performance targets of SSCs and corresponding design basis ground motions accounting for varying seismic dose consequence of NPP technologies. NEI acknowledges that use of DG 1410 on an SSC-specific basis may require exemptions to certain elements of 10 CFR 50 Appendix S. However, no such exemption would be required for its use in defining a seismic safety basis for RDRHA justifying a plant-level SSE definition at a shorter return period than currently implied by RG 1.208.

DG 1370

DG 1370 (future RG 1.252) should be updated to reflect pending regulatory review of SC-SND8932-001, “Guidelines for Implementing Seismic Base Isolation in Advanced Nuclear Reactors,” which provides more recent and comprehensive methodology guidance than contained in the sources referenced in current DG 1370. Pending update, DG 1370 should be issued for use by Part 50 and Part 52 applicants. Issuing DG 1370 for use provides applicant confidence in the use of seismic isolation technology for NPPs to filter design basis ground motions to a pre-determined vibration frequency, which is one seismic design strategy that could be employed to support site-independent design.

3.2 Acceptance Criteria and Licensing Approach

Acceptance Criteria

Advanced reactor designs with an EPZ at the site boundary would be permitted to use a graded approach for defining the site seismic ground motion that leverages the use of the USGS NSHM and corresponding commercial practices to support site geo-characterization necessary for seismic site classification (e.g., core borings). NEI guidance under development and NRC review provides more information on assessment of seismic events for EPZ sizing.

Licensing Approach

Any licensing approach can use USGS NSHM data and process, including its embodied site classification methodology. To achieve the deployment timelines of RHDRA for geologic and seismic, the rapid efficient repeatable licensing (ReLic) process should be used to minimize the scope, content and purpose of the site-specific reviews. This type of site-specific review would enable completion of all, or as much as possible, of the safety and environmental reviews and public engagement processes as possible one-time prior to the identification of a specific site. Where the entire site-specific review is not possible before site identification, performing a site license review that only needs to verify that the site characteristics conform to the site parameters in the envelope established in the one-time up-front reviews is recommended.

This would include use of a standardized design that has been approved by the NRC including Standard Design Approval, Design Certification, and Manufacturing License. These offer different levels of NRC approvals in terms of scope of the design and finality in the NRC decision.

NRC approvals on a standardized design will define a site parameter envelope to which an actual site must conform, including subsurface conditions necessary to support suitable foundation performance to potential geologic and geotechnical effects and definition of the SSE. The former allows definition of a site-specific investigation to focus on the potential effects that are meaningful to the performance of plant safety features as reviewed and approved. The latter allows confirmation that the SSE is bounded by what was considered in the design with reliance on geotechnical investigations completed within the schedule constraints of RHDRA. Both aspects support one-time up-front reviews prior to selection of a specific site, in the ML / DCD.

The site license application would use the NSHM and corresponding site classification procedure with pre-existing reliable site data, thereby shortening the time needed to collect site-specific data. Site geo-characterization would be according to the conditions established in the standardized design approved by the NRC to provide regulatory clarity on the scope and acceptability of data. The applicant would then demonstrate that the data for the site is bounded by the site parameter envelope.

4 OTHER OPTIONS FOR RESOLUTION OF THE ISSUE

4.1 AEA Change – Minimal Regulation

The technical and safety bases for power reactors with potential consequences on the order of magnitude of non-power reactors should be sufficient to enable the NRC to adapt the non-power reactor requirements and implementation guidance for those qualifying power reactors. Adaption of the non-power reactor regulatory framework, as discussed in this appendix, should achieve a similar level of regulation that accounts for the safety and operational characteristics of the qualifying power reactors that will tailor requirements and applicability to the technology. An AEA change to direct the NRC to regulate power reactors with potential consequences that are on the same order of magnitude as non-power reactors, e.g., with minimal regulation or under Section 104, is an option that was identified. However, such a change does not appear necessary, since the AEA provides sufficient authority to the NRC to regulate power reactors commensurate with their potential impacts, and is capable within the current AEA provisions to apply regulatory approaches to qualifying power reactors that are similar to those used today for non-power reactors. More discussion on NRC Regulation of Non-Power Reactors is included in Attachment A.

4.2 Unmitigated Consequence Analysis

Use of unmitigated consequence analysis of SSC failures to define seismic design categories and earthquake return periods for design in accordance with dose consequences could be used to specify a seismic target performance goal. This approach would require similar modifications to RG 1.132 and RG 1.208 as described above. However, unmitigated consequence analysis does not fully account for the inherent safety features of the rapid high-volume deployable reactor concepts currently contemplated, and therefore could unnecessarily amplify dose consequences and penalize the seismic design category accordingly. This alternative might then encourage more time-consuming site exploration than is warranted or could be accommodated by the business model.

4.3 Graded SSHAC Process

Use of the Senior Seismic Hazard Analysis Committee (SSHAC) process graded levels (as described in NUREG/CR-6372, NUREG-2117, and NUREG-2213) to define appropriate level of detail in various steps of seismic hazard analysis is a technically viable alternative to the use of the USGS NSHM. This approach would require fewer modifications to RG 1.132 and RG 1.208 than previously described and is more familiar to NRC staff with experience in GMRS development according to RG 1.208. However, even SSHAC Level 1 and Level 2 studies can require considerable resources compared to leveraging the existing NSHM, and could require more time for seismic siting than is supported by the business model. Therefore, this option is not recommended as it is not expected to be able to enable the business model for deployments of 6 months or less.

4.4 International Building Codes

Use of the International Building Code to define a risk-consistent maximum credible earthquake, like in ASCE 7, as basis for an SSE was evaluated. This approach would require more extensive alternatives to RG 1.132 and RG 1.208 than described above but could be achieved within the timeframe supported by the business model. However, the treatment of design ground motion in IBC and ASCE 7 is risk-consistent based on different assumed structure and component functional performance during and following an earthquake than current regulatory approaches for nuclear power reactors. The downstream implications on seismic and structural design were considered too extensive to be preferred over the alternative described above.

5 ACKNOWLEDGEMENTS

NEI Issue Lead: Jon Facemire

Appendix 12 – External Hazards

1 ISSUE INTRODUCTION

Other External Hazards encompass transportation and industrial hazards, volcanic hazards, hydrology and any other hazards potentially threatening the site, many of which today require site-specific analysis.[1]

The desired outcome is a process for characterizing, analyzing, and establishing other external hazards that will enable the deployment of RHDRA within 180 days from site identification to operations, and are adaptable for use by other advanced reactors.

2 BACKGROUND

The purpose of characterizing and evaluating the other external hazards is to ensure that flooding and activities from nearby facilities could not result in events that would lead to potential consequences that could exceed the NRC's dose limits.

10 CFR 100 requires an assessment of nearby industrial, military and transportation hazards. RG 1.91 provides guidance on assessing explosive hazards. EPRI 3002005287, "Identification of External Hazards for Analysis in Probabilistic Risk Assessment," contains guidance on the broader hazards screening process. Volcanic Hazards have specific guidance in RG 4.26. While it may be possible, it is not clear whether the NRC's existing regulatory framework for other external hazards enables a site licensing process of less than five months from site identification to issuance of the license, with all approvals and authorizations to operate the reactor. This is discussed in detail in Appendix 5, "Site License Scope and Purpose."

The current guidance for definition of the design basis flood can be found in RG 1.59 R2. There is a draft Revision 3 in DG-1290 published in 2022. This DG provides methodologies for calculating potential flooding impacts from local intense precipitation, storm surge, seiche, tsunami, ice effects and combined events. The DG provides considerations for advanced reactors (ARs) and small modular reactors (SMRs) but does not appear to have fully considered the technological capabilities or concept of deployment of rapid high-volume deployable reactors. The guidance provides a progressive screening approach which consists of a series of gradually refined methods that increasingly use more detailed site-specific data or analysis methods or both. This gives applicants flexibility in addressing flooding hazards by choosing sites that screen quickly (hilltop away from dams), grading the site appropriate to encourage run-off, or by factoring in design considerations that can withstand significant floods and choosing the design basis flood conservatively. Because the DG has flexibility and does not specify site specific data collection outside of site surveys required to determine site topography and create inundation maps, the flooding considerations in the site licensing of rapid high-volume deployable reactors are likely to enable the applicant to conduct site characterization and application preparation within 30 days and an NRC site license review within 150 days from the application submittal to operating license issuance.

[1] The following external hazards are addressed in other topic papers: Meteorology (scope described in RG 1.23), Seismology, Geology, and Aircraft Impact

Once R3 to RG 1.59 is issued, these guidance documents will likely be able to inform a plant performance envelope and site performance envelope that facilitates rapid deployment of micro-reactors.

Non-power reactors must comply with the same Part 50 requirements related to other external hazards that apply to power reactors. The approach to implementing these requirements for non-power reactors is discussed in NUREG-1537, Section 2.2 for industrial, transportation and military facilities, and Section 2.4 hydrology. For hydrology, the guidance specifies the following site characterization: *the possible hydrologic events, their causes, historic and predicted frequencies, and the water table should be located, and the potential for radioactive contamination of ground and surface waters should be discussed.* For Section 2.2, the guidance requires the following site characterization: *location and separation distances from existing and planned industrial, military, and transportation facilities and routes, including air, ground, and water traffic, pipelines, and fixed manufacturing; processing, and storage facilities.*

3 PROPOSED SOLUTION AND APPROACH

The current approach to characterizing and analyzing other external hazards seems feasible for all advanced reactors. This approach uses pre-existing data and simple supplemental surveys to collect the data needed to characterize the other external hazards. It appears that the NRC's process may currently enable the external hazards and flooding assessments to be performed within a month from site identification, i.e., during the development of the license application. However, it is not clear whether the NRC would be able to review and approve these assessments within two months in order to enable the RHDRA business model.

3.1 Changes Needed to Regulations, Policy and Guidance

The regulations are flexible, and Appendix K of DG-1290 once approved as RG 1.59 R3, provides flexible high-level guidance for applicants. Future revisions could endorse a methodology that meets RHDRA goals for increased regulatory certainty.

The NRC will need to clarify that its existing regulatory approach for other external hazards currently enables (or a regulatory framework is established that would enable) other external hazards to be addressed generically outside of a site specific license (i.e., through a one-time up-front review in a generic technology-inclusive approval, or an approval of a standardized design). This regulatory approach would enable the site license application to solely focus on verification of the site's conformance to the site parameter envelope (established during design approval) for other external hazards and not requiring any additional analysis or result in new or additional considerations in the site license application. Similarly, the NRC will need to clarify (e.g., in RG 1.59 Revision 3) that site specific data collection, outside of site surveys, is not required to determine site topography and create inundation maps, such that the flooding considerations in the site licensing of rapid high-volume deployable reactors enables the applicant to conduct site characterization and application preparation within 30 days. Appendix K of DG-1290 provides appreciated flexibility and future revisions could endorse a methodology for increased regulatory certainty. The process would allow site characterization (including the collection of any necessary locally sampled data) to occur within 30 days from the site identification to application submittal. NRC acceptance review, verification of conformance to the site parameter envelope, public engagement, final Commission approval, and could be completed within 150 days.

3.2 Acceptance Criteria and Licensing Approach

Acceptance Criteria

There are no acceptance criteria; the current approach for other external hazards can be used by any advanced reactor.

Licensing Approach

Any licensing approach can use the current approach for other external hazards.

To achieve the deployment timelines of RHDRA for other external hazards, the rapid efficient repeatable licensing (ReLic) process should be used to minimize the scope, content and purpose of the site-specific reviews. This type of site-specific review would enable completion of all, or as much as possible, of the safety and environmental reviews and public engagement processes as possible one-time prior to the identification of a specific site. Where the entire site-specific review is not possible before site identification, performing a site license review that only needs to verify that the site characteristics conform to the minimum set of site parameters in the envelope established in the one-time up-front reviews is recommended.

This would include use of a standardized design that has been approved by the NRC including Standard Design Approval, Design Certification, and Manufacturing License. COLs referencing identical designs can make use of Part 50 Appendix N and Part 52 Appendix N to facilitate site license reviews. These offer different levels of NRC approvals in terms of scope of the design and finality in the NRC decision. It is expected that the NRC review relative to analyses and design bases supported by characterization of other external hazards, would be performed during the design approval, and would establish a site parameter envelope for the data to be determined for each specific site.

The site license application would then demonstrate that the data for the site is bounded by the site parameter envelope. For more details, see Appendix 5, “Site License Scope and Purpose.” The guidance for “Other External Hazards” discussed in this report should not preclude site characterization within 1 month.

4 OTHER OPTIONS FOR RESOLUTION OF THE ISSUE

4.1 AEA Change - Minimal Regulation

The technical and safety bases for power reactors with potential consequences on the order of magnitude of non-power reactors should be sufficient to enable the NRC to adapt the non-power reactor requirements and implementation guidance for those qualifying power reactors. Adaption of the non-power reactor regulatory framework, as discussed in this appendix, should achieve a similar level of regulation that accounts for the safety and operational characteristics of the qualifying power reactors that will tailor requirements and applicability to the technology. An AEA change to direct the NRC to regulate power reactors with potential consequences that are on the same order of magnitude as non-power reactors, e.g., with minimal regulation or under Section 104, is an option that was identified.

However, such a change does not appear necessary, since the AEA provides sufficient authority to the NRC to regulate power reactors commensurate with their potential impacts, and is capable within the current AEA provisions to apply regulatory approaches to qualifying power reactors that are similar to those used today for non-power reactors. More discussion on NRC Regulation of Non-Power Reactors is included in Attachment A.

4.2 Maximum Hypothetical Accident

Applicants could analyze a hypothetical maximum accident (or a small set of bounding accidents) such that the application does not have to consider all external hazards explicitly. This approach would provide reasonable assurance of adequate protection of public health and safety even under extreme circumstances postulated under extreme hazard conditions. Reactors with potential dose consequences small enough to never threaten public health and safety should be exempt from Part 100 requirements.

5 ACKNOWLEDGEMENTS

NEI Issue Lead: Jon Facemire

Appendix 13 – Fire Brigade Staffing

1 ISSUE INTRODUCTION

This topic addresses the minimum fire brigade staffing requirements to support the RHDRA business model. Traditionally, a five-person fire brigade is required to be onsite to support the fire protection plan. Given that RHDRA designs are expected to incorporate safety features that allow them to deploy with limited, intermittent, or no on-site staff, the existing guidance exceeds the threshold of reasonable assurance of adequate protection for public health, safety, and environment. Refer to Appendices 14, 15, 16, and 17 for more information regarding the intended concepts of operation and staffing. The desired outcome is for the NRC to permit, when justified by the design features, fire brigade sizes fewer than five people per shift, with options for designs to achieve fire brigade size of one person per shift, and for designs to achieve no on-site staff (i.e., no on-site fire brigade).

2 BACKGROUND

Fire is a hazard that all advanced reactors must consider. A fire protection plan describing fire prevention/mitigation design features, manual suppression capabilities (e.g., fire brigade), programmatic elements, and reduction of fire sources is part of a nuclear power plant's defense-in-depth strategy. The advantage of a fire brigade is their flexibility to respond to various situations and locations. However, with advancements in technology, there are also advantages to using automatic fire fighting capabilities since they can perform reliably, respond more quickly and do not put lives at risk when they are fighting fires.

In November 1977, the NRC provided licenses with proposed interim Technical Specification that included a five-person fire brigade. This position led to the creation of 10 CFR 50, Appendix R, which provides requirements for establishing a Fire Protection Program. The NRC also issued an Evaluation of Minimum Fire Brigade Shift Size white paper on June 8, 1979. This white paper concluded:

- Control and extinguishment of potentials fires varies greatly in different areas of a given plant
- Specific actions of a fire brigade cannot be precisely defined
- Plant areas important to safety should consider a certain set of fire-fighting actions
- Some margin should be provided in the fire brigade size to account for unanticipated events
- Minimum fire brigade size should consider defense-in-depth and general design criteria aimed at minimizing the adverse effects of fires.

10 CFR 50.48(a) requires applicants to have a fire protection plan that satisfies 10 CFR 50, Appendix A General Design Criterion 3 and features necessary to implement that fire protection plan. Advanced reactor applicants will establish Principal Design Criteria (PDCs) associated with their design. Advanced reactor applicants will likely include a PDC similar to GDC 3, consistent with the guidance in RG 1.232.

Appendix 13 – Fire Brigade Staffing

10 CFR 50.48(b) requires compliance with Appendix R for Nuclear Power Plants (NPPs) licensed to operate before January 1, 1979. Regulatory Guide 1.189 provides regulatory guidance for fire protection plans intended to meet 10 CFR 50.48(b). This regulatory guide states:

> *"The minimum number of trained fire brigade members available on site for each operating shift should be consistent with the activities required to combat credible and challenging fires but should be no fewer than five members. The size of the fire brigade should be based on the functions required to fight fires, with adequate allowance for injuries. Fire brigade staffing should account for all operational and emergency response demands on shift personnel in the event of a significant fire."*

This excerpt from Regulatory Guide 1.189 provides the prescriptive guidance for an onsite brigade of "no fewer than five members" to comply with 10 CFR 50.48(b).

10 CFR 50.48(c) provides an alternative for the development of fire protection plans that comply with NFPA 805; however, this regulation does not require NFPA 805 compliance. Regulatory Guide 1.205 endorses NEI 04-02, which provides guidance on establishing a fire protection plan compliant with NFPA 805. NFPA 805 states:

> *"A fully staffed, trained, and equipped fire-fighting force shall be available at all times to control and extinguish all fires on site. This force shall have a minimum complement of five persons on duty[…]."*

As shown, NFPA 805 provides the prescriptive guidance for an onsite brigade of "no fewer than five members" to comply with 10 CFR 50.48(c).

DANU-ISG-2022-09 provides guidance to NRC staff reviewing fire protection programs that use risk-informed, performance-based licensing approaches. DANU-ISG-2022-09 states:

> *"This ISG provides one acceptable approach to meeting regulatory requirements and was developed from guidance for large LWRs, including measures such as fire brigades to provide timely manual fire suppression responses. Applicants considering fire protection programs that do not rely on these measures (for example, an onsite fire brigade) should demonstrate their ability to safely shut down the facility and minimize radioactive releases to the environment in the event of a fire without the excluded measures. The NRC staff encourages preapplication discussions for facilities that primarily rely on offsite fire response."*

This excerpt indicates that measures traditionally relied upon in fire protection programs, such as an onsite fire brigade, are not required so long as the applicant demonstrates their ability to safely shut down the facility and minimize radioactive relates to the environment.

RHDRA applicants are only required to comply with 10 CFR 50.48(a), which requires a fire protection plan and the features necessary to implement that fire protection plan. 10 CFR 50.48(b) and (c) are not required for RHDRA applicants unless the applicant elects to include either of these within their licensing basis. No exemption requests are necessary to reduce the size of the fire brigade to fewer than five persons; however, the applicant should be prepared to provide justification for their fire brigade size to support their fire protection plan considering previous NRC staff positions. Alignment on the expected content and acceptance criteria for this justification between the industry and NRC staff would provide regulatory confidence to RHDRA applicants.

In the draft proposed Part 53 rule, similar approaches are described that allow for deterministic approaches similar to Appendix R to Part 50 and risk-informed approaches similar to NFPA 805. Part 53 does not specifically address the presence, responsibility, or size of a fire brigade. However, the rulemaking is not yet complete.

3 PROPOSED SOLUTION AND APPROACH

The proposed approach is to develop a process to determine:

1. the need for onsite fire response, based upon radionuclide inventory, inherent safety features, and credible events resulting in unacceptable losses,
    a. If no onsite fire response is required, Step 2 may be skipped. For RHDRA applicants, it is expected that no onsite fire response will be required.
2. the need for an onsite incipient fire brigade,
3. the adequacy of offsite fire response organizations.

Regardless of the outcome of the fire response evaluation, fire protection defense-in-depth must be maintained. This analysis will provide justification for each reactor applicant’s fire brigade onsite presence and size. For RHDRA applicants, this analysis will be required to support the staffing model described in Appendix 14 (i.e., one onsite operator or no onsite staff).

NEI is developing a technical report to provide advanced reactor applicants guidance on performing a fire brigade staff analysis. The proposed approach in the NEI guidance will need to be found acceptable by NRC staff.

3.1 Changes Needed to Regulations, Policy and Guidance

There are no changes to 10 CFR 50.48 required to support this topic. However, improvements in regulatory guidance will provide regulatory confidence. DANU-ISG-2022-09 already sets an expectation for NRC staff that advanced reactors may not need to rely on onsite fire brigades; however, no criteria are provided in the ISG to promote consistent justification. Acceptance of the forthcoming NEI technical report providing a fire brigade staffing analysis would provide RHDRA applicants with regulatory confidence in the development of their fire protection plans and allow for consistent and timely reviews.

3.2 Acceptance Criteria and Licensing Approach

General Acceptance Criteria:

Applicants will provide adequate justification in their Fire Protection Programs. If the applicant determines that no on-site brigade is required, the justification should be based on the following criteria:

- Radionuclide inventory significantly lower than large LWRs
- Fail-safe, long term passive cooling
- No credible event that could result in unacceptable off-site doses

Licensing Approach:

Any licensing approach permits flexibility in determining the size of the fire brigade. To achieve the deployment timelines of RHDRA, the rapid efficient licensing for rapid high-volume deployment process should be used to minimize the scope, content and purpose of the site-specific reviews. This type of site-specific review would enable completion of most, if not all, of the safety and environmental reviews and public engagement processes one-time prior to the identification of a specific site. Where the entire site-specific review is not possible before site identification, performing a site license review that only needs to verify that the site characteristics conform to the minimum set of site parameters in the envelope established in the one-time up-front reviews must be established.

This would include use of a standardized design that has been approved by the NRC. Such approval processes include Standard Design Approval, Design Certification, and Manufacturing License. OL applications and COLs referencing identical designs can make use of Part 50 Appendix N and Part 52 Appendix N to facilitate site license reviews. These offer different levels of NRC approvals in terms of scope of the design and finality of the NRC's decision. It is expected that the NRC's review of the fire protection plan would be performed during the design approval and would likely include a template plan for operator staffing and responsibilities, as applicable, for the licensee's operational program.

NRC pre-approval of a licensee's operational programs (e.g., using of a topical report) could also be used for the fire protection plan. Applicant submittal of non-site-specific information to the NRC for early review and approval can significantly reduce the scope of the NRC's site-specific license review.

4 OTHER OPTIONS FOR RESOLUTION OF THE ISSUE

No other solutions are considered.

5 ACKNOWLEDGEMENTS

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Appendix 14 – Operator On-Site Staffing

1 ISSUE INTRODUCTION

The design of the nuclear power plant (NPP), including both inherent safety features and active systems, structures and components (SSCs), will govern what design functions need to be executed and/or monitored during normal, off-normal and accident conditions. Based on the design of the plant and concept of operation, the Human Factors Engineering (HFE) analysis (including Functional Requirements Analysis, Function Allocation and Task Analysis) will inform the role of a human operator, if any, and required human-system interface design attributes. The following concepts of operation are potential options being considered to support the rapid high-volume deployable reactors for remote applications (RHDRA) business model:

1. Option 1 (Onsite Operation, Optional Remote Monitoring): Automatic operation with some operator actions needed. Operator actions will be performed onsite by as few as a single person with collateral duties without the need for continuous monitoring of the controls. The NPP may be monitored at a remote facility, if desired.

2. Option 2 (Remote Operation): Automatic operation with some operator actions needed. Operator actions and monitoring will be performed remotely with no on-site operator.

3. Option 3 (Autonomous Operation): Fully autonomous operation with no operator actions needed. Remote facility providing high-level oversight.

   Note – Option 3 is not needed to achieve the RHDRA business model. This concept of operation is included because it would greatly improve the business model. Additionally, Option 3 may be necessary to achieve other business models.

This topic paper will focus on regulatory challenges and recommended solutions to assure Option 1 site staffing supports RHDRA business models, focusing on the use of design features and use of automatic operations. The alternative regulatory approach recommended in this paper provides the most efficient, consistent and use of some of the work already started by the NRC under draft part 53 regulation that needs additional clarification.

The technological capabilities and concept of operations for RHDRAs create opportunities for operations staffing that are not enabled by the current NRC regulatory framework. NRC's current regulations and implementing guidance are generally prescriptive, and do not allow use of technology-inclusive, performance-based and risk-informed approaches to address the following elements for operations staffing:

- The types of plant staff roles,
- The number of staff required to fill those roles,
- Training and qualifications for the roles (including whether accreditation is necessary), and
- The criteria by which those roles perform operational functions.

Appendix 14 – Operator On-Site Staffing

Examples of operational roles prescribed by regulation include licensed operators and shift technical advisors (STA). The staff performing these roles perform many functions, including normal surveillance and reactivity manipulations. The use of automatic/autonomous operations, remote monitoring and remote operations (see appendices 15, 16, and 17) will modify the roles and functions of such staff for the type of reactor deployment described in this appendix.

The NRC also requires on-site staffing for other functions such as physical security, emergency preparedness, fire protection, and radiation protection, and indirectly for access authorization and fitness for duty. Those functions will be covered separately (see appendices 19, 20, 21, and 22).

Operations staffing requirements are currently defined in 10 CFR 50.54(m) and guidance is provided in NUREG-0737. Training requirements are defined in 10 CFR 50.120. These regulations and guidance drive the definition and implementation of operations staffing. New reactor designs have not been factored into existing regulations, and therefore exemptions are required to implement the range of proposed concepts of operations for RHDRAs. Thus, the concept of operations for RHDRAs requires a new alternative NRC regulatory approach, including requirements, guidance, and possibly Commission direction on new policy issues.

The desired outcome is that the NRC establishes an alternative regulatory approach for staffing that is commensurate with the technology capabilities and concept of operations for RHDRA and other advanced reactors. The alternative regulatory framework would address how:

- the basis for staffing is established and sustained,
- staffing analyses and supporting technical bases are developed, and
- training and qualification standards are set and maintained.

For RHDRA and other advanced reactors with risk profiles like non-power reactors, the alternative regulatory framework should be based upon the current regulatory framework utilized for research and test reactors (RTRs). The alternative regulatory framework should also consider incorporating automatic operations, remote monitoring and operations, and the potential to leverage staff from co-located facilities.

2 BACKGROUND

Given the expected variety of technology and use case combinations, the concept of operations is key to defining the ability to address normal, off-normal and accident conditions and establishing staff size, level of training for operators, and shift complement needed to provide reasonable assurance of adequate protection of public health and safety. For RHDRA, there are two general concepts of operations, both of which are enabled using automatic and/or autonomous operations features (Appendix 15). These concepts include the use of inherent (or passive) safety features and digital systems:

1. One Operations staff on-site at any time (with collateral duties), potentially enabled with Remote Monitoring (Appendix 16), and

Appendix 14 – Operator On-Site Staffing

2. Remote Operations staff with no permanent on-site personnel. Field technicians visit the site periodically (Appendix 17).

The Atomic Energy Act (Sections 11 and 107) contains definitions and requirements for operators at nuclear power plants. The regulations in 10 CFR 50.54 contain license conditions that are generally applicable to nuclear power reactor operating and combined license holders. Specifically, 10 CFR 50.54(i) through (m) contain requirements related to licensed operators: reactor operators (ROs) and senior reactor operators (SROs). Those regulations provide the following:

- Require the licensing of ROs and SROs
- Allow for the manipulation of reactor controls only by ROs or SROs
- Require a RO or SRO to be present at the reactor controls at all times, and in the control room
- State that an SRO shall be present at the facility or readily available on call at all times during its operation
- Require training and requalification of ROs and SROs
- Specify the minimum number of ROs and SROs for each shift
- Require an operator to be present at the facility or on call at all times during operations, and at the facility during reactor startup

In addition, 10 CFR Part 55 contains requirements for the licensing of ROs and SROs, and NUREG-1021 contains guidance on Operator License Examination Standards for Power Reactors. For example, 10 CFR 55.46 requires the construction and use of simulation facilities to train licensed operators. Post-Three Mile Island (TMI) requirements under 10 CFR 50.34(f)(2) also provide main control room and simulator requirements.

Therefore, key regulations to understand and create necessary exemptions for RHDRA and other advanced reactors include 10 CFR 50.54(m), 50.120, 50.54(i-l), and 10 CFR Part 55.

NUREG-0800, Section 13.1.2 – 13.1.3, "Operating Organization," is the standard review plan (SRP) that the NRC established to evaluate adequacy of operations staffing for power reactors. In addition, DANU-ISG-2022-05, *Advanced Reactor Content of Application Project Chapter 11, "Organization and Human-System Considerations," Interim Staff Guidance March 2024,* provides both applicant content of application and NRC staff rev iew guidance for the portion of a non-LWR application associated with an applicant's organization and human system interface considerations. Exemptions for operations staffing will be reviewed by the staff using NUREG-1791, "Guidance for Assessing Exemption Requests from the Nuclear Power Plant Licensed Operator Staffing Requirements Specified in 10 CFR 50.54(m)." This document identifies the key elements needed for a successful exemption from applicable portions of 10CFR 50.54(m). Draft document DRO-ISG-2023-03, "Development of Scalable Human Factors Engineering Review Plans Draft Interim Staff Guidance," can also be used.

In Information SECY-11-0098, "Operator Staffing for Small or Multi-Module Nuclear Power Plant Facilities" (July 22, 2011), the NRC acknowledged that "[t]he number of licensed operating personnel

Appendix 14 – Operator On-Site Staffing

that the rule prescribes are based on assumptions and operating experience from the operation of large light-water reactors"[1] (LWRs) and that those assumptions may not be appropriate for small module reactors (SMRs). As a result, the NRC staff stated that it:

> ...expects to use a two-step approach to address operator staffing requirements for SMRs. In the near-term, applicants can request exemptions to the current operator staffing requirements in 10 CFR 50.54(m) and the staff will review the request using existing or modified guidance. Once experience is gained, the staff would initiate the long-term solution which is to revise the regulations to provide specific control room staffing requirements for SMRs.

Although NUREG-1791 applies to requests for exemptions from the staffing requirements in 10 CFR 50.54(m), Sections 1.3 and 1.4 of NUREG-1791 also recognize that other provisions in Section 10 CFR 50.54 and Part 55 might be impacted, and it provides a useful model for requesting exemptions from those provisions. Additionally, NUREG-0800, SRP Chapter 18 and NUREG-0711 contain a Human Factors Engineering Program Review Model suitable for supporting an exemption request. It should be noted that DANU-ISG-2022-05 and DRO-ISG-2023-03 also provide relevant guidance, and that NUREG-1791 and NUREG-0711 were never designed to reduce the number of onsite licensed operators to zero.

For design certifications (DC), the NRC staff has identified two possible mechanisms for deviating from the operator staffing requirements in 10 CFR 50.54(m).[2] First, the DC applicant could justify different operator staffing levels and specify staffing levels in Tier 1 of the design certification. Alternatively, the DC applicant could provide the technical basis for different operator staffing levels in Tier 2, which could then be used by an applicant for a reactor license to request an exemption from Part 50.54(m).

The NRC position is that reliance on exemptions is appropriate when such exemptions are expected to be infrequently used for specialized cases. However, reliance on exemptions is not a desired process when it is expected that those exemptions will be routine and extensive in nearly all applications. This is the case for RHDRA and other advanced reactors, where the current requirements are overly prescriptive, were developed to suit large LWRs and business models associated with these reactor types, and are not commensurate with the enabling features of new technologies and concepts of operations. Furthermore, the NRC has the information necessary today to establish an alternative technology-inclusive, performance-based and risk-informed rule for operator staffing. This is evidenced by the NRC's proposed Part 53 rulemaking that attempts to achieve this outcome.

In the most recent version of the Part 53 proposed rule,[3] the NRC proposes several alternative approaches to operator staffing. These include proposing to adapt the requirements of 10 CFR 50.54(x) and (y) to permit specific individuals to authorize departures from facility license conditions or technical specifications when emergency conditions warrant doing so for the protection of the public health and safety. Recognizing that certain facilities licensed under Part 53 may be staffed by Generally Licensed Reactor Operators (GLROs) in lieu of specifically licensed senior operators, the NRC proposes to extend this authority to GLROs. Specifically, the NRC proposes to establish a new class of facility (defined as a "self-reliant-mitigation facility") and the criteria for classification of such a commercial nuclear plant.

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[1] SECY-11-0098: Operator Staffing for Small or Multi-Module Nuclear Power Plant Facilities

[2] Frank Akstulewicz to Thomas Bergman, NuScale Control Room Configuration and Staffing Levels, January 14, 2016. NRC ADAMS Accession Number ML15302A516

[3] SECY-23-0021: Proposed Rule: Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors, March 6, 2024. ML21162A093

Appendix 14 – Operator On-Site Staffing

These facilities would employ GLROs rather than specifically licensed operators and senior operators. In contrast, those commercial nuclear plants not meeting those criteria would instead be considered "interaction-dependent-mitigation facilities" and would require staffing by specifically licensed operators and senior operators.

However, the draft proposed Part 53 regulations do not fully address the needs of RHDRA and other similar advanced reactors that will be factory-fabricated and have the same design from site to site. Such reactors also are expected to be more like RTRs than other power reactors in terms of their operational simplicity and low potential radiological health and safety consequences. The draft proposed Part 53 does not fully address the operation staffing that would be appropriate for reactors that make extensive use of automatic/autonomous features, and remote monitoring and operations.

Guidance for operations staffing for RTRs is in Section 12 of NUREG-1537. Although the requirements in Part 50 for operator staffing for RTRs are largely the same as for power reactors, the implementation guidance for RTRs is much more flexible and appropriate for RHDRA and other similar advanced reactors.

3 PROPOSED SOLUTION AND APPROACH

The proposed solution is an alternative regulatory approach for RHDRA and other similar advanced reactors with operational simplicity and low potential consequences, as compared to large LWRs upon which the current regulatory framework is based. The alternative regulatory approach should:

1. Be technology-inclusive, performance-based and risk-informed so that it may be applicable to all advanced reactors and can be adapted for a wide range of technologies and concepts of operations,
2. Permit concepts of operations that include: 1) one individual on-site at any time, and 2) potentially no on-site staff with remote operations staff and field technicians that visit the site periodically,
3. Explicitly address the use of automatic and autonomous operations, and remote monitoring and operations to reduce to the maximum extent practicable the reliance on on-site operations staffing,
4. Consider the use of individuals from co-located facilities to provide defense-in-depth that enables the reduction or elimination of NRC required staffing,
5. Ensure staffing requirements for operators, fire response, emergency preparedness, physical security, radiation protection, access authorization/fitness for duty, and other NRC required staffing are compatible in addressing the range of technologies and concepts of operations, and
6. Be based upon, as appropriate, the regulatory approach for non-power reactors.

For these reactors that significantly reduce or eliminate the need for human actions under normal, off-normal and accident conditions, the NRC requirements for human operators should be commensurate with the role of the human operator in protecting the public health and safety. These reduced needs for human actions will be different for each design but are expected to come from a combination of

Appendix 14 – Operator On-Site Staffing

inherent or passive features, and the use of automatic/autonomous controls. The alternative regulatory approach for operator staffing should be performance-based and graded according to the degree in which these features are incorporated, and the residual role that human operators would retain to meet NRC requirements for protecting the public health and safety. For designs where human actions have a minimal or no role in protecting public health and safety, it is expected the NRC would impose minimal or no requirements for human operators.

The alternative regulatory approach for operator staffing will need to address the following key elements: 1) what functions and actions, that are not performed by automatic or autonomous features, must be performed by a human operator in order to protect the public health and safety, 2) where must the controls for human action be located and whether they can be accessed remotely either at an off-site centralized operations center or on-site with the use of near-field portable communication devices, 3) of those required human actions, what is the response time for the human action that would allow them to be away from the controls, and 4) what collateral duties would the human operator be able to handle while still being able to take the required actions to operate the reactor.

The objective should be to address staffing requirements based on specific design and safety case bases; these requirements include multiple reactors operated by the same operator, an alternative to the traditional control room, shared roles, and on-site operators.

This approach will require the applicant to perform an evaluation considering the specific design whether operator actions are needed to protect public health and safety. The following provides a graded approach to apply requirements based upon the role that human operators would serve in protecting the public health and safety:

- For applicants that demonstrate that no operator actions are needed to protect public health and safety,[4] no requirements related to reactor controls or operators should be imposed. In such a case, the requirements in 10 CFR 50.54 for the number of licensed operators on shift and for continuous presence of licensed operators in the control room, training and requalification programs, and simulators may not be warranted. It is noted that even if a design does not require any NRC licensed operators, the plant will likely still have at least one individual that is knowledgeable about the control system and would be able to manipulate the operator controls, either locally or remotely as a measure of defense-in-depth. The NRC should also provide opportunities to expand the acceptable use of technology and/or non-licensed personnel to fulfill requirements related to Technical Specifications.

- If the evaluation concludes that one or more operator actions are needed to protect the public health and safety, either full time or only for certain reactor operations or conditions, then the alternative requirements should be in performance-based terms to provide predictability and flexibility; address the number of operators; determine the need and duration for presence at the controls, training, accreditation, requalification; and establish simulator requirements. The evaluation should consider whether having one or more licensed operators not at the controls,

[4] This subject has received some coverage in early Licensing Modernization Project (LMP)-based applications of the non-LWR PRA standard, which decomposes actions according to risk and safety-significance, their bearing on the plant's defense-in-depth profile, and other regulatory-influenced functional requirements of plant staffing. Resolution of this subject may involve further guidance on how such a determination is made and the standards it will be based upon.

but available within a certain period of time to be at the controls, would be sufficient to protect public health and safety.

- The evaluation should also address a scenario with multiple reactors located on a site, including the acceptability of a small team of operators capable of operating a large number of reactors. The NRC approved the NuScale concept of operations of up to twelve reactors from the same on-site control room and with 6 operators per 12 reactors. However, for some advanced reactor deployments, it is conceivable that there could be 10s of reactors at one site, and that there could be only a few operators per 100 reactors located at a remote operations facility.

- Due to advances in technology and decreased complexity of design, a traditional control room may not be necessary. For advanced reactors that demonstrate reactor safety can be maintained without the need for operator action within a certain response time, and if an individual is unable to compromise the safety of the reactor through the manipulations of the controls, then there would be no need for requirements relating to the control room or for an operator-initiated shutdown. Technology could also permit the operator to carry the controls of the reactor with them on a portable wireless communications device. Therefore, requirements for control rooms may not be applicable to certain advanced reactors. The use of portable monitoring devices may also allow responsible personnel to monitor plant parameters and maintain operational control from either outside the control room or offsite during normal operations. Finally, to the extent that the need for licensed operators at certain advanced reactors is significantly less than for large LWRs, it is likely that their training, accreditation and requalification could be substantially different (and less extensive) than that contemplated in Part 55 and NUREG-1021.

Specific areas recommended for consideration in NRC development of this alternative approach include the following:

- The concept of a Generally Licensed Reactor Operator (GLRO) presented in draft Part 53 rule should also be part of this rulemaking process for advanced reactors that can demonstrate they are self-mitigating facilities and will not need to have traditionally licensed reactor operators. To support high-volume rapid deployment, a license could be issued to a facility, or series of facilities, for which the operating organization or company maintains and implements a qualification program for onsite staff and/or remote facilities staffing requirements. Future consideration could be operators licensed to a design regardless of who owns the plant or where it is located. This would provide owners with a larger pool of qualified licensed operators to operate their facilities.

- The NRC staff has proposed a technology-inclusive set of requirements for concepts of operation that do not rely on prescriptive staffing requirements and acknowledges autonomous operations (see SECY-23-0021, Enclosure 1 – proposed 10 CFR 53.730)

- Reconsideration of training needs and implementation practices to reflect inherent design capabilities including reduced complexity of control actions, event responses, minimalized maintenance activities, and limited releases.

- Similar approaches need to be considered for Fire Plan response, which typically includes requirements for on-site operations staffing, and the operations staffing training program.

Depending on the design, a trained individual may be able to perform multiple roles, to support reactor operations, including controls operator, maintenance technician, radiation protection technician, fire safety, and security. It should also be noted that with the envisioned simpler designs, the full suite of INPO-accredited training programs may not be necessary for assuring adequate training. Likewise, the "operator" qualifications typically utilized for today's LWR operators may not be necessary for providing qualified operators. DRO-ISG-2023-01, "Operator Licensing Programs," also provides guidance in this area.

To help inform the NRC's consideration of approaches for operators and reactor control for advanced reactors, detailed information should be developed on the automatic and remote operational features that are included in these designs. Details should include design information for the features that will be used to meet safety and cyber security requirements, and how the design would be able to meet the intent of the regulations without the need for licensed operators or traditional control rooms. A generic methodology for advanced reactors to evaluate the need for operator actions for designs with automatic or remote operation features would also help to streamline the NRC review.

3.1 Changes Needed to Regulations, Policy and Guidance

Rulemaking is needed to amend or create new regulations that consider the technological capabilities and concepts of operation that advanced reactors convey in a technology-inclusive, performance-based and risk-informed approach to staffing rather than the descriptive minimum staffing that currently exists. The rulemaking will have to consider different concepts of operation, including automatic and autonomous operations; remote control center(s) with responsibility for multiple reactors being monitored by small, licensed staff to a more traditional model of a site-based control room staff; and any number of permutations in between. It is likely that amendments or alternatives to the following requirements will be necessary:

- 10 CFR 50.54(i) to (m)
- 10 CFR 55
- Associated guidance documents

Furthermore, since some advanced reactors may not have a control room, it may be beneficial to modify several regulations to refer to "reactor controls" rather than the "control room." Applicable regulations include the following: 10 CFR 50.36(c)(ii)(A)(2)(ii)(A) dealing with limiting conditions for operation, and 10 CFR 50.67(b)(iii) dealing with protection against accident source terms.

In addition, if a new Commission Policy Statement establishing a framework for the safe use of automatic and autonomous operations, and remote monitoring and operations, is needed to provide direction to the NRC staff, then this policy statement will likely need to include the considerations for alternative approaches to operator staffing discussed in this paper.

In the near-term, the NRC should develop the regulatory basis with performance-based acceptance criteria, and with graded requirements for the alternative approach to operator staffing. The regulatory basis should include the considerations proposed above. The regulatory basis will support efficient processing of exemptions to 10 CFR 50.54 and Part 55 to provide clarity to the first set of applicants for design certification or licenses for advanced reactors. The two-step process described in SECY-11-0098 for determining operating staffing for SMRs appears to be equally appropriate for the issues surrounding other advanced reactors (e.g., operator training and qualification including accreditation, requalification, use of simulators, continuous presence of an operator in the control room, requirements for licensed operators to manipulate the reactor controls, as well as operator staffing requirements).

The first license applicants for design certification or licenses for advanced reactor designs may need to request exemptions from the requirements in 10 CFR 50.54 and Part 55 or demonstrate compliance with these requirements in a different manner. It is noted that while historically exemption requests were developed based upon the guidance in NUREG-1791, NUREG 0800, SRP Chapter 18 and NUREG-0711, advanced reactors are significantly different than the large LWRs for which the guidance was developed. Therefore, while the guidance may provide useful insights into the process, it need not be followed to submit an exemption request. To reflect the specific concepts of operation for advanced reactors, which are different from those for large LWRs, the regulations in 10 CFR 50.54 and Part 55 may need to be augmented, or new Parts created, to establish alternative requirements. These requirements should be scalable to accommodate the variety of advanced reactors and their needs in operator licensing, training, accreditation, and requalification applicable to all types of advanced reactors. It is noted that DANU-ISG-2022-05 and DRO-ISG-2023-03 and NUREG-1537 provide some guidance, although more may be needed in this area. The regulatory basis for exemptions would also facilitate more streamlined and timely rulemakings for alternative requirements to be codified in Parts 50 and 55 related to operator staffing as discussed above, as well as in the ongoing Part 53 proposed rulemaking.

3.2 Acceptance Criteria and Licensing Approach

Acceptance Criteria:

The alternative approach to operations staffing is expected to be largely enabled by the design's ability to achieve simplicity in operations and low potential consequences, as well as a concept of operations that includes the use of automatic/autonomous operations, remote monitoring and operations, and centralized functions (e.g. licensed operator training). As these factors are expected to be included in all, or most, advanced reactors, and are likely to vary widely, the NRC should use a graded approach for the acceptance criteria based upon these considerations. Simplicity of operations and small off-site doses are expected to be achieved through inherent system features including passive design, simplicity of design and other features that result in higher safety margins and lower risks. The EPZ for which doses are to be less than the Environmental Protection Agency's Protection Action Guides (PAGs) limits are expected to be achieved at the site boundary for many advanced reactors. For some advanced reactors the site boundary may be less than a few hundred meters.

Licensing Approach:

The alternative approach for the Operations Staffing topic is not dependent upon any specific licensing approach and may be applicable to any licensing approach. However, for the RHDRA deployment timeline of less than 6 months, the rapid efficient licensing for rapid high-volume deployment process should be used to minimize the scope, content and purpose of the site-specific reviews. This type of site-specific review would enable completion of all, or significant portions, of the safety and environmental reviews and public engagement processes as possible one-time prior to the identification of a specific site. Where the entire site-specific review is not possible before site identification, performing a site license review that only needs to verify that the site characteristics conform to the minimum set of site parameters in the envelope established in the one-time up-front reviews is recommended.

This would include use of a standardized design that has been approved by the NRC using existing licensing processes including Standard Design Approval, Design Certification, Manufacturing License, reference and subsequent COLAs, and Part 50 Appendix N. These licensing processes offer different levels of NRC approvals in terms of scope of the design and finality in the NRC decision. These design approvals would include templates of various operational programs that would be used with the design.

NRC pre-approval (e.g., through an SER on a Topical Report) of a licensee's operational programs (based on the design's Operations Plan template) can also be used for Operations Staffing. By including more non-site-specific license information that can be standard and reviewed and approved by NRC under the standardized licensing processes, the information needed in the site-specific review will be reduced. The licensee would be able to amend the Operations Program as necessary when new designs or sites are added or when the concept of operations is changed (e.g., from an on-site staffing to a remote operations model)

Operator training/licensing could be for a specific design, not for a specific site, either by the licensee, the reactor designer or a third party. This would allow operators to be deployed to a site quickly when one is identified.

4 OTHER OPTIONS FOR RESOLUTION OF THE ISSUE

4.1 AEA Changes – Minimal Regulation

The technical and safety bases for power reactors with potential consequences on the order of magnitude of non-power reactors should be sufficient to enable the NRC to adapt the non-power reactor requirements and implementation guidance for those qualifying power reactors. Adaption of the non-power reactor regulatory framework, as discussed in this appendix, should achieve a similar level of regulation that accounts for the safety and operational characteristics of the qualifying power reactors that will tailor requirements and applicability to the technology. An AEA change to direct the NRC to regulate power reactors with potential consequences that are on the same order of magnitude as non-power reactors, e.g., with minimal regulation or under Section 104, is an option that was identified. However, such a change does not appear necessary, since the AEA provides sufficient authority to the NRC to regulate power reactors commensurate with their potential impacts, and is capable within the current AEA provisions to apply regulatory approaches to qualifying power reactors that are similar to those used today for non-power reactors. More discussion on NRC Regulation of Non-Power Reactors is included in Attachment A.

5 ACKNOWLEDGEMENTS

NEI Issue Lead: Stew Yuen and Tim Riti

Appendix 15 – Autonomous Operations

1 ISSUE INTRODUCTION

The design of the nuclear power plant (NPP), including both inherent safety features and active SSCs, will govern what design functions need to be executed and/or monitored during normal, off-normal and accident conditions. Based on the design of the plant and concept of operation, the Human Factors Engineering (HFE) analysis (including Functional Requirements Analysis, Function Allocation and Task Analysis) will provide input on the role of a human operator, if any, and required human-system interface design attributes. The following concepts of operation are potential options being considered to support the rapid high-volume deployable reactors in remote applications (RHDRA) business model:

1. Option 1 (Onsite Operation, Optional Remote Monitoring): Automatic operation with some operator actions needed. Operator actions will be performed onsite by as few as a single person with collateral duties without the need for continuous monitoring of the controls. The NPP may be monitored at a remote facility, if desired.

2. Option 2 (Remote Operation): Automatic operation with some operator actions needed. Operator actions and monitoring will be performed remotely with no on-site operator.

3. Option 3 (Autonomous Operation): Fully autonomous operation with no operator actions needed. Remote facility providing high-level oversight.

   Note – Option 3 is not needed to achieve the RHDRA business model. This concept of operation is included because it would greatly improve the business model. Additionally, Option 3 may be necessary to achieve other business models.

This appendix focuses on Option 3, Autonomous Operations.

A key feature being designed into rapid high-volume deployable reactors (RHDRA) is the ability to leverage automatic normal power control and automatic off-normal safety control. During routine operations, these reactors would control power automatically based on signals from the load center, such that changes in power level will be performed by the reactor's automatic control system. During off-normal events, these reactors would have reactor safety control systems that would return the reactor to a normal operating condition, and when necessary, completely shut down the reactor and place it in a long-term steady-state safe configuration. The reactor would be designed to do all these operational functions automatically, without reliance on the operator to perform any of these functions.

In this case, automatic operations are defined as the reactor responding to changes in monitored conditions according to an algorithm with deterministic behavior[1]. While some designs may seek to incorporate non-human controls that are more like autonomous operations (i.e., the reactor could predict future conditions and take actions that are not pre-programmed) such features are not necessary to the RHDRA business model. Autonomous operation is different than system/equipment automatic actions, which are necessary to meet the business case for on-site operations and with remote operations. In SECY 24-0008 (page 10 of Enclosure 1), the NRC staff states "Autonomous systems

[1] Per DI&C-ISG-06, "deterministic behavior" ensures predictable and repeatable behavior of systems performing safety functions.

can, when the necessary capabilities are provided, potentially respond to situations beyond those explicitly programmed or anticipated in the design. Thus, autonomous systems can be capable of a certain amount of self-directed behavior and potentially act as a proxy for humans in decision-making situations." Autonomous operations would be a future state as technology and experience improve.

2 BACKGROUND

The NRC has already begun the consideration of autonomous operations in SECY 24-0008. The NRC has said that the requirements in 50.54(i), (j), (k), and (m), which require that only licensed operators be allowed to manipulate controls and other mechanisms that affect reactivity, would be applicable to a microreactor licensed under the existing regulatory framework. Some members of the ACRS have stated their opposition to the notion of unsupervised operations, regardless of the level of automation,[2] and the NRC has indicated that a licensed operator may be required to be present at the controls even if they are not necessary, as a matter of defense in depth. Should a licensed operator be required by regulation, consideration should be given to what is necessary to qualify and license that operator.

NUREG-0700 Table 9.1, "Levels of Automation for NPP Applications," (copied below) addresses the definition of "autonomous operations" with "levels of autonomy" providing more precise definitions of the intended concept of operations. This regulatory framework would ensure that HFE guidance is developed for autonomous operations, including levels of autonomy up to the use of artificial intelligence. For remote operations (Appendix 17), the concept of operations relies on a minimum automation level of 2 or 3 which is achievable with currently available technology. Autonomous operations rely on minimum automation levels of 4 or 5.

Level	Automation Tasks	Human Tasks
(1) Manual Operation	No automation	Operators manually perform all tasks
(2) Shared Operation	Automatic performance of some tasks	Operators perform some tasks manually
(3) Operation by Consent	Automatic performance when directed by operators to do so, under monitoring and supervision	Operators monitor closely, approve actions, and may intervene to provide supervisory commands that automation follows
(4) Operation by Exemption	Essentially autonomous operation unless specific situations or circumstances are encountered	Operators must approve of critical decisions and may intervene
(5) Autonomous Operation	Fully autonomous operation. System cannot normally be disabled but may be started manually	Operators monitor performance and perform backup, if necessary, feasible, and permitted

[2] Advisory Committee on Reactor Safeguards to Chairman Hanson, Fourth Interim letter on 10 CFR Part 53 Rulemaking Language, August 2, 2022. ML22196A292

Appendix 15 – Autonomous Operations

Existing regulations in 10 CFR 50 (as referenced in 10 CFR 52) require human oversight and intervention for nuclear power plant regulation. Those regulations and relevant NRC policy and guidance documents are identified below.

- 10 CFR 50.34(f) requires specific indications and operator actions resulting from the Three Mile Island (TMI) incident.
- 10 CFR 50.54 includes requirements related to licensed operators performing certain plant activities and defines minimum staffing requirements.
- 10 CFR 50.55a(h) endorses IEEE 603-1991 which provides requirements for manual operator actions (manual control and bypasses).
- 10 CFR 50, Appendix A General Design Criteria (GDC) 19 requires a main control room to operate the plant for water-cooled nuclear power plants.
- SRM-SECY-22-0076 approves the NRC staff's recommendation in SECY-22-0076 to expand the existing policy for digital instrumentation and control (I&C) common-cause failures to allow the use of risk-informed approaches to demonstrate the appropriate level of defense-in-depth. SECY-22-0076 also discusses possible alternate approaches for manual operator controls for critical safety functions in the main control room. The SRM notes that the new policy is independent of the licensing pathway selected by reactor licensees and applicants.

NRC staff guidance documents (SRP Chapter 7 and Design Review Guide (DRG): Instrumentation and Controls for Non-Light-Water Reactor (Non-LWR) Reviews) require staff to review manual operation capabilities.

Draft 10 CFR 53.740(f) provides requirements associated with load following operation. These regulations allow for load following given the presence of protection or control systems that are "immediately capable of refusing demands when they could challenge the safe operation of the plant or when precluded by the plant equipment conditions."

"Autonomous operations" may imply the use of artificial intelligence in some industries. NRC staff in the Office of Nuclear Regulatory Research (RES) are actively engaged with research in artificial intelligence; however, the current regulations require deterministic behavior. The concept of operations described within this appendix utilizes deterministic processing for the operation of the protection and control systems. Artificial intelligence may be used for business purposes (e.g., predictive maintenance, corrective action programs, etc.); however, this appendix is solely focused on protection and control systems affecting the operation of the plant.

Furthermore, HFE guidance has been developed with traditional concepts of operation in mind. NRC HFE staff in RES conducted a workshop on January 31-February 1, 2024, related to remote operations that also discussed reliance on autonomous operation.

3 PROPOSED SOLUTION AND APPROACH

The proposed solution is to develop an alternative regulatory approach for RHDRA that can achieve a high degree of automatic and autonomous operations. For these reactors that achieve autonomous operations to significantly reduce or eliminate the need for human actions to align systems and components, control the reactor power and maintain safe reactor conditions during normal, off-normal and accident conditions, the NRC requirements for human operators should be commensurate with the role of the human operator in protecting public health and safety. Autonomous operation of the reactor relies on inherent or passive features in addition to robust I&C systems.

The alternative regulatory approach for autonomous operations should be performance-based and graded according to the degree to which these features are incorporated, and the residual role that the human operator would retain to meet NRC requirements for protecting public health and safety. For designs where human actions have a minimal or no role in protecting public health and safety, the NRC should also have minimal or no requirements for the human operator.

The alternative regulatory approach for autonomous operations will need to address the following key elements: 1) what functions and actions, that are not performed by automatic or autonomous features, if any, must be performed by a human operator in order to protect public health and safety, 2) where must the controls for human action be located and can they be accessed remotely either at an off-site centralized operations center or on-site, 3) of those required human actions, what is the response time for the human action that would allow them to be away from the controls, and 4) what collateral duties would the human operator be able to handle while still being able to take the required actions to operate the reactor.

Each applicant for design approval would perform an evaluation to determine whether operator actions are needed to protect public health and safety based upon the design of the plant.

- For future applicants that demonstrate that no operator actions are needed to protect public health and safety, requirements applicable to reactor controls or operators should not be imposed. In such a case, the requirements of 10 CFR 50.54 for the number of licensed operators on shift and for continuous presence of licensed operators in the control room, training and requalification programs, and simulators may not be warranted. It is noted that even if a design does not require any NRC licensed operators, the plant will likely still have at least one individual that is knowledgeable about the control system and would be able to manipulate the operator controls, in a timely fashion (for example, within a number of days).

- If the evaluation concludes that one or more operator actions are needed to protect public health and safety, either full time or only for certain reactor operations or conditions, then the applicant should propose alternative operator requirements for the design. These alternative requirements should address the number of operators, need and duration for presence at the controls, training, requalification and simulators. The evaluation should consider whether having one or more operators available within a certain period of time to man the control room would be sufficient to protect public health and safety. See the Operations Staffing, Remote Operations, and Remote Monitoring Topics for more information (Appendices #14, 16, 17).

- Due to advances in technology, a traditional control room may not be necessary. For RHDRAs that demonstrate the safety of the reactor can be assured without the need for operator action, and if an individual is unable to compromise the safety of the reactor through the manipulations of the controls, then there would be no need for requirements relating to the control room or for an operator-initiated shutdown. The use of portable monitoring devices may also allow responsible personnel to monitor plant parameters and maintain operational control from either outside the control room or offsite during normal operations.

3.1 Changes Needed to Regulations, Policy and Guidance

A new regulation should be established for the use of autonomous operations, which includes alternative, performance-based requirements. The new regulation should:

- Exclude RHDRA from all 10 CFR 50.34 post-TMI requirements.

- Provide alternative requirements to 10 CFR 50.54 provisions that establish the licensed operator requirements (if any licensed operators are needed) or required monitoring/control capabilities for the control room for reactors with autonomous features.

- Provide alternative requirements to 10 CFR 50.55a(h) to eliminate endorsement of IEEE 603-1991 so that reactors with autonomous features do not have requirements for manual operator actions (manual control and bypasses).

In the near-term, the NRC and industry should develop the regulatory basis with performance-based acceptance criteria, and with graded requirements for operator actions and human interface controls based on various levels of automatic or autonomous operations to facilitate exemptions. The NRC should supplement load following provisions, such as draft 10 CFR 53.740(f), to allow for autonomous operation of the plant. The regulatory basis for such exemptions would facilitate more streamlined and timely rulemakings for alternative requirements to be codified in Parts 50 and 55 related to human oversight and intervention for nuclear power plant regulation as discussed above, as well as in the ongoing Part 53 rulemaking. The regulatory basis should include allowances for autonomous operations through automatic load following, or a specific rulemaking addressing just RHDRAs. Both the near-term and longer-term changes would also require the development of regulatory guidance that is specific to autonomous operations.

In addition, a new Commission Policy Statement establishing a framework for the safe use of autonomous operations and providing direction to the NRC staff to incorporate the framework into staff review guidance may be needed.

3.2 Acceptance Criteria and Licensing Approach

General Acceptance Criteria:

For Autonomous Operations, the use of a graded approach for the acceptance criteria, based upon different levels of potential off-site consequences or other factors (such as source term or thermal power), would be appropriate. For RHDRA and other advanced reactors, small potential off-site doses are expected to be achieved through the use of passive and inherent systems, design simplicity, and other features that result in higher safety margins and lower risks.

Licensing Approach:

Any licensing approach can use automatic and autonomous operations. To achieve the deployment timelines of RHDRA for Autonomous Operations, the RHDRA process should be used to minimize the scope, content and purpose of the site-specific reviews. This type of site-specific review would enable completion of most, if not all, of the safety and environmental reviews and public engagement processes one-time prior to the identification of a specific site. Where the entire site-specific review is not possible before site identification, performing a site license review that only needs to verify that the site characteristics conform to the minimum set of site parameters in the envelope established in the one-time up-front reviews is recommended.

This would include use of a standardized design that has been approved by the NRC (e.g., via a Standard Design Approval, Design Certification and Manufacturing License. OL applications and COLs referencing identical designs can make use of Part 50 Appendix N and Part 52 Appendix N to facilitate site license reviews. These offer different levels of NRC approvals in terms of scope of the design and finality in the NRC decision. It is expected that the NRC review relative to automatic and autonomous features, as well as the design of the human controls for the reactor, would be performed during the design approval, and would likely include a template plan for operator staffing and responsibilities, if any, for the licensee's operational program.

NRC pre-approval of a licensee's operational programs (e.g., through the use of a topical report) can also be used for Autonomous Operations. The more non-site-specific site-license information that applicants are able to submit to the NRC, and the more the NRC can review and approve such information, the less information that will need to be included in the site-specific review.

4 OTHER OPTIONS FOR RESOLUTION OF THE ISSUE

4.1 AEA Change - Minimal Regulation

The technical and safety bases for power reactors with potential consequences on the order of magnitude of non-power reactors should be sufficient to enable the NRC to adapt the non-power reactor requirements and implementation guidance for those qualifying power reactors. Adaption of the non-power reactor regulatory framework, as discussed in this appendix, should achieve a similar level of regulation that accounts for the safety and operational characteristics of the qualifying power reactors that will tailor requirements and applicability to the technology. An AEA change to direct the NRC to regulate power reactors with potential consequences that are on the same order of magnitude as non-power reactors, e.g., with minimal regulation or under Section 104, is an option that was identified. However, such a change does not appear necessary, since the AEA provides sufficient authority to the NRC to regulate power reactors commensurate with their potential impacts, and is capable within the current AEA provisions to apply regulatory approaches to qualifying power reactors that are similar to those used today for non-power reactors. More discussion on NRC Regulation of Non-Power Reactors is included in Attachment A.

5 ACKNOWLEDGEMENTS

NEI Issue Lead: Alan Campbell

Appendix 16 – Remote Monitoring

1 ISSUE INTRODUCTION

The design of the nuclear power plant (NPP), including both inherent safety features and active SSCs, will govern what design functions need to be executed and/or monitored during normal, off-normal and accident conditions. Based on the design of the plant and concept of operation, the Human Factors Engineering (HFE) analysis (including Functional Requirements Analysis, Function Allocation and Task Analysis) will provide input on the role of a human operator, if any, and required human-system interface design attributes. The following concepts of operation are potential options being considered to support the rapid high-volume deployable reactors for remote applications (RHDRA) business model:

1. Option 1 (Onsite Operation, Optional Remote Monitoring): Automatic operation with some operator actions needed. Operator actions will be performed onsite by as few as a single person with collateral duties without the need for continuous monitoring of the controls. The NPP may be monitored at a remote facility, if desired.

2. Option 2 (Remote Operation): Automatic operation with some operator actions needed. Operator actions and monitoring will be performed remotely with no on-site operator.

3. Option 3 (Autonomous Operation): Fully autonomous operation with no operator actions needed. Remote facility providing high-level oversight.

   Note – Option 3 is not needed to achieve the RHDRA business model. This concept of operation is included because it would greatly improve the business model. Additionally, Option 3 may be necessary to achieve other business models.

This appendix focuses on Option 1, Remote Monitoring, and what is needed to allow a remote facility to monitor one or more reactors.

The NRC has previously addressed remote and autonomous operations (e.g., SECY-24-0008), but not explicitly remote monitoring, which will include cyber security considerations, but likely have less sensitivity to the responsiveness and capabilities associated with reactor control (autonomous and remote). Remote monitoring is envisioned to be utilized in situations where there is a preference or need for on-site staff to perform reactor operations, but also a desire or need to centralize other activities that need real-time access to monitored plant parameters. For example, remote monitoring may be necessary to enable a staffing model where there may be only one operator on-site, and where remote personnel may need to be credited for the regulatory requirements of detection, assessment, and notification (e.g., for physical security and emergency preparedness). Remote monitoring may also be used as the first step toward remote operations generating essential data that will form the foundation for implementing secure and reliable remote operations, particularly in areas of connectivity and cybersecurity.

Remote monitoring does not include the performance of any operator actions necessary to manipulate the reactor to protect the public health and safety (i.e., remote operations); however, remote monitoring could be used to access real-time data needed to perform other functions that protect the public health and safety, such as EP or Security. The ability to protect the public is then dependent upon having accurate and timely access to the plant-monitored parameter data. Wireless communication is anticipated to be used to support remote monitoring. The NRC has stated that wireless communication is acceptable for use in monitoring applications[1]. This topic focuses on the integrity and reliability of the data, and in particular the protection of that data from cyber attacks, or from diversion of that data to support a security threat against the reactor.

2 BACKGROUND

Current cyber security regulations applicable to nuclear power plants licensed under Part 50 or Part 52 are contained in 10 CFR Part 73.54, "Protection of digital computer and communication systems and networks." 10 CFR 73.54 applies to (1) digital computer and communication systems and networks that are associated with safety-related, important-to-safety, security, and emergency preparedness (SSEP) functions and (2) support systems and equipment that, if compromised, could adversely impact SSEP functions.

It is assumed that remote monitoring would normally be performed using wireless technology, but the cyber security regulations are silent on wireless communications. However, in accordance with NEI 13-10, Revision 7, current licensee Cyber Security Plans, Appendix D, Cyber Control D1.17, "Wireless Access Restrictions," as well as Regulatory Guide (RG) 5.71, "Cybersecurity Programs for Nuclear Power Plants," the use of wireless technologies is prohibited for critical digital assets (CDAs) associated with safety-related and important-to-safety functions. To address this challenge, a proposed revision to NEI 08-09, "Cyber Security Plan for Nuclear Power Reactors," was submitted for NRC review and endorsement to clarify the use of wireless communications, under certain conditions, if "alternative controls" and countermeasures that eliminate the applicable cyber threat/attack vectors can be established. The NRC review is expected to be complete in Q1 2025. Currently, licensees can implement wireless communication technologies associated with monitoring systems, but not for system control. Licensees would need to implement the appropriate technical cyber security controls, document that the wireless approach maintains the current defensive architecture, and address the unique aspects of their Radio Frequency (RF) spectrum controls relevant to the wireless devices employed. If a different approach to remote monitoring is used, the applicant would need to justify how that data communication path is protected.

It is also noted that current operating nuclear power plants utilize remote monitoring for some non-safety related, balance of plant, and emergency preparedness digital assets. Defensive architectures allow for one-way data communication (remote monitoring) out of the plant within the corporate network. This enables advanced data analysis capabilities (e.g., predictive maintenance) and supports Emergency Response Facilities data.

A proposed Part 53 rulemaking, which includes Cyber Security, is currently in progress. The associated draft Regulatory Guide, DG-5075, has been released for preliminary review. The proposed cybersecurity guidance implements a three-tier approach with analyses at three different levels.

[1] Letter from Brian Yip, Cyber Security Branch Chief, "Response to NEI "Wireless Cyber Security Guidance," Dated March 2023," NRC ADAMS Accession No. ML23118A248, May 17, 2023

3 PROPOSED SOLUTION AND APPROACH

The proposed solution is an alternative regulatory approach that provides flexibility (i.e., graded requirements) in protecting the integrity of remotely monitored data needed to perform human actions that protect public health and safety, and to protect sensitive plant data that could be used to aid in an attack (physical or cyber) against the reactor. The proposed alternative approach for remote monitoring and cyber security would simplify cyber requirements for RHDRAs (refer to Appendix 18). NRC cyber requirements should only be applicable to data transmitted off site in relation to the function it serves to protect public health and safety (i.e., SSEP functions) or that, if intercepted, could be used to create a security threat that could lead to off-site radiological releases exceeding regulatory requirements. These requirements should be graded and streamlined for RHDRAs, as further discussed below.

Suitable acceptance criteria to qualify for this new framework need to be established and should be consequence-based (i.e., based on projected offsite doses) or consider features of the reactor design (e.g., a source term or core thermal power limit). This would streamline the analyses needed to define which digital components would need to be covered under the Cyber Security Plan.

A "security by design" approach may also resolve or mitigate additional security issues. Documentation of the design basis elements and physical protection system features are needed to justify why a cyber-attack does not result in unacceptable consequences as described in the regulation.

3.1 Changes Needed to Regulations, Policy and Guidance

As the NRC's draft proposed Part 53 rulemaking package (which includes Cyber Security) progresses, Part 50/52 applications in the near-term could use this rulemaking as a basis for implementing remote monitoring using wireless communication pathways. The associated draft Regulatory Guide, DG-5075, has also been released for preliminary review. The proposed cybersecurity guidance implements a three-tier approach with analyses at three different levels. As noted in DG-5075, the intent of this approach is to ensure that the analyses of each tier are performed until it is demonstrated that a cyberattack cannot result in the consequences listed in 10 CFR 73.110(a). This may result in one, two, or all three tiers being analyzed as part of this approach.

The NRC's current Cyber Security regulations and guidance allow for remote monitoring when implemented consistent with an approved Cyber Security Plan and defensive architecture. While not necessary for implementation, guidance for Cyber Security Plans (e.g., Regulatory Guide 5.71) could be revised, or RHDRA-specific guidance created, to provide a graded approach to cyber security requirements commensurate with the RHDRA consequences.

The ongoing Part 53 rulemaking could also incorporate more of a graded approach for cyber security, physical security, or other response actions, to enable using real-time data to perform other functions that protect the public health and safety, depending on the applicant's concept of operations. Criteria for the graded approach could use the reactor technology DBA analysis as an entry point for RHDRAs. If the entry criteria can be met for all DBA analyses, simplified cyber analyses and requirements could be established (see additional discussion in Appendix 18).

Consistent with the physical security topic, certain aspects of the DBT would not need to be evaluated, if the entry conditions above could be met. This would eliminate some DBT-type analyses.

3.2 Acceptance Criteria and Licensing Approach

General Acceptance Criteria:

All advanced reactors should be able to implement remote monitoring consistent with their approved Cyber Security Plan.

Licensing Approach:

Any licensing approach can be used for Remote Monitoring. To achieve the deployment timelines for RHDRA, the rapid efficient licensing for rapid high-volume deployment process should be used to minimize the scope, content and purpose of the site-specific reviews. This type of site-specific review would enable completion of most, if not all, of the safety and environmental reviews and public engagement processes one-time prior to the identification of a specific site. Where the entire site-specific review is not possible before site identification, performing a site license review that only needs to verify that the site characteristics conform to the minimum set of site parameters in the envelope established in the one-time up-front reviews is recommended.

This would include use of a standardized design that has been approved by the NRC. Such approval processes include Standard Design Approval, Design Certification and Manufacturing License. OL applications and COLs referencing identical designs can make use of Part 50 Appendix N and Part 52 Appendix N to facilitate site license reviews. These offer different levels of NRC approvals in terms of scope of the design and finality in the NRC decision.

NRC pre-approval of a licensee's operational programs can also be used for remote monitoring. An applicant's submittal of such non-site-specific information for early NRC review and approval can significantly reduce the scope of and time required for the NRC's review of the site license application.

4 OTHER OPTIONS FOR RESOLUTION OF THE ISSUE

No other solutions are considered.

5 ACKNOWLEDGEMENTS

NEI Issue Lead: Alan Campbell

Appendix 17 – Remote Operations

1 ISSUE INTRODUCTION

The design of the nuclear power plant (NPP), including both inherent safety features and active SSCs, will govern what design functions need to be executed and/or monitored during normal, off-normal and accident conditions. Based on the design of the plant and concept of operation, the Human Factors Engineering (HFE) analysis (including Functional Requirements Analysis, Function Allocation and Task Analysis) will provide input on the role of a human operator, if any, and required human-system interface design attributes. The following concepts of operation are potential options being considered to support the rapid high-volume deployable reactors (RHDRA) business model:

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2. Option 2 (Remote Operation): Automatic operation with some operator actions needed. Operator actions and monitoring will be performed remotely with no on-site operator.

3. Option 3 (Autonomous Operation): Fully autonomous operation with no operator actions needed. Remote facility providing high-level oversight.

   Note – Option 3 is not needed to achieve the RHDRA business model. This concept of operation is included because it would greatly improve the business model. Additionally, Option 3 may be necessary to achieve other business models.

This appendix focuses on Option 2, Remote Operation.

The NRC staff has already begun considering remotely operated reactors in their "Ground Rules for Regulatory Feasibility of Remote Operations of Nuclear Power Plants"[1] document and in SECY 24-0008. The NRC staff has indicated that they would apply the requirement of 10 CFR 50.34(f)(2)(iii), which requires that control room designs meet state-of-the-art human factors engineering principles. The NRC staff also indicated in SECY-24-0008 that it would need to determine whether remote control rooms are capable of ensuring that a reactor can reach 1) prompt hot shutdown with I&C to maintain a safe condition, and 2) (potential) subsequent cold shutdown through suitable procedures. These considerations are driven by the existing language in General Design Criterion 19 from 10 CFR 50 Appendix A. While the GDC only serve as requirements for water-cooled designs, it is expected that the Principal Design Criteria established for non-water-cooled reactor designs would include analogous criteria for ensuring these capabilities.

For the remote facility, the NRC staff have said that the requirements in 50.54(m) for minimum operator staffing would be applicable, and deviations from those requirements would require exemption requests. However, these efforts have not considered the unique concept of remote operations for RHDRAs, which are expected to rely on remote operations from a central location once the licensee's deployment of reactors reaches a certain number or geographic distribution. This would mean that

[1] ML21291A024

there are no permanent on-site operators, and that remote operators would oversee multiple reactors. As an example, there may be 4 operators continuously at the controls in a remote facility (1 ops manager, 2 operators for over 50 reactors each, and 1 flex position) for a large fleet of over 100 reactors. This would be a dramatic change, even from the NRC's approval of the NuScale design, which requires 6 operators on-site for 12 reactors.

The desired outcome is that the NRC establishes a regulatory framework for the use of remote operations of many reactors by only a few operators, consistent with the HFE analysis.

2 BACKGROUND

NRC's current Part 50 and Part 52 regulations require human oversight and intervention for nuclear power plant regulation.

- 10 CFR 50.34(f) requires, in part, specific control indications and operator actions in the control room. Refer to 10 CFR 50.34(f)(2)(iii), (vi), (xi),(xii), (xvi), and (xvii) for specific control room requirements.

- 10 CFR 50.54 includes requirements regarding licensed operators for certain plant activities and defines minimum staffing requirements in the control room. Refer to Appendix 14 for more information related to operations staffing. In addition, 10 CFR 50.54(j) and (k) provide requirements for operator actions "at the controls."

- 10 CFR 50.55a(h) endorses IEEE 603-1991, "Standard Criteria for Safety Systems for Nuclear Power Generating Stations," which provides requirements for manual operator actions (manual control and bypasses) and indications in the control room.

- 10 CFR 50, Appendix A General Design Criterion (GDC) 19 requires a main control room to operate the plant for water-cooled nuclear power plants. The GDC serves as guidance for the development of principal design criteria (PDC) for non-light-water reactors, with more recent guidance in RG 1.232 (PDCs for non-LWR designs) retaining criteria related to main control room capabilities.

- SRM-SECY-22-0076 approves the NRC staff's recommendation in SECY-22-0076 to expand the existing policy for digital instrumentation and control (I&C) common-cause failures to allow the use of risk-informed approaches to demonstrate the appropriate level of defense-in-depth. SECY-22-0078 also discusses possible alternate approaches for manual operator controls for critical safety functions in the main control room. The SRM clarifies that the new policy is independent of the licensing pathway selected by reactor licensees and applicants.

HFE guidance has been developed with traditional concepts of operation in mind. NRC HFE research staff conducted a workshop in January 31-February 1, 2024, related to remote operations that also discussed reliance on autonomous operation (see ML24030A001 and ML24061A181). As discussed during that workshop, the operator's role operating multiple reactors simultaneously from a remote location must be accounted for in the HFE analysis.

Appendix 17 – Remote Operations

These regulations are considered as part of the Autonomous Operations (Appendix 15) with the outcome of that proposed alternative approach being the identification of human actions that could be performed at a remote operating facility. Autonomous operation is not a pre-requisite to remote operation; however, it may optimize the desired business model.

3 PROPOSED SOLUTION AND APPROACH

The proposed solution is an alternative regulatory approach that enables safe and secure operation from a remote location. It is expected that an applicant pursuing remote operations will have incorporated the following into its approach, at a minimum:

1. Automatic operations (or autonomous operations as discussed in Appendix 15)
2. A remote monitoring approach (Appendix 16)
3. A cyber security approach (Appendix 18)
4. An operations staffing analysis (Appendix 14)

For reactors that also incorporate remote operations features to enable the required human actions to be performed off-site at a remote operations facility, the requirements for remote control of reactor power and maintaining safe reactor conditions during normal, off-normal and accident conditions should be commensurate with the role of the remote operations in protecting the public health and safety.

The alternative regulatory approach for remote operations will need to address the following key elements: 1) what performance-based acceptance criteria must the automatic (or autonomous) operation features achieve to ensure that all human actions can be performed remotely without the need for any required routine or accident response on-site human actions; 2) what functions and actions must be performed at the remote operations facility that protect the public health and safety, and eliminate the need for any on-site human actions to control the reactor; and 3) what staffing organization is necessary to perform the required human actions at the remote operations facility. The alternative regulatory approach should account for response time for the human action that would allow them to be away from the controls, and collateral duties the human operator would be able to handle while still being able to take the required actions to operate the reactor.

There are a number of considerations that will need to be addressed for remote operations. These include:

- Level of automation to assure safety (e.g., needs for local operator action in response to events and what could a person do to cause an event; and the “what if” the remote facility loses contact or control) (Appendix 15)
- Needs for onsite personnel (whether anyone is needed permanently, what periodicity of site visits would be needed, and whether credit could be taken for the ability to utilize people from non-nuclear site operations), including fitness for duty and access authorization if there will be times when as few as one person is at the reactor (Appendices 14 and 21)

- Remote operator's role and human factors in determining how many reactors one person can oversee (this appendix)
- Cyber security for the remote operations connection (Appendix 18)
- Physical security, especially in the area of insider threat (Appendix 19)

3.1 Changes Needed to Regulations, Policy and Guidance

A new regulation should be established that supports remote reactor operations. The new regulation should be included with the proposed alternative regulation for automatic and autonomous operations. The requirements for remote operations should be performance-based and define the acceptance criteria for use of remote operations and the requirements for design, licensing and operational programs for the remote operations facility. The requirements should remove location specific requirements such as those in 10 CFR 50.34(f) and 10 CFR 50.54(j) and (k).

In the near-term, the NRC should develop a regulatory basis with performance-based acceptance criteria, and with graded requirements for the remote operations facility and operator actions and human interface controls based on various levels of automatic or autonomous operations to facilitate exemptions. The regulatory basis for exemptions would facilitate more streamlined and timely rulemakings for alternative requirements to be codified in Parts 50 and 55 related to human oversight and intervention for nuclear power plant regulation, as well as the ongoing Part 53 draft proposed rulemaking. Both the near-term and longer-term changes would also require the development of regulatory guidance that is specific to automatic/autonomous operations.

3.2 Acceptance Criteria and Licensing Approach

<u>General Acceptance Criteria:</u>

For the Remote Operations topic, the use of a graded approach for the acceptance criteria, based upon different levels of potential off-site consequences or other basis (such as source term or thermal power), would be appropriate. Small off-site doses are expected to be achieved through the use of passive systems, design simplicity and other features that result in lower risks.

<u>Licensing Approach:</u>

Any licensing approach can use remote operations. To achieve the RHDRA deployment timelines for the Remote Operations topic, the rapid efficient licensing for rapid high-volume deployment process should be used to minimize the scope, content and purpose of the site-specific reviews. This type of site-specific review would enable completion of most, if not all, of the safety and environmental reviews and public engagement processes one-time prior to the identification of a specific site. Where the entire site-specific review is not possible before site identification, performing a site license review that only needs to verify that the site characteristics conform to the minimum set of site parameters in the envelope established in the one-time up-front reviews is recommended.

This would include use of a standardized design that has been approved by the NRC (e.g., via Standard Design Approval, Design Certification and Manufacturing License. OL applications and COLs referencing identical designs can make use of Part 50 Appendix N and Part 52 Appendix N to facilitate site license reviews. These offer different levels of NRC approvals in terms of scope of the design and finality in the NRC decision.

NRC pre-approval of a licensee's operational programs can also be used for Remote Operations. The more non-site-specific information that applicants are able to submit to the NRC early in the process, and the more the NRC can review and approve such information, the less information that will need to be included in the site-specific review. It is expected that the NRC review relative to remote operations features, as well as the design of the human controls away from the reactor, would be performed during the design approval, and would likely include a template plan for operator staffing and responsibilities, if any, for the licensee's operational program.

4 OTHER OPTIONS FOR RESOLUTION OF THE ISSUE

4.1 AEA Change - Minimum Regulation

The Atomic Energy Act (AEA) directs the NRC to license reactors for industrial and commercial purposes under Section 103, which provides a standard of "*reasonable assurance that the facility will be constructed and will operate in conformity with the license, the provisions of this Act, and the Commission's rules and regulations."* In contrast, non-power reactors are licensed under Section 104 of the AEA, which directs the NRC to "*impose the minimum amount of regulation consistent with its obligations under this Act to promote the common defense and security and to protect the health and safety of the public."* While there are differences between these two standards of protecting the public health and safety, those differences are very small in comparison of the differences between RHDRAs (and other advanced reactor designs with similar safety profiles), and the large Light Water Reactors (LWRs) for which the current regulatory framework was developed.

Under this option, a new Section of the AEA could be added for RHDRAs, separate from Section 103 and 104 (or bifurcating Section 103 into two subclasses, similar to 104a and 104b). The new Section would allow the creation of specific NRC regulations and requirements for RHDRAs (and possibly create a graded regulatory approach for micro to small modular reactors).

5 ACKNOWLEDGEMENTS

NEI Issue Lead: Alan Campbell

Appendix 18 – Cyber Security

1 ISSUE INTRODUCTION

Autonomous operations, remote monitoring, and remote operations (see Appendices 15, 16, and 17) all depend on operations that could be susceptible to cyber-attacks, which could intercept the controls and result in undesired outcomes. The most cost-effective approach would be to design the rapid high-volume deployable reactors for remote applications (RHDRAs) to eliminate cyber-attack threat vectors. This approach will support the ability to provide high (reasonable) assurance of adequate protection to public health and environment (e.g., reactor protection overrides not susceptible to cyber-attacks would always put the reactor in a safe configuration). Reactor design and programmatic elements will be needed to assure protection from cyber-attacks that would adversely impact the integrity or confidentiality of data and/or software; deny access to systems, services and/or data; or adversely impact the operation of systems, networks, and associated equipment.

The desired outcome is a cybersecurity program scoped to ensure that only systems performing or relying on functions that contribute to the consequences stated in 10 CFR 73.54 are assessed and protected. A "security by design" approach, as well as adequately independent (diverse) methods to fulfill the safety and security functions, may also resolve or mitigate additional security issues. Documentation of the design basis elements and physical protection system features are needed to justify why a cyber-attack does not result in unacceptable consequences as described in the regulation.

2 BACKGROUND

Current cyber security regulations to operate a nuclear power plant licensed under Part 50 or Part 52 are contained in 10 CFR Part 73.54, "Protection of digital computer and communication systems and networks." 10 CFR 73.54 applies to (1) digital computer and communication systems and networks that are associated with safety-related, important-to-safety, security, and emergency preparedness (SSEP) functions and (2) support systems and equipment that, if compromised, could adversely impact SSEP functions.

Regarding the licensing of future commercial nuclear plants, the NRC staff is currently developing a draft proposed Part 53 rulemaking package that would offer a voluntary, performance-based alternative regulatory framework.

As previously mentioned, implementing RHDRA includes a high degree of automatic operations, remote monitoring, and remote operations. Currently, cyber security regulations are silent on wireless communications. However, in accordance with NEI 13-10, Revision 7, current licensee Cyber Security Plans, Appendix D, Cyber Control D1.17, "Wireless Access Restrictions," as well as Regulatory Guide (RG) 5.71, "Cybersecurity Programs for Nuclear Power Plants," prohibit the use of wireless technologies for CDAs associated with safety-related and important-to-safety functions. To address this challenge, a proposed revision to NEI 08-09, "Cyber Security Plan for Nuclear Power Reactors," was submitted for NRC review and endorsement to clarify the use of wireless communications, under certain conditions, if "alternative controls" and countermeasures that eliminate the applicable cyber threat/attack vectors can be established. The NRC review is expected to be complete in Q1 2025. Currently, licensees can implement wireless communication technologies associated with monitoring systems, but not for system control. Licensees would need to implement the appropriate technical cyber security controls, document that the wireless approach maintains the current defensive architecture, and address the unique aspects of their Radio Frequency (RF) spectrum controls relevant to the wireless devices employed.

It is also noted that current operating nuclear power plants utilize remote monitoring for some non-safety related, balance of plant, and emergency preparedness digital assets. Defensive architectures allow for one-way data communication out of the plant within the corporate network. This enables advanced data analysis capabilities (e.g., predictive maintenance) and supports Emergency Response Facilities data.

As the NRC's draft proposed Part 53 rulemaking package (which includes Cyber Security) progresses, Part 50/52 applications in the near-term could use this rulemaking as a basis for an exemption request. The associated draft Regulatory Guide, DG-5075 has also been released for preliminary review. The proposed cybersecurity guidance implements a three-tier approach with analyses at three different levels. As noted in DG-5075, the intent of this approach is to ensure that the analyses of each tier are performed until it is demonstrated that a cyberattack cannot result in the consequences listed in 10 CFR 73.110(a). This may result in one, two, or all three tiers being analyzed as part of this approach.

3 PROPOSED SOLUTION AND APPROACH

The proposed approach provides flexibility (i.e., levels of requirements) in protecting the integrity of operations, remotely monitored data, and remote operations related to the performance of plant functions and human actions that protect the public health and safety, and to protect sensitive plant data that could be used as a security threat against the reactor. Although DG-5075 provides a graded approach for determining the level of cyber protections commensurate with potential consequences, this alternative regulatory approach is needed.

The tiers, as described in DG-5075, provide a graded approach for determining the level of cyber protections commensurate with potential consequences. Based on the information available, the requirements focus on protecting from a Cyber-Enabled Accident Scenario and a Cyber-Enabled Physical Scenario. This approach seeks to ensure that only systems that perform or rely on functions that can contribute to the consequences stated in the regulation are assessed and protected. It is possible that some sites' plant design basis and physical protection systems are sufficient to prevent the potential consequences from a cyber-attack. Licensees will need to develop scenarios to analyze an adversary's access to attack pathways that allow for the compromise of plant functions.

The proposed alternative regulatory approach for cyber security would simplify cyber requirements for advanced reactors (even beyond what is in the draft proposed Part 53 package). Suitable acceptance criteria to qualify for this new framework need to be established and should be consequence-based (i.e., projected offsite doses) or consider features of the reactor design (e.g., a source term or core thermal power limit). For example, because site boundary doses are expected to be very low for the RHDRA technology and for other similar technologies for all design basis accidents (DBA), therefore certain requirements to meet the design basis threat (DBT) would not be required, and cyber-related analyses included in the draft proposed Part 53 package using the DBT would not be necessary. This would streamline the analyses needed to define which digital components would need to be covered under the Cyber Security Plan.

Appendix 18 – Cyber Security

The proposed approach would exclude certain balance of plant (BOP) digital assets (that are not identified as safety-related or important-to-safety) for those situations in which the reactor is not connected to the offsite grid. The BOP critical digit assets (CDAs) for light water reactors were included in the scope of 10 CFR 73.54 based on discussion and agreement between the NRC and FERC. However, since the BOP digital assets for RHDRAs may not be connected to the offsite grid, if those digital assets are not identified as safety-related or important-to-safety, then they need not be covered under an applicant's Cyber Security Plan. If that is not the case, then the applicant would need to address the BOP digital assets in its Cyber Security Plan and protect them like other FERC-regulated small electric generators.

In addition, similar to the current requirements for the Emergency Preparedness digital assets, as outlined in NEI 10-04, Revision 3, "Identifying Systems and Assets Subject to the Cyber Security Rule," requirements could be established for certain safety-related, security, and important-to-safety digital assets. Under this approach, if alternate methods could be implemented as required to ensure the equipment can meet the SSEP intended function and an appropriate response initiated, the digital asset would not need to be a CDA.

A "security by design" approach may also resolve or mitigate additional security issues. Documentation of the design basis elements and physical protection system features are needed to justify why a cyber-attack does not result in unacceptable consequences as specified in the regulations.

3.1 Changes Needed to Regulations, Policy and Guidance

The alternative regulatory approach to cyber security would require a change to the Part 73 requirements, beyond the draft proposed Part 53 rulemaking package, to enable advanced reactors in achieving a high degree of automatic and/or autonomous operations and utilize remote monitoring and/or operations. These reactors are expected to rely more on digital systems to significantly reduce or eliminate the need for human actions to align systems and components, control the reactor power, and maintain safe reactor conditions during normal, off-normal, and accident conditions. Furthermore, the digital I&C for these reactors are expected to be much simpler than current reactors, as the design will also include passive features. The NRC's requirements should be commensurate with the role of digital I&C technology in protection of public health and safety.

Revised regulatory requirements are needed for RHRDA and other advanced reactors to incorporate more of a graded approach for cyber security. This may include using the reactor technology DBA analysis as an entry point for the RHDRA. If the offsite consequences or another basis (such as source term or thermal power) can be met for all DBA analyses, simplified cyber analyses and requirements could be established. The requirements would then be more focused on the concept of operations for the RHDRAs. Changes to the associated guidance documents, including NEI 08-09 and RG 5.71, would also need to be made.

Consistent with the physical security topic, certain requirements to address the DBT would not need to be evaluated if the entry conditions above could be met. This would eliminate some DBT-type analyses currently included in the draft proposed Part 53 rulemaking guidance.

A cyber security program could then be developed to ensure the security of the digital assets needed for remote monitoring and remote operations of the reactor. The cyber program would also need to protect security digital assets as discussed in the physical security topic.

In the near-term, the NRC should develop a regulatory basis with a graded approach to performance-based acceptance to facilitate exemptions. The regulatory basis for such exemptions would, in parallel, facilitate more streamlined and timely rulemaking for alternative requirements to be codified in Parts 50 and 52 as well as in the ongoing Part 53 rulemaking, as discussed above. In this manner, the regulatory basis provides the regulatory clarity for this issue to support both the near-term and longer-term regulatory changes and applications for RHDRA and other advanced reactors.

3.2 Acceptance Criteria and Licensing Approach

General Acceptance Criteria:

For the cyber security topic, the use of a graded approach for the acceptance criteria, based upon different levels of potential off-site consequences or other basis (such as source term or thermal power), would be appropriate. Small off-site doses are expected to be achieved using passive systems, simplicity in design, and other features that result in higher safety margins and lower risks.

Licensing Approach:

Under the RHDRA business model, the deployment schedule is six months from site identification to operations. To achieve this goal, most of the facility application content (cyber security included) will need to be based on a generic model that has been developed and approved by the NRC in advance of the first application to minimize the amount of new or site-specific information in an application. This means that the NRC review and approval of cyber security plan templates and features for a given technology should be accomplished to the maximum extent practicable during the design certification phase and use all available administrative tools (e.g., NRC-approved topical reports or NRC-endorsed NEI technical reports).

For example, a RHDRA developer could submit a cyber security plan template for a standard design to the NRC for review as a topical report or in an application for a Design Certification, a Standard Design Approval, or a Manufacturing License. The guidance for using the template would specify the bounding conditions (i.e., a parameter envelope) for its use and provide instructions for completion of a site-specific plan. Once the NRC has endorsed the template and guidance, the application for any given deployment site would have a cyber security plan based on the template and completed with site-specific information. This should significantly shorten the NRC's review time while still allowing the NRC to verify any site-specific information prior to facility start-up.

4 OTHER OPTIONS FOR RESOLUTION OF THE ISSUE

4.1 AEA Change Option – Minimal Regulation

The technical and safety bases for power reactors with potential consequences on the order of magnitude of non-power reactors should be sufficient to enable the NRC to adapt the non-power reactor requirements and implementation guidance for those qualifying power reactors. Adaption of the non-power reactor regulatory framework, as discussed in this appendix, should achieve a similar level of regulation that accounts for the safety and operational characteristics of the qualifying power reactors that will tailor requirements and applicability to the technology. An AEA change to direct the NRC to regulate power reactors with potential consequences that are on the same order of magnitude as non-power reactors, e.g., with minimal regulation or under Section 104 is an option that was identified. However, such a change does not appear necessary, since the AEA provides sufficient authority to the NRC to regulate power reactors commensurate with their potential impacts, and is capable within the current AEA provisions to apply regulatory approaches to qualifying power reactors that are similar to those used today for non-power reactors. More discussion on NRC Regulation of Non-Power Reactors is included in Attachment A.

5 ACKNOWLEDGEMENTS

NEI Issue Lead: Richard Mogavero

Appendix 19 – Physical Security

1 ISSUE INTRODUCTION

The U.S. Nuclear Regulatory Commission (NRC) regulatory frameworks for physical security, including those being developed in the ongoing Alternative Physical Security Requirements for Advanced Reactors and Part 53 rulemakings, do not fully contemplate the technological capabilities, and deployment and operations concepts for rapid high-volume deployable reactors for remote applications (RHDRA). These designs will have relatively lower radionuclide inventories, simplified systems, and passive or inherent safety features. As a result of these design features, the potential radiological consequences of accidents at a RHDRA facility are more similar to those of Research and Test Reactors (RTRs), and much less than those associated with the larger advanced power reactors contemplated in the proposed rulemakings. Given these characteristics, it does not seem reasonable to apply the threat and physical protection requirements developed for larger power reactors to RHDRA.

The desired outcome is that the NRC establishes alternative physical security requirements appropriate for a class of smaller power reactors with potential accident and threat consequences comparable to those from RTRs. This alternative framework should consider, and be based upon, the regulatory approach for RTRs, and adjusted as appropriate to be commensurate with the risk profiles of RHDRA. In addition, whether incorporated into the ongoing alternative requirements for advanced reactors and draft proposed Part 53 rulemakings , or addressed in a new rulemaking, the set of alternative requirements should be available in all licensing pathways, i.e., Part 50, Part 52, and Part 53.

2 BACKGROUND

The purpose of physical security programs is to protect nuclear facilities and material against sabotage, theft, diversion, and other malicious acts. The NRC applies a graded approach to physical security across the broad range of nuclear facilities that it regulates, consistent with the significance of the facilities or material to be protected. Nuclear facilities that require physical protection include nuclear reactors, fuel cycle facilities, and spent fuel storage and disposal facilities. The NRC lists the key elements of physical protection programs for these facilities,[1] which can include the following features:

- Threat Assessment to determine requirements for sufficient physical protection
- Physical Protection Areas graded to provide defense-in-depth with barriers and controls for the Exclusion Area, Protected Area, Vital Area, and Material Access Area
- Intrusion Detection to notify the site's security force of a potential intruder
- Intrusion Alarm Assessment to distinguish between false or nuisance alarms and actual intrusions and to initiate response
- Armed Response to protect public health and safety and the common defense and security by defending nuclear material or a nuclear facility against an intrusion or attack

[1] U.S. Nuclear Regulatory Commission, "Physical Protection," at https://www.nrc.gov/security/domestic/phys-protect.html

Appendix 19 – Physical Security

- Regulatory Initiatives to ensure that the NRC's Domestic Safeguards Regulations, Guidance, and Communications continue to adequately protect the Nation's nuclear facilities and material in a changing threat environment

In addition, local, state, and federal agencies may provide offsite assistance, as necessary.

The NRC requirements for physical security for commercial power reactors are contained in 10 CFR 73.55, "Requirements for physical protection of licensed activities in nuclear power reactors against radiological sabotage." Since these requirements were developed for large light water reactors (LWRs), many are not suitable for RHDRA facilities and other advanced reactor designs. To address this challenge, the NRC has two rulemakings underway that would create physical protection requirements appropriate for advanced reactors.

The first rulemaking is the "Alternative Physical Security Requirements for Advanced Reactors" (APSRAR) proposed rule.[2] This is a limited scope rulemaking that seeks to adjust the NRC's physical security requirements for power reactors in § 73.55 to make them suitable for advanced reactors. It would establish voluntary alternative physical security requirements for the following areas: (1) number and location of armed responders, (2) capability for interdiction and neutralization, (3) types of physical barriers, (4) locations of secondary alarm stations, and (5) designation of vital areas. While of benefit to larger advanced reactors, the APSRAR does not address the physical security licensing issues for RHDRA because most of the prescriptive framework in § 73.55 is retained.

The second rulemaking is the "Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors" draft proposed rule (hereinafter referred to as the Part 53 rule).[3] This draft proposed rule is broader in scope and seeks to establish, among other things, technology-inclusive requirements and a performance-based regulatory framework for physical protection programs and security organizations. The proposed requirements include criteria that, if met, would relieve the applicant of the need to protect against the Design Basis Threat (DBT). However, those criteria refer to the draft proposed § 53.860(a)(2)(i)) use an "all or nothing" approach, as opposed to providing a graded approach that could offer stepped differences in protection requirements. In addition, the proposed criteria are problematic because the assumptions required for the consequence assessment would lead to results with unrealistically high offsite doses. For applicants that cannot meet the DBT relief criteria, the rule provides the option to establish physical protection capabilities through compliance with the prescriptive requirements in § 73.55, as modified by the APSRAR rule, or new performance-based requirements in § 73.100. It is not clear that the security provisions in § 73.100 will be sufficiently graded and performance-based to accommodate RHDRA.

The draft proposed Part 53 rulemaking would necessitate full adoption of all Part 53 provisions for a project-specific application, making the DBT relief criteria and the performance-based framework in § 73.100 inaccessible to non-Part 53 applicants.

[2] Refer to SECY-22-0072 (https://www.nrc.gov/docs/ML2133/ML21334A003.html) and SRM-SECY-22-0072 (https://www.nrc.gov/docs/ML2417/ML24170A753.html). The status of this rulemaking can be found here: https://www.nrc.gov/reading-rm/doc-collections/rulemaking-ruleforum/active/ruledetails.html?id=76

[3] Refer to SECY-23-0021 (https://www.nrc.gov/docs/ML2116/ML21162A093.html) and SRM-SECY-23-0021 (https://www.nrc.gov/docs/ML2406/ML24064A047.html). The status of this rulemaking can be found here: https://www.nrc.gov/reading-rm/doc-collections/rulemaking-ruleforum/active/ruledetails.html?id=1108

Appendix 19 – Physical Security

The NRC has assessed threat scenarios applicable to RTRs and identified as potential threats the theft of fuel for use in a nuclear weapon, dirty bomb, radiological exposure device, and sabotage to disperse radioactive material. In addressing these threats, the NRC must ensure that its security requirements are consistent with section 104(c) of the Atomic Energy Act (AEA) of 1954. Section 104(c) directs the NRC to impose only "such minimum amount of regulation" of an RTR licensee as the Commission finds necessary to promote the common defense and security and protect public health and safety of the public while permitting the conduct of widespread and diverse research and development. For this reason, security requirements for RTRs are based on a graded approach; that is, reactors possessing larger quantities of nuclear material or using material potentially more attractive to adversaries are generally required to have more security measures in place. Note that while the NRC maintains a DBT for commercial power reactors, it has not set one for RTRs.

The NRC requirements for security of RTR facilities are presented in § 73.60, "Additional requirements for physical protection at nonpower reactors." The NRC has provided a summary of the approach that the agency takes to physical security requirements for RTR facilities on their website.[4] Given their similar power levels and accident consequences, it seems the RTR approach to physical security could be applied to RHDRA facilities. As an example, consider the threat- and risk-related topics addressed in the NRC's "Non-Power Reactor Security Questions & Answers" document[5] – several of these agency positions, presented below, should also apply to RHDRA facilities.

- RTRs have only limited quantities of radioactive material on-site. The nature and form of this material make it not easily dispersed or handled. As a result, RTRs pose a relatively low risk to public health and safety from potential radiation exposure or theft of the nuclear material. Moreover, these reactors are designed and operated in a manner that minimizes the possibility of unintended radiation exposure.

- The risk to the public from radiological exposure or release is primarily related to reactor power level and fuel quantity. RTRs are licensed to operate at different maximum power levels and utilize various quantities and types of nuclear material as fuel. The power levels and fuel quantities at these facilities are very small when compared to large electrical power generation plants. Because of the relatively low power levels, and the small quantities of material present, the risk to the public is also low. Inherently-safe facility designs, coupled with effective implementation of security measures and emergency preparedness plans ensure that the public remains at low risk.

- Security requirements at these facilities are based on a "graded" approach; in general, RTRs that possess larger quantities of nuclear material or utilize material that is potentially more attractive to adversaries have more security measures in place. The quantity of nuclear material at these facilities is very small when compared to nuclear power reactor facilities. In addition, RTRs have robust engineering designs that incorporate a variety of safety features which make them highly resistant to mis-operation (intentional or unintentional)

- The type and quantity of security measures in place at any given facility are "graded" depending

[4] U.S. Nuclear Regulatory Commission, "Non-Power Facilities," https://www.nrc.gov/reactors/non-power.html
[5] U.S. Nuclear Regulatory Commission, "Non-Power Reactor Security Questions & Answers," https://www.nrc.gov/docs/ML1406/ML14069A528.pdf

on the potential for radiological release or exposure from the specific facility. Security plans describing the details of the searches that are conducted and what types of materials are permitted in each facility, in combination with other safety and security measures, collectively provide assurance that the public remains protected.

Finally, the requirements in Section 170D of the AEA direct the NRC to "conduct security evaluations at each licensed facility that is part of a class of licensed facilities, as the Commission considers to be appropriate, to assess the ability of a private security force of a licensed facility to defend against any applicable design basis threat." This statute gives the NRC the authority to determine the type of security evaluations that would be applied to a RHDRA class of reactors.

3 PROPOSED SOLUTION AND APPROACH

The proposed approach is to establish a physical security framework that is specifically tailored to the needs and capabilities of RHDRA and, because of the similarity in potential consequences, like that used for RTRs. This means a framework that uses an RTR-like graded approach to setting threat and protection requirements for RHDRA facilities (e.g., some designs may not be subject to the DBT or have characteristics that reduce or eliminate the need for certain protection requirements). The criteria could be consequence-based (i.e., examine potential offsite doses) and/or consider key features of the reactor design (e.g., radionuclide inventories or core thermal power limits). The alternative approach should also consider the relative attractiveness of a RHDRA facility, as compared to larger power reactors, in the same way that the NRC considered these differences for RTRs with similar potential consequences. For example, when compared to other possibilities, a RHDRA facility would likely not be an attractive target for terrorists because of the comparatively smaller offsite consequences resulting from an attack. While both the APSRAR and draft proposed Part 53 rules have useful features and offer improvements over current NRC regulations, neither rulemaking thoroughly satisfies the needs of RHDRA in its present form.

The proposed new physical security framework would include consideration of:

- Physical barriers to prevent unauthorized access (e.g., fences and structures)
- Barriers to protect against Vehicle Borne Improvised Explosive Devices (land and water)
- Access measures to allow controlled entry into the facility (e.g., gates, personnel verification, search capability, etc.)
- Facilities and equipment for intrusion detection and assessment (e.g., cameras, sensors, alarms, etc.). Alarms could be received both on-site and at one or potentially more offsite (remote) locations.
- Support from or reliance on an offsite response force, such as local law enforcement or a company security force, to interdict and neutralize an adversary force attempting radiological sabotage

The alternative framework needs to establish security staffing requirements that are sufficiently flexible as to accommodate limited or no onsite staffing, including consideration of security functions such as access control, detection, assessment and notification of local responders. This includes alternative alarm assessment and notification provisions for a facility that does not have an onsite Central Alarm Station. In addition, requirements or guidance for staffing should consider alternative criteria and methods for deterring insider threats. For example, some sensitive plant areas could have locked doors, and the on-site staff member does not have a key to open them. Also needing consideration are requirements associated with the use of an offsite response force to perform interdiction and neutralization.

The alternative requirements should also consider the potential for using automated systems/equipment and leveraging the staff at a co-located facility to perform some security functions. Further, consideration should be given to how the requirements might change for RHDRA located on military installations (e.g., an adversary force could not access the facility without engaging and defeating a base security force). Finally, the requirements should not preclude the use of advanced technologies, such as biometric/facial recognition and artificial intelligence (AI) solutions, to meet performance goals.

3.1 Changes Needed to Regulations, Policy and Guidance

Through rulemaking, the NRC should establish a technology-inclusive, performance-based, and consequence-oriented physical security framework for advanced reactors that uses a graded approach to set threat and protection requirements. Because of the similarity in accident consequences, the framework's graded approach for RHDRA should reflect the security requirements and guidance applied to RTRs. The development of the framework should also be guided by the principle that the Commission's statutory mandate to "promote the common defense and security and to protect the health and safety of the public" is not incompatible with the need to "impose the minimum amount of such regulations and terms of license as will permit the Commission to fulfill its obligations" under the AEA.

When assessing options for creating regulations that could accommodate RHDRA facilities, it appears that this could be done most rapidly and efficiently by making appropriate changes to the APSRAR and draft proposed Part 53 rulemakings. It is also possible to establish a new framework for RHDRA in Part 73 through a separate rulemaking, but this would likely take longer than making the needed changes to the APSRAR and draft proposed Part 53 rules. Thus, the industry urges the NRC staff to consider including these changes in the forthcoming proposed rules to the extent practicable. At a minimum, the staff should include a question(s) in the proposed rules seeking public comment on this topic – i.e., the creation of physical security framework for RHDRA that uses an RTR-like graded approach to setting threat and protection requirements. If the NRC ultimately agrees to implement this approach, then the Statements of Considerations for the final rule(s) should clearly explain that due to the similarities in the risk and consequence profiles of RTRs and RHDRA, the physical security approach for RTRs is acceptable for use by RHDRA.

Regardless of its location in NRC regulations, a technology-inclusive, performance-based, and consequence-oriented physical security framework for RHDRA should be available to applicants seeking a license under Part 50, Part 52, or Part 53. In addition, the performance-based framework currently proposed in the draft proposed Part 53 rule package, § 73.100, must be accessible to applicants using a Part 50 or Part 52 licensing path (i.e., there is a "connection" to the § 73.100 framework from Part 50 and Part 52). This will help foster greater consistency and efficiency in the licensing process for advanced reactors, including RHRDA.

Appendix 19 – Physical Security

In the near-term, the NRC should develop a regulatory basis with a graded approach to performance-based acceptance to facilitate exemptions. The regulatory basis for such exemptions would, in parallel, facilitate more streamlined and timely rulemaking for alternative requirements to be codified in Parts 50 and 52 as well as in the ongoing Part 53 rulemaking, as discussed above. In this manner, the regulatory basis provides the regulatory clarity for this issue to support both the near-term and longer-term regulatory changes and applications for RHDRA and other advanced reactors.

3.2 Acceptance Criteria and Licensing Approach

General Acceptance Criteria:

As noted above, RHDRA facilities are expected to have low offsite consequences (dose) from accidents due to their relatively smaller radionuclide inventories, simplified systems, and passive or inherent safety features. These accident consequences will be closer in magnitude to those associated with RTR facilities than to those for the larger power reactors on which the requirements in § 73.55 are based. For this reason, a graded approach to physical security requirements based on offsite consequences or features of the reactor design (e.g., a core thermal or radionuclide inventory limit) would be appropriate for RHDRA. As an alternative or additional approach, it may be possible to leverage the results of an emergency planning zone (EPZ) sizing analysis performed under the requirements of § 50.33(g)(2) to establish the threat and protection requirements for a given facility. This could provide a simple consequence-based approach for determining security requirements since EPZ sizing analyses examine offsite consequences from a spectrum of accidents (e.g., demonstrating that no EPZ is needed beyond the site boundary may provide a basis for minimizing security requirements).

Licensing Approach:

Under the RHDRA business model, the deployment schedule is six months from site identification to operations. To achieve this goal, most of the facility application content (security included) will need to be based on a generic model that has been developed and approved by the NRC in advance of the first application, thus minimizing the amount of new or site-specific information in an application.[6] This means that the NRC review and approval of security plan templates and features for a given technology should be accomplished to the maximum extent practicable during the design certification phase and use all available administrative tools (e.g., NRC-approved topical reports or NRC-endorsed NEI technical reports).

For example, a RHDRA developer could submit a security plan template for a standard design to the NRC for review as a topical report or in an application for a Design Certification, a Standard Design Approval, or a Manufacturing License. The guidance for using the template would specify the bounding conditions (i.e., a parameter envelope) for its use and provide instructions for completion of a site-specific plan. Once the NRC has endorsed the template and guidance, the application for any given deployment site would have a security plan based on the template and completed with site-specific information. This should significantly shorten the NRC's review time while still allowing the NRC to verify any site-specific information prior to facility start-up.

[6] Also see the broader discussion of this topic in Appendix 2, "Design Approvals Scope and Authorizations."

4 OTHER OPTIONS FOR RESOLUTION OF THE ISSUE

4.1 AEA Change – Minimal Regulation

The technical and safety bases for power reactors with potential consequences on the order of magnitude of non-power reactors should be sufficient to enable the NRC to adapt the non-power reactor requirements and implementation guidance for those qualifying power reactors. Adaption of the non-power reactor regulatory framework, as discussed in this appendix, should achieve a similar level of regulation that accounts for the safety and operational characteristics of the qualifying power reactors that will tailor requirements and applicability to the technology. An AEA change to direct the NRC to regulate power reactors with potential consequences that are on the same order of magnitude as non-power reactors, e.g., with minimal regulation or under Section 104, is an option that was identified. However, such a change does not appear necessary, since the AEA provides sufficient authority to the NRC to regulate power reactors commensurate with their potential impacts, and is capable within the current AEA provisions to apply regulatory approaches to qualifying power reactors that are similar to those used today for non-power reactors. More discussion on NRC Regulation of Non-Power Reactors is included in Attachment A.

5 ACKNOWLEDGEMENTS

NEI Issue Lead: David Young

Appendix 20 – Emergency Preparedness

1 ISSUE INTRODUCTION

The technical characteristics and concepts of deployment and operations for rapid high-volume deployable reactors for remote applications (RHDRA) have emerged since the NRC regulatory frameworks for Emergency Preparedness (EP) were established, including the framework in the recently promulgated 10 CFR 50.160, "Emergency preparedness for small modular reactors, non-light water reactors, and non-power production or utilization facilities."[1] The provisions in § 50.160 provide a performance-based, technology-inclusive, risk-informed, and consequence-oriented EP framework for use by advanced reactor facilities. However, it is not clear whether the rule provides all the flexibility necessary to achieve cost-effective emergency plans and programs for RHDRA.

The desired outcome for this topic is to ensure that agency positions described in the U.S. Nuclear Regulatory Commission (NRC) guidance used for application reviews and made available to licensees gives sufficient flexibility on methods for complying with § 50.160 and can support the development of emergency plans and EP programs suitable for RHDRA. This includes confirmation that EP program elements can be implemented and evaluated using a graded approach for topics such as the locations from which emergency response functions are implemented and emergency responder staffing. Verification of these agency positions is important because it will allow RHDRA applicants to propose EP program elements that meet both regulatory requirements and business needs. If it is determined that § 50.160 does not provide the needed flexibility, then a rulemaking, exemption requests, and/or additional guidance would be necessary.

2 BACKGROUND

The Atomic Energy Act (AEA) established the NRC's responsibility to regulate radiological hazards to protect the public health and safety in pursuit of the overall goal of the Act to "make the maximum contribution to the general welfare" … "to the maximum extent consistent with the common defense and security and with the health and safety of the public." To meet this mandate, the NRC issues regulations governing the use of nuclear technologies, including power reactor technologies. One such set of regulations are those describing EP requirements that provide reasonable assurance that adequate protective measures can be taken to protect public health and safety during a radiological emergency.

The NRC states "a key component of the NRC's public health and safety mission is ensuring that U.S. nuclear power plants have adequate protective actions in place to protect public health and safety if an accident were to occur. These protective actions are designed to avoid or reduce radiation dose to the public and are sometimes referred to as protective measures." Emergency plans ensure U.S. nuclear power plants can implement adequate measures to protect the public in the event of a radiological emergency. The nation's Response and Recovery Federal Interagency Operational Plan[2] lays out how the NRC acts as the Primary Authority for radiological events involving facilities and/or materials licensed under its regulations. As the Primary Authority, NRC takes the technical lead for the Federal government's response to the event. If the incident could affect the general public, the Department of Homeland Security's Federal Emergency Management Agency (FEMA) may assume coordination of the

[1] See the "Emergency Preparedness for Small Modular Reactors and Other New Technologies: Final Rule;" 88 FR 80050; Nov. 16, 2023

[2] Refer to the Nuclear/Radiological Incident Annex (https://www.fema.gov/sites/default/files/documents/fema_incident-annex_nuclear-radiological.pdf)

federal response, while the NRC would remain the primary federal authority for onsite response. Besides FEMA, other federal agencies responding to an NRC-related event could include the Department of Energy, the Environmental Protection Agency, the Department of Agriculture, the Department of Health and Human Services, the National Oceanographic and Atmospheric Administration, and the Department of State.

The NRC regulatory frameworks for EP for power reactors are defined in 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities." A long-standing prescriptive framework, applicable to the existing fleet of large light water reactors (LLWRs), is provided in § 50.47 and Appendix E to 10 CFR Part 50. An alternative performance-based EP framework was made available in late 2023 when the NRC promulgated a revised § 50.33(g) and the new § 50.160. This rule also updated 10 CFR 50.54(q), which establishes the requirements for following emergency plans and maintaining them in effect.

10 CFR 50.33(g)(2) and § 50.160 provide performance-based EP regulations suitable for advanced reactor technologies. The NRC describes these regulations as "alternative requirements" because they comprise a framework that is an alternative to the prescriptive EP framework and requirements applied to LLWRs. In addition to being performance-based, the alternative framework is technology-inclusive, risk-informed, and consequence-oriented, and considers various anticipated reactor use applications, modular designs, and co-location of a facility with other NRC-licensed facilities and industrial facilities that are not subject to licensing by the NRC.

To better understand the alternative EP requirements contained in the Emergency Preparedness for Small Modular Reactors (SMRs) and Other New Technologies (ONTs) Final Rule, the reader should be aware of several statements of consideration contained in the rule. The first of these is at 88 FR 80064, which states:

> "In carrying out its responsibility under the Atomic Energy Act of 1954, as amended (AEA), the NRC establishes regulatory standards for onsite and offsite radiological emergency planning. If an applicant's or licensee's emergency plan meets the NRC's regulations, then the NRC has reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. In the case of existing EP regulations for NPUFs [non-power production or utilization facility], fuel cycle facilities, and ISFSIs [independent spent fuel storage installations], there are no regulatory requirements for dedicated offsite radiological emergency plans as part of the NRC license. Accordingly, NRC guidance for such facilities states that FEMA findings and determinations are not needed to support NRC licensing decisions. Similarly, for SMRs and ONTs within the scope of this final rule, FEMA findings and determinations regarding reasonable assurance under § 50.54(s)(3) are only needed for a facility where a plume exposure pathway EPZ extends beyond the site boundary requiring dedicated offsite radiological EP plans for the facility."

At 88 FR 80056:

> "The NRC initiated this rule to seek a wide-range of public views and increase regulatory predictability and flexibility in the development of an alternative, generic approach that designers, vendors, and applicants may use to determine the appropriate EP requirements for SMRs and ONTs, for which emergency planning may otherwise be addressed on a case-by-case basis. In particular, this final rule provides additional predictability and flexibility for advanced

> reactor developers that use simplified or other innovative means to accomplish their safety functions and provide enhanced margins of safety."

And this at 88 FR 80057:

> "Based on the information currently available to the NRC, unique design considerations (e.g., passive safety characteristics, advanced fuel types, and chemical processes) and the potential for multi-module facilities and siting contiguous to, or near, NRC-licensed facilities or facilities not licensed by the NRC could lead to a variety of accident frequencies, progression times, and potential consequences for SMRs or ONTs. To incorporate recent and potential technology advancements and reduce the need for future EP rulemaking, this final rule offers a technology-inclusive approach to EP for SMRs and ONTs. In this context, technology-inclusive means the establishment of performance requirements for any SMR or ONT applicant or licensee to use in its emergency plan, developed using methods of evaluation that are flexible and practicable for application to a variety of reactor technologies."

Finally, with regard to microreactors, the NRC provided this response to a public comment on the proposed regulations in NRC 2015-0225; 3150-AJ68 (ML21200A077):

> "Microreactors may present accident consequences comparable to existing non-power reactors, which are already not subject to offsite emergency planning requirements. However, this rulemaking addresses EP for all advanced reactors, including microreactors. Both the rule and accompanying guidance are technology-inclusive, which provides for the scope of EP to be scaled commensurate to the dose consequence risk for a facility on a case-specific basis and using design-specific and site-specific information. The NRC will consider addressing other microreactor regulations in other advanced reactor rulemaking efforts."

3 PROPOSED SOLUTION AND APPROACH

The proposed approach is for an applicant to follow the alternative EP requirements in § 50.33(g)(2) and § 50.160, and associated implementing guidance, to establish an emergency plan and EP program for a RHDRA facility.

Because of design advances, RHDRA are expected to have postulated accidents with low offsite dose consequences due to their slower transient response times, and relatively small and slow releases of fission products. Accordingly, these facilities will likely meet the criteria in § 50.33(g)(2) and be able to justify an emergency planning zone (EPZ) that does not extend beyond the site boundary (i.e., property fence line), which will typically be within 100 meters of the reactor. This may be because either the specified dose limit of 1 rem Total Effective Dose Equivalent (TEDE) (i.e., the U.S. EPA Protective Action Guide limit) is not exceeded beyond the site boundary or because the response to the accident sequences will not require predetermined, prompt protective measures to protect the health and safety of the public.

The requirements in § 50.160 govern the content of emergency plans and program elements for SMRs and ONTs, and are presented below.

Appendix 20 – Emergency Preparedness

1. 10 CFR 50.160(b)(1)(iii) addresses the following performance-based EP functions:
    - Event Classification (50.160(b)(1)(iii)(A))
    - Protective Actions (50.160(b)(1)(iii)(B))
    - Communications (50.160(b)(1)(iii)(C))
    - Command and Control (50.160(b)(1)(iii)(D))
    - Staffing and Operations (50.160(b)(1)(iii)(E))
    - Radiological Assessment (50.160(b)(1)(iii)(F))
    - Reentry (50.160(b)(1)(iii)(G))
    - Critique and Corrective Actions (50.160(b)(1)(iii)(H))
2. 10 CFR 50.160(b)(1)(iv)(A) addresses the following performance-based onsite EP activities:
    - Public information
    - Coordination with the Safeguards Contingency Plan
    - Communication with the NRC
    - Emergency facility or facilities
    - Site familiarization training
    - Emergency plan maintenance
3. The requirements pertaining to offsite coordination and planning are addressed in § 50.160(b)(1)(iv)(B). The requirements of § 50.160(b)(1)(iv)(B) only apply if the facility's plume exposure EPZ extends beyond the site boundary.
4. 10 CFR 50.160(b)(2) – (4) contain additional EP requirements for the assessment of hazards posed by contiguous or nearby facilities and their impact on emergency plans, a description of the EPZ (if necessary), and a description of ingestion response planning.

Each of the requirements listed above, except for those associated with offsite EPZs, would be applicable to RHDRA. However, the characteristics of the technology would be a major consideration in determining the required capabilities and resources necessary to maintain the EP program and implement the emergency plan. The NRC considers this possibility in Regulatory Guide (RG) 1.242, "Performance-Based Emergency Preparedness for Small Modular Reactors, Non-Light-Water Reactors, and Non-Power Production or Utilization Facilities," where they state their intent to employ a graded approach to the assessment of proposed emergency plans and programs for advanced reactor facilities:

> "The NRC will review each application to determine whether an applicant has described how the performance-based framework in 10 CFR 50.160 will be met. The NRC staff will evaluate applications using a graded approach based on site-specific consequence analyses. Program elements that may be implemented and evaluated according to a graded approach include frequency between inspections, drills, exercises, number of performance objectives, and staffing."

Based on the above review, it is concluded that the alternative performance-based EP framework in § 50.160 can support the timely and predictable licensing of RHDRA facilities. Specifically, the requirements and guidance in the alternative framework should provide the flexibility necessary to create cost-effective emergency plans and EP programs suitable for RHDRA technologies. Nevertheless, engagement with the NRC is needed to ensure alignment on certain aspects of the EP requirements. For example, it is important to get confirmation that the envisioned graded approach is sufficiently flexible to accommodate limited or no onsite staffing, performance of emergency plan functions at remote locations (e.g., a remote operations center), extended staff response times commensurate with expected accident development timelines, and reasonable assignment of collateral duties.

3.1 Changes Needed to Regulations, Policy and Guidance

Because the alternative EP framework is technology-inclusive, risk-informed and performance-based, no significant changes to § 50.33(g), § 50.160, or the associated guidance in RG 1.242 were identified as needed to support RHDRA. The NRC review of the initial applications may identify enhancements that can be addressed in the future. It is noted that NEI is developing additional implementing guidance as specific needs are identified (e.g., in NEI white paper, "Selection of a Seismic Scenario for an EPZ Boundary Determination").

However, there is uncertainty associated with how efficiently the NRC could review/address the implementation of EP in a fleet-employment model. An organization that owns and manages many reactors of the same type across many operating sites (potentially dozens or hundreds) and seeks to deploy new reactors within a constrained period (the RHDRA business model goal is 180 days or less from final site identification to declaration of commercial operations) may choose to implement EP through institutional program development and management practices. While likely not rising to the level of a policy or rulemaking issue, the NRC staff's ability to review and "pre-approve" an operating company's plans to deploy multiple plants across multiple sites within a region of interest, and to do that in an expedited manner, may benefit from additional guidance or clarification within the existing guidance for how such fleet-deployment implementation can be achieved acceptably.

The use of a fleet deployment model also raises specific questions about emergency plan requirements concerning the locations from which emergency response functions are implemented and emergency responder staffing. In addition, there may be opportunities to leverage staff and resources at a co-located industrial facility to support an emergency response. These topics need to be discussed with the NRC to confirm that the envisioned arrangements would be acceptable under the graded approach described in RG 1.242. Given that RHDRA facilities have characteristics and accident consequences more like those of Research and Test Reactors (RTRs) than large LWRs, any additional guidance on these topics, if needed, should be based on the relevant RTR guidance.

Appendix 20 – Emergency Preparedness

Although a RHDRA facility may have an EPZ within the site boundary (or no EPZ), it is still expected that offsite organizations (i.e., law enforcement, fire, and medical/rescue) may respond in the event of an emergency. If formal agreements need to be developed and maintained with these offsite organizations, additional guidance may be necessary regarding the point in the licensing process at which these agreements must be in place (i.e., would these agreements need to be included in the license application or would a license condition be necessary) to support the concept of rapid deployment.

Related to EP, the guidance in RG 1.23, "Meteorological Monitoring Programs for Nuclear Power Plants," states that a minimum of two years (preferably three) of site-specific meteorological data is needed to support atmospheric dispersion calculations for Main Control Room dose (GDC 19), offsite dose (10 CFR Parts 20, 50, 52), occupational dose (10 CFR Part 20), design basis hazard characterization (10 CFR Parts 50 and 52), and emergency planning (10 CFR 50.47). An EP requirement for an onsite meteorological tower to support offsite dose assessments during an accident is codified in Appendix E to 10 CFR 50; however, under the performance-based approach in § 50.160, alternative data sources could be found acceptable. These sources are discussed in Appendix 10 on Meteorology and Weather Data and could include the National Oceanic and Atmospheric Administration-National Centers for Environmental Information (NOAA-NCEI), state/federal environmental protection agencies, or other local sources. This is another area where a clear understanding of the NRC position is needed to ensure alignment on an approach that meets both regulatory requirements and RHDRA business needs.

In summary, it is expected that the alternative performance-based EP requirements in § 50.33(g) and § 50.160 can support the timely licensing and deployment of RHDRA facilities. As noted in several locations above, the NRC should consider establishing official agency positions that will give assurance that the envisioned graded approach to compliance with EP requirements can accommodate the business needs of RHDRA applicants. The vehicle for agency positions could take different forms, including the issuance of Interim Staff Guidance or the revision of a Regulatory Guide.

3.2 Acceptance Criteria and Licensing Approach

The only acceptance criterion necessary for an advanced reactor facility to qualify for using the alternative performance-based EP framework discussed above is that the reactor (module) produce less than 1,000 megawatts thermal power (refer to § 50.2, § 50.33(g), § 50.34(a), and § 50.160). RHDRA facilities will be able to meet this criterion.

A licensing approach for EP that would support RHDRA includes:

- Seeking NRC acceptance of a one-time review and approval of non-site-specific emergency plan content (e.g., performance objectives, event classification and mitigation, protective actions, communications, command and control, staffing, radiological assessment, reentry, critiques and corrective actions, locations of emergency response equipment and supplies, emergency response facility[ies], and maintaining the emergency plan).
    - As one approach, a generic emergency plan could be developed and submitted by the applicant/operator or technology designer to the NRC as a Topical Report. The report would be structured with bounding conditions describing when and how each section could be used. Once approved, applicants could use the contents of the report to develop the emergency plan for a facility application, thus significantly shortening the NRC review time.

  - Upon submittal of a license application, NRC would then review and approve site-specific EP content (e.g., offsite support to onsite response efforts and hazards associated with contiguous or nearby facilities) and verify that the rest of the EP content conforms to the approved topical report. The staff would also ensure that any limitations and conditions placed on the use the topical report have been met in the site-specific application.

- One-time NRC review and approval of an EPZ sizing analysis based on a technology-specific site parameter envelope.

  - Upon submittal of a license application by the licensee/operator, NRC would then review the application to ensure the site falls within the set of bounding site parameters and the EPZ is appropriate for the site.

- Each site license application would incorporate by reference the prior approved NRC emergency plan and EPZ size.

4 OTHER OPTIONS FOR RESOLUTION OF THE ISSUE

4.1 AEA Option – Minimal Regulation

The technical and safety bases for power reactors with potential consequences on the order of magnitude of non-power reactors should be sufficient to enable the NRC to adapt the non-power reactor requirements and implementation guidance for those qualifying power reactors. Adaption of the non-power reactor regulatory framework, as discussed in this appendix, should achieve a similar level of regulation that accounts for the safety and operational characteristics of the qualifying power reactors that will tailor requirements and applicability to the technology. An AEA change to direct the NRC to regulate power reactors with potential consequences that are on the same order of magnitude as non-power reactors, e.g., with minimal regulation or under Section 104 is an option that was identified. However, such a change does not appear necessary, since the AEA provides sufficient authority to the NRC to regulate power reactors commensurate with their potential impacts, and is capable within the current AEA provisions to apply regulatory approaches to qualifying power reactors that are similar to those used today for non-power reactors. More discussion on NRC Regulation of Non-Power Reactors is included in Attachment A.

5 ACKNOWLEDGEMENTS

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Appendix 21 – Access Authorization and Fitness for Duty

1 ISSUE INTRODUCTION

The Access Authorization and Fitness for Duty (AA/FFD programs) programs are designed to provide assurance that personnel meet high standards of trustworthiness and reliability, by providing assurance that personnel are fit to perform nuclear duties safely and completely free from impaired conditions. The integrity of AA/FFD programs directly contributes to viable insider threat mitigation initiatives and supports an effective safety program. Operator reactor staffing and the concept of operations applicable to the design will help determine the AA/FFD program requirements. The current regulatory framework for Access Authorization (10 CFR 73.56) and Fitness for Duty (10 CFR Part 26) establishes the criteria for each program. The NRC draft proposed rulemaking, Part 53, proposed alternative requirements with less restrictive AA/FFD mandates than would be required today for large light-water-reactors (LLWRs). However, it is not clear whether the draft proposed Part 53 alternative requirements have fully contemplated the concept of operations for the rapid high-volume deployable reactors for remote applications (RHDRAs).

The desired outcome is that the NRC establishes an alternative regulatory framework for AA/FFD that is commensurate with the technology capabilities and concept of operations for RHDRAs. RHDRA are more similar to non-power research and test reactors (RTRs) than to other commercial power reactors and the approach for AA/FFD for RHDRA should be closer to the programs implemented for RTRs or 10 CFR Part 37 Category 1 and Category 2 quantities of radioactive material. The alternative regulatory framework would create an AA/FFD program that enables the two options of concept of operations: 1) as low as a single person on-site, and 2) no on-site staffing, operations from a remote center and field technicians that visits site periodically.

2 BACKGROUND

Although AA/FFD are addressed in separate parts of the regulations, Part 73.56 and Part 26 respectively, they are typically addressed together since they serve similar purposes.

- The purpose of AA is to protect against an *insider* threat at the plant. The purpose of an AA program is to demonstrate that each person granted unescorted access to the facility 1) is trustworthy and reliable, 2) does not constitute an unreasonable risk to the health and safety of the public or the common defense and security, and 3) does not pose a threat to interrupt the normal operations of the plant or to commit radiological sabotage.

- The purpose of FFD is to provide reasonable assurance that nuclear facility personnel are trustworthy, will perform their tasks in a reliable manner, are not under the influence of any substance, legal or illegal, that may impair their ability to perform their duties, and are not mentally or physically impaired from any cause that can adversely affect their ability to safely and competently perform their duties.

The NRC has established requirements for AA/FFD for the following licensed activities:

- Personnel Access Authorization
    - 10 CFR 73.56 establishes AA requirements for commercial power reactors

  - 10 CFR 73.57 establishes requirements for criminal history records checks of individuals granted unescorted access to a nuclear power facility, a non-power reactor or access to Safeguards information

- Fitness for Duty

  - 10 CFR Part 26 establishes FFD program requirements for licensees authorized to operate a nuclear power reactor under 10 CFR 50.57 and holders of combined operating licenses under Part 52, as well as licensees authorize to possess, use, or transport strategic special nuclear material under Part 70

The current regulatory framework for Access Authorization and Fitness for Duty is prescriptive and not flexible for the use of RHDRA.

The most recent draft proposed version of the Part 53 rulemaking[1] is more performance-based and flexible for the purposes of RHDRA and other advanced reactors. Specifically, the current version of draft proposed Part 53 rule package (proposed 73.120 and Subpart M of Part 26) includes requirements that allow applicants meeting certain criteria to:

- Develop, implement, and maintain an FFD program that demonstrates compliance with the proposed requirements in 10 CFR Part 26.601-26.619

- Develop, implement, and maintain an AA program that demonstrates compliance with the proposed requirements in 10 CFR Part 73.120

These programs are modeled on the existing large light water reactor programs for AA/FFD. The draft proposed Part 53 standard enables advanced reactors that meet the entry requirements to meet more appropriate AA/FFD mandates than the full programs currently required for LLWRs. Programs not meeting the entry requirements would implement the full AA/FFD requirements, which are extensive, but provide reasonable assurance that individuals that are subject to the program are trustworthy and reliable.

In contrast, RTRs and licensees that possess Category 1 and Category 2 quantities of radioactive material do not have similar requirements for AA/FFD. These classes of licensee have reduced AA requirements, and typically do not have FFD requirements. Since the concept of operations relies on significantly reduced staffing, whether on-site or offsite, it is strongly believed that the NRC will require applicants of RHDRAs to have both AA and FFD programs.

3 PROPOSED SOLUTION AND APPROACH

Advanced reactors are expected to have relatively small cores (material at risk/source terms), simplified systems, and passive or inherent safety features. It is also expected that the potential offsite consequences for RHDRAs and similar advanced reactors will be similar to those for RTRs rather than to those of LLWRs for which the existing regulations were developed. The alternative regulatory framework

[1] The most recent draft of the proposed rule is dated March 2023 – ML21162A095 and ML21162A102

should consider, and be based upon, both the existing AA/FFD programs, as applicable, for RTRs and large LWRs, and adjusted as appropriate to be commensurate with the simplicity, safety features, and consequences and risks of the technology. The alternative regulatory approach should also credit advanced technologies, e.g., facial recognition, artificial intelligence (AI), to meet the required function of the AA/FFD program. The proposed program would continue to meet the standard of providing reasonable assurance that individuals that are subject to both programs are trustworthy and reliable.

Access Authorization:

An alternative approach that is performance-based and graded is needed for RHDRA and other advanced reactors. The alternative approach should establish the acceptance criteria that must be met and the corresponding requirements for features and functions that must be implemented. The alternative approach should include guidance to provide clarity to applicants.

It would be appropriate that these AA requirements for RHDRA to provide reasonable assurance that individuals are trustworthy and reliable include the following: background investigation, verification of true-identity, employment evaluation, unemployment, education, military service, credit history evaluation, character reputation evaluation, FBI criminal history, behavior observation, self-reporting.

One challenge noted is that of behavior observation. In a full operating 10 CFR 73.56 framework, there are requirements for training in behavior observation. For the proposed approach, personnel should have some level of training in observing concerning or aberrant behaviors, including insider threat. The frequency or level of training for RHDRAs should be less stringent than the 10 CFR 73.56 program requirements based on their lesser offsite dose consequences. Furthermore, the alternative approach should consider alternative methods of observing behavior, such as greater reliance on technology (e.g., biometrics, facial recognition or AI pattern recognition) and less frequent interactions (e.g., limited to shift turnover or virtual meetings) rather than direct constant human to human interactions.

As mentioned, program elements include background investigation, psychological screening, fingerprinting, and fitness for duty (drug screening). Behavior observation is a hallmark program that supports safety and security programs in assuring that aberrant behavior is observed, documented and reported. The current 10 CFR 73.56 operating program requires formal annual review from supervisors. An annual review may not be necessary for the proposed approach for RHDRA and other advanced reactors, as personnel are expected to report aberrant behaviors immediately. Additionally, the current AA programs require an annual FFD training followed by an exam (continued AA is predicated on completing training). However, there are considerations for training a population of personnel on what specific behaviors to look for and the frequency could be varied depending on the needs of the organization.

Initial background investigations are required under both the draft proposed Part 53 and 10 CFR 73.56. The elements of the background investigation are ostensibly the same, however, once an individual exceeds 30 days unobserved from the Behavior Observation program, the individual must be processed as a reinstatement for reissuance of the clearance. For RHDRAs and in consideration for sites that are isolated, modifying the requirement to longer than 30 days based on the applicant's concept of operations or eliminating the requirement may be appropriate. The reduced burden of reduced reinstatements would provide relief to the site administrators. Additionally, a random-pre-access drug/alcohol screen could be implemented providing assurance that personnel can never know whether a drug/alcohol screen will be conducted. The employee should sign a program document stipulating there have been no arrests, drug/alcohol activity etc. during the time outside Behavior Observation, and if signed untruthfully, could result in termination.

Some type of reinvestigation will be necessary. Currently 10 CFR 73.56 requires reinvestigations every three years with a psychological component every five years for personnel designated as critical for LLWRs. Increases in reinvestigation periodicity may be suitable given the limited ability for workers to affect plant safety and security.

Fitness For Duty:

An alternative approach that is performance-based and graded is needed for RHDRA and other advanced reactors. The alternative approach should establish the acceptance criteria that must be met and the corresponding requirements for features and functions that must be implemented. The alternative approach should include guidance to provide clarity to applicants. It would be appropriate that these FFD requirements for RHDRA provide reasonable assurance that individuals are trustworthy and will perform their tasks in a reliable manner, are not under the influence of any substance, legal or illegal, that may impair their ability to perform their duties, and are not mentally or physically impaired from any cause that can adversely affect their ability to safely and competently perform their duties.

It would be appropriate for FFD requirements to require conditions for testing such as Pre-Access, Random, For Cause, Post-Event, Follow-Up. A modified program that considers reducing the random testing population based on the level of detected abuse may be a reasonable approach. The population could be adjusted annually based on current metrics and trends.

Varied FFD testing devices and materials should also be considered. Oral fluid testing allows for portable transport, easy administration, and meets the same screening standards as urine collection. A program should also consider other options, such as rapid testing with kits that can determine the presence of a drug metabolite within minutes. An individual detected with this mechanism could be referred for full specimen collection at the program's request. Additional consideration will be needed into how and who administers the testing since many of these sites may be remote.

The alternative approach should be based upon the duties that workers perform that could impact the safety or security of the plant. It is expected that RHDRAs will have greatly reduced potential for workers to impact the safety and security of the plant.

The alternative approach should consider alternative methods of testing, such as greater reliance on technology (e.g., biometrics, facial recognition or AI pattern recognition or self-serve scanning/testing devices) to verify the identity of the individual and that the test specimen is from that individual. Use of such technology could be more easily implemented in operational models where there are not constantly two individuals together, with one being an administrator of the FFD program testing. Such approach could consider notification methods for random unannounced testing, with appropriate response time for use of the self-serve testing machines, and a response time from the FFD program administrators to respond if a test indicates the personnel needs to be removed from duty. Additionally, technology also offers options for scanning for alcohol detection through the skin and swab devices that can detect the presence of drugs by swabbing exterior surfaces.

Appendix 21 – Access Authorization and Fitness for Duty

Construction:

The alternative approach should also consider AA/FFD during construction. An alternative approach that is performance-based and graded is needed for RHDRA and other advanced reactors. The alternative approach should establish the acceptance criteria that must be met and the corresponding requirements for features and functions that must be implemented.

The alternative approach should establish the acceptance criteria that must be met and the corresponding requirements for features and functions that must be implemented.

The approach could consider, for example, random testing and performance monitoring.

3.1 Changes Needed to Regulations, Policy and Guidance

The alternative approach is expected to need new NRC requirements as alternatives to existing 10 CFR 73.56 and Part 26 requirements and would need go beyond the NRC proposed 73.120 and Subpart M of Part 26. The alternative regulations should be limited to individuals whom the licensee intends to grant unescorted access to the facilities' most sensitive areas – those for which the individual could impact the safety or security of the reactor such that it could result in off-site releases. Additional guidance will also be needed, which goes beyond the NRC proposed DG-5073 and DG-5074.

Consideration for an annual adjustment of the random testing rate should be considered. Rather than utilizing the Part 26 test standard of fifty percent of the population, consider an adjustable random rate of testing. Additionally, frequency of random generation should be adjusted commensurate with the population size.

3.2 Acceptance Criteria and Licensing Approach

General Acceptance Criteria:

For the AA/FFD topic, it is expected that the majority of the proposed approach would be applicable to any advanced reactor that utilizes the requisite technology to enable these approaches (e.g., biometrics, facial recognition or AI pattern recognition or self-serve scanning/testing devices). The use of a graded approach for the acceptance criteria, based upon different levels of potential off-site consequences (such as doses) or based on features of the reactor design (e.g., a source term or core thermal limit), would be appropriate. Small off-site doses are expected to be achieved through the use of passive and inherent systems, simplicity and other features that result in higher safety margins and lower risks.

Licensing Approach:

For RHDRA that need to achieve a 6 month or less deployment timeline, it is expected that the NRC review relative to AA/FFD would be performed during the design approval to establish a program template for site licenses, and would be addressed in a Topical Report for the AA/FFA Program by the potential licensee/operator for pre-approval prior to submitting the site license application. For these applications the licensing approach is expected to be based on the following:

- For the AA/FFD topic, the rapid efficient licensing for rapid high-volume deployment process should be used to minimize the scope, content and purpose of the site-specific reviews. This type of site-specific review would enable completion of all, or as much as possible, of the safety and environmental reviews as possible one-time prior to the identification of a specific site. Where the entire site-specific review is not possible before site identification, performing a site license review that only needs to verify that the site characteristics conform to the minimum set of site parameters in the envelope established in the one-time up-front reviews is recommended.

- This would include use of a standardized design that has been approved by the NRC, such processes include, Standard Design Approval, Design Certification, Manufacturing License, COL and subsequent COLs, and Part 50 Appendix N. These offer different levels of NRC approvals in terms of scope of the design and finality in the NRC decision.

- The rapid efficient licensing for rapid high-volume deployment process should also be used for the construction period. In that way, the AA/FFD program for construction would be in place at the time of site application submittal to the NRC and would support immediate construction upon approval of a limited work authorization.

4 OTHER OPTIONS FOR RESOLUTION OF THE ISSUE

4.1 AEA Change– Minimal Regulation

The technical and safety bases for power reactors with potential consequences on the order of magnitude of non-power reactors should be sufficient to enable the NRC to adapt the non-power reactor requirements and implementation guidance for those qualifying power reactors. Adaption of the non-power reactor regulatory framework, as discussed in this appendix, should achieve a similar level of regulation that accounts for the safety and operational characteristics of the qualifying power reactors that will tailor requirements and applicability to the technology. An AEA change to direct the NRC to regulate power reactors with potential consequences that are on the same order of magnitude as non-power reactors, e.g., with minimal regulation or under Section 104 is an option that was identified. However, such a change does not appear necessary, since the AEA provides sufficient authority to the NRC to regulate power reactors commensurate with their potential impacts, and is capable within the current AEA provisions to apply regulatory approaches to qualifying power reactors that are similar to those used today for non-power reactors. More discussion on NRC Regulation of Non-Power Reactors is included in Attachment A.

5 ACKNOWLEDGEMENTS

NEI Issue Lead: Johnny Rogers

Appendix 22 – Radiation Protection

1 ISSUE INTRODUCTION

Radiation protection (RP) program approval (including radiation monitoring strategy) will depend upon the approved operations approach (e.g., remote operations or remote monitoring).

With remote monitoring or operations, onsite RP will not be needed. However, if someone is required to be onsite, the individual would potentially either need to be qualified in RP or access to specific locations would need to be precluded. The desired outcome for the radiation protection part of the business case would be the NRC accepting that:

1. a corporate RP program can provide the oversight of multiple remote micro-reactor sites, where RP qualified individuals are not on site at all times.

2. evaluation of preoperational baselines (e.g., background radiation studies) are unnecessary and that the baseline can rely entirely on previously established data (e.g., U.S. Geological Survey USGS), if necessary.

It is expected that this approach is compatible with the existing requirements of 10 CFR 20.1101, “Radiation protection programs.”

2 BACKGROUND

The purpose of a radiation protection program is to ensure the protection of members of the public, occupational workers, and the environment while complying with the requirements of 10 CFR Part 20, “Standards for Protection Against Radiation.” This is done, in part, by maintaining doses to individuals (occupational & public) as low as is reasonably achievable (ALARA) and ensuring regulatory dose limits are not exceeded. An OMB Circular dated December 7, 1973, established the Responsibility for Setting Radiation Protection Standards delegated to the EPA and NRC (then AEC).

The NRC has established dose limits for the public and occupational workers in 10 CFR Part 20. In addition, in 40 CFR Part 190, “Environmental Radiation Protection Standards for Nuclear Power Operations,” the EPA has established dose limits for members of the public for exposures from the uranium fuel cycle. The NRC has also incorporated these EPA limits in 10 CFR 20.1301(e).

10 CFR 20.1101 requires licensees to develop, document, and implement an RP program commensurate with the scope and extent of licensed activities sufficient to demonstrate compliance with 10 CFR Part 20. The main functions of an RP program are to ensure the adequate protection of the individuals by establishing several technical areas and programs such as: 1) procedures, processes and engineering controls that implement the principles of time, distance and shielding to maintain actual doses to individuals ALARA; 2) training programs to inform individuals of the potential radiological hazards and the use of procedures and engineering controls; and 3) monitoring/survey strategies for plant areas, occupational exposures, effluents and the environment.

An RP program is founded on practical procedures (e.g., training, posted signage, guidelines for workers) and engineering controls (e.g., radiation monitors, shielding, protective equipment). In most cases, workers trained and qualified in RP can conduct work activities in areas with measurable radiation

Appendix 22 – Radiation Protection

without the need for dedicated and separate RP personnel. Increased use of technology (e.g., remote monitoring, digital twins, shielding, robotics, etc.) can also reduce the need for RP functions to be performed by individuals onsite.

Large light water reactor guidance in NUREG-0800, Chapter 12, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants – LWR Edition: Radiation Protection," is not generally applicable to RHDRAs. RHDRAs are expected to have relatively small cores (material at risk/source terms), simplified systems, and passive or inherent safety features. Therefore, the guidance for non-power reactors found in NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors," is more applicable.

NUREG-1537, Ch. 11, "Radiation Protection Program and Waste Management," notes that the responsibilities of the radiation protection organization at the facility and any other onsite radiation protection and radioactive waste management organizations be described in an application. Although there is no specific requirement for onsite radiation protection personnel, the guidance and precedents imply that radiation protection will be onsite during operations (at a minimum).

Specific review/acceptance criteria in NUREG-1537, Part 2 for non-power reactors, however, do not mention "onsite." The guidance does note that the radiation protection programs for non-power reactors should be expected to vary and may be found acceptable if the program meets the intent of the requirements to adequately protect the health and safety of the public (which also includes occupational workers).

The radiological hazards of RHDRA are expected to be similar to non-power (i.e., research and test) reactors. Changes to the guidance may not be needed for RHDRAs, but a technical basis will be needed to justify why it is acceptable to not have dedicated and separate RP personnel onsite during operations, and how the radiation protection program will be able to adequately protect health and safety.

NUREG-1537, Ch. 11 and Ch. 7.7, "Radiation Monitoring Systems," discuss radiation monitoring systems from the exposure/dose perspective and from a reactor diagnostic and safety perspective. The reactor design and expected radiation monitoring capabilities will need to be well understood because the expectation is for no personnel to be onsite.

Changes to guidance may not be needed since a lot of the acceptance criteria are flexible in the sense that they are dependent upon designs and radiation sources. However, since RP personnel will not always be on-site during operations, the approach for remote monitoring via radiation monitors will need to be explained to justify how periodic surveys and other activities are performed to demonstrate compliance with 10 CFR Part 20.

NUREG-1537, Ch. 11.1.7, "Environmental Monitoring," discusses the evaluation of environmental monitoring programs, including, for new facilities, establishment of preoperational baselines for natural background to better understand the potential facility impact on the environment. The baseline environmental survey establishes the background radiation at the location of the nuclear facility so that impact of operations on the environment is well understood.

The NRC currently expects the baseline environmental survey to be conducted over two years before submittal of the site license application. However, the RHDRA business model (e.g., 6 months from site identification to operation) would require a more optimized approach to allow for a streamlined site identification to operation timeline, which would not allow sufficient time for data collection and will need to rely on pre-existing data. A technical basis will most likely need to be provided that justifies why establishment of a preoperational baseline study/survey is not needed. This can potentially be done using pre-existing data from generally available sources (e.g., USGS).

Guidance for large light water reactors in Regulatory Guide 4.1, "Radiological Environmental Monitoring for Nuclear Power Plants," addresses the environmental monitoring program. The guide discusses principles and concepts important to environmental monitoring at nuclear power plants. The regulatory guide also addresses the need for preoperational and background characterization of radioactivity.

Because guidance in NUREG-1537 is more appropriate for RHDRA, the principles and acceptance criteria for research and test reactors may be more suitable. NUREG-1537 guidance, which expects a preoperational baseline, does not specify details for what a baseline must include, but rather gives the applicant broad discretion to select the methods used to understand natural background levels for the purpose of determining the radiological impacts of the facility on the environment.

3 PROPOSED SOLUTION AND APPROACH

The proposed approach is an RP program for RHDRA and other similar advanced reactors that meets the guidance in NUREG-1537, avoids the need for dedicated RP staff on-site, and allows a small RP staffing organization at the Remote Operations Center to run the RP program and perform RP oversight activities at sites when needed. This approach would be technology-inclusive and performance-based and would comply with existing Part 20 requirements.

In addition, the alternative approach would establish guidelines (based on the reactor design, available pre-existing data, using conservative assumptions as necessary) that justify why a preoperational study is unnecessary to establish the background radiation baseline. That justification would be documented to provide a technical basis for future use in NRC licensing and potentially the development of NRC guidance on alternative approaches to radiation protection programs for RHDRA and similar advanced reactors. This approach should not pose a major risk to the proposed business model since these issues can be addressed through changes to guidance and do not require changes to regulations.

Applicants will need to develop the concept of deployment (e.g., fuel load or criticality testing), operations (e.g., dose rates in all locations, management of radioactive effluents), and reactor module replacement to identify activities that will be impacted by radiation sources, and develop potential radiological hazards/considerations (e.g., shielding, dose rates outside of housing, radiation sources (if any), potential online maintenance RP support, etc.) to demonstrate that they will protect public health and safety utilizing the proposed operations strategy.

In addition, without NRC guidance that supports RHDRA not needing to perform a preoperational baseline, applicants will also need to demonstrate that pre-existing data provide sufficient justification for not performing a preoperational baseline study/survey.

3.1 Changes Needed to Regulations, Policy and Guidance

The alternative approach is expected to meet current NRC requirements in 10 CFR 20.1101, and changes to NRC regulations are not expected to be needed.

Appendix 22 – Radiation Protection

The NRC will need to clarify that the radiation protection programs for RHDRA and other advanced reactors should follow NUREG-1537. This may need to be documented through some type of official agency position.

The following minor revisions to guidance documents would be helpful, but are not required to enable the business model:

- NUREG-1537 should be revised to clarify and augment some of the guidance. For example, clarifications in areas like RP staffing needs/expectations and preoperational radiological environmental monitoring programs (REMPs) would be beneficial.
    - RG 4.1, "Radiological Environmental Monitoring for Nuclear Power Plants"
        - Although we expect to use NUREG-1537 to identify acceptance criteria, RG 4.1 provides guidance on preoperational REMP programs at nuclear power plants. While RG 4.1 is not suitable for use with RHDRA, it contains useful guidance on the structure and contents of a preoperational REMP program. RG 4.1 recommends that a REMP should be established at least 2 years before initial facility operations, which would conflict with the current business case.

          Thus, NUREG-1537 should be modified to include the conditions for which a preoperational REMP is not needed, or a much shorter survey is acceptable (e.g., because the site and/or region is remote and/or well understood, pre-existing data are available, or conservative assumptions can be used).

3.2 Acceptance Criteria and Licensing Approach

General Acceptance Criteria:

For the RP topic, the use of a graded approach for the acceptance criteria, based upon different site-specific radiological hazards and different levels of potential off-site doses, would be appropriate. Small on-site radiological hazards and off-site doses are expected to be achieved through the use of passive and inherent safety systems, simpler designs, and other features that result in higher safety margins and lower risks. The extent to which technology is incorporated into the plant will also determine the functions needed to be performed by workers. For facilities with very small potential radiological hazards, the RP programs are expected to be simple and not require dedicated RP staff (except in rare plant evolutions like the replacement of a used reactor module).

It is too early to know the range of reactor types or sizes that would be suitable for use of the alternative RP approach until the performance-based and graded acceptance criteria and program elements are established. It is conceivable that the technical basis for the alternative regulatory approach could permit larger advanced reactors (e.g., 300 MWe or more) to use all or some of the elements of the approach based on NUREG-1537.

Licensing Approach:

Any licensing approach can be used for radiation protection. To achieve the timelines for the RHDRA, for the RP topic, the rapid efficient licensing for rapid high-volume deployment process should be used to optimize the scope, content and purpose of the site-specific reviews. This type of site-specific review would enable completion of most, if not all, of the safety and environmental reviews and public engagement processes one-time prior to the identification of a specific site. Where the entire site-specific review is not possible before site identification, performing a site license review that only needs to verify that the site characteristics conform to the minimum set of site parameters in the envelope established in the one-time up-front reviews is recommended.

This would include use of a standardized design that has been approved by the NRC. Such processes include, Standard Design Approval, Design Certification, and Manufacturing License. Operating license applications and COLAs referencing identical designs can make use of Part 50 Appendix N and Part 52 Appendix N to facilitate site license reviews. These offer different levels of NRC approvals in terms of scope of the design and finality in the NRC decision.

NRC pre-approval of a licensee's operational programs can also be used for Radiation Protection. An applicant's submittal of non-site-specific information for early NRC review and approval can significantly reduce the scope and duration of the NRC's review of the site license application.

4 OTHER OPTIONS FOR RESOLUTION OF THE ISSUE

4.1 AEA Change – Minimal Regulation

The technical and safety bases for power reactors with potential consequences on the order of magnitude of non-power reactors should be sufficient to enable the NRC to adapt the non-power reactor requirements and implementation guidance for those qualifying power reactors. Adaption of the non-power reactor regulatory framework, as discussed in this appendix, should achieve a similar level of regulation that accounts for the safety and operational characteristics of the qualifying power reactors that will tailor requirements and applicability to the technology. An AEA change to direct the NRC to regulate power reactors with potential consequences that are on the same order of magnitude as non-power reactors, e.g., with minimal regulation or under Section 104, is an option that was identified. However, such a change does not appear necessary, since the AEA provides sufficient authority to the NRC to regulate power reactors commensurate with their potential impacts, and is capable within the current AEA provisions to apply regulatory approaches to qualifying power reactors that are similar to those used today for non-power reactors. More discussion on NRC Regulation of Non-Power Reactors is included in Attachment A.

5 ACKNOWLEDGEMENTS

NEI Issue Lead: Micheal Smith

Appendix 23 – NRC Oversight and Inspection

1 ISSUE INTRODUCTION

NRC conducts oversight and inspection of a number of regulated activities, including on-site construction of the nuclear energy facility, select manufacturing activities at vendor facilities, pre-operational readiness, and on-going operations. NRC's oversight program for power reactors today uses a variety of NRC inspectors who monitor plant activities. The program includes baseline inspections common to all nuclear plants. The baseline inspection program, based on the Reactor Oversight Program (ROP) cornerstone areas, focuses on activities and systems that are "risk significant" (in other words, those activities and systems that have a potential to trigger an accident, can mitigate the effects of an accident, or can increase the consequences of a possible accident). The inspections are performed by NRC resident inspectors stationed at each nuclear power plant and inspectors based in the NRC regional offices or in NRC Headquarters. Inspectors follow guidance in the NRC Inspection Manual, which contains objectives and procedures to use for each type of inspection. The contents of the Inspection Manual address licensed nuclear power plants, fuel cycle facilities, and radioactive materials activities and operations. However, the focus is primarily on nuclear power plants. There are numerous Chapters in the Inspection Manual covering the full range of inspection topics. There is a companion list of Inspection Procedures that provide details of each inspection.

Today the NRC has two resident inspectors at each power reactor site, which for a fleet of 100 micro-reactors (potentially all at different sites) would be 200 NRC inspectors, plus Regional or Headquarters inspectors for specific inspections where subject matter expertise is needed. However, to enable the business model and meet the business requirement that regulatory costs are less than 1% of total O&M costs, the NRC will need to achieve about three total inspectors for a fleet of 100 micro-reactors. This means that the inspectors would not visit a site more than one or a few times per year. While this may be similar to the level of oversight and inspection for research and test reactors (RTRs), the NRC has not provided clarity on whether the operations oversight and inspections will achieve the effectiveness and efficiency commensurate with the technology.

For construction oversight and inspection the NRC is developing the Advanced Reactor Construction Oversight Program (ARCOP), but is not yet clear whether the ARCOP will achieve effective and efficient oversight and inspections commensurate with the technology, or whether oversight and inspection considerations will support rapid high-volume deployment of reactors.

To meet the needs of the business model and the business requirement that regulatory costs are less than 1% of total O&M costs, the NRC should establish, for both construction and operations, an oversight and inspection program for rapid high-volume deployable reactors commensurate with the technology, which is based on, and very similar to, the oversight for RTRs. This program should take into account the novel features of factory pre-fabrication, closure of all ITAAC prior to emplacement at site, simplicity and reduced safety systems/controls, and remote operations. The Inspection Manual Chapters and Inspection Procedures to be used by NRC's inspectors should be made specific to the reactor technology and operational considerations for rapid high-volume deployable reactors in remote applications (RHDRA).

2 BACKGROUND

The NRC's inspection program is authorized by the Atomic Energy Act of 1954, as amended; Section 161.o. Section 206(d) of the Energy Reorganization Act of 1974 and 10 CFR Part 21 provide the NRC with inspection authority for vendors. The statutory requirements provide broad discretion to the NRC, and are flexible to enable the NRC to implement the AEA through regulatory requirements that are appropriate to the technology. The NRC has implemented the current inspection program as a fundamental component of the Reactor Oversight Program.

The statements of consideration (SOC) for NRC's 1988 final rule, "Licensee Announcements of Inspectors" (53 FR 42939), state as follows:

> "As discussed above, the purpose of the rule is to enhance the credibility of the inspection process. Inspections are specifically authorized under Section 161o of the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2201(o). The regulation is narrowly drawn to achieve a legitimate governmental interest (effective NRC inspections) without infringing on an individual's right to express ideas and opinions on any subject. Thus, the regulation does not impermissively intrude upon freedom of speech protected by the First Amendment to the Constitution."

The regulation does not raise any significant Fourth Amendment considerations. The Atomic Energy Act creates a pervasive regulatory scheme that puts licensees on clear notice that they will be subject to inspection, and the granting of a license is conditioned on consent to reasonable inspections. Thus, NRC inspections of licensees' premises, activities and records do not require a warrant under the Fourth Amendment.

Inspection requirements for power reactors are addressed in § 50.70, "Inspections." This regulation, in § 50.70(a), requires that each applicant or holder of a license permit NRC to perform inspections of their licensed facility. There is a similar requirement in § 21.41, "Inspections." In § 50.70(b) each licensee and holder of a construction permit shall, upon request of the NRR Office Director, provide rent-free office space for the exclusive Commission inspection personnel, including heat, air conditioning, light, electrical outlets, and janitorial services, and includes guidance on the size of the office and general location of the space. In § 50.70(b)(3) licensees or construction permit holders are required to provide "immediate unfettered access, equivalent to access provided regular plant employees."

The provisions in the AEA and the NRC regulations would apply to inspections at manufacturing facilities under a Manufacturing License issued under Part 52.

Inspector findings of violations of NRC regulations are addressed through the ROP and the Enforcement Program. The NRC's enforcement jurisdiction is drawn from the Atomic Energy Act (AEA) of 1954, as amended, and the Energy Reorganization Act (ERA) of 1974, as amended. Subpart B of 10 CFR Part 2 of NRC's regulations sets forth the procedures the NRC uses in exercising its enforcement authority.

NRC uses three primary enforcement sanctions:

1. Notice of Violation: A Notice of Violation (NOV) identifies a requirement and how it was violated, formalizes a violation pursuant to 10 CFR 2.201, and normally requires a written response.

2. Civil Penalties: A civil penalty is a monetary fine issued under authority of Section 234 of the AEA or Section 206 of the ERA. The most recent dollar amounts are provided in the Enforcement Policy.

3. Orders: Orders modify, suspend, or revoke licenses or require specific actions by licensees or persons.

The Commission's order issuing authority under Section 161 of the AEA is broad and extends to any area of licensed activity that affects the public health and safety. NOVs and civil penalties are issued based on violations. Orders may be issued for violations, or in the absence of a violation, because of a public health or safety issue. The Commission's authority to revoke a license is addressed in Section 187 of the AEA.

Because an Inspector finding that a regulation has been violated is addressed in the Enforcement Program, with the potential for sanctions, it is important that the regulations and Inspection Manual Chapters and Inspection Procedures are specifically applicable to RHDRA and do not capture requirements for other reactor types.

In SECY-23-0048, the NRC lays out a "Vision for the Nuclear Regulatory Commission's Advanced Reactor Construction Oversight Program." The NRC's vision is "As the nuclear industry's design and construction methodologies evolve to accommodate new technologies, the Nuclear Regulatory Commission (NRC) must adapt by developing a flexible oversight program to ensure the agency is applying a level of regulatory oversight commensurate with the risk posed by a variety of new facilities. Consistent with the NRC Principles of Good Regulation, the ARCOP framework reflects an approach that optimizes the NRC's established oversight framework to ensure the program is responsive to the evolving landscape of advanced reactor technologies. The ARCOP will provide reasonable assurance that advanced reactor facilities are built and will operate in accordance with their approved designs and licensing bases. The ARCOP will address each aspect of an effective oversight program (i.e., performance monitoring, enforcement, and assessment)." It is reasonable that the NRC would extend these concepts to oversight and inspection during operations.

3 PROPOSED SOLUTION AND APPROACH

As noted in the Introduction, in meeting the needs of the business model and the business requirement that regulatory costs are less than 1% of total O&M costs the NRC should establish, for both construction and operations, an oversight and inspection program for rapid high-volume deployable reactors commensurate with the technology, which is based on, and very similar to, the oversight for RTRs, as well as takes into account the novel features of factory pre-fabrication, closure of all ITAAC prior to emplacement at site, simplicity and reduced safety systems/controls, and remote operations.

The specific changes needed include:

<u>General Approach</u>

- The Oversight and Inspection activities should be performance-based, risk-informed and provide a graded approach to inspection.

- NRC oversight and inspection activities should maximize the reliance on the licensee's implementation of NRC required programs, e.g., QA, and consider the use of modern technologies for remote verification.

- For licenses that the NRC determine that permanent on-site resident inspectors are not required, it should not require office space be maintained, but rather that it make space available for when inspections do occur.

Construction Oversight

- NRC's oversight and inspection should be focused on activities at the manufacturing facility and at the deployment site, and at a level of oversight commensurate with the safety significance of the activities being performed. On-site construction oversight and inspection requirements should focus on construction of safety related structures, the proper installation of safety-related components, and commissioning of the manufactured reactor according to the approved licensing basis.

- The Inspection Program requirements (Manual Chapters and Inspection Procedures) for work done under a Manufacturing License should be focused on the safety significance of the specific activities being conducted. This applies to the general fabrication, non-nuclear testing (e.g., non-destructive fabrication inspection of SSCs, hydrotesting (if required), fuel loading, operational testing of a fueled reactor, and preparation for transportation.

Operations Oversight

- Modify the Inspection Program to remove Resident Inspectors for micro-reactor plants in general and specifically for RHDRA. There could be a need for on-site inspectors during the site preparation, reactor emplacement, and initial operations, particularly for the first reactor on a site. However, once the reactor is in operation periodic site visits for inspections should be sufficient, without need for a permanent on-site (or Resident) inspector and certainly not for two inspectors.

Creating an inspection program for RHDRA and other similar reactors that is similar to that used for RTRs, and for which reasonable assurance of adequate protection is provided through periodic NRC inspections of, and without the need for resident inspectors at, the operating sites, will involve considerable effort on the part of NRC, including stakeholder engagement. It is important that a complete inspection program that is applicable to RHDRA and other similar advanced reactors be in place to support deployments by 2030.

3.1 Changes Needed to Regulations, Policy and Guidance

The only specific regulatory requirement that likely needs to be changed regards office space as specified in § 50.70(b)(1) and (2). Specifically the requirements in § 50.70(b)(1) and (2) regarding rent-free office space should be limited to licenses that require permanent on-site resident inspectors. Requirements for office space at a manufacturing facility will depend on the level of effort in that facility (a small number of reactors being fabricated, or many reactors being fabricated (perhaps 10s) at the same time). This will influence NRC's decision regarding the need for resident inspectors, permanent or on a rotating basis, at the manufacturing facility.

Appendix 23 – NRC Oversight and Inspection

In 1977 the Commission approved the NRC staff proposal to introduce Resident Inspectors for each power reactor plant site. The NRC should modify that Policy or establish a new Policy for advanced reactors that permit power reactors without Resident Inspectors if justified by the application, which would be expected for micro-reactor sites as well as for sites for the RHDRA**.**

The majority of needed regulatory changes come in the Inspection Program and particularly in the Inspection Manual Chapters and Inspection Procedures to make them specific to the manufacturing, deployment/construction, and operation considerations for RHDRA.

The Inspection Manual Chapters and Inspection Procedures are largely focused on existing large light-water reactors. Changes to bring about a risk-informed, performance-based Inspection Program that is specific to micro-reactors in general and specifically to the RHDRA that recognize the very small potential consequences of these reactors, and the small potential impacts to land, water, and the atmosphere. The Inspection Program should address activities conducted in the manufacturing facility, at the deployment site (construction and emplacement of the reactor), startup testing, and operation. The revised Inspection Program should continue to contribute to assurance of public health and safety but do so in a manner that recognizes the unique features of these new reactors.

Revise the Inspection Program (Inspection Manual Chapters and Inspection Procedures) to be specific to RHDRA. This would involve significant revision to the Inspection Manual Chapters and Inspection Procedures, deleting most of them and replacing them with Inspection Manual Chapters and Inspection Procedures that are specific to micro-reactors in general and specifically to RHDRA. Since the oversight and inspection of micro-reactors is expected to be very similar to RTRs, the NRC should build a new set of inspection manuals for micro-reactors based on those for RTRs, or clarify that RTR inspection manuals will be used for micro-reactors.

3.2 Acceptance Criteria and Licensing Approach

Acceptance Criteria

A graded approach to oversight and inspections would apply to all advanced reactors. A performance-based approach to the NRC use of resident or periodic inspections, including the locations where the NRC oversight and inspection would occur, would be inclusive and flexible. This would enable the NRC's oversight and inspection to be tailored to each specific design and business model in the most effective and efficient manner possible.

Licensing Approach

A graded approach to oversight and inspection would apply to all licensing approaches. However, the specific implementation of the NRC's oversight and inspections would be tailored to the particular business model (e.g., degree of factory manufacturing, degree of remote operations). Implementing a focused Oversight and Inspection program, coupled with changes in other topics, such as topics related to Approvals Prior to Site Licensing and topics related to Approvals with Site Licensing (see Appendix 5), would support NRC public health and safety mission while still enabling the business model and the business requirement that regulatory costs are less than 1% of total O&M costs. Implementing approaches for Factory Fabrication, and Remote Monitoring and/or Operations necessitates an oversight program and inspection manuals that account for new approaches to the concept of deployment and operations.

4 OTHER OPTIONS FOR RESOLUTION OF THE ISSUE

A variation of the proposed option for creating an NRC's Oversight program and Inspection manuals for RHDRAs and other similar advanced reactors involves eliminating unnecessary NRC inspection activities, including the Resident Inspectors, and relying on the applicant and licensee Appendix B Quality Assurance Program. Note that this alternative approach would still require modification of § 50.71(b).

The Inspection Program, and particularly the Inspection Manual Chapters and Inspection Procedures, would be significantly revised, to be risk-informed and performance-based and focused on micro-reactors and the RHDRA so that only the most safety significant, highest potential risk activities would warrant NRC inspection. In the manufacturing facility such activities might include:

- inspection of ITAAC associated with the final assembly of the reactor,
- inspection of fuel loading activities and closure of ITAAC associated with that activity,
- inspection of operational testing and closure of ITAAC associated with that activity, and
- inspection of the preparation of the reactor for transport, including installation of physical features to preclude criticality, and closure of ITAAC associated with that activity.

The quality of all other activities conducted under the manufacturing license would be assured by the licensee's conformance to the Commission's regulations and the requirements of the license.

Inspection activities at the deployment site might include:

- verification that the site parameters postulated for the reactor design are enveloped by the specific site parameter envelope,
- verification that the environmental report required by § 51.55 conforms with the Site Parameter Envelope addressed in the ANR GEIS,
- verification that the safety-significant site construction parameters (e.g., reactor pad rebar and concrete strength) conform to the site design requirements,
- verification that any essential infrastructure and services are installed and available before the reactor is emplaced, and
- verification that required pre-operational activities and startup testing is conducted in accordance with design criteria and requirements of the license.

The quality of all other activities conducted at the deployment site would be assured by the licensee's implementation of their Quality Assurance Plan and conformance to the Commission's regulations and the requirements of the license.

5 ACKNOWLEDGEMENTS

NEI Issue Lead: Marc Nichol

Appendix 24 – Annual Fees

1 ISSUE INTRODUCTION

Annual regulatory costs will include the annual fee, fees for service (e.g., direct fees for oversight and inspection), and the licensee's internal costs to support regulatory affairs. In order to achieve the requirements for the rapid high-volume deployable reactors in remote applications (RHDRA) business model, these three regulatory cost components together must be less than 1% of the reactor operations and maintenance (O&M) costs. Based on historical fee collection data, the Nuclear Regulatory Commission (NRC) annual fees typically represent roughly 1/3 of the total of these annual regulatory costs.

Based on NEI's report, "Cost Competitiveness of Micro-Reactors for Remote Markets,"[1] O&M costs are estimated to be between $5M and $8M per year for Nth-of-a-Kind (NOAK) deployments of 50 MWt reactors, or roughly $120k to $180k per MWt. Based on this, one-third of 1% of annual O&M costs would be roughly $20,000 to $30,000 for a 50 MWt reactor, or in more scalable terms, would be roughly $400 to $600 per MWt

While it is expected that most companies will deploy RHDRA in fleets, the size of these fleets could range from small to large, and there may be some companies that only deploy one or a few of these reactors. Thus, the consideration of the NRC annual fees impact on the business case needs to consider the range from a single reactor (e.g., 5 MWt or smaller), up to a fleet of 1,000s of reactors (that could each be 50 MWt or larger, with some sites having one or a few reactors, and some sites containing hundreds of reactors).

Annual fees for Small Modular Reactors (SMRs) (whether light water or non-light water) were revised in the FY2023 Final Fee Rule.[2] Currently, microreactors would fall into this new fee structure. The flat minimum fee is reserved for reactors with a power level of 20 MWt or less, which is equal to the annual fee paid by the non-power production or utilization facilities fee class (for the FY24 Final Fee Rule, this amount was $97,200; amount is subject to change each Fiscal Year).[3]

Reactors with thermal power ratings between 20 MWt and 250 MWt would be assessed the flat minimum fee (i.e., $97,200), *plus* a "variable fee" based on reactor power. The variable amount specified in Part 171 is:

[(b-a) / 230] x the difference between 20 MWt for the first bundled unit(s) and the actual cumulative licensed thermal power rating up to 250 MWt.

Where (b) is: The average of the annual fees for the spent fuel storage/reactor decommissioning and the non-power production or utilization facilities fee class

And (a) is: The annual fee paid by the non-power production or utilization facilities fee class.

[1] Estimate of annual plant generating costs used in this paper come from "NEI Input on NRC Annual Fee Assessment for Non-Light Water Reactors", November 23, 2020. (ML20342A170)
[2] NRC's final fee rule for FY 2023 was published in the Federal Register on June 15, 2023. See FRN Vol.88, No. 115, page 39132.
[3] NRC's final fee rule for FY 2024 was published in the Federal Register on June 20, 2024. See FRN Vol. 89, No. 119, page 51793.

Appendix 24 – Annual Fees

Therefore, as an example, the “variable fee” for a 250 MWt reactor would be $114,400. When this is added to the base fee (i.e., $97,200), the total annual fee would be $211,600 for a 250 MWt reactor.

While the NRC allows bundling micro-reactor outputs to use as the basis for calculating the annual fees, the fee for bundling reactors to 100 MWt would be $136,991 for FY2024 rates, which is up to 1.2% of annual O&M costs. This percentage is even higher for smaller output microreactors, as most designs are less than 100 MWt. For instance, if the minimum fee alone was applied to a 50 MWt microreactor (when in reality, the minimum + variable fee would apply), the annual fee would represent 1.8% of annual plant generating costs. This is *more* than what a large power reactor pays today (1.4% of annual plant generating costs). This alone demonstrates that the current fee structure for microreactors is inequitable; plus, O&M costs are expected to be significantly less for microreactors. Yet, they would be expected to pay a much larger percentage than large power reactors in operation today, which simply cannot be justified.

> Example: For a bundled large fleet of reactors that reach 4,500 MWt, the point at which the NRC would require the licensee to create a new bundle, the NRC annual (maximum) fee would be $5.336M for FY2024, equal to the fee for an existing large power reactor in operation today (an annual fee that is 1.4% of annual plant generating costs).

For a 5 MWt microreactor, applying the minimum annual fee of $97,200 (from FY2024 values) would represent a staggering 18% of annual plant O&M costs. These FY2024 fees are cost prohibitive for any business model.

The NRC’s response to NEI’s input on the annual fee rule (see footnote 1) is that the NRC could not charge *less* than the fees for non-power reactors (such as research and test reactors). While it is recognized that it is difficult to establish a bottom-up estimation for the annual fee basis for a new technology that has not been regulated before, it is also recognized that the NRC annual fees cause an undue disproportionate economic burden, and inequitable outcome, for future microreactor licensees. Further, this regulatory gap creates uncertainty for prospective applicants who are currently making investment decisions. Regulatory costs imposed by the NRC should not be so high that they prevent business models and use of nuclear technologies that meet the AEA goals of “adequate protection of the health and safety of the public” and “maximize the contributions to the general welfare,” especially for technologies that enable decarbonization of hard to abate sectors, strengthening of national security, and which pose minimal potential consequences.

Annual fees for microreactors should be related to the lower costs of providing regulatory and oversight services, due to their lower risk profile. The expected lower costs of providing these services for microreactors should reflect their inherent simplicity, small radionuclide inventories, and reliance on inherent and passive safety features, resulting in significantly lower regulatory and oversight costs. Given these considerations, an equitable annual fee structure would avoid disproportionate impacts to licensees and their customers.

2 BACKGROUND

The NRC is required to collect “fees for service” and annual fees. Each fiscal year, the Commission is required to assess and collect fees and charges in a manner that ensures that, to the maximum extent

Appendix 24 – Annual Fees

practicable, approximately 100 percent of the Commission's budget authority for the fiscal year is recovered, not including certain amounts excluded from this fee-recovery requirement.

The Nuclear Energy Innovation and Modernization Act (NEIMA) amended Section 6101(c)(2)(A) of the Omnibus Budget Reconciliation Act of 1990 (42 U.S.C. 2214(c)(2)(A)), which thereby provided additional direction on updating the fee collection process to support deployment of advanced nuclear technology.

Fees for services are addressed in 10 CFR Part 170 which specifies the hourly fees charged for licensing services, inspection services, and special projects rendered by the NRC as authorized under title V of the Independent Offices Appropriation Act, 1952 (31 U.S.C. 9701(a)).

Annual fees are assessed in 10 CFR Part 171. The annual fee charged to non-power production or utilization licensees, reactor licensees, and independent spent fuel storage licensees are specified in § 171.15.

The fees for service in § 170, and annual fees in § 171, are updated annually via rulemaking. The NRC published the FY2024 final fee rule on June 20, 2024.

The FY2023 fee rule included the following explanation of the fees applicable to micro-reactors:

> "The NRC promulgated a new fee structure for SMRs in 2016, which established a minimum fee, variable fee, and maximum fee for SMRs. In the FY2023 fee rule the NRC amended § 171.15 to "(1) expand the applicability of the small modular reactor (SMR) variable fee structure to include non-light water reactor (non-LWR) SMRs, and (2) establish an additional minimum fee and variable rate applicable to SMRs with a licensed thermal power rating of less than equal to 250 megawatts-thermal (MWt)." Additionally, in the FY2023 fee rule, the NRC changed the minimum fees and the variable annual fee scale for SMRs that have a licensed thermal power rating of less than or equal to 250 MWt in order to "fairly and equitably assess annual fees for those SMRs." The new minimum fee will be equal to the lowest annual fee that is assessed to the non-power production or utilization facility fee structure and will be the only annual fee assessed for an SMR, or for bundled units, with a combined licensed thermal power rating per site that is less than or equal to 20 MWt. This change also created a new variable annual fee for an SMR or for bundled units with a combined licensed thermal power rating per site greater than 20 MWt but less than or equal to 250 MWt that will be added to the minimum fee (the non-power production or utilization facilities fee structure annual fee). The minimum fee currently included in § 171.15, which is equal to the average of the spent fuel storage/reactor decommissioning and non-power production or utilization facilities fee structures annual fees, is retained as a component of the annual fee with an added variable fee assessed for an SMR, or for bundled units, with a combined licensed thermal power rating per site greater than 250 MWt but less than or equal to 2,000 MWt.
>
> Three different variable fees will be assessed: (1) a new variable fee assessed for power reactors with a licensed thermal power rating greater than 20 MWt but less than or equal to 250 MWt; (2) the existing variable fee assessed for power reactors with a licensed thermal power rating greater than 250 MWt but less than or equal to 2,000 MWt; and (3) for bundled units added above 4,500 MWt, the maximum fee (equal to the annual fee for the operating power reactor fee structure) plus a variable fee will be assessed for the incremental licensed thermal power rating greater than 4,500 MWt up to 6,500 MWt (another 2,000 MWt range), which constitutes

> an additional bundled unit. This pattern for assessed fees will continue as licensed thermal power rating capacity is added."

NRC established the minimum annual fee for micro-reactors at the rate for RTRs, in part due to similarities in the potential impacts and thermal power levels. However, the NRC did not consider that micro-reactors must also be competitive in the market, and that the disproportionate impact that these relatively high NRC fees have on micro-reactors could prevent their contribution to the general welfare. Furthermore, the NRC did not consider the efficiencies that could be gained by increased use of inherent safety features, standardization of designs, or the potential for large fleets.

3 PROPOSED SOLUTION AND APPROACH

The proposed approach is to establish a fee structure appropriate for RHDRA and other similar advanced reactors that reflects this class of reactors' inherent simplicity, small radionuclide inventories, reliance on inherent and passive safety features, as well as a generally reduced need for NRC oversight and inspection. The fee structure will also need to result in fees that enable the business model by being around 0.33% of the total O&M for the reactors.

Thus, the target for annual fees should be less than $600 per MWt. A more accurate and appropriate annual fee for a 50 MWt micro-reactor would then be between $20,000-$30,000 per unit. (This fee would vary based on output and would take into account the "bundled unit" concept addressed in the FY2023 fee rule). Thus, the maximum fee, intermediate bundled fees (e.g., at 250 MWt and 2,000 MWt) and variable fees would all need to be adjusted to enable the business model. While the NRC has included non-LWR designs along with a new minimum fee and variable fee beginning with the FY2023 fee rule, the simplicity of the designs and the concept of operations for RHDRA argues for even lower NRC costs, which should translate into a different fee structure for these reactors, providing a fair and equitable assessment of fees.

3.1 Changes Needed to Regulations, Policy and Guidance

To support the proposed alternative regulatory approach, a change to §171 would be needed to provide a fee structure for Rapid High-Volume Deployable Nuclear Reactors. Specifically, the NRC should create a new annual fee for small unit-size power reactors, e.g., reactor units of 250 MWt or less, that applies a flat fee of $400 per MWt to allow scaling from the very smallest bundle (e.g., a 1-unit 5 MWt reactor) to the largest bundle (e.g., a 1,000-unit 50 MWt reactor fleet).

The NRC should use this new small unit-size fee structure to replace the current variable fee structure from 20 MWt to 250 MWt. The variable fees for 250 MWt and above would continue to apply for larger power reactors.

In the near-term, the NRC should develop the regulatory basis with a graded approach to performance-based acceptance to facilitate appropriate exemptions (licensees may claim undue economic burden, under Section 171.11(c)). The regulatory basis for such exemptions would, in parallel, facilitate a more streamlined and timely rulemaking for alternative requirements to be codified in Part 171. In this manner, the regulatory basis provides the regulatory clarity for this issue to support both the near-term and longer-term regulatory changes and applications for RHDRA and other advanced reactors.

3.2 Acceptance Criteria and Licensing Approach

In order to be able to utilize the proposed alternative regulatory approach for NRC annual fees, the reactors would need to be very small in power output, since the critical factor driving a departure from the NRC's current annual fee structure is that it currently imposes a disproportionate impact to these small reactors, such that the market may not adopt the technology. Thus, this alternative is needed to enable the business model for RHDRA and other micro-reactors to ensure that the NRC is compliant with the AEA requirement for nuclear technologies to make the maximum contribution to the general welfare.

Acceptance Criteria

Thus, the acceptance criteria (specific to this topic) are:

- Reactor units must be 250 MWt or less in size.
- There is no requirement or restriction on the number of co-located or fleet-wide bundled reactor units.

These acceptance criteria are consistent with the three cross-cutting acceptance criteria of small consequences, small impacts and small dependence on site conditions, in that the technology features that enable those conditions are generally related to the small size of the reactors thermal power.

Licensing Approach

Any licensing approach can use the proposed approach to annual fees.

4 OTHER OPTIONS FOR RESOLUTION OF THE ISSUE

4.1 Fee Cap for Low Power

A micro-reactor "fee cap" in § 171.15 could be established via rulemaking. This would include details that outline, "plants with a total output of 250 MWth or less, shall not be assessed an annual fee greater than $400/MWth in order to avoid the disproportionate impacts of NRC fees on reactors with very small power levels."

4.2 Congressional Funding

Congress could provide funding to support the associated annual fees for micro-reactors, either singly or in fleets, similar to the longstanding precedent set for university research reactors. We want to acknowledge the NRC staff's efforts to date, in addressing the unique considerations of annual fees for SMRs and microreactors. However, legislative requirements to recover essentially 100% of the NRC's budget make further significant changes to the annual fee structure challenging.

Congress should recognize the public good brought about by deploying significant numbers of microreactors, and provide funds to support their licensing and deployment. This could be accomplished by either increasing NRC's "off fee base" annual budget, by providing a program where the potential licensees would receive funding directly, much like the current DOE's Advanced Reactor Demonstration Program, or some combination of these approaches.

5 ACKNOWLEDGEMENTS

NEI Issue Lead: Hilary Lane

Appendix 25 – Use of Contractors By Manufacturing Licensees

1 ISSUE INTRODUCTION

Manufacturing a reactor requires significant capabilities and specialized expertise. This is especially true when loading fuel and operational testing are included in the scope of activities of the manufacturing license (ML). Not every organization that is qualified to apply for and be granted a Manufacturing License will have the skilled labor, specialized facilities, and required licenses to support the full range of manufacturing, fuel loading, and operational testing necessary to have reactors ready for deployment to support the business model. The use of contractors and sub-contractors that possess the necessary skills, specialized facilities, and applicable licenses could be needed to support the Manufacturing License holder in producing the fully capable micro-reactors ready for deployment that are envisioned in the business model.

The use of contractors and subcontractors is a normal business practice in the nuclear and other industries. Contractors and sub-contractors are addressed in numerous regulations, including 10 CFR 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." Despite past precendent, use of contractors and sub-contractors is not addressed in Subpart F, leaving open concerns that NRC might object to the practice for the manufacture of reactors, particularly where factory fueling and operational testing are involved. The concern in this area related to liability and coverage of the scope of the licenses is addressed in Appendix 26.

The ability to use contractor or sub-contractor facilities that are not owned by entities that hold the Manufacturing License for the fabrication, assembly, fueling, and operational testing of the reactor is essential to enabling this business model. In this model, the ML holder would utilize contractor or sub-contractor facilities to perform those activities under the auspices of its license and approved programs, as well as transport of a fueled reactor by a contractor or subcontractor. If contractors and sub-contractors cannot be used to perform licensed activities, then it could significantly increase the cost or schedule to the point where business models are not viable.

The desired outcome is that contractors and subcontractors, and their facilities, can be used in fabrication, assembly, fueling, and operational testing of a reactor at the factory, transport of an assembled and fueled reactor, and replacement of reactor modules. For more information on those activities see Appendices 2, 26, 27, 28, 29, and 30.

2 BACKGROUND

Reliance on a Manufacturing License under 10 CFR Part 52, Subpart F, is an essential aspect of the business model of rapid high-volume reactors in remote applications (RHDRA). Approaches used today for large LWRs where major components are shipped to the reactor site for construction and assembly does not meet the needs for RHDRA. It is likely that loading fuel in the factory, and potentially operational testing in the factory, will be needed to enable the business model requirement of 6 months from site selection to operation.

Activities performed under a Manufacturing License granted by the Commission under 10 CFR Part 52, Subpart F, involve the physical manufacture of the reactor, inspection and non-destructive examination and testing of the manufactured reactor to assure its quality, and potentially fueling and operational testing of the manufactured reactor. The Manufacturing Licensee would be required to obtain additional licenses and implement a number of operational programs to facilitate fueling and operational testing.

In some cases, the Manufacturing Licensee may not have all the necessary skilled labor, specialized facilities, and required licenses to support the full range of manufacturing steps. In other cases, the workload demand may exceed the resources available to the Manufacturing Licensee in the facilities they own. In these cases, the Licensee may use contractors or subcontractors to provide the requisite capabilities. The use of subcontractors was highlighted in NEI's 2021 paper, "Proposed Approach for Manufacturing License Requirements in 10 CFR Part 53,"[1] noting that factory fabrication could involve the licensee owning or controlling through contracts and subcontracts all necessary facilities and that some of those facilities might not be co-located with the primary manufacturing facility. In this scenario, the ML Holder's QA, security, and AA/FFD programs would be applicable, and would be permitted to pass down requirements to enable the use of the applicable contractor and subcontractor programs.

The implementation of NRC requirements becomes less clear if the manufacturer wants to load fuel and potentially perform operational testing in the factory. Fueling and testing a reactor involves a number of NRC regulations. As discussed in the 2021 NEI paper, loading fuel could be performed under a Part 70 possession license, which may draw in other requirements, e.g., Parts 26, 30, 40, 70, 73, 74 and 75. Subpart F does not address the situation where an ML holder wanted to subcontract fuel loading, using the subcontractor's facilities. Similarly for operational testing of the fueled reactor, this activity would need a utilization license to either be included with the ML or obtained through a separate and limited Part 50 or Part 52 operating license.

NRC SECY 24-0008 does not address the ML holder's use of contractor and subcontractor facilities to perform these activities (e.g., factory loading of fuel and operational testing in a factory), even though the SECY does address the performance of these activities as part of the ML. Therefore, it is unclear what expectations the NRC will have for the implementation of these activities under the ML regarding the use of contractors. A regulatory approach where the ML Holder is permitted to use contractors and subcontractors to perform the authorized activities in the ML, using their programs, would be consistent with the current NRC approach for the manufacturing of nuclear facility components for site licenses. A regulatory approach where the NRC would require that the contractors and subcontractors also be directly licensed by the NRC to authorize the scope of the contractor's activities and to approve, as required, any programs would not improve the NRC's ability to provide reasonable assurance of adequate protection, but would add significant cost, time and risk to the point that the business model may not be viable.

3 PROPOSED SOLUTION AND APPROACH

The proposed approach for the use of contractors and subcontractors by ML holders would:

1. Provide the ability for contractors and sub-contractors of an ML holder to perform activities authorized by the ML, including fabrication, assembly, fueling and operational testing of

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reactors in the contractor or sub-contractor facilities, and transport of a fueled reactor (both fueled and unfueled), such that:

a. the ML holder is permitted to use contractors and subcontractors to perform the authorized activities in the ML, using their programs, consistent with the current NRC approach for the manufacturing of nuclear facility components under site licenses

b. does not require that contractors and subcontractors also be directly licensed by the NRC, either through separate/independent licenses to the ML or as an amendment to or condition of the ML to add specifically authorized contractors and subcontracts and specify the authorized scope of activities for those additional entities.

It is essential that NRC also clarify the requirements for factory fuel loading and operational testing, and that they specifically address the regulations (e.g., required Parts of 10 CFR) and operational programs (e.g., QA, Security, etc.) that would be required of the holder of the Manufacturing Licensee and that would be required of subcontractors performing fuel loading or operational testing of the fueled reactor or ITAAC activities and closeout of ITAAC. NRC must also clarify the requirements for financial protection to be provided by an ML holder or his contractors or subcontractors if operational testing is to be performed in their facilities.

SECY 24-0008 discusses options for factory fuel loading and for operational testing in the factory. The options discussed largely rely on a regulatory framework appropriate for LWRs that would be orders of magnitude larger than the micro-reactors being considered. A regulatory construct that is risk-informed and performance based, and that reflects a micro-reactor’s inherent simplicity, small radionuclide inventories, and reliance on inherent and passive safety features should be developed.

In the near term, it may be necessary to address the issues associated with fuel loading and operational testing with exemptions or other vehicles such as orders. Guidance should be developed that expressly addresses the use of contractors and subcontractors and their facilities. While flexibility in developing an alternative regulatory approach will be necessary, the approaches must provide adequate protection of the health and safety of the public.

The specific guidance or regulatory change should address the full range of licenses and operational programs (e.g., QA, Security FFD/AA, EP, etc.) that a contractor or sub-contractor would have to possess, or how they could operate if the ML holder possessed those licenses and conducted oversight programs, and the regulations and guidance that would have to be followed in performing contracted activities.

Clearly and completely addressing the use of contractors and sub-contractors by Manufacturing License holders is important in establishing a credible business model, but much of it has been demonstrated in current nuclear industry practices.

3.1 Changes Needed to Regulations, Policy and Guidance

Rulemaking is needed to clarify the use of contractors and subcontractors by an ML holder to perform activities authorized under the ML. The rulemaking is expected to amend and add to the requirements in 10 CFR Part 52 Subpart F. Corresponding changes to Part 53 for requirements related to these topics are also needed.

Appendix 25 – Use of Contractors By Manufacturing Licensees

The requirements in 10 CFR Part 52, Subpart F, are silent on the use of contractors or subcontractors to perform activities authorized by the ML, including fabrication, assembly, fuel loading or operational testing. A clear and complete understanding of these activities, including the role of contractors and subcontractors, are needed to support the range of scenarios needed to enable micro-reactor business models that rely on Manufacturing Licenses.

In the near-term, the NRC and industry should coordinate to develop a regulatory basis for the use of contractors for the issues identified in this paper. This regulatory basis will be useful for near-term applicants to prepare their applications, and if necessary, to submit exemption requests or for the NRC to issue rules of applicability. The regulatory basis will also be useful in the development of rulemaking in the long term.

Guidance development is likely needed, which NRC and industry should coordinate for common understanding of the scope and application of licenses to contractors for RHDRA business models and other advanced reactors, depending on the level of clarity that is incorporated into the regulations. As previously noted, SECY 24-0008 discusses options for factory fuel loading and for operational testing in the factory. The options discussed largely rely on a regulatory framework appropriate for LWRs that would be orders of magnitude larger than the micro-reactors being considered. A regulatory construct that is risk-informed and performance based, and that reflects a micro-reactor's inherent simplicity, small radionuclide inventories, and reliance on inherent and passive safety features should be developed.

Changes to other requirements may be necessary to implement requirements addressing factory fuel loading and operational testing by contractors or subcontractors to the Manufacturing Licensee.

3.2 Acceptance Criteria and Licensing Approach

<u>Acceptance Criteria</u>

Any advanced reactor design could benefit from obtaining clarity on the ML holder's use of contractors and ML holder scope of activities. However, the majority benefits that would be needed to meet the deployment timelines for RHDRA business models are expected to include technical features that enable the reactor to be fully assembled in the factory and transported as a fully assembled reactor. Additional benefits will be realized by reactors relevant to RHDRA that are designed to enable fuel loading and operational testing at the factory, and transport of the fueled reactor.

<u>Licensing Process</u>

Only the licensing processes that use a Manufacturing License under Part 52 Subpart F, and a future Part 53, would benefit from clarity on the ML Holder's use of contractors, to ML holder scope of activities. Reliance on a Manufacturing License under 10 CFR Part 52, Subpart F, is an essential aspect of the business model for rapid high-volume deployable nuclear reactors. Modifying Part 52, Subpart F, as described in the previous section clarifying the use of contractors and subcontractors in performing activities authorized by the ML, including fabrication, assembly, factory fueling and operational testing to be provided by contractors and subcontractors performing these activities, is vitally important to enabling the full use of Manufacturing Licenses in supporting timely deployment of micro-reactors in general and specifically the rapid high-volume deployable nuclear reactors.

Having clear and complete requirements that are specific to RHDRA business models will support other topics (i.e., Appendices 2, 4, 26, 27, 29, and 30), including closure of ITAAC as part of the Manufacturing License as well as the topics of factory fuel loading and testing at the factory (or operational testing) which are closely related to the use of contractors and subcontractors. Taken together, these topics are significant contributors to enabling the RHDRA business model.

4 OTHER OPTIONS FOR RESOLUTION OF THE ISSUE

4.1 AEA Change – General License

A general licensing approach would be more efficient and effective in regulating nuclear reactors, such as RHDRA, and would be capable of enabling even shorter deployment timeframes that would be needed to support other business models. Currently, the AEA does not grant the NRC authority to issue general licenses for nuclear reactors, although it does grant authority to the NRC to issue general licenses for other regulated activities. If Congress were to amend the AEA to authorize and direct the NRC to develop a general licensing approach for certain nuclear reactors, and the NRC subsequently pursued a rulemaking to develop such a general license framework for nuclear reactors, this would be a more optimal solution to the issue discussed in this appendix. However, since the NRC could achieve the business requirements with currently granted authorities, and since there is significant uncertainty on whether or when Congress would grant NRC authority for issuing general licenses for reactors, the proposed resolution discussed herein is focused on approaches the NRC can implement without changes to the AEA. This enables the fastest path toward a more effective and efficient regulatory framework for RHDRA and other advanced reactors, and would build the basis of experience that could inform a longer term General License approach if Congress eventually enables it. More discussion on NRC Regulation Through General Licenses is included in Attachment B.

4.2 Exemptions, Orders, Policy Statement

As noted in the Proposed Alternative Regulatory Approach, the use of approaches such as exemptions, Policy Statements and, possibly, orders to clarify the issues of use of contractors and financial protections could provide the desired level of clarity, since the rules are vague and would permit the approach proposed in this paper. However, these other tools do not provide the certainty, durability and general applicability or clarity that is needed. As such they would not be as effective and efficient as rulemaking.

Guidance is likely a needed component of the solution to providing clear and complete requirements regarding the use by a Manufacturing Licensee of contractors and subcontractors to support performing activities authorized by the ML, including fabrication, assembly, fuel loading and operational testing.

5 ACKNOWLEDGEMENTS

NEI Issue Lead: Julianne McCallum

Appendix 26 – Loading Fuel at the Factory

1 ISSUE INTRODUCTION

Fully assembling and loading fuel into a reactor in the factory is an important option for the rapid high-volume deployable reactors in remote applications (RHDRA) business model, and for other advanced reactors that are capable of these activities. While not all RHDRA concepts of deployment depend upon loading fuel at the factory, there are many companies that are pursuing this approach. The advantage is that fueling at the factory, and subsequent transport of that fueled reactor to the deployment site, enables these activities to be performed in a central location where there are better controls and lessons learned through repetion can improve the process, all of which can improve safety. It also reduces the required site infrastructure to load fuel at the deployment site, can accelerate the deployment times, and can reduce deployment costs. All of which are important considerations for each single reactor, and when considered over large numbers of reactors the benefits are even greater. This also benefits the NRC's oversight and inspection program enabling it to be more focused on the manufacturing facility where these activities are happening repetitively for production level manufacturing of various reactors, rather than needing to be spread geographically to remote locations for infrequent and potentially unique evolutions for each deployment site.

However, NRC regulations, neither in Part 52, Subpart F nor in the draft proposed Part 53, address loading fuel in the factory. Other Parts, such as Part 70, may be used to load fuel at the factory, but currently lack clarity. NRC staff have reiterated these messages in SECY-24-0008, which has been sent to the Commission for a vote. This paper would allow fuel load to occur with a Manufacturing License (ML) and a 10 CFR Part 70 license alongside features to preclude criticality. Additionally, in its Staff Requirements Memoranda (SRM) regarding the proposed 10 CFR Part 53 rule, the Commission directed the staff to develop regulatory text to allow fuel loading at the manufacturing facility. As discussed in SECY-24-0008, it is assumed that any regulatory framework that would allow fuel load at a factory would require features to preclude criticality (FPC) (see Appendix 28).

The desired outcome is the establishment of a regulatory approach that is effective and efficient to load fuel in the factory, and provides sufficient clarity to applicants.

2 BACKGROUND

Fueling a reactor in the factory was addressed by NEI in the 2021 White Paper, "Proposed Approach for Manufacturing License Requirements in 10 CFR Part 53."[1] That paper noted that a Manufacturing Licensee could load fuel in a fully manufactured micro-reactor under a Part 70 possession license, under which the primary function is to assure radiological safety and that the reactor is maintained subcritical at all times. In addition, factory fuel loading under a Part 70 license may draw in other requirements, e.g., Parts 26, 30, 40, 71, 73, 74, 75, and 140, and possibly others.

NRC also has addressed fueling a micro-reactor in the factory in SECY 24-0008. The discussion in SECY 24-0008 discussed two options. The first option, Option 2a, would authorize fuel loading at the factory under a power reactor license. As discussed in SECY 24-0008, Option 2a "would be consistent with the Commission's historical position that reactor operation commences with the loading of fuel. Under the

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current regulatory framework and this historical position, each factory-fabricated module that would be loaded with fuel at the factory would be required to have a facility operating license or combined license issued pursuant to AEA Section 103 before loading fuel. A manufacturing license would allow the manufacture of unfueled reactors, but it would not authorize fuel loading or any other aspect of operation, decommissioning, or the possession of special nuclear material."

The second option, Option 2b, would authorize fuel loading at the factory under a 10 CFR Part 70 license. As discussed in SECY 24-0008, Option 2b "would provide an approach for loading fuel at the factory without requiring a facility operating license under 10 CFR Part 50 or a combined license under 10 CFR Part 52 for a factory-fabricated module. Instead, a manufacturing license would authorize possession of the module, and loading fuel would be authorized and conducted solely under a license issued pursuant to 10 CFR Part 70 for possession of special nuclear material. This option is contingent on the Commission approving Option 1b so that the factory-fabricated module with features in place to preclude criticality would not be "in operation" when loaded with fuel and would not require a 10 CFR Part 50 facility operating license or a 10 CFR Part 52 combined license to load fuel."

A Commission decision approving the proposed policy on the use of FPC as well as the NRC staff developing appropriate guidance or endorsing guidance developed by the industry, is central to a licensee or subcontractor being authorized to load fuel under a Manufacturing License and a Part 70 possession license. Details regarding FPC and the use of contractors and subcontractors by Manufacturing Licensees are discussed in Appendices 25 and 28.

In the 2021 White Paper, NEI noted that a Manufacturing Licensee could load fuel under a Part 70 license. In SECY 24-0008, the NRC staff recommended that the Commission allow the holder of a manufacturing license to load fuel at the factory under a license issued pursuant to Part 70, as long as the factory-fabricated micro-reactor includes FPC and the criticality safety controls required by Part 70 are in place. The NEI and NRC staff approaches are essentially the same with the staff adding the requirement that FPC be in place.

In SECY 24-0008, the NRC provides discussion of requirements under Part 51 to address the environmental considerations for both a Manufacturing License and a Part 70 license through an EA or EIS. The NRC also addresses financial protection considerations under 10 CFR Part 140, noting that "there may be inconsistent application of the financial protection requirements under 10 CFR Part 140 to a licensee authorized to load fuel into a micro-reactor at a factory compared to a combined license or construction permit holder that is authorized to possess fuel prior to being authorized to operate." The NRC also notes that there are no financial protection regulations in 10 CFR Part 140 explicitly addressing a manufacturing license holder that is authorized to load fuel in a reactor under a 10 CFR Part 70 license. Therefore, the NRC staff would propose to use license conditions or another appropriate regulatory vehicle to address this inconsistency."

Both NEI's 2021 White Paper, "Proposed Approach for Manufacturing License Requirements in 10 CFR Part 53," and NRC staff's SECY 24-0008 recognize that factory fuel loading avoids the burden of performing the fueling in numerous remote locations, and generally improves safety by performing the fueling in the controlled factory setting, eliminating on-site fueling. Similarly, NRC noted in SECY 24-0008, "depending on the reactor design, fuel loading and any subsequent fabrication steps, such as closing the reactor vessel, may require expertise and specialized equipment that would be inefficient or impractical to make available at each deployment site." Despite NRC regulations in Part 52, Subpart F and in the draft proposed Part 53, not currently addressing loading fuel in the factory, there has been some progress. NRC staff has submitted SECY-24-0008 to the Commission for a vote on proposed policy changes that would enable factory fuel loading.

Viable options for permitting fuel loading in the factory have been discussed and generally involve using the provisions in 10 CFR Part 70 as the regulatory basis for factory fuel loading, but these options have not yet been employed. However, activities under this topic are expected to move from viable options to specific changes in regulations and policies that create a regulatory structure that fully addresses factory fuel loading for micro-reactors. This should include provisions that would support the potential for operational testing in the factory and fueled transport to the deployment site (See Appendices 27 and 29).

3 PROPOSED SOLUTION AND APPROACH

The proposed solution is to permit the loading of fuel at the factory by a Manufacturing License holder. This approach builds on the NRC and NEI recommendations and would include the use of FPC so that the fueled reactor would not be "in operation." This approach would also permit NRC review and approval of the license applications to load fuel in the factory to address all environmental considerations in accordance with Part 51 to satisfy requirements in the National Environmental Protection Act. Additionally, the insurance requirements under Part 140 would have to be addressed by NRC, presumably using license conditions.

This proposed approach is not without risk to the successful implementation of the proposed alternative regulatory approach. For example, the Commission decision on the NRC staff's proposal for FPC to render a fueled micro-reactor "not in operation" remains pending. A negative vote would preclude the use of a Manufacturing License and Part 70 license as the basis for fuel loading in the factory. However, the Commission directed staff to include the ability to load fuel in the proposed 10 CFR Part 53 in SRM-SECY-23-0021. The Department of Transportation could also object to the transportation of a fueled reactor with FPC present. This would prevent the ability to load fuel in the factory, perform operational testing in the factory, transport the fueled reactor and replace the module at the site, which are essential to the RHDRA business model. The only concept of deployment available would be the traditional approaches where the manufactured reactor was delivered to the deployment site, and the fuel and any specialized equipment needed to fuel the reactor are delivered separately. The amount of additional time it would add to the deployment timeline will depend on the delivery timeliness and the staging of fuel and the specialized equipment and staff resources. It is not clear at this time whether this regulatory limitation would enable the RHDRA business model.

3.1 Changes Needed to Regulations, Policy and Guidance

Rulemaking is not necessary to enable a Manufacturing License holder with a Part 70 license (and other licenses as may be necessary, e.g., Parts 26, 30, 40, 71, 73, 74 and 75) to load fuel into a reactor (with FPCs) at the factory. As noted above, the Commission directed that staff to include the ability to load fuel in the revised 10 CFR Part 53 rule. The NRC draft proposed Part 53 rulemaking is expected to include provisions in the requirements for the ML to enable it to be a single license for all the activities being pursued by the RHDRA business model (e.g., fuel in the factory, operations testing in the factory, transport fueled, and replace module at site). A rulemaking would be necessary to enable an ML holder to perform those activities completely under the Part 52 ML authorizations, and a Part 50 or 52 operating license. Such a rulemaking would need to grant authorities for those activities at the ML Subpart, include the requirements for FPC to perform the activities, and establish the criteria for those features. The requirements that are ultimately to be included in the proposed Part 53 when it is issued for comment should be used as a basis for changes to Part 52, Subpart F.

This approach depends upon the NRC resolution of the topic on FPC, which is discussed in Appendix 28.

NRC and industry should work together to develop guidance on how the applicant for both the Manufacturing License and the Part 70 license should address the environmental considerations. The NRC review should leverage the proposal for environmental reviews in Appendix 1.

Guidance also is needed to communicate expectations for Part 140 financial protection requirements for factory fuel loading authorized under a Manufacturing License and Part 70 license. In SECY 24-0008, the NRC indicated that it would "propose to use license conditions or another appropriate regulatory vehicle" to address the inconsistency of not having any Part 140 requirements apply to a Part 70 licensee, even though similarly situated CP/COL holder would be required to maintain $1 million in financial protection. The NRC could clarify that a Part 70 license would include a condition requiring the maintenance of $1 million in financial protection, ensuring parity between the Manufacturing License/Part 70 approach and the Part 50/52 approach.

3.2 Acceptance Criteria and Licensing Approach

<u>Acceptance Criteria</u>

It is expected that the ability to load fuel at the factory would only be available under an ML to reactors that are capable of performing these activities and incorporate design features that enable the efficient inclusion of features to preclude criticality. This includes reactors for RHDRA business models and reactors capable of being transported with loaded fuel. While theoretically other advanced reactors could demonstrate the ability to safely load fuel at the factory, there is not anticipated to be any value to the business model for reactors that are not able to be transported fueled.

<u>Licensing Process</u>

Only the licensing processes that use a Manufacturing License under Part 52 Subpart F with a Part 70 license, or a future Part 53, would benefit from the use of loading fuel at the factory. If the NRC also pursues a rulemaking for an ML holder to perform all activities under the Part 52 Subpart F license, without the need for a Part 70 or Part 50/52 license, then all Part 52 ML holders would benefit.

4 OTHER OPTIONS FOR RESOLUTION OF THE ISSUE

4.1 AEA Change – General License

A general licensing approach would be more efficient and effective in regulating nuclear reactors, such as RHDRA, and would be capable of enabling even shorter deployment timeframes that would be needed to support other business models. Currently, the AEA does not grant the NRC authority to issue general licenses for nuclear reactors, although it does grant authority to the NRC to issue general licenses for other regulated activities. If Congress were to amend the AEA to authorize and direct the NRC to develop a general licensing approach for certain nuclear reactors, and the NRC subsequently pursued a rulemaking to develop such a general license framework for nuclear reactors, this would be a more optimal solution to the issue discussed in this appendix. However, since the NRC could achieve the business requirements with currently granted authorities, and since there is significant uncertainty on whether or when Congress would grant NRC authority for issuing general licenses for reactors, the proposed resolution discussed herein is focused on approaches the NRC can implement without changes to the AEA. This enables the fastest path toward a more effective and efficient regulatory framework for RHDRA and other advanced reactors, and would build the basis of experience that could inform a longer term General License approach if Congress eventually enables it. More discussion on NRC Regulation Through General Licenses is included in Attachment B.

5 ACKNOWLEDGEMENTS

NEI Issue Lead: Julianne McCallum

Appendix 27 – Operational Testing at the Factory

1 ISSUE INTRODUCTION

Operational testing of a reactor in the factory is a key consideration for the rapid high-volume deployable reactors in remote applications (RHDRA) business model. While not all RHDRA concepts of deployment depend upon operational testing at the factory, there are several companies that are pursuing this approach. Some ML holders may choose to only do criticality testing, while other ML holders may choose to do all operational testing. Alternatively, some ML holders may only do operations testing for the first several modules produced, thereby reducing first-of-a-kind or early manufacturing business risks, while other ML holders may choose to continue to perform operational tests at the factory as part of their long term, i.e., past nth-of-a-kind, concept of deployment. The advantage is that operational testing at the factory enables these activities to be performed in a central location where there are better controls, and lessons learned through repetion can improve the process, all of which can improve safety. It also reduces the required site infrastructure to perform operational testing at the deployment site, can accelerate the deployment times, and can reduce deployment costs. All of which are important considerations for each single reactor, and when considered over large numbers of reactors the benefits are even greater. This also benefits the NRC's oversight and inspection program, enabling it to be more focused on the fabrication facility where these activities are happening repetitively for production level manufacturing of reactor designs, rather than needing to be spread geographically to remote locations for infrequent and potentially unique evolutions for each deployment site (see Appendix 23).

This could also permit more ITAAC or ITAAC-like testing and inspection requirements to be closed at the factory (see Appendix 4). Performing these ITAAC or ITAAC-like tests and inspections, combined with those that would be conducted in fully assembling the reactor and during 50.43(e)(1) proof of design testing, and, potentially, prototype testing under 50.43(e)(2), would reduce the scope of on-site inspection and testing activities.

However, NRC regulations, neither in Part 52, Subpart F nor in the draft proposed Part 53, address operational testing in the factory. Other Parts, such as Part 70, may be used to load fuel at the factory, but do not address operational testing. Operational testing in the factory would require the removal of features to preclude criticality (FPC) to perform the test, and reinstallation of the FPC after the test (see Appendix 28).

The desired outcome is the establishment of a regulatory approach that is effective and efficient to perform operational testing in the factory and provides sufficient clarity to applicants.

2 BACKGROUND

NEI addressed testing at the factory in the 2021 White Paper "Proposed Approach for Manufacturing License Requirements in 10 CFR Part 53."[1] As discussed in that paper, after fully assembling an operable micro-reactor module and loading fuel at the factory, it may be desirable to perform criticality and

[1] ML21197A103

power ascension testing (herein defined as operational testing). This is distinguished from loading fuel, which does not include control manipulation and criticality testing.

Enabling operational testing would clearly require significant changes from the existing regulatory framework and facilities, controls, and oversight. Under the current regulatory framework, such activities generally require a utilization facility license, since the criticality prevention requirements for a Part 70 possession license (which governs the licensing of special nuclear material) would specifically preclude this type of testing. Thus, under current practices, this activity would need the utilization license to either be included with the ML or obtained through a separate and limited Part 50 operating license or a Part 52 Combined License. Fueling and testing a reactor involves a number of other NRC regulations, which may include Parts 26, 30, 40, 55, 70, 73, 74, 75. NRC regulations in Part 52, Subpart F and the draft proposed Part 53 also do not address loading fuel in the factory or operational testing at the factory. However, in the Staff Requirements Memorandum on the draft proposed Part 53 (SRM-SECY 23-0021) the Commission directed the staff to work with stakeholders to develop regulatory text that "would allow a holder of a manufacturing license to accomplish operational testing of a fueled reactor at the factory prior to delivery to the site where it will ultimately be used."

SECY 24-0008 includes an extensive discussion of pathways for operational testing in a factory. Two options to enable operational testing in the factory are discussed. In the first option, a 10 CFR Part 52 Manufacturing License and either a 10 CFR Part 50 Licenses (i.e., Power Reactor Construction Permit and Operating License) or 10 CFR Part 52 Combined License would be required. In the second option a 10 CFR Part 52 Manufacturing License and a 10 CFR Part 50 Power Reactor Construction Permit and Operating License (applying the appropriate safety, and possibly the environmental regulations for non-power reactors).

The second option appears to be a practical approach and is generally adopted herein as the proposed alternative regulatory approach. This option was also recommended by the NRC staff in SECY 24-0008.

3 PROPOSED SOLUTION AND APPROACH

The proposed solution is to permit the loading of fuel at the factory by a Manufacturing License holder, through the issuance of both a 10 CFR Part 52 Manufacturing License and a 10 CFR Part 50 Power Reactor Construction Permit and Operating License (applying the appropriate safety, and possibly the environmental regulations for non-power reactors). This approach (the second option proposed by the NRC in SECY 24-0008) was also recommended by the NRC staff. The approach uses a Manufacturing License for the manufacture of the micro-reactors and a construction permit and operating licenses under 10 CFR Parts 50 or 52 to support both fuel loading and operational testing at the factory. This approach will necessitate addressing the removal of FPC for the purposes of operational testing, and the reinstallation of the FPC.

This proposed approach includes the application of non-power reactor regulations and guidance for the safety review of the construction permit and operating license application(s) (which may be submitted, reviewed and approved concurrently) through the use of appropriate regulatory vehicles (e.g., exemptions or a rule of particular applicability). The environmental review requirements for non-power reactors should also be applied, in addition to the other enhancements to environmental reviews proposed for RHDRA and other advanced reactors. An applicant for the ML and Part 50 or 52 licenses would have to address other operational programs such as quality assurance, radiation protection, security (including access authorization requirements), emergency preparedness, and fitness-for-duty. (see Appendices 1, 13, 14, 19, 20, 21, 22, for more information)

As noted in SECY 24-0008, the operational characteristics of and safety considerations for RHDRA operated at the factory only for testing would be similar to those for most currently licensed non-power reactors. Thus, the non-power reactor safety regulations better reflect the considerations for these reactors. The non-power reactor regulations and guidance in NUREG-1537 should be used to account for a wide variety of designs and operational testing characteristics.

The Manufacturing License approval of the reactor design would provide the basis for the safety evaluations related to the construction permit(s) and operating license(s) for operational testing. Thus, under this approach, the NRC staff would focus its review of the construction permit and operating license, or combined operating license applications on siting; environmental reviews; operational programs such as technical specifications, operator licensing, and radiation protection; and any other unique considerations not covered in the approval of the power reactor design in the manufacturing license. However, under the proposed regulatory approach, siting and environmental reviews would employ the approaches for these topics discussed in the applicable appendices herein.

As testing is completed, ITAAC that were incorporated under the 10 CFR Part 52 design approval and that are related to the testing process may be verified and closed. Since ITAAC are required under the Manufacturing License either directly through the Manufacturing License design process or through reference to a Standard Design Certification, the testing process provides a clear opportunity to close related ITAAC should a vendor choose to. However, at Nth-of-a-kind, this type of testing may not be necessary.

3.1 Changes Needed to Regulations, Policy and Guidance

Rulemaking is likely not necessary for the proposed regulatory approach that enables a Manufacturing License holder with a Part 50 license to perform operational testing at the factory. When issued for public comment, the proposed Part 53 rule is expected to include provisions in the requirements for the ML to enable it to be a single license for all activities being pursued by the RHDRA business model (e.g., fuel in the factory, operational testing in the factory, transport fueled, and replace module at the deployment site) without the need for a Part 50 or Part 53 site Operating License. Rulemaking would be necessary to enable an ML holder to perform those activities completely under the Part 52 ML authorizations, and without the need to seek a Part 50 operating license. Such a rulemaking would need to grant authorities for those activities at the ML Subpart, include the requirements for FPC to perform the activities, and establish the criteria for those features. The requirements that are ultimately included in Part 53 should be used as a basis for changes to Part 52, Subpart F.

A rulemaking may be necessary to authorize the operational testing at the factory as a non-power reactor rather than a commercial power reactor, which would avoid the need to use application-specific regulatory tools, such as exemptions or rules of particular applicability. Even if current regulations do not preclude operational testing at the factory as a non-power reactor, implementation of the proposed alternative regulatory approach would still likely require Commission approval as a matter of policy given its novelty and practical implications. That is, under this approach, factory-fabricated module(s) would be licensed for operational testing at the factory using safety regulations for non-power reactors, even though the micro-reactors would have been manufactured and licensed as power reactors at the factory and would ultimately be operated as power reactors at the deployment sites. Implementing this novel approach would also require new guidance on the use of the non-power regulations to authorize operational testing at the factory.

While a new approach to RHDRA site licensing has been proposed (see Appendix 5), the licensing for the manufacturing and testing facilities would make use of the safety evaluation requirements for non-power reactors. In addition, licensing operational testing at a factory by applying the non-power reactor safety regulations would limit the ability to combine licensing proceedings at the factory with licensing proceedings at deployment sites because different regulatory requirements would apply to each proceeding.

One aspect of the proposed approach that is not addressed by the non-power regulations and guidance is the use of features to preclude criticality. Those features may be integrated into the original design or installed when fuel is loaded. With the latter, these features would have to be removed prior to operational testing and re-installed after the testing and before preparing the micro-reactor for transportation. A specific provision, such as a license condition, would be employed to make features to preclude criticality a requirement until such time as the applicable requirements in Part 52 were changed, or the new Part 53 was finalized.

Until a rulemaking is established to amend the requirements and avoid the need for exemption to use this proposed approach, and as discussed in SECY 24-0008, "exemption requests to apply non-power reactor safety requirements would need to address the pertinent exemption criteria for the regulations in each part."

To support implementation of the proposed alternative regulatory approach once the Commission has acted to approve use of the non-power reactor regulations and guidance, the NRC should establish the regulatory basis for operational testing at the factory. This regulatory basis will support the near-term development of applications, and NRC use of license conditions, exemptions, hearing orders, rules of particular applicability, or other regulatory vehicles, as appropriate. The regulatory basis would also support the rulemaking to amend the regulations to avoid the need for these near-term solutions. This regulatory basis should provide clarity on the specific use of the non-power reactor regulations or guidance in NUREG-1537 for operational testing at the factory.

3.2 Acceptance Criteria and Licensing Approach

Acceptance Criteria

It is expected that the ability to perform operational testing at the factory would only be available to RHDRA and other similar reactors that are capable of being transported with loaded fuel. While theoretically other advanced reactors could demonstrate the ability to safely perform operational testing at the factory, there is not anticipated to be any value to the business model for reactors that are not able to be transported fueled.

Licensing Process

Only the licensing processes that use a Manufacturing License under Part 52 Subpart F with a Part 50 license, a Part 52 license, or a future Part 53, would benefit from the operational testing. If the NRC also pursues a rulemaking for an ML holder to perform all activities under the Part 52 Subpart F license, without the need for a Part 50 license, then all Part 52 ML holders would benefit.

4 OTHER OPTIONS FOR RESOLUTION OF THE ISSUE

4.1 AEA Change – General License

A general licensing approach would be more efficient and effective in regulating nuclear reactors, such as RHDRA, and would be capable of enabling even shorter deployment timeframes that would be needed to support other business models. Currently, the AEA does not grant the NRC authority to issue general licenses for nuclear reactors, although it does grant authority to the NRC to issue general licenses for other regulated activities. If Congress were to amend the AEA to authorize and direct the NRC to develop a general licensing approach for certain nuclear reactors, and the NRC subsequently pursued a rulemaking to develop such a general license framework for nuclear reactors, this would be a more optimal solution to the issue discussed in this appendix. However, since the NRC could achieve the business requirements with currently granted authorities, and since there is significant uncertainty on whether or when Congress would grant NRC authority for issuing general licenses for reactors, the proposed resolution discussed herein is focused on approaches the NRC can implement without changes to the AEA. This enables the fastest path toward a more effective and efficient regulatory framework for RHDRA and other advanced reactors, and would build the basis of experience that could inform a longer term General License approach if Congress eventually enables it. More discussion on NRC Regulation Through General Licenses is included in Attachment B.

4.2 SECY-24-0008 Option A

The NRC's first option in SECY-24-0008 discussed the use of a Part 52 Manufacturing License with either a Part 50 Construction Permit and Operating License or a Part 52 Combined License without reference to non-power regulations or guidance. This is very similar to the Proposed Alternative Regulatory Approach.

The primary difference between the proposed approach and this option is that this option would not make use of non-power reactor regulations or guidance but would draw on the existing safety requirements in Parts 50 or 52 for commercial power reactors. This avoids the need for Commission approval of a novel approach, with the potential for lengthy decision time and would provide more certainty in the licensing processes since the NRC staff is familiar with them and avoids the need for new guidance to be developed on the use of non-power reactor regulation for the proposed scenario. However, it would be less effective and efficient, since the non-power regulations are more appropriate for the activities associated with operational testing at the factory.

5 ACKNOWLEDGEMENTS

NEI Issue Lead: Julianne McCallum

Appendix 28 – Use of Features to Preclude Criticality

1 ISSUE INTRODUCTION

Features to preclude criticality (FPC) were identified as a requirement to enable fuel loading in a factory and safe transport of factory fuel-loaded micro-reactors in SECY 24-0008. SECY-24-0008 proposes that a reactor module with FPC installed is not considered "in operation" and therefore does not require an operating license to load fuel. The reactor module would not be deemed to be "in operation" until the FPC are removed at the operating site. However, technology-inclusive, performance-based acceptance criteria for FPC were not addressed. Therefore, it is unclear what the performance-based acceptance criteria will be for a design that would enable a fueled rapid high-volume deployable reactors in remote applications (RHDRA) to be transported to site. FPC will almost certainly be included to enable factory fuel loading provisions and operational testing in the factory.

Nuclear Regulatory Commission (NRC) staff have made significant progress in this area using forward-thinking, risk-informed thinking in SECY-24-0008. Additional clarity related to the future NRC regulatory requirements, policy and implementation through guidance of the FPC remains a significant risk to designers of RHDRA and other similar reactors that plan to load fuel in the factory, perform operational testing at the factory, and/or transport fueled reactors (see also Appendices 26, 27 and 29). One of these risks is the uncertainty of Commission approval of the staff proposals in SECY 24-0008. Additionally, the lack of clarity leaves designers and future applicants guessing at what the performance based design criteria will be, what design features the NRC will accept for meeting those criteria, and any other requirements specific to crediting the use of those design features. Furthermore, without knowing the requirements and expectations the NRC will establish for FPC, it is not possible for designers to know whether the requisite design features are technically feasible with the designs under development or cost-effective for the RHDRA business model. As such, this lack of clarity represents considerable risk for the future success of alternative business models. On the other hand, this approach does allow reactor designers to propose their own strategy through pre-application engagement.

The desired outcome is a technology-inclusive, performance-based and risk-informed guidance for FPC that enable the transport of fueled reactors

2 BACKGROUND

A long-standing position of the NRC is that nuclear power reactor operation begins with loading fuel into the reactor. The challenges created by this policy are addressed by staff with the proposed policy changes sent to the Commission in SECY 24-0008, including the recommendation that the installation and removal of FPC be recognized in lieu of a 103(g) finding.

FPC are integral to the success of the RHDRA business model, particularly in enabling authorization of transportation of utilization facilities, which have historically been considered “in operation.” Without streamlined, risk-informed authorization to load fuel, conduct operational testing, and transport fueled reactors, it will be difficult to meet the business model criteria of 6 months from site selection to operation and regulatory costs less than 1% of the O&M costs.

As discussed in SECY 24-0008, another consequence of fueled micro-reactors being considered “in operation” is that each factory-fabricated micro-reactor that is fueled in the factory would be required to have a facility operating license or a combined license, regardless of whether it is operated for testing at the factory. (Note that operational testing of a fueled micro-reactor in the factory and transportation of a fueled micro-reactor are addressed in separate appendices.)

In SECY 24-0008, the NRC staff recommended to the Commission an approach that would allow the holder of a manufacturing license to load fuel at the factory under a license issued pursuant to Part 70, as long as the factory-fabricated micro-reactor includes FPC and the criticality safety controls required by Part 70 are in place. Specifically, SECY 24-0008 states, "For Topic 1, the NRC staff recommends that the Commission take the position that a factory-fabricated micro-reactor with FPC would not be "in operation" when loaded with fuel, which would allow fuel loading at a factory without the need for a facility operating license issued pursuant to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," or a combined license issued pursuant to 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants."

This position would also facilitate safe transportation of fueled micro-reactors without the need for a major rulemaking to establish requirements for operating reactors in transit. For fueling a reactor in the factory, the NRC staff recommends that the Commission allow the holder of a manufacturing license to load fuel at the factory under a license issued pursuant to 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," as long as the factory-fabricated micro-reactor includes FPC and the criticality safety controls required by 10 CFR Part 70 are in place. For operational testing, the NRC staff recommends that the Commission allow the use of most of the safety (and possibly the environmental) regulations for non-power reactors to be applied to operational testing at the factory. And, "In this paper, the NRC staff proposes that a factory-fabricated module with FPC would not be "in operation" when loaded with fuel."

Factory fueling was addressed in rulemaking for the first time in a preliminary draft of the Manufacturing License provisions of the draft proposed Part 53 but was removed before the draft proposed rule was sent to the Commission in SECY 23-0021. However, in the Commission's Staff Requirements Memorandum on the draft proposed rule, the Commission directed the staff to include a provision for factory fuel load in the proposed rule. That proposed rule language has not yet been made public.

Features to preclude criticality were discussed extensively in SECY 24-0008 but technology-inclusive, performance-based acceptance criteria were not addressed nor were design criteria proposed. Therefore, while the potential benefits of using FPC seem clear, it is unclear what the performance-based acceptance criteria will be for a design that would enable a fueled RHDRA to be transported to the deployment site. NRC staff should confirm that the Part 70 framework and other existing acceptable methods as presented in approved standards adequately address requirements for FPC. Features to preclude criticality will have a direct bearing on factory fuel loading provisions, operational testing in the factory, and transportation of a fueled micro-reactor.

3 PROPOSED SOLUTION AND APPROACH

The proposed solution is to establish technology-inclusive, performance-based and risk-informed guidance for FPC that enable the following activities, independent of a site operating license (OL or COL with 103(g) finding):

1. Loading of fuel at the factory (see Appendix 26),

2. Performing operations testing at the factory (see Appendix 27),

3. Transport of fueled reactors (see Appendix 29) from:

    a. (fresh fuel) from the factory to the operating site,

    b. (spent or used fuel – see Appendix 31) from the operating site to the location where fuel will be removed from the reactor, and.

    c. (irradiated fuel) from one operating location to another operating location (a.k.a. mobile reactors).

4. Replacing modules at Site (see Appendix 30).

The guidance should clarify the requirements to attain NRC approval of standardized designs (e.g., ML) that enable the reactors to be delivered to site and installed in their operating location. The guidance should also provide additional clarity on the use of FPC, as they will be a critical element of reactor module design. The requirements for the design, installation, or removal of the required FPC, including any reliability considerations that must be addressed by the licensee and designer, should be addressed as well. This should consider both features that may be integrated in the design and features that require installation and removal of hardware to prevent criticality both before fuel load and after operation of the reactor. Thus, the guidance should include options for design features that can be implemented without a configuration change (such as opening the reactor) as well as hardware that is installed and removed but that does necessitate a configuration change. For installed FPC, this industry should develop guidance on identification of any potential accident scenarios associated with installation or removal of the FPC and mitigation strategies, specifically addressing worker and public safety.

The proposed approach should make use of the approach recommended by the NRC staff in SECY 24-0008, the combined application of a Manufacturing License and a Part 70 license with the required use of FPC. This approach will support loading fuel in the factory, transportation of a fueled micro-reactor to the deployment site, as well as return of the micro-reactor containing used fuel to a refueling or refurbishment site. While not as closely linked to operational testing in the factory, the post-testing requirements will necessarily address the presence or installation of FPC before transporting the fueled micro-reactor.

Requirements associated with the Manufacturing License and the Part 70 license to address environmental considerations and insurance considerations will have to be addressed as discussed in Appendix 26 on factory fuel loading. Hearings will also have to be addressed using the streamlined contested hearing procedures as discussed in Appendix 6, and the mandatory hearing requirement potentially will have been eliminated through legislative action, as discussed in Appendix 7. This proposed approach is not without risk to the successful implementation of the proposed alternative regulatory approach. For example, the Commission could reject the NRC staff's proposal for FPC to render a fueled micro-reactor "not in operation." This would preclude the use of a Manufacturing License and Part 70 license as the basis for fuel loading in the factory. Similarly, the Department of Transportation could object to the transportation of a fueled reactor with FPC present. This would prevent the ability to load fuel in the factory, perform operational testing in the factory, transport the fueled reactor and replace the module at the site, which are essential to the business model for RHDRA.

The only concept of deployment available would be the traditional approaches where the manufactured reactor was delivered to the deployment site, and the fuel and any specialized equipment needed to fuel the reactor are delivered separately. The amount of additional time it would add to the deployment timeline will depend on the delivery timeliness and the staging of fuel and the specialized equipment and staff resources. It is not clear at this time whether this regulatory limitation would enable the business model for RHDRA.

3.1 Changes Needed to Regulations, Policy and Guidance

Rulemaking is not necessary for the proposed regulatory approach that utilizes FPC to enable a Manufacturing License Holder with a Part 70 license to load fuel at the factory, perform operational testing at the factory and transport a fueled (fresh or irradiated) reactor. The draft proposed Part 53 rule, or subsequent rulemaking, should include provisions in the requirements for the ML to enable it to be a single license for all of the activities being pursued by the RHDRA business model (e.g., fuel in the factory, operations testing in the factory, transport fueled, and replace module at site) without the need for a separate Part 70 application. A rulemaking would be necessary to enable an ML Holder to perform those activities completely under their ML authorizations, and without the need to seek a Part 70 license or a Part 50 or 52 operating license. Such a rulemaking would need to grant authorities for those activities at the ML Subpart, include the requirements for FPC to perform the activities, and establish the criteria for those features. The requirements that are ultimately included in Part 53 should be used as a basis for changes to Part 52, Subpart F.

Central to this proposed alternative regulatory approach is Commission approval of the use of FPC as the basis for classing a reactor fueled in the factory as “not in operation.” However, since the NRC’s traditional view is not codified in the regulations as a specific term “in operation” meaning the loading of fuel in a reactor, a rulemaking does not appear necessary to address a change in the NRC’s definition of “in operation” to include reactors that are fueled but have FPC installed. This clarity can be established in policy, which is in progress with the evaluation of SECY 24-0008.

To the extent that rulemaking is necessary to address the topics of fuel loading at the factory, operational testing at the factory, transport of a fueled reactor and replacement of reactor modules at site (see Appendices 26, 27, 29, and 30), and if FPC are necessary in order to enable those activities by an ML Holder, then it is expected that the NRC would include in the rulemaking a requirement related to the use of FPC. If a requirement for FPC is established, it should clarify the minimum set of characteristics the FPC need to achieve through technology-inclusive, performance-based and risk-informed criteria.

While rulemaking is not required to implement the proposed regulatory alternative, addressing the use of FPC, factory fuel loading, operational testing, and transportation of a fueled RHDRA and other similar advanced reactors to the deployment site and after operation to a refueling or refurbishment site will be important aspects of the proposed Part 53 to be issued for public comment.

3.2 Acceptance Criteria and Licensing Approach

Acceptance Criteria

Although any advanced reactors may benefit from clarity on the definition of “in operations” and FPC, it is expected to only provide benefits to RHDRA and other similar reactors, which incorporate design features that enable the efficient inclusion of FPC, which enable the reactor to be fully assembled in the factory, operated in the factory, transported fueled, and replaced as a module at the site.

Licensing Process

Only the licensing processes that use a Manufacturing License under Part 52 Subpart F with a Part 70 license, or a future Part 53, would benefit from the use of FPC. If the NRC also pursues a rulemaking for an ML holder to utilize one application to perform all activities, including those under a Part 70 or Part 50/52 license, then all Part 52 ML holders would benefit.

4 OTHER OPTIONS FOR RESOLUTION OF THE ISSUE

4.1 AEA Change – General License

A general licensing approach would be more efficient and effective in regulating nuclear reactors, such as RHDRA, and would be capable of enabling even shorter deployment timeframes that would be needed to support other business models. Currently, the AEA does not grant the NRC authority to issue general licenses for nuclear reactors, although it does grant authority to the NRC to issue general licenses for other regulated activities. If Congress were to amend the AEA to authorize and direct the NRC to develop a general licensing approach for certain nuclear reactors, and the NRC subsequently pursued a rulemaking to develop such a general license framework for nuclear reactors, this would be a more optimal solution to the issue discussed in this appendix. However, since the NRC could achieve the business requirements with currently granted authorities, and since there is significant uncertainty on whether or when Congress would grant NRC authority for issuing general licenses for reactors, the proposed resolution discussed herein is focused on approaches the NRC can implement without changes to the AEA. This enables the fastest path toward a more effective and efficient regulatory framework for RHDRA and other advanced reactors, and would build the basis of experience that could inform a longer term General License approach if Congress eventually enables it. More discussion on NRC Regulation Through General Licenses is included in Attachment B.

5 ACKNOWLEDGEMENTS

NEI Issue Lead: Julianne McCallum

Appendix 29 – Transport of a Fueled Reactor

1 ISSUE INTRODUCTION

Transporting a fueled reactor module (fresh, irradiated and used/spent) is a key feature for the rapid high-volume deployable reactors in remote applications (RHDRA) business model. While not all RHDRA concepts of deployment depend upon transporting the reactor module fueled, there are many companies that are pursuing this approach. The advantage is that transporting a fueled reactor module reduces the infrastructure needed at each operating site for fuel loading and unloading operations, can accelerate the deployment times, and can reduce deployment costs. All of which are important considerations for each single reactor module, and when considered over large numbers of reactor modules the benefits are even greater. Transportation of fueled reactor modules enables the business model to benefit from loading fuel at the factory, performing the inspections, testing, and analysis associated with ITAAC, and performing operational testing at the factory, if desired, so that these other activities can be performed in a central location in a controlled environment. Implementation of lessons learned through repetion can improve the process, thereby improving safety. This also benefits the NRC's oversight and inspection program by enabling it to be more focused on the fabrication facility where these activities are happening repetitively for manufactured reactor modules at production level scale, rather than needing to be spread geographically to remote locations for infrequent evolutions for each site. Existing regulations in 52.157(f)(26)(iv), 52.167(c)(2) and draft 53.620(e) address transport of a manufactured reactor module. However, they do not address transporting a fueled reactor module.

The desired outcome is the establishment of a regulatory approach that is effective and efficient to transport fueled reactor modules, including fresh, irradiated and spent/used fuel, and provides sufficient clarity to applicants. A regulatory framework that enables the transport of a fueled reactor module from the factory to the site of operation, and a reactor module containing used fuel from the site of operation to a facility for removing the fuel will be key elements supporting both near- and long-term objectives of the business model.

2 BACKGROUND

The potential for and desirability of loading fuel in a factory and performing operational testing in the factory has been discussed in a number of white papers put forward by both the NRC staff and NEI. The RHDRA business model entails three phases of the transportation process for a fueled reactor module, including licensing action, or getting a certificate of compliance; pre-deployment evaluations for demonstrating adequate protection; and logistics of a specific shipment. In the RHDRA business model, the reactor module is considered a part of a transportation package, along with the radioactive contents. There are three modes that a reactor designer may pursue for transport: the fueled micro-reactor module is fully encapsulated as contents within a package, the module design accounts for transportation packaging, or the module design includes credited packaging alongside some additional packaging. Existing regulations in 10 CFR Part 52, Sections 52.157(f)(26)(iv), 52.167(c)(2) and the draft proposed 53.620(e) address transport of a manufactured reactor module. However, they do not address transporting a fueled reactor module. Changes to, or exemptions from, these regulations to permit transporting a fueled reactor module may have to be developed depending on direction from the Commission. Resolutions to unique technical issues may also be necessary. It is not clear how the requirements in Part 52, Subpart F, and Part 71 will need to be reconciled, if at all. Additionally, harmonization with international standards may present a challenge for globally focused business models depending on the solution.

Appendix 29 – Transport of a Fueled Reactor

The regulations in Part 52, Subpart F, and in Part 71 are deterministic requirements. There are ongoing activities addressing a risk-informed regulatory framework for the transportation of micro-reactor transportation packages. There also have been recent efforts to develop a risk assessment approach for transportation package approval of a mobile nuclear power plant for domestic highway shipment.

The RHDRA business plan intends for factory fabrication of micro-reactors to conduct fueling and testing of the reactor module in the factory and then transporting the fueled reactor module to the operating site. The transport of a fueled reactor module is intended to eliminate or minimize the amount of testing and inspection required at the operating location to facilitate more rapid reactor deployment. In the July 2021 NEI paper, "Proposed Approach for Manufacturing License Requirements in 10 CFR Part 53,"[1] NEI noted that shipping a fueled reactor module would trigger requirements in 10 CFR 71 in addition to requirements in 10 CFR Part 52, Subpart F. Additionally, shipment of irradiated fuel is traditionally limited to a small number of fuel bundles/assemblies to meet thermal and radiation requirements. However, the ability to ship an entire micro-reactor in or as a shipping cask may depend on the reactor and fuel technologies and their ability to meet those thermal and radiation requirements, as well as the other criteria.

A consideration that NRC staff addressed in SECY 24-0008 is the Commission's long-standing view that reactor "operation" begins with the loading of fuel into the reactor module. NRC advocated for the use of features to preclude criticality installed upon fuel loading (discussed in Appendix 28), noting they "would allow for transportation of a fueled module under the current regulations" because the module would not be "in operation" during transport. The module would be considered "in operation" following the removal of FPC. The module could be covered by provisions in the manufacturing license that allow for transfer to a licensee authorized to acquire the module, while the radioactive material in the module would be controlled by materials licenses and the existing transportation regulations in 10 CFR Part 71. NRC contends this "would allow for safe, efficient, and novel approaches for licensing fuel loading in a factory-fabricated module without requiring a facility operating license or combined license, and for regulating the safe transport of fueled modules without a rulemaking to establish requirements for transportation of utilization facilities that are in operation."

In SECY 24-0008, the NRC noted that transport of a fueled reactor module would require features to preclude criticality (FPCs) and would classify the module as a Type AF package for front-end transport and either Type AF or BF package for back-end transport. Packages would also be subject to requirements from the Department of Transportation (DOT) and potentially other agencies, including tests and conditions for normal conditions of transport, hypothetical accident conditions, and maintenance of criticality safety. Current regulations allow this with exemptions for each reactor module, but not on a large, production-level scale. In addition, there may be a public perception issue associated with large-scale transportation of numerous quantities of fully fueled, manufactured reactor modules envisioned for rapid high-volume deployment, particularly with an exemption process for each.

Given the three options for transportation of a fueled reactor module as part of the RHDRA business model, as discussed in the introduction, there are challenges to each approach for generic certification as a transport system, which is necessary to adhere to the RHDRA criteria of 6 months between site identification and deployment. A reactor module that is transported as contents of a package can be pursued today under the well-understood and internationally harmonized requirements under Part 71

[1] ML21197A103

Appendix 29 – Transport of a Fueled Reactor

and NUREG-2216 with existing safety standards and Certificate of Compliance Safety Analysis Report for Packaging. However, the reactor module may be at risk due to the challenges of meeting performance standards due to the size or weight of the package. If the reactor module were to be its own package by design, challenges may include the limited feasibility or commercial viability of current demonstration methods, as well as the perceived large uncertainties of alternative means of demonstration. Additionally, deterministic series demonstration for normal conditions of transport and hypothetical accident conditions can be challenging. The third mode, where a reactor module design includes packaging credit alongside additional packaging, would require work to determine when a reactor module is a package or not, as well as performance-based approaches to demonstrating acceptable package performance and credit for safety performance of varying features. For both the second and third modes, aging management (given the transportation features would need to remain functional throughout the lifecycle and compliant with NUREG-2216) and harmonization with international standards may present challenges.

While these existing approaches could be viable there are current efforts to develop a risk-informed regulatory framework for the transportation of reactor module transportation packages that should be considered. The Pacific Northwest National Laboratory (PNNL) published a report in December 2021 entitled "Plan for Development and Application of Risk Assessment Approach for Transportation Package Approval of an MNPP for Domestic Highway Shipment."[2] In the Plan's introduction it was noted that PRA techniques have also been applied to the transportation of spent nuclear fuel, most notably in NUREG/CR-4829, NUREG/CR-6672, and NUREG-2125. The stated purpose of the plan "is to provide the planning bases for the development and application of a PRA methodology for the highway transport of the Project Pele prototype mobile nuclear power plant (MNPP) that would support a risk-informed pathway for regulatory approval." The plan's products included a MNPP Transportation PRA, the methodology, technical information, data, and example analyses that could be used to support a request for a 10 CFR 71.12 exemption.

In August 2021, PNNL published a report entitled "Proposed Risk-Informed Regulatory Framework for Approval of Microreactor Transportation Packages."[3] The stated objective of the report is "to propose a risk-informed regulatory framework for the licensing of the transportation of micro-reactors, focused on the transportation of irradiated nuclear fuel that is assumed to be an integral component of the micro-reactor transportation package. Other transportation variations are possible such as transporting a micro-reactor with fresh fuel but, transport of a micro-reactor with irradiated fuel is the most challenging case."

The August 2021 PNNL report proposed a phased strategy "in which existing regulatory approval options in 10 CFR Part 71 are used for Near-Term regulatory approvals of prototype/demonstration unit micro-reactors. In the Intermediate- and Long-term, it is proposed that the regulations be amended to support risk-informed regulatory approvals of production unit micro-reactors with the objective of increasing micro-reactor transportation package license application development and review efficiency and reducing regulatory uncertainty."

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[2] Maheras S.J., G.A. Coles, J.R. Phillips, C.A. Condon, S.M. Short, H.E. Adkins, and P.P. Lowry, et al. PNNL-33524, "Plan for Development and Application of Risk Assessment Approach for Transportation Package Approval of an MNPP for Domestic Highway Shipment," December 2021. Note: MNPP stands for Mobile Nuclear Power Plant.

[3] Coles G.A., S.M. Short, S.J. Maheras, and H.E. Adkins. PNNL-31867, "Proposed Risk-Informed Regulatory Framework for Approval of Microreactor Transportation Packages," August 2021.

3 PROPOSED SOLUTION AND APPROACH

The proposed solution is to permit ML holders with a Part 71 license to transport fueled reactor modules with the RHDRA business plan and other similar reactor modules in the following conditions:

1. (fresh fuel) from the factory to the operating site,
2. (spent or used fuel – see Appendix 31) from the operating site to the location where fuel will be removed from the reactor module, and
3. (irradiated fuel) from one operating location to another operating location (a.k.a. mobile reactors).

This approach is consistent with SECY 24-0008 which discusses enabling the transport of fueled reactor modules that include features to preclude criticality. This approach would also require the ML holder to possess a Part 70 license (see Appendix 26 for Fuel Loading) and/or a Part 50 license (see Appendix 27 for Operational Testing).

This approach would need to address the Part 71 transportation requirements for the fueled reactor module, including:

1. Permit the shipment of the fueled reactor module from the factory to the operating site once the NRC has accepted and docketed the site operating license application,
2. Permit the ML holder to perform inspection and testing at the operating site to verify the operability of the reactor module after transport,
3. Permit the removal of the FPC by the ML holder from the reactor module once it is emplaced in its final location, the ML holder has verified operability, and the NRC has issued the site operating license to the Part 50, 52 or Part 53 operating license holder,
4. Permit various forms of design features, including impact limiters, overpacks and the reactor features to meet the requirements for transportation packages, provided the design would be capable of meeting applicable requirements related to transportation accidents,
5. Permit the use of licensed contractors and sub-contractors to perform the transportation activities (see Appendix 25).

While near-term activities are expected to focus on making use of the existing deterministic regulations, long-term efforts need to expand and implement the current activities addressing a risk-informed fueled reactor transportation regulatory framework.

3.1 Changes Needed to Regulations, Policy and Guidance

Rulemaking is the most effective or efficient means to achieve the proposed regulatory approach for the transport of fueled reactor modules. As proposed in the PNNL regulatory framework, amending the regulations to support risk-informed regulatory approvals of production unit RHDRA and other similar reactors that can be safely transported fueled would increase the efficiency of fueled reactor module transportation package license application development and review while reducing regulatory uncertainty. Making such regulatory changes would likely require coordination with the Department of Transportation, who has related regulatory responsibility. There may also be opportunities to tackle a broad suite of the issues highlighted in these topic papers, including transportation of a fueled reactor module, by defining a new class of reactors or adding appendices to existing regulations. The NRC draft proposed Part 53 rulemaking, or subsequent rulemaking, should include provisions in the ML requirements so that a single license would permit all the activities being pursued by the RHDRA business model (e.g., fueling in the factory, ITAAC closeout at the factory, operational testing in the factory, transportation fueled, and module replacement at the site) without the need for a Part 71 license. A rulemaking would be necessary to enable an ML holder to perform those activities completely under the Part 52 ML authorizations, without a Part 70 license or a Part 50 or 52 operating license. The requirements that are ultimately included in Part 53 should be used as a basis for changes to Part 52, Subpart F.

This is consistent with the near-term approach that uses regulatory approval options in Part 71. If exemptions from the existing Part 71 regulations are necessary, the results from the PNNL MNPP plan and the previous transportation risk studies could provide a basis for exemptions.

It is noted that rulemaking is not necessary to enable the business model for RHDRA transport of fueled reactor modules; however, the use of existing requirements is not the most effective or efficient approach. Until the implementation of a more risk-informed rule for transporting fueled reactor modules, a near-term approach could be for an ML holder with a Part 71 license to transport fueled RHDRA and other similar reactors.

This proposed approach depends upon the Commission approving the SECY 24-0008 proposal that the installation of features to preclude criticality would be adequate to designate a fueled reactor module as not “in operation” and safe for transportation. The reactor module would be considered “in operation” following removal of the physical features to preclude criticality at the operating site. This policy change, if approved by the Commission, would enable transport of fueled RHDRA reactor modules without a rulemaking to establish requirements for transportation of utilization facilities.

NRC and industry should work together to develop guidance to clarify the applicable requirements for the transport of a fueled reactor module, including any NRC expectations for the implementation of those requirements for these activities. The guidance should address the considerations identified in the earlier discussion of the proposed approach.

3.2 Acceptance Criteria and Licensing Approach

Acceptance Criteria

Only RHDRA and other similar reactors, which are small and light enough to be transportable with fuel loaded, and which incorporate design features that enable the efficient inclusion of features to preclude criticality can be transported with fuel loaded. These capabilities would need to exist for fresh fuel, irradiated fuel and used/spent fuel in order to obtain the full benefits of this approach.

Appendix 29 – Transport of a Fueled Reactor

Licensing Process

Only the licensing processes that use an ML under Part 52 Subpart F with a Part 71 license, or a future Part 53 provision, would enable transportation of a fueled reactor module. Rulemaking that permits an ML holder to perform all activities under the Part 52 Subpart F license, without the need for a Part 71, would be beneficial.

4 OTHER OPTIONS FOR RESOLUTION OF THE ISSUE

No other options were identified.

5 ACKNOWLEDGEMENTS

NEI Issue Lead: Julianne McCallum

Appendix 30 – Replacing Fueled Modules at the Operating Site

1 ISSUE INTRODUCTION

Replacing fueled reactors at the end of their fuel life (i.e., the fuel has become spent/used) without removing the fuel on-site is a significant feature for the rapid high-volume deployable reactors in remote applications (RHDRA) business model. While not all RHDRA concepts of deployment depend upon replacing fueled reactors on-site, there are many companies that are pursuing this approach. The advantage is that replacing a fueled reactor (containing spent fuel) with another fueled reactor (containg new or slightly irradiated fuel) reduces the infrastructure needed at each reactor operating site for loading and unloading fuel from the reactors. It also permits the business model to consolidate spent fuel from many reactor sites at a single location, and to bring the reactors to a refurbishment facility periodically (during refuelings) to perform maintenance. These activities can accelerate the deployment times and reduce deployment costs. Both of which are important considerations for each single reactor, and when considered over large numbers of reactors the benefits are even greater. Performing the defueling and potential maintenance in facilities designed for those purposes rather than at the operating site can also improve safety by performing these activities in facilities specifically designed for these purposes, with appropriate radiation protection and waste handling capabilities, as acknowledged by NRC staff in SECY-24-0008. Currently, there are licensing challenges when a site is licensed for 40 years, but the reactor module sited has a lifetime of, for example, 5-15 years. Licensing multiple iterations of the same decision for the same site is currently too burdensome to enable the RHDRA business model, but the NRC staff has been considering efforts to address similar issues in both SECY-11-0079 and SECY-24-0008.

The replacement of fueled reactors at the operating site depends upon, and creates the value proposition for, transportation of fueled reactors, loading fuel at the factory, and performing operational testing at the factory. Performing these activities in a central location where there are better controls and lessons learned through repetition can improve the process and improve safety, as acknowledged by NRC staff in SECY-24-0008. These benefits might include handling fuel for many reactors in the controlled environment of the factory such that operating experience would rapidly accumulate, as opposed to fuel handling at many deployment sites where such fuel handling would be less common. Another benefit could be the manufacturer's ability to identify and correct defects or operational issues at the factory, which could potentially avoid having to transport modules back and forth between the deployment sites and the factory if such defects or issues were identified at deployment sites.

Other advanced reactors could benefit from the ability to replace fueled modules at the operating site even if they are not capable of being transported fueled to the site. This would require fueling and defueling the reactors at the operating site, but potentially in a location other than the final operating location (e.g., a refueling bay). This could enable more efficient loading of the reactor that will continue to remain at the operating location, or also permit the swapping out of reactor modules. Enabling the replacement of fueled reactor modules at the operating site also benefits the NRC's oversight and inspection program, enabling it to be more focused on the fabrication facility where these activities are happening repetitively for production-level manufactured reactor modules, rather than needing to be spread geographically to remote locations for infrequent evolutions at each site.

The Nuclear Regulatory Commission (NRC) regulatory framework does not address the concept of deployment and operations, where a fueled reactor module at the end of its operating life is replaced by a newly fueled reactor module transported to the site. While replacing modules at the operating site may not seem like a near-term issue, it is important to the overall business model that this issue be resolved or a path to resolution be identified due to its potential impact on the licensing process and associated content and scope of an initial license application. The desired outcome is the establishment of a regulatory approach that is effective and efficient to license and replace fueled reactors at the operating location and provides sufficient clarity to applicants.

2 BACKGROUND

The NRC regulations do not contemplate a scenario where a reactor module reaches the end of the useful life of the fuel prior to the end of its 40-year site license where that reactor module is removed from service and transported to a refueling and refurbishment facility or facilities. Rather, it is historically assumed that the spent fuel would be removed from the reactor pressure vessel and placed in a water pool to cool down, typically for at least one year per the definition of spent fuel in §72.3 and the reactor would continue operating once refueled. However, for the RHDRA business model, the reactor may be decommissioned and replaced with a new reactor module; otherwise, the site would be prepared for other use. The 1-year cooldown period is designed to keep the spent fuel from overheating and being damaged. However, the nature of the fuels expected to be used in RHDRA and other similar reactors may tolerate much higher temperatures than typical light water reactor (LWR) fuel so that the 1-year cooldown, or decay, time may be excessive. This is discussed in more depth in Appendix 31.

A technology-independent approach and licensing process for refueling or replacing reactor modules must be identified. Some reactor modules and the associated business model could call for on-site refueling similar to what is done today, where the spent fuel is removed from the reactor module, placed in a spent fuel processing (SFP) facility and eventually moved to a dry storage facility. Fresh fuel would be installed in the reactor module and the reactor could resume operation after any necessary inspection or testing (assuming no onsite refurbishment is required). For some reactor modules, the cooldown or decay period and water cooling may not be warranted. In that case, the fuel could be removed from the reactor module and placed in a dry storage cask and stored for eventual disposal. Storage of spent fuel at the site is addressed in Appendix 31.

A different, and potentially more likely, scenario is that once the fuel has reached the end of its useful life, the reactor module is shut down, allowed to cool down to safe temperatures and decay to safe or manageable dose levels for workers. It would then be disconnected from the other plant systems, the features to preclude criticality (FPC) re-installed, and the reactor module prepared for shipment to an appropriately licensed refueling and refurbishment facility.

A reactor module of the same design would have been shipped to the operating site and stored until the operating unit was shut down. The module containing fresh fuel would then be installed with the FPC removed, and after any required inspection or testing, it could begin operating. Having multiple fueled reactor modules on a site at the same time was addressed in SECY 11-0079 which the NRC identified as a viable approach for reactors with the RHDRA business model. However, SECY 11-0079 did not go so far as to envision a licensing process for sites with multiple reactor modules potentially manufactured under an ML that could be replaced several times with reactor modules manufactured under the same ML during the life of the site license.

Appendix 30 – Replacing Fueled Modules at the Operating Site

The reactor module that has been removed from service would be prepared for transportation "very likely be those for a Type BF package" as described in SECY-24-0008. For more information on transportation of a reactor module, see Appendix 29.

The NRC staff stated in SECY 24-0008 that they intend to use the existing regulatory framework in 10 CFR Part 71 to review transportation of commercial fueled factory-fabricated modules in the near term. This is consistent with the proposed alternative regulatory approach described in the topic paper on transporting a fueled reactor module. The deterministic approach in Part 71 for transporting a fueled reactor module is viable for the near term. However, as discussed in the topic paper on transporting a fueled reactor module, a risk-informed structure is needed to support longer-term actions particularly considering the business model of production-level manufacturing of rapid high-volume deployable nuclear reactors being shipped both to and from the licensed deployment sites.

In SECY 24-0008, the NRC identified a path forward under Parts 50 and 52, as described originally in SECY-11-0079. However, this only addresses licensing issues for multiple reactor modules on a site at the same time. In addition to the licensing challenges for replacement reactor modules, there are operational challenges that warrant consideration. These include operational challenges associated with the installation and removal of FPC, radiation protection for workers and the public during the replacement, preparing the reactor module for transportation as an approved package, and identifying any accident scenarios and mitigation strategies associated with potential re-installation of the FPC or removing the reactor from the operation location. In addition, there is a licensing issue with Part 72 regarding the large reactor-based definition of spent fuel as being aged for at least 1 year. The fuels that will be used in reactor modules may be able to withstand higher temperatures without failure than fuel historically used in light-water reactors. This would have to be resolved by a change to Part 72 or by exemptions, so that the micro-reactor containing the spent fuel can be transported to a refueling or refurbishment facility. This is closely related to the issue of storing spent fuel at the operating site, addressed in Appendix 31 of this package.

NRC and industry must coordinate to clarify the regulatory and technical issues involved with replacing a reactor module and transporting it to a refueling, refurbishment, or decommissioning facility, as well as licensing approaches that could be used to obtain NRC approval for these activities. As needed, industry and NRC should pursue resolution of any potential policy issues that may be identified and completion of a rulemaking if additional requirements are needed.

3 PROPOSED SOLUTION AND APPROACH

The proposed solution is to establish the acceptability of activities for effective and efficient replacement of fueled reactors at the operating location, including:

1. the shutdown and any associated cooldown period required to place the reactor in a safe condition for removal,

2. re-installation of the FPC,

3. disconnection from the structures, systems and components that are not integral to the reactor,

4. removal of the fueled reactor from its operating location,

5. movement of the used/spent fueled reactor to the location for preparation for on-site storage and/or off-site shipment, and

6. preparation of the used/spent fueled reactor for on-site storage or off-site shipment.

It is anticipated that the licensee's radiation protection program required by Part 20, among others, would specifically address these activities. The same process would be used for an irradiated fueled reactor (i.e., the fuel is irradiated but still has an adequate reactivity, so that the reactor may be shipped to another location for additional use). The installation of the new fueled reactor would be performed under the ML or other standardized design approval (see Appendix 2).

The site operating license holder would also be responsible for any inspections or tests required for installing that module, removing the FPC as applicable, and bringing the reactor module into operation. This work is performed under the site license for the operating reactors. Having multiple reactors on site at the same time was addressed in SECY-11-0079, and referenced in SECY-24-0008, where the concept of one license application resulting in multiple licenses for the same or similar modules, demonstrably bounded by the existing license, at the same site is considered the best path forward, as individually licensing each replacement module is not feasible.

The proposed approach is to build on the existing work in both SECY papers produced by the NRC staff to develop a risk-informed, performance-based licensing condition for an OL or COL that would support replacement of a reactor module with a new module from the factory using either the 50.59 process or a 50.50-like process to demonstrate that a license amendment is not required. The transport of both the new fueled reactors from the factory to the licensed deployment site and the used/spent fueled reactors from that site to an appropriately licensed refueling or refurbishment site would be reliant on the path forward discussed in Appendix 29, "Transporting a Fueled Reactor Module," including the risk-informed, performance-based revision to Part 71.

3.1 Changes Needed to Regulations, Policy and Guidance

No rulemaking is needed to enable the proposed approach for replacement of fueled reactor modules at the operating site using the site operating license (e.g., Part 50 OL, Part 52 COL or future Part 53 operating license). It is expected that the proposed actions would be addressed either in guidance or specifically in the site operating license, either Part 50 Operating License, Part 52 Combined License (COL), or a site operating license under a future Part 53.

However, the proposed approach does require an expansion of the scope addressed in SECY-11-0079 and a decision from the NRC Commission on the approach originally recommended by the NRC staff in SECY-11-0079, which proposed that, for sites with multiple reactor modules, each reactor module would have a separate license but be reviewed under one application. While this is largely an issue for the site license and scope topic, it becomes an issue when considering one reactor in operation and nearing the end of its fuel cycle and another fueled module on site being stored in anticipation of the replacement process. Expansion of the scope of SECY 11-0079 to address the replacement process would be prudent. The Commission did not act on SECY-11-0079, and a firm position has not been developed, although the NRC staff in SECY-24-0008 recommended use of the approach in SECY-11-0079. The NRC must expand the scope of issues addressed of SECY 11-0079 to include replacement of reactor modules during the life of the site license and act on this issue. NRC and industry must coordinate to clarify the regulatory and technical issues involved by developing specific criteria and potentially guidance to make clear the requirements for a licensing condition authorizing multiple reactor modules on site at the same time as well as scheduled replacement of these reactor modules during the life of the site license.

3.2 Acceptance Criteria and Licensing Approach

Acceptance Criteria

Only RHDRA and other similar reactors, which are moved on-site at the operating location with loaded fuel and incorporate design features that enable the efficient inclusion of features to preclude criticality are expected to be able to use the approach for replacing fueled reactors at the operating site. The reactor site would need to have the infrastructure, e.g., cranes and trolleys capable of moving the fueled reactor around the site. For reactors that are fueled on-site, they would need to have appropriate fueling and de-fueling infrastructure.

Licensing Process

Any Part 50 OL, Part 52 COL or future Part 53 site operating license holder could use this approach.

4 OTHER OPTIONS FOR RESOLUTION OF THE ISSUE

4.1 AEA Change – General License

A general licensing approach would be more efficient and effective in regulating nuclear reactors, such as RHDRA, and would be capable of enabling even shorter deployment timeframes that would be needed to support other business models. Currently, the AEA does not grant the NRC authority to issue general licenses for nuclear reactors, although it does grant authority to the NRC to issue general licenses for other regulated activities. If Congress were to amend the AEA to authorize and direct the NRC to develop a general licensing approach for certain nuclear reactors, and the NRC subsequently pursued a rulemaking to develop such a general license framework for nuclear reactors, this would be a more optimal solution to the issue discussed in this appendix. However, since the NRC could achieve the business requirements with currently granted authorities, and since there is significant uncertainty on whether or when Congress would grant NRC authority for issuing general licenses for reactors, the proposed resolution discussed herein is focused on approaches the NRC can implement without changes to the AEA. This enables the fastest path toward a more effective and efficient regulatory framework for RHDRA and other advanced reactors, and would build the basis of experience that could inform a longer term General License approach if Congress eventually enables it. More discussion on NRC Regulation Through General Licenses is included in Attachment B.

5 ACKNOWLEDGEMENTS

NEI Issue Lead: Julianne McCallum

Appendix 31 – Used Fuel Storage at the Operating Site Location

1 ISSUE INTRODUCTION

Traditional nuclear power plant operators store their used fuel in pools and eventually transfer it into dry storage systems (DSS), either casks or canisters in overpacks, for onsite storage on pads licensed under 10 CFR Part 72 (e.g., Independent Spent Fuel Storage Installations – ISFSIs). Advanced reactors, like microreactors, likely will use different fuel technologies and used fuel management approaches that change the nature of both storage and the definitions used in used fuel management. Some RHDRA and other similar advanced reactors intend to be fully fueled at the factory and when shipped to site. Fueled but not-yet-operated reactors may be stored at a manufacturing facility ahead of transport to their operating sites. Following cessation of a specific RHDRA's operation, that reactor may be replaced and will need to be stored temporarily until it is safe to transport (interim storage may also be required for other logistical reasons).

Once removed from the operating site, the reactor may be stored in a facility specifically designed and licensed to possess that type, form, and quantity of material, or held by a third party at an interim storage facility with other used fuel storage systems. Some RHDRA deployment models will incorporate disposition and either a disposal or refurbishment pathway at a separate facility that may need to store used reactor fuel (including fuel stored within a reactor) for short periods of time before it is unloaded. Each of these lifecycle stages poses unique safety and security standards that must be addressed in an efficient manner. Two specific issues have been identified for used fuel on-site for this class of reactors:

1. The definition of spent fuel in 10 CFR Part 72.3 will need to be clarified through rulemaking. It currently reads: "Spent Nuclear Fuel or Spent Fuel means fuel that has been withdrawn from a nuclear reactor following irradiation, has undergone at least one year's decay since being used as a source of energy in a power reactor, and has not been chemically separated into its constituent elements by reprocessing. Spent fuel includes the special nuclear material, byproduct material, source material, and other radioactive materials associated with fuel assemblies." Essentially, the key to doing this will be to build on the commonalities between storage in used reactor vessels and storage in dry casks to demonstrate that the used RHDRA/advanced reactor vessels are as safe or better than existing dry cask storage systems.

2. The NRC's implementation of the Part 72 requirements for dry storage does not fully incorporate risk insights, and the NRC has taken regulatory positions that are not commensurate with the potential consequences and risks of the technology or necessary to provide reasonable assurance of adequate protection of public health and safety. Such implementation of Part 72 requirements by the NRC has resulted in evolving and increasingly more stringent interpretations of the requirements for issues that are of very low safety significance, often without establishing that a new unresolved safety issue has been identified through operating experience. The NRC's resolution of these very low safety significant issues typically takes years, resulting in the expenditure of considerable NRC and licensee resources and sometimes the cessation of dry storage activities while the issue is being resolved. These NRC Part 72 implementation trends could challenge the RHRDA business model.

The desired outcome is NRC clarification on the regulatory and technical issues related to the storage of RHDRA and other advanced reactor spent fuel on site, and the associated licensing approaches for addressing those issues.

Appendix 31 – Used Fuel Storage at the Operating Site Location

This issue paper seeks to resolve the post-operational storage matters related to the subject deployment model as well as potential changes to the regulatory framework to address non-LWR fuel technologies and performance-based criteria for onsite storage requirements.

2 BACKGROUND

Large LWRs manage their used fuel based, in part, on historical changes regarding how and when ultimate disposition was supposed to occur for the industry. Plants were initially designed with minimal onsite storage capability in pools to manage initial cooldown (thermal and radiation) of fuel bundles before packaging for subsequent transport offsite to a DOE-managed repository. Since that disposition pathway has not yet materialized, the current fleet of plants have incrementally increased the allowable loading of their pools through re-racks (with substantive engineering, analysis, and programmatic changes to manage the greater inventory) and transferred used fuel into DSS for storage at ISFSIs co-located with the reactor plant site. There have also been efforts to establish either publicly owned/operated or government-managed Consolidated Interim Storage Facilities (CISFs) for centralized management of these used fuel canisters, until long-term repository options materialize, but these facilities will not be available in the near-term.

The NRC developed Part 72 to license and regulate the storage of conventional large LWR fuel assemblies and related material in a DSS design. DSS designs to date are either bare fuel casks or canister-based storage systems. Both presume wet transfer of used fuel assemblies from the used fuel racks to the DSS.

Implicit in the definition of used fuel in 10 CFR 72.3 is the assumption that post-operations, fuel of any form has a significant thermal and radiation profile, and allowing it to cool for the first year is necessary to ensure the decay of many short-lived fission products to the point where the radiation and thermal loads are suitable for performing allowed operations with such used fuel (e.g., movement or storage in DSS). For advanced reactors, this assumption should be assessed against the proposed technical characteristics and concepts of operation and deployment model associated with RHDRA.

For example, microreactor technologies that are more viable for rapid large-scale deployment may use non-LWR fuel that may require different cooldown and decay periods prior to dispositioning of the used fuel. In addition, deployment models may consider either used fuel storage within the reactor module post-operation or facilities for used fuel removal and storage onsite that facilitates refurbishment of the reactor module at an offsite facility. Technology-neutral performance criteria and potential revisions to the regulatory definition of spent fuel likely will be needed via rulemaking to facilitate resolution of this topic.

3 PROPOSED SOLUTION AND APPROACH

The proposed solution is to establish a definition of "Spent Fuel" that is technology-inclusive, performance-based, and risk-informed such that it encompasses the characteristics of RHDRA and other advanced reactor used fuel. This approach would establish a definition of spent fuel to enable use of Part 72 for all advanced reactor technologies and concepts of deployment and operation, without the need to change other Part 72 requirements. The regulatory changes would need to enable licensees to store used fuel on-site inside of the reactors in which the fuel was used during operations, without the need for additional overpacks. The regulatory approach would need to address the technological capabilities and concept of deployment and operations for this class of reactors, including the substantially lower risks associated with the onsite storage of used fuel within these reactors post-operation.

Substantial technical review of potential advanced reactor designs may be needed to develop a more comprehensive definition; however, a definition that may be workable, or at least could serve as a starting point, would be:

- *Spent Nuclear Fuel* or *Spent Fuel* means fuel that, following irradiation as a source of energy in a power reactor, is not intended to be used again in a nuclear reactor in its current form, and has decayed to a level of heat and radiation and is of a stable chemical form so that it can be safely stored in an independent spent fuel storage installation or similar facility licensed under Part 72. Spent fuel includes the special nuclear material, byproduct material, source material, and other radioactive materials associated with nuclear fuel of power reactors.

NRC should develop guidance for the implementation of these proposed Part 72 changes.

For the post-operation storage topic, a successful outcome is a general approach that aligns with the proposed deployment model using an efficient licensing structure with clear and implementable approaches to meet any safety and security standards. The approach must acknowledge the entire lifecycle of a RHDRA and the various stages of used fuel management. Further, the approach, with a regulatory framework to support it, should acknowledge the difference in risk associated with used fuel management compared to full-power operations and have a commensurate basis for the work necessary to conform to it.

3.1 Changes Needed to Regulations, Policy and Guidance

An NRC rulemaking to amend Part 72 to change the definition of “Spent Fuel” is needed. Several specific issues associated with the storage of used fuel on site should be addressed:

1. The definition of “Spent fuel” (or “Spent nuclear fuel”) in 10 CFR 72.3 should be revised to address the unique nature of RHDRA storage or RHDRA fuel storage following cessation of operations compared to traditional large LWR used fuel storage. Near-term modification of the definition of this term using a performance-based, technology inclusive approach would minimize any potential implementation issues for the RDHRA deployment model. Develop a performance-based approach based on technical parameters to be fuel technology agnostic.

2. The requirements for an acceptable DSS design should be modified to recognize RHDRA fuel, including storage of the fueled reactor itself (with criticality control devices installed). The reactor could be certified as the Part 72 confinement system or inserted into an outer storage cask that is appropriately designed for shielding, heat removal, and structural protection.

There may be many permutations of RHDRA and advanced reactor used fuel storage and refueling as part of the broader industry deployment models. The developed framework should be sufficiently flexible to accommodate different approaches.

3.2 Acceptance Criteria and Licensing Approach

Acceptance Criteria:

This approach is intended to be technology-inclusive so that Part 72 is clear and workable for all types of advanced reactors. Acceptance criteria for storing used fuel in the reactor module after it has been replaced and is in on-site storage mode, before off-site shipment, is expected to be applicable to RHDRA and other similar advanced reactors. Addressing traditional design criteria for used fuel storage systems, the technology-inclusive, performance-based and risk-informed criteria should provide an avenue to achieve regulatory approval for:

- Preclusion of criticality – By incorporating features to preclude criticality in the transport mode, such a provision may be equally utilized when the device is in the storage mode and comparable credit taken for the feature.
- Component safety functions – Applicant would ensure the safety functions of each component are described for both operation and storage modes, and SSC treatment and quality assurance are adequate for the SSCs to perform their functions.
- Certificate of Compliance (CoC) & Package Approval – Traditionally, DSS have Safety Analysis Reports (SARs) developed and reviewed in accordance with NUREG-2215, and a Certificate of Compliance (CoC) is issued to license the technology as a product. Implementation is accomplished using general or specific licenses at each site. This approach may not fully address the lifecycle of a RHDRA from a storage perspective, considering that the RHDRA itself may be considered a utilization facility during operation or a used fuel storage package following cessation of operations. Therefore, the RHDRA may need to be designed and approved to meet Part 72 requirements for DSS.

Licensing Approach:

The licensing approach for advanced reactor used fuel storage is not expected to depend on any specific licensing approach for the nuclear reactor under Parts 50, 52 or 53. For RHDRA that would use the reactor module as the DSS under Part 72, the licensing process is expected to maximize the use of addressing Part 72 consideration in the approval of the design in the Part 50, 52 or 52 license application. The Part 72 approvals for using the RHDRA as a DSS may likely need to be obtained as part of the design approval (e.g., ML).

4 OTHER OPTIONS FOR RESOLUTION OF THE ISSUE

4.1 AEA Change - Minimal Regulations

The technical and safety bases for power reactors with potential consequences on the order of magnitude of non-power reactors should be sufficient to enable the NRC to adapt the non-power reactor requirements and implementation guidance for those qualifying power reactors. Adaption of the non-power reactor regulatory framework, as discussed in this appendix, should achieve a similar level of regulation that accounts for the safety and operational characteristics of the qualifying power reactors that will tailor requirements and applicability to the technology. An AEA change to direct the NRC to regulate power reactors with potential consequences that are on the same order of magnitude as non-power reactors, e.g., with minimal regulation or under Section 104 is an option that was identified. However, such a change does not appear necessary, since the AEA provides sufficient authority to the NRC to regulate power reactors commensurate with their potential impacts, and is capable within the current AEA provisions to apply regulatory approaches to qualifying power reactors that are similar to those used today for non-power reactors. More discussion on NRC Regulation of Non-Power Reactors is included in Attachment A.

4.2 Creation of a New Term and Definition

Another option would be the development of a new term that could be used to resolve some of the issues noted above regarding storage of RHDRA and other advanced reactor fuel at a site following permanent cessation of operations. One approach is to modify the “used fuel” term in 10 CFR Part 72 to be applicable to RHDRA or a similar class of reactors with analogous deployment models.

5 ACKNOWLEDGEMENTS

NEI Issue Lead: Rod McCullum

Attachment A – NRC Regulation of Non-Power Reactors

1 INTRODUCTION

The purpose of this report is to discuss the NRC regulatory framework for non-power reactors in order to provide an understanding of how the NRC currently regulates nuclear reactor technologies with potential consequences similar to those of advanced reactor technologies, how the regulation of non-power reactors provides reasonable assurance of adequate protection of the public health and safety and the common defense and security, and a comparison of the characteristics of non-power reactors and power reactors with a similar order of magnitude of potential consequences.

Not all regulatory requirements in Part 50 are applicable to non-power reactors, and further, the implementation of those requirements through guidance, e.g., NUREG-0800 for power reactors and NUREG-1537 for non-power reactors, differs significantly. Notably, all currently operating non-power reactors are licensed pursuant to Section 104 of the Atomic Energy Act (AEA). Section 104(c) states that the NRC should "***impose only such minimum amount of regulation*** of the licensee as the Commission finds will permit the Commission to fulfill its obligations under this Act to promote the common defense and security and protect the health and safety of the public ***and will permit the conduct of widespread and diverse research and development***." (Emphasis added).

When these frameworks were established, non-power reactors were relatively simple and small with low potential consequences, while commercial power reactors were relatively complex and large with much more significant potential consequences. Understandably, the different technical characteristics of non-power and commercial power reactors led to the development of two very different regulatory frameworks. Today, advanced reactors, especially micro-reactors, are being developed with technical characteristics that are much more similar to those of non-power reactors than to those of existing commercial power reactors.

For purposes of this paper, the class of power reactors called micro-reactors, and the class of non-power reactors called research[1] and test reactors (RTRs), are compared and discussed in terms of opportunities and challenges of applying RTR regulatory approaches to commercial micro-reactors. These classes of reactors were chosen for comparison and discussion because they are relatively well understood as having a similar order of magnitude of potential consequences, as well as being similar in terms of size and power level. However, micro-reactors are not the only advanced reactors that could have potential consequences similar to those of non-power reactors.

2 TECHNICAL CHARACTERISTICS OF POWER AND NON-POWER REACTORS

Some advanced reactors, such as rapid high-volume deployable reactors in remote applications (RHDRA), micro-reactors, and other advanced reactors with increased use of inherent and passive safety designs are unlike current operating nuclear plants. In fact, these designs are much more similar – in terms of size and potential consequences – to non-power reactors than they are to existing large light-water reactors (LLWRs).

[1] *Research reactor* means a nuclear reactor licensed by the NRC under the authority of Section 104c of the Act and pursuant to the provisions of 10 CFR 50.21(c) for operation at a thermal power level of 10 megawatts or less, and is not a testing facility

Attachment A – NRC Regulation of Non-Power Reactors

Non-power reactors encompass a broad range of technologies ranging in size from a few kilowatts to many megawatts, with a mission centered on education, research, and testing. Based on information from NRC's website,[2] there are 29 RTRs licensed by the NRC and currently operating. Within this fleet, the largest RTR operates at 20 MWt and is approximately 80 times smaller than the smallest U.S. commercial power reactor, which operates at 1,677 MWt (and less than 1% of the power level of the largest power reactor at 4,408 MWt). RHDRA reactors are expected to operate at between 2 MWt to 150 MWt, which is much more similar in size to an RTR than LLWRs.

Most advanced reactors are closed systems[3] that do not perform tests and experiments, while RTRs range from open pool to pressurized light-water systems with power ranges of less than 1 MWt to 20 MWt. RTRs also have varying duty cycles from infrequent to nearly continuous operation and typically perform tests and experiments (i.e., frequently perform non-routine operations).

However, size alone is not an accurate measure of the level of safety in terms of types of potential accidents and their associated potential consequences. The use of inherent and passive safety features to reduce reliance on active safety features and human actions can also significantly reduce the potential for accidents and their consequences for reactors of the same power level. Thus, reactors of much higher power levels that make substantial use of inherent and passive safety features could have similar potential consequences as reactors with much lower power levels that do not implement inherent and passive safety features.

Fuel types are appreciably different between RTRs and micro-reactors. RTRs typically use rod or plate fuel, while many micro-reactors, and RHDRAs in particular, will use Tri-structural Isotropic (TRISO) fuel, which is a coated particle fuel.[4] Coolants can vary from light water to salts, gases, and liquid metals. The operating temperature for RTRs can vary depending on the specific design and purpose of the reactor. Most micro-reactors operate at significantly high temperatures, with high-temperature gas reactors potentially operating up to 950°C. Other differences include sodium's fission product retention for sodium-cooled reactors, thermal capacity of molten salt, low linear heat rates, and natural circulation.

Micro-reactor designs include very few, if any, moving parts, and make use of passive safety systems. Reactor controls are expected to feature inherent and automatic safe shutdown systems that dramatically reduce or even eliminate the need for human action to achieve safe shutdown under any potential event scenario and to maintain the reactor in a safe condition for long periods of time, or even indefinitely. RTRs typically have on-site control rooms with on-site reactor operators.

Thus, while RTRs and micro-reactors have similar power outputs, with similar source terms, the actual system designs and operational characteristics are significantly different. The following table reflects the similarities in the potential consequences of non-power and power reactors of similar power levels. It is worth noting that the NRC has promulgated 10 CFR 50.160, "Emergency Preparedness for Small Modular Reactors, Non-Light-Water Reactors, and Non-Power Production or Utilization Facilities," which provides performance-based requirements for the emergency plan for these reactor types.

[2] https://www.nrc.gov/info-finder/nonpower/index.html

[3] i.e., systems where coolant flows by either forced or natural circulation without a direct opening to the containment or confinement atmosphere, (i.e., pool type)

[4] The advanced reactors in pre-application discussion or application reviews with the NRC are proposing various fuel types, including TRISO, metal fuel, ceramic fuel, and liquid fuel in a molten salt coolant.

Attachment A – NRC Regulation of Non-Power Reactors

	Power Level	**EPZ Size**
Non-Power Reactors (kilo-watt scale)	0.25 to 1.1 MWt	Operating Boundary (e.g., reactor building)
Non-Power Reactors (mega-watt scale)	10 to 20 MWt	150 m to 400 m
Power Reactors (mega-watt scale)	6 to 50 MWt	50 m to 100 m

Table 1. This table is based on operating non-power reactors, in addition to actual designs of micro-reactors, and is not intended to represent a limit of power levels or emergency planning zone (EPZ) distances. Nor does it exclude the possibility that other designs with larger power levels could attain smaller EPZ sizes.

Each advanced reactor will have different inherent safety profiles resulting in a different set of potential accidents and corresponding potential consequences. The following discussion of the National Bureau of Standards Reactor (NBSR) at the National Institute of Standards and Technology Center for Neutron Research (NCNR) and Kairos Hermes design is used as an illustrative example of the postulated design basis accidents. These examples illustrate the similarity between the non-power and advanced reactor potential events.

These examples utilize a maximum hypothetical accident (MHA), which is a scenario that bounds other postulated event groups. The MHA is an event where hypothesized conditions result in a conservatively analyzed release of radionuclides that bounds a potential release from other postulated events. The MHA analysis is consistent with the fission product release accident analysis required for the 10 CFR 100.11 determination of exclusion area, low population zone, and population center distances (i.e., a whole body dose of 25 rem or a total radiation dose of 300 rem to the thyroid from iodine exposure).

The NIST NBSR[5] is a heavy water (D_2O) cooled, moderated, and reflected, tank-type reactor that operates at a design power of 20 MWt. The accident scenarios that need to be considered for the NIST NBSR equilibrium core with low-enriched uranium (LEU) fuel are:

- reactivity insertion accidents
- loss-of-flow accidents
- loss-of-coolant accidents
- natural circulation cooling at low power operation
- flow blockage in one fuel element

[5] "Conversion Preliminary Safety Analysis Report for the NIST Research Reactor," Brookhaven National Laboratory, BNL-107265-2015-IR, December 2014.

- misloaded fuel elements
- experiment malfunctions and external events
- loss of normal power

The flow blockage in one fuel element is not considered credible and is treated as the "maximum hypothetical accident."

While the NRC has issued the construction permit for Kairos' Hermes as a non-power reactor,[6] a 35 MWt fluoride salt-cooled, high-temperature reactor, this design is also illustrative of advanced power reactors since it is a small-scale pilot for the company's planned commercial power reactor. The Hermes postulated design basis accidents are:

- Maximum Hypothetical Accident or MHA
- Insertion of Excess Reactivity
- Salt Spills
- Loss of Forced Circulation (includes a loss of normal electric power)
- Mishandling or Malfunction of Pebble Handling and Storage System
- Radioactive Release from a Subsystem or Component
- General Challenges to Normal Operation
- Internal and External Hazard Events

The Hermes PSAR states that the site boundary and the Exclusionary Area Boundary (EAB) are coincident. The Emergency Planning Zone (EPZ) boundary is also set coincident to the site boundary. The doses at the EPZ are below the Environmental Protection Agency (EPA) Protective Action Guide (PAG) Manual guidelines for protective action of 1 rem total effective dose equivalent (TEDE).

The NRC already has experience licensing advanced reactors as RTRs, and other advanced reactors are being planned to utilize the RTR framework. These include:

Kairos Hermes – "Hermes Non-Power Reactor" – As a non-power reactor, the Hermes reactor is consistent with 10 CFR 50.21(c) and Sec. 104 of the AEA. A construction permit for the Hermes 1 facility has been issued and review of the construction permit application for the Hermes 2 reactor is in progress. (The NRC staff recently issued its final safety evaluation (ML24200A114) for Hermes 2.) The Hermes is a small-scale pilot of the larger planned commercial reactor.

Abilene Christian University (ACU) Natura – This is a molten salt research reactor with a power output of 1 MWt and will not produce electricity. It is consistent with 10 CFR 50.21(c) and

[6] "Hermes Non-Power Reactor Preliminary Safety Analysis Report," Rev. 2, February 2023 (ML23055A674).

Section 104 of the AEA. The construction permit for ACU Natura is under review. Natura is also planning to deploy reactors commercially.

University of Illinois at Urbana-Champaign (UIUC) and Ultra Safe Nuclear Corporation (USNC) – A high-temperature gas-cooled reactor (HTGR) that is consistent with 10 CFR 50.21(c) and Section 104 of the AEA. The project sponsors are in pre-application discussions with the NRC. The UIUC plans are to use the research reactor for campus power and heat; it would also use the reactor for research purposes. The USNC design is also being planned for commercial deployments.

3 NRC REQUIREMENTS AND GUIDANCE

All reactors (power and non-power) are licensed to operate as utilization facilities under Title 10 (10 CFR) in accordance with the Atomic Energy Act (AEA or Act) of 1954, as amended. The AEA was written to promote the development and use of atomic energy for peaceful purposes and to control and limit its radiological hazards to the public. With certain exceptions for military applications, Section 101 of the AEA makes it "unlawful for any person within the United States to transfer or receive in interstate commerce, manufacture, produce, transfer, acquire, possess, use, import, or export any utilization or production facility except under and in accordance with a license issued by the Commission pursuant to section 103 or section 104." In turn, with certain exceptions not relevant here, Section 102a of the Act requires that, ***unless specifically authorized by law***, "any license hereafter issued for a utilization or production facility for industrial or commercial purposes shall be issued pursuant to section 103 [Commercial Licenses]." Thus, unless specifically authorized, licenses for construction and operation of new commercial micro-reactors will be issued pursuant to Section 103 of the Act, just like other commercial reactors.

While the AEA Section 189 applies the requirement for the NRC to "provide reasonable assurance of adequate protection of the public health and safety" to reactors licensed pursuant to Section 103, AEA Section 104(c) states that the NRC should "impose only such minimum amount of regulation of the licensee as the Commission finds will permit the Commission to fulfill its obligations under this Act to promote the common defense and security and protect the health and safety of the public and will permit the conduct of widespread and diverse research and development." Notably, both of these standards have as their end goal to "protect the public health and safety."

To understand the differences between the NRC's regulation of power and non-power reactors, it is therefore important to understand how the NRC implements these differing standards from the AEA. NRC requirements for nuclear reactors to implement Sections 103 and 104 of the AEA are promulgated in 10 CFR Part 50. For the most part, the higher-level requirements for Safety Analysis Report (SAR) content in 10 CFR Part 50 apply to both commercial power reactors under AEA Section 103 and non-power reactors under AEA Section 104. NUREG-1537 notes that the guidance therein is based on 10 CFR 50.34, which describes the information to be supplied in a SAR. Notably, not all requirements in Part 50 are applicable to non-power reactors. The implementation of those requirements through guidance, e.g., NUREG-0800 for power reactors and NUREG-1537 for non-power reactors, is substantially different. Additional requirements specific to commercial power reactors under AEA Section 103 are further promulgated in 10 CFR 50.42, 50.43, and in other parts of Title 10 that deal with power reactors. Additional requirements specific to non-power reactors under AEA Section 104 are further promulgated in 10 CFR 50.40, 50.41, and in other parts of Title 10 that deal with non-power reactors.

Attachment A – NRC Regulation of Non-Power Reactors

The challenge is determining how the NRC regulations and guidance for non-power reactors were established to address the two primary differences with the power reactors at the time the frameworks were established. The first is the NRC implementation of the "minimum regulation standard" for licensing and regulating utilization facilities for use in medical therapy licensed pursuant to section 104a., as well as research and development reactors licensed pursuant to section 104c. The second is the NRC's implementation of the non-power reactor regulatory framework to align with the much lower potential consequences of such reactors, as compared to the potential consequences of LLWRs, which serve as the basis for the power reactor regulations and guidance.

There is not sufficient historical documentation to fully characterize the degree to which the differences in the AEA standards influenced the NRC's development of different regulatory frameworks for power and non-power reactors. However, from NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors," it appears that the differences between the NRC's regulatory frameworks for power and non-power reactors is primarily based upon the potential consequences of those technologies:

> "The AEA was written to promote the development and use of atomic energy for peaceful purposes and to control and limit its radiological hazards to the public. These purposes are expressed in paragraph 104 of the Act for non-power reactors, which states that utilization facilities for research and development should be regulated to the minimum extent consistent with protecting the health and safety of the public and promoting the common defense and security. These concepts are promulgated in 10 CFR 50.40 and 50.41, and in other parts of Title 10 that deal with non-power reactors. **The licensed thermal power levels of non-power reactors are several orders of magnitude lower than current power reactors. Therefore, the accumulated inventory of radioactive fission products in the fuel (in core) of non-power reactors is proportionally less than power reactors and requires less stringent and less prescriptive measures to give equivalent protection to the health and safety of the public. Thus, even though many of the regulations of Title 10 apply to both power and non-power reactors, the regulations may be implemented in a different way for each category of reactor** and are intended to be consistent with protecting the health and safety of the public. Because the potential hazards may also vary widely among non-power reactors, regulations also may be implemented in a different way within the nonpower reactor category." **(emphasis added)**

Thus, differences in NRC's power and non-power reactor regulations and its implementation of those regulations to protect the public health and safety reflects the differences in the potential consequences of those technologies. Many of the appendices to our proposal paper discuss the similarities and differences between the requirements and guidance for power and non-power reactors.

4 APPLICATION OF INSIGHTS

The size, simplicity, and potential consequences of some advanced reactors are very similar to non-power reactors, also called RTRs. In this respect, the regulations and implementation guidance for RTRs is likely a better starting point for the development of requirements and guidance for advanced reactors with a similar order of magnitude of potential consequences. This is in contrast to on-going efforts to adapt the regulations and guidance originally developed for LLWRs to advanced reactors, which are expected to have much smaller potential consequences than LLWRs.

Attachment A – NRC Regulation of Non-Power Reactors

An adaptation of the non-power reactor requirements and guidance would result in a framework that is more effective and efficient for advanced reactors with an order of magnitude of potential consequences similar to RTRs. The NRC staff has recognized that the reduced risks posed by operation of commercial micro-reactors could warrant licensing and regulatory approaches that differ from approaches applicable to LLWRs. One such approach discussed in SECY-24-0008 involves allowing applicants for construction permits and operating licenses under Part 50 to load fuel and perform operational testing of micro-reactors at the manufacturing facility subject to "most of the safety (and possibly environmental) regulations for non-power reactors." The discussion in SECY-24-0008 is a recognition that the risks posed by fuel load and operational testing of micro-reactors at the factory are more like the risks posed by non-power reactors than the risks posed by LLWRs.

There are several important factors when considering the applicability of the regulatory framework for RTRs to advanced reactor designs with similar safety profiles. These include:

1. **Acceptable Doses** – Power and non-power reactors (including those with an advanced reactor design) must meet Part 20 occupational and public dose limits for normal operations. Current power reactors and test reactors[7] must also meet Part 100 dose limits for postulated fission product releases.

2. **Safety Features** – Advanced reactors are being designed to include safety features that are not typically included in RTRs. These safety features are typically included to limit doses during postulated accident scenarios. While micro-reactors (and other advanced reactor designs with similar safety profiles) have similar power levels and quantities of radiological material, the use of additional safety features could result in lower source terms and lower potential off-site doses. Advanced reactors plan to use more inherent and automatic safety features that will result in less reliance on human actions for safety, as compared to RTRs.

3. **Operations** – Most advanced reactors are closed systems that do not perform tests and experiments, while RTRs range from open pool to pressurized light-water systems with power ranges of less than 1 MWt to 20 MWt. RTRs also have varying duty cycles from infrequent to nearly continuous operation and typically perform tests and experiments (i.e., frequently perform non-routine operations). Continuous full-power operation of advanced reactors creates more operational experience that is useful in improving the safety of operations. Furthermore, high-volume deployment of standardized advanced reactor designs means that the operating experience from all the plants can be shared, increasing the rates of learning and improving operational performance, which is directly related to safety.

The NRC has already acknowledged that commercial reactors that are similar to non-power reactors should be regulated in a similar manner. As discussed in Section 3, the NRC recognized in NUREG-1537 that thermal power levels in non-power reactors are significantly lower than in current power reactors (LLWRs). Consequently, the accumulated inventory of radioactive fission products in the core of non-power reactors is proportionally less, requiring less stringent and less prescriptive measures to protect

[7] NUREG-1537 states "*If the facility conforms to the definition of a test reactor, the doses should be compared with 10 CFR Part 100. As discussed in the footnotes to 10 CFR 100.11, the doses given in 10 CFR Part 100 are reference values. Any further references to 10 CFR Part 100 in this document apply to test reactors only*."

the health and safety of the public. Thus, implementation of the regulations of Title 10 will be different for each category of reactor.

Therefore, it is anticipated that advanced reactors like RHDRA and micro-reactors that are around the same order of magnitude lower in potential consequences would be regulated in a proportionally similar manner, with flexibility in the implementation of regulations since designs may vary widely. The only major difference in the concept of an alternative regulatory framework in this paper, and the NRC statement in NUREG-1537, is that this paper does not propose to identify similarities in potential consequences to the public health and safety in terms of thermal power and radiological inventories (which are rough proxies for the potential consequences and risks), but rather to use more directly related measures to the protection of public health and safety, such as the source term and risks.

NRC establishment of a licensing and regulatory framework that is specific to advanced reactors with potential consequences on the order of non-power reactors, and which is adapted from the framework for non-power reactors, appears to be within the NRC's current statutory authority. There do not appear to be any significant differences in the types of requirements and implementation guidance that could be developed based on the potential consequences, whether the reactors are for commercial power or for non-power applications.

5 ACKNOWLEDGEMENTS

NEI Leads: Marc Nichol, Hilary Lane, and Jerry Bonanno

Attachment B – NRC Regulation Through General License

1 INTRODUCTION

Today, advanced reactors, especially rapid high-volume deployable reactors (RHDRA), are being developed with technical characteristics that are much more similar to non-power reactors than the current operating fleet of large light-water reactors. Furthermore, these RHDRA are being developed in view of new business models that require reactor deployments in 6 months (or less in some cases) from site identification to reactor operation. The specific licensing process – as currently implemented for large light-water reactors, and as is being adapted for advanced reactors – is not optimal for facilitating such rapid deployments. As technology and business models change, the NRC's regulations and licensing processes must also adapt.

The appendices to the Regulatory Proposal Paper propose solutions that the NRC could implement, using the authority and flexibiity currently provided by the Atomic Energy Act (AEA). That said, numerous Appendices also identify situations where the use of a general licensing framework would provide a more efficient and effective solution for enabling rapid deployments. We recognize that the licensing of utilization facilities, like RHDRA, through general licenses would require an amendment to the AEA.

The purpose of this attachment is to discuss the NRC's use general licensing in other regulatory contexts, how general licensing frameworks are tailored to specific materials, activities and technologies, and how general license frameworks compare with the regualtory framework for specific licenses that is currently used for nuclear reactors.[1]

2 LICENSING APPROACHES

This section describes the specific and general licensing approaches currently used by the NRC.

2.1 Specific License

The current AEA licensing framework for utilization facilities requires submittal and review of license applications to construct and operate commercial power reactors. Specifically, section 103a. of the AEA authorizes the Commission to issue licenses "to persons applying therefor to transfer or receive in interstate commerce, manufacture, produce, transfer, acquire, possess, use import, or export . . . utilization or production facilities for commercial purposes."[2] Section 103 also requires that such licenses be issued pursuant to chapter 16 of the AEA which, in turn, requires the filing of applications by persons seeking to construct and operate a production or utilization facility.[3] These types of licenses –

[1] The NRC regulates nuclear reactors as 1) power reactors, which includes use for industrial or commercial purposes, and 2) non-power reactors, which includes research and test reactors and reactors for medical applications.

[2] Section 101 of the AEA makes it "unlawful . . . for any person within the United States to transfer or receive in interstate commerce, manufacture, produce, transfer, acquire, possess, use, import, or export any utilization or production facility except under and in accordance with a license issued by the Commission pursuant to section 103 or section 104." Section 102a. requires that, with certain exceptions, any license "issued for a utilization or production facility for industrial or commercial purposes shall be issued pursuant to section 103." In turn, section 103 authorizes the Commission to issue licenses for construction and operation of commercial reactors "to persons applying therefor." Section 11(s) of the Act defines the term "person" as meaning "(1) any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, Government agency other than the Commission, any State or any political subdivision of, or any political entity within a State, any foreign government or nation or any political subdivision of any such government or nation, or other entity; and (2) any legal successor, representative, agent, or agency of the foregoing."

[3] *See* AEA at Sec. 185, 182.

which require the filing of applications by, and issuance of licensing documents to, specific persons – are known as "specific licenses."[4]

Applications for specific licenses for nuclear reactors are governed by 10 CFR Parts 50 and 52 and require individual safety and environmental reviews by the NRC staff. These reviews culminate in the NRC staff's issuance of a final safety evaluation report and final environmental impact statement that are specific to the application under review. In addition, under AEA section 189a.(1)(A), applications seeking authorization to construct commercial reactors are subject to the mandatory "uncontested" hearing requirement, as well as requests by affected parties for hearings on contested issues (i.e., "contested" hearings).[5]

In the context of large light-water reactors, recent experience has shown that the review and hearing processes for combined license applications can require approximately 4 to 9 years from tender of the application to a final Commission decision to issue the license.[6] The NRC also recently issued a construction permit for the Kairos non-power test reactor. That process took just over two years from docketing of the application to issuance of the construction permit.[7] Less recently, the NRC issued construction permits for the SHINE and Northwest Medical Isotopes facilities, which are non-power or very low power medical radioisotope production facilities.[8] For SHINE, the process took approximately 26 months from docketing of the application to issuance of the construction permit[9] and required 22,000 hours of staff and contractor time.[10] For Northwest Medical Research, the process took approximately 29 months from docketing of the application to issuance of the construction permit[11] and required 12,000 hours for staff and contractor time.[12] These facilities still require NRC approval of Part 50 operating licenses, which will add to the overall deployment schedule.

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[4] *See, e.g.*, 10 CFR 110.2 (defining a specific license as "an export or import license document issued to a named person and authorizing the export or import of specified nuclear equipment or materials based upon the review and approval of an NRC Form 7 application filed pursuant to this part and other related submittals in support of the application.").

[5] The mandatory "uncontested" hearing requirement applies to applications for construction permits, combined licenses, early site permits, and limited work authorizations. The opportunity to request a hearing on contested issues applies to "any proceeding under [the AEA] for the granting, suspending, revoking, or amending of any license or construction permit, or application to transfer control. . . ."). AEA, Sec. 189a.(1)(A).

[6] https://www.nrc.gov/reactors/new-reactors/large-lwr/col.html.

[7] https://www.nrc.gov/reactors/non-power/new-facility-licensing/hermes-kairos/documents.html.

[8] After submittal of the construction permit application for the SHINE facility, the NRC staff determined that the "accelerator-driven subcritical operating assemblies" (i.e., the "irradiation facility") described in the application did not meet the definition of a "production facility" in 10 CFR 50.2. "Definition of a Utilization Facility: Direct final rule," 79 Fed. Reg. 62329 (Oct. 17, 2014). To facilitate licensing the irradiation facility pursuant to 10 CFR Part 50, the NRC modified the definition of "utilization facility" in 10 CFR 50.2 to include the operating assemblies described in the SHINE application. *See* 10 CFR 50.2. In contrast, the associated radioisotope production facility was defined as a production facility. *See* SHINE Medical Technologies, Inc. (Medical Radioisotope Production Facility), CLI-16-04, 83 NRC 58, 74-75 (2016).

[9] https://www.nrc.gov/info-finder/nonpower/shine-schedule.html.

[10] *SHINE Medical Technologies, Inc*. (Medical Radioisotope Production Facility), CLI-16-04, 83 NRC 58, 61 (2016).

[11] https://www.nrc.gov/info-finder/nonpower/nw-isotopes-schedule.html.

[12] *Northwest Medical Isotopes, LLC* (Medical Radioisotope Production Facility), CLI-18-06, 87 NRC 130, 133.(2018).

Attachment B – NRC Regulation Through General License

2.2 General License

In contrast to a specific license, a general license is typically issued via a rulemaking proceeding and becomes effective without the filing and review of a specific application or issuance of licensing documents to a particular person or entity.[13]

Although the AEA limits the NRC to the specific licensing approach for nuclear reactors, several sections of the AEA grant the NRC authority to use general licenses in other contexts. For example, use of a general license is authorized for the licensing of component parts of a production or utilization facility (section 109), the distribution of special nuclear material (SNM) (section 53b.), the distribution of source material (section 63b.), and the use of byproduct material (section 81a.). In addition, for decades the NRC has used a general license to license the storage of spent fuel in independent spent fuel storage installations at power reactor sites, pursuant to authority granted in the Nuclear Waste Policy Act of 1982, as amended (NWPA).[14] Examples of NRC's implementation of the general licensing authority granted to the agency in the AEA are discussed in more detail in Section 3.

NRC's regulations implementing the authorization to use general licenses in the AEA and NWPA demonstrate that while general licenses share certain overarching attributes (e.g., issued via a rulemaking proceeding and effective without the filing and review of a specific application or issuance of licensing documents to a particular person or entity), general licensing frameworks can vary significantly depending on the types of materials and activities being authorized. In the context of microreactors, any general license authorizing construction, operation, or both would need to integrate other existing approvals, such as design certifications, early site permits, manufacturing licenses, pre-approvals of operator qualifications and programs, and generic environmental reviews (e.g., generic or programmatic Environmental Impact Statements).

3 CURRENT NRC GENERAL LICENSE PROCESSES

The NRC currently uses a general licensing process for several regulated activities. As each regulated activity is unique in its characteristics, including the potential consequences to public health and safety and the environment, so too are the general licensing processes unique and tailored to their applications. The main point is that the NRC uses general licenses in a variety of applications involving the need to repeatedly license similar or identical activities, and where using specific license processes would add unnecessary time and cost burdens.

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[13] *See, e.g.*, 10 CFR 110.2 ("General license means an export or import license effective without the filing of a specific application with the Commission or the issuance of licensing documents to a particular person. A general license is a type of license issued through rulemaking by the NRC. . . ."); 10 CFR 40.20(a) ("The general licenses provided in this part are effective without the filing of applications with the Commission or the issuance of licensing documents to particular persons. Specific licenses are issued to named persons upon applications filed pursuant to the regulations in this part."); 10 CFR 70.18 ("Any general license provided in this part is effective without the filing of applications with the Commission or the issuance of licensing documents to particular persons.").

[14] *See* Nuclear Waste Policy Act of 1982, as amended, Sec. 218(a) ("The Secretary shall establish a demonstration program, in cooperation with the private sector, for the dry storage of spent nuclear fuel at civilian nuclear power reactor sites, with the objective of establishing one or more technologies that the Commission may, by rule, approve for use at the sites of civilian nuclear power reactors without, to the maximum extent practicable, the need for additional site-specific approvals by the Commission.")(emphasis added). *See also*, Sec. 133 ("The Commission shall, by rule, establish procedures for the licensing of any technology approved by the Commission . . . or [SIC] use at the site of any civilian nuclear power reactor.") (emphasis added).

3.1 10 CFR Part 72 Storage of Spent Fuel at a Reactor Site

The NRC created the Part 72 general license process in response to congressional direction contained in the 1987 amendments to the Nuclear Waste Policy Act.[15] Congress's intent was to allow reactor operator licensees to leverage existing programs for reactor operation to operate an Independent Spent Fuel Storage Installation (ISFSI) on site without additional NRC site-specific approvals. NRC regulations in 10 CFR 72, Subpart K, grant the general license to Part 50 and 52 licensees (10 CFR 72.210) and establish conditions for the general license in 10 CFR 72.212. These license conditions provide, in part, that a Part 72 general licensee may store only spent fuel that it is authorized to possess at the site under the specific Part 50 or 52 license, and that the general licensee must use a Dry Storage System (DSS) design certified by the NRC and for which a Part 72 Certificate of Compliance (CoC) has been issued.

The DSS designer submits an application, including a SAR, for design approval. The DSS SAR includes details on the cask design, operation, and safety analyses, as well as the allowed contents and how to load and operate the DSS. Upon approving the application, the NRC issues a Part 72 CoC and lists the DSS design in 10 CFR 72.214. Once a CoC is issued, any Part 72 general licensee may use the DSS design.[16]

The Part 72 general licensee must notify the NRC of its intent to operate an ISFSI under the general license and must create (but not submit to the NRC) a 10 CFR 72.212 Report ("212 Report") before beginning ISFSI operation.[17] The purpose of the 212 Report is for the general licensee to:[18]

1. Describe licensee compliance with the DSS CoC,
2. Describe the design and analysis of the ISFSI storage pad,
3. Summarize the offsite dose analysis showing expected annual doses from normal ISFSI operation and anticipated occurrences will be less than the limits in 10 CFR 72.104,
4. Describe how the generic cask design criteria (e.g., seismic, temperature, wind, etc.) bound the reactor site where the ISFSI will be constructed and operated, and
5. Determine if a Part 50 license amendment is required to operate the ISFSI under the Part 72 general license.

While not required to be included in the 212 Report, other conditions of the general license in 10 CFR 72.212 require certain Part 50 programs to be reviewed and revised as necessary to include ISFSI operations.[19] Other regulations in Part 72 apply equally to both specific and general licensees (e.g., operator training, facility decommissioning, reporting, SNM accounting, facility change control, etc.).

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[15] *Id. See also* Sec. 133 ("The Commission shall, by rule, establish procedures for the licensing of any technology approved by the Commission . . . or [sic] use at the site of any civilian nuclear power reactor.") (emphasis added).

[16] Part 72 specific licensees may also use a certified DSS design by incorporating the design by reference in its license application. If they choose to do so, 10 CFR 72.46(e) states, "the scope of any public hearing held to consider the application will not include any cask design issues."

[17] As germane to later discussion, the Part 72 general license is not legally effective until the licensee begins loading spent fuel into the DSS. However, by virtue of the general licensee also having a Part 50 or 52 specific license, the NRC has inspection and enforcement jurisdiction at the site.

[18] *See* 10 CFR 72.212(b)(5), (b)(6), and (b)(8).

[19] *See* 10 CFR 72.212(b)(9) and (b)(10).

3.2 10 CFR Part 110 Export and Import of Nuclear Equipment and Material.

The NRC's regulations governing the import and export of nuclear equipment and material are contained in 10 CFR Part 110, "Export and Import of Nuclear Equipment and Material." As explained in 10 CFR 110.19, licenses for the import and export of nuclear equipment and material consist of both general and specific licenses, with a general license becoming "effective without the filing of an application with the Commission or issuance of licensing documents to a particular person." Generally licensed activities are described in sections 110.21-24 and 110.26-27 and include:

- Exporting of certain special nuclear, source, and byproduct materials;[20]
- Exporting of deuterium for nuclear end use;[21]
- Exporting of nuclear reactor components;[22] and
- Importing of certain byproduct, source, or special nuclear material where the U.S. consignee is authorized to receive and possess the material.[23]

These general licenses are appropriately conditioned, for example, by placing limitations on the types and quantity of radioactive materials that can be exported and imported, as well as the permissible destinations of generally licensed exports. The use of general licenses in this context clearly simplifies the export control process.

3.3 10 CFR Part 70 Domestic Licensing of Special Nuclear Material.

NRC's regulations pertaining to licensing SNM are found in 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material." As explained in 10 CFR 70.18, SNM licenses include both general and specific licenses, with a general license becoming "effective without the filing of an application with the Commission or issuance of licensing documents to particular persons." Generally licensed activities are described in sections 70.19 – 70.20b and include:

- Receiving title to, owning, acquiring, delivering, receiving, possessing, using and transferring plutonium in the form of calibration sources;[24]
- Receiving title to and owning special nuclear material without regard to quantity;[25]
- Possession of formula quantities of special nuclear material of certain types and quantities, and certain irradiated reactor fuel, in the regular course of carriage for another or storage incident to such carriage;[26] and

[20] 10 CFR 110.21, 22, 23.
[21] 10 CFR 110.24.
[22] 10 CFR 110.26.
[23] 10 CFR 110.27.
[24] 10 CFR 70.19.
[25] 10 CFR 70.20.
[26] 10 CFR 70.20a.

- Possession of transient shipments of certain kinds and quantities of special nuclear material.[27]

These general licenses are appropriately conditioned, for example, by placing limitations on the physical characteristics, quantities, and intended uses of special nuclear materials subject to the license, as well as specifying additional requirements (e.g., requirements for security and physical protection) that apply to the general licensee. As with Part 110, the use of general licenses under Part 70 greatly simplifies the process for managing certain special nuclear materials. If a specific license were required for each of the activities specified under Subpart C to Part 70, it would impose undue burden (both cost and time) on relatively routine activities.

3.4 10 CFR Part 40 Domestic Licensing of Source Material

NRC's regulations pertaining to licensing of source material are found in 10 CFR 40, "Domestic Licensing of Source Material." As explained in 10 CFR 40.20, licenses for source material consist of both general and specific licenses, with a general license becoming "effective without the filing of an application with the Commission or issuance of licensing documents to particular persons." Generally licensed activities are described in sections 40.21-40.23 and 40.25-40.28 and include:

- Custody and long-term care of residual radioactive material at uranium mill tailings disposal sites remediated under title I of the Uranium Mill Tailings Radiation Control Act of 1978, as amended;[28]
- Custody and long-term care of byproduct material at uranium or thorium mill tailings disposal sites under title II of the Uranium Mill Tailings Radiation Control Act of 1978, as amended;[29]
- Receipt of title to source or byproduct material (as defined in Part 40), without regard to quantity;[30]
- Receipt, possession, use, and transfer of uranium and thorium, in their natural isotopic concentrations and in the form of depleted uranium, by commercial or industrial firms for research, development, educational, commercial, or operational purposes in certain forms and quantities;[31]
- Possession of transient shipments of natural uranium (other than ore or ore residue) in amounts exceeding 500 kilograms;[32]
- Receipt, possession, use, or transfer of depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device;[33] and

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[27] 10 CFR 70.20b.
[28] 10 CFR 40.27.
[29] 10 CFR 40.28.
[30] 10 CFR 40.21 (this general license does not authorize receipt, possession, delivery, use, or transfer of source or byproduct material).
[31] 10 CFR 40.22.
[32] 10 CFR 40.23.
[33] 10 CFR 40.25.

- Receive title to, own, or possess byproduct material (as defined in Part 40) without regard to form or quantity.[34]

These general licenses are appropriately conditioned, for example, by placing limitations on the physical characteristics, quantities, and intended uses of source materials subject to the license, as well as specifying additional requirements (e.g., requirements for notification, registration with NRC, inspections, etc.) that apply to the general licensee.

3.5 10 CFR Part 31 General Domestic License for Byproduct Material

A general licensing approach is also used by the NRC to grant authorization for certain activities involving byproduct materials in 10 CFR Part 31. Generally licensed activities permitted under Part 31 include:

- Acquisition, receipt, possession, use, and transfer of certain detecting, measuring, gauging, or controlling devices, and certain devices for producing light or an ionized atmosphere;[35]

- Ownership, receipt, acquisition, possession, and use of certain quantities of tritium or promethium-147 contained in luminous safety devices used for aircraft;[36]

- Ownership, receipt, acquisition, possession, use, and transfer of americium-241 and radium-226 in the form of calibration or reference sources;[37]

- Ownership of byproduct materials without regard to quantity;[38]

- Ownership, receipt, acquisition, possession, use, and transfer of certain quantities of strontium-90 contained in ice detection devices;[39]

- Receipt, acquisition, possession, transfer, or use of certain byproduct material by physicians, veterinarians, clinical laboratories, or hospitals for certain in vitro clinical or laboratory testing;[40] and

- Acquisition, receipt, possession, use, or transfer of radium-226 in certain items and self-luminous products.[41]

While the general licensing provisions of Part 31 authorize activities such as ownership, receipt, possession, use, and transfer of a variety of devices and items that contain byproduct materials,

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[34] 10 CFR 40.26.
[35] 10 CFR 31.5
[36] 10 CFR 31.7.
[37] 10 CFR 31.8.
[38] 10 CFR 31.9 (this general license does not authorize manufacture, production, transfer, receipt, possession, use, import or export byproduct material, except as authorized in a specific license).
[39] 10 CFR 31.10.
[40] 10 CFR 31.11.
[41] 10 CFR 31.12.

manufacture and initial transfer of such devices requires a specific license.[42] In addition, while Part 31 general licensees are not required to file applications with the NRC, in certain circumstances they are required to register with the agency and pay fees prescribed pursuant to 10 CFR 170.[43] So, in this general licensing framework, manufacture of a device containing byproduct-material requires a specific license; and the general licensee, who in this case may not have a specific license, must register and provide certain information to NRC about certain devices.[44]

4 APPLICATION OF INSIGHTS

As discussed in the Regulatory Proposal paper, it is possible for the NRC to substantially shorten the licensing timeframes for reactors within the current AEA authorities that would achieve the 6-month deployment timeline from site identification to reactor operation that is needed to enable the RHDRA business model. However, a general licensing approach would be more efficient and effective in regulating nuclear reactors, such as RHDRA, and could enable even shorter deployment timeframes that would be needed to support other business models.[45] If and when Congress amends the AEA to authorize and direct the NRC to develop a general licensing approach for certain nuclear reactors, then the NRC would be able to pursue a rulemaking to develop such a general license framework for nuclear reactors.

A nuclear reactor general licensing framework may borrow certain attributes from existing NRC general licensing frameworks, but would need to consider the unique attributes of the relevant nuclear reactors and associated concepts of deployment. If coupled with other approvals provided via existing tools, such as design certifications, manufacturing licenses, early site permits, as well as bounding generic environmental evaluations (e.g., generic or programmatic Environmental Impact Statements) – a general license approach has the potential to eliminate many of the barriers to rapid deployment of RHDRA and other advanced nuclear reactors.

Specifically, adoption of a general licensing approach could streamline the administrative process for licensing both construction and operation by replacing multiple application-specific reviews and adjudications with a rulemaking proceeding that establishes the terms and conditions of, as well as granting, the general license. This streamlining could:

- Eliminate or greatly reduce the need for the NRC staff to review application-specific safety analyses and environmental reports, and produce application-specific safety evaluations and environmental impact statements (or environmental assessments), instead relying on previous NRC analyses and approvals, as described above; and

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[42] *See, e.g.*, 10 CFR 31.5(b)(1)(limiting the general license to byproduct material contained in devices that have been manufactured or initially transferred in accordance with a specific license); 31.7(c), (d) (specifying that the general license does not authorize manufacture, assembly, repair, import, or export of luminous devices containing tritium or promethium-147); 31.8(b) (specifying that the general license applies only to calibration or reference sources that have been manufactured or initially transferred in accordance with the specifications contained in a specific license); 31.10(c)(specifying that the general license does not authorize manufacture, assembly, disassembly, repair, or import of strontium 90 in ice detection devices).

[43] *See, e.g.*, 10 CFR 31.5(13) and 31.11(b).

[44] *See* 10 CFR 31.5(c)(13)(i)-(iii).

[45] In addition to a general license being more well suited for the business model considered in development of this Paper, it would also be necessary for other potential uses of reactors, such as deployment as part of emergency response or disaster relief.

Attachment B – NRC Regulation Through General License

- Replace or greatly reduce the scope of application-specific mandatory and contested hearings, instead using a single administrative proceeding in the form of a rulemaking to codify the general license, which could be used by multiple entities to deploy reactors.

If the AEA were amended to authorize the NRC to develop a general licensing process for certain reactors, then a framework, including regulations, policy decisions and guidance, would need to be created. Certainly, it would be reasonable for the NRC to consider the various ways in which it currently implements general license approaches for other technologies and materials, and the unique characteristics of all of these technologies, as it contemplates the creation of a reactor general license framework. A key goal of a reactor general license would be to enable the use of qualified reactors by qualified entities in a way that does not require specific approvals for each site use, while providing assurances that the reactors will be used only at qualifying sites.

Implementation of the proposed approaches to create the rapid efficient repeatable licensing (ReLic) process described in other portions of the Regulatory Proposal Paper could also provide useful insights in the types of prior approvals necessary to develop a general licensing framework. In this regard, if the AEA were to be amended to enable a general license, and if the NRC was already pursuing the development of a ReLic process, then the work performed to establish the ReLic process would also be useful in creating a reactor general license process.

Broadly speaking, a general licensing framework for nuclear reactors, such as RHDRA, could contain the following attributes:

		General License		
Key Characteristics	**Other (Prior) Approvals/Evaluations**	**Owner/ Operator**	**Location**	**Responsibilities**
Low potential accident consequences Small physical/site footprint Little on-site construction	Standardized design Early Site Permit or bounding environmental analysis Owner qualification verification Generically approved operating programs	Entities that meet criteria established by the NRC	Any location meeting the conditions of the design specification and bounded by prior environmental analysis	Evaluation to confirm standardized design Evaluation to confirm deployment site conforms to design Evaluation to confirm operating programs conform with generically approved programs Notification to NRC prior to use of reactors Subject to NRC inspection and oversight

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