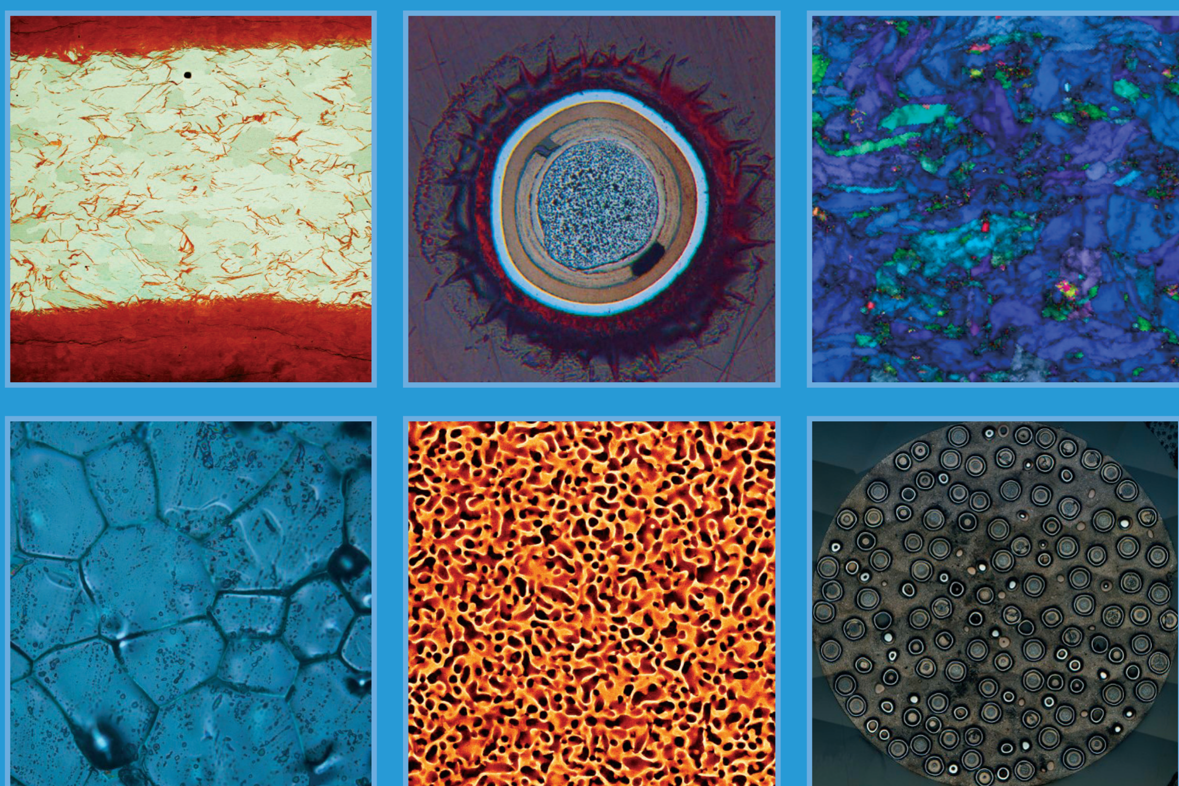
Enabling Nuclear Innovation

Strategies for Advanced Reactor Licensing



A Report by the
Nuclear Innovation Alliance

Enabling Nuclear Innovation

Strategies for Advanced Reactor Licensing

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NUCLEAR INNOVATION ALLIANCE

A Report by the Nuclear Innovation Alliance

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Enabling Nuclear Innovation:
Strategies for Advanced Reactor Licensing

NUCLEAR INNOVATION ALLIANCE

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Clean Air Task Force, Energy Innovation Reform Project, Third Way, and The Breakthrough Institute endorse the recommendations of this report.

DISCLAIMER

This report emerges from the knowledge and experience of a core team of industry and regulatory experts, as well as a broader range of inputs that address the specific needs of stakeholder communities. Not all of the issues that the team brought up are included in this report, nor did all parties agree on the relative importance of or solution to each of the issues raised here. Thus, although they recognize the many valuable contributions to this effort, the authors and NIA assume full responsibility for this document's contents, conclusions, and recommendations. The views expressed are those of the authors and not necessarily those of the funders.

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EXECUTIVE SUMMARY

THE PURPOSE OF THIS REPORT is to propose strategies that facilitate the efficient, cost-effective, and predictable licensing of advanced nuclear power plants in the United States. These are nuclear plants that would generate clean, safe, sustainable, reliable, affordable, and proliferation-resistant energy through the use of innovative technologies, and that would improve the quality of our lives and the health of our environment.

In the US and elsewhere, dozens of innovative start-up companies and other stakeholders are pioneering new designs that promise to lower risk and cost, and reduce deployment barriers.

Specifically, this report is intended to lay the foundation for a consultation among stakeholders that results in a licensing process for advanced nuclear reactors. Such a process would incorporate discrete stages for improved project risk management and, where appropriate, risk-informed and performance-based strategies.

The need for an advanced reactor licensing process is urgent. The world will double or triple its energy demand in 30 years, driven by an emerging middle class in the developing world and the need to bring electricity to 1.4 billion people who lack it today. At the same time, many analyses point to the pressing need, by 2050, to reduce global carbon emissions by 80% or more if we are to avoid the worst impacts of climate change. A more rapid expansion of nuclear power, though an essential part of the solution, faces stiff challenges. Accidents raise public fears about safety; large cost overruns and protracted schedules deter investors and owners; and concern over spent nuclear fuel disposal and weapons proliferation continues to block expansion in some parts of the world.

Innovation will be necessary if these challenges are to be addressed. In the US and elsewhere, dozens of innovative start-up companies and other stakeholders are pioneering new designs that promise to lower risk and cost, and reduce deployment barriers. But, despite the American talent for developing advanced nuclear reactor technologies, the transition from design to commercialization and deployment —both in the US and globally—has been slow. Two of the most critical barriers are the lack of a clear and efficient pathway for a first demonstration project, and continuing doubt that the Nuclear Regulatory Commission (NRC) will be able to issue a license for a non-light water reactor in a time frame compatible with private-sector needs. *These obstacles **must** be addressed before we can realize the benefits of the next generation of nuclear technology*.

Many other hurdles exist, including technology challenges, supply chain limitations, a difficult market environment, inaction on nuclear waste management, and restrictions on international cooperation. In addition, clean air policy must be updated to recognize the benefits of nuclear power. Progress on all of these fronts is urgently required.

The analysis here focuses on a key initial obstacle—a nuclear regulatory process badly in need of an update. It is important to keep in mind that addressing this challenge is a necessary first step; other steps will be required.

Current NRC regulation confronts the licensing of advanced technologies with two major challenges.

First, NRC design certification or approval calls for enormous front-loaded investment during a protracted development and licensing phase—without a staged structure to provide applicants with clear, early feedback on an agreed schedule and with appropriate finality. Second, current regulation primarily evolved to oversee light water technologies; it must be adapted to the features and performance characteristics of advanced reactors. The latter rely on substantially different fuels, cooling systems, and safety strategies, and require novel operating strategies.

To develop a workable path forward using staged licensing and an evaluation process suitable to advanced, non-light water reactors, the Nuclear Innovation Alliance (NIA) consulted with nuclear innovators, safety experts, former NRC staff and Commissioners, members of the financial community, and other nuclear industry stakeholders. The NIA also examined nuclear reactor licensing systems in the United Kingdom and Canada, and scrutinized analogous regulatory systems administered in the United States by the Federal Aviation Administration and the Food and Drug Administration.

Based on this research and analysis, the NIA offers the following recommendations:

A. Regulatory Recommendations

1. To structure a staged review of advanced reactors and support long-range resource planning by the agency and the applicant, the NRC and industry should develop and employ guidelines for a licensing project plan (LPP). The LPP would be a living document that serves as a roadmap for the entire process, defining—in as much detail as possible—project schedules, testing requirements, deliverables, and NRC review budgets. The most effective approach will be for the applicant and the NRC to design a licensing project plan that establishes milestones corresponding to meaningful stage-gates along a given project's development pathway and that take full advantage of the NRC's readiness to review specific aspects of the design. To provide the foundation for open communication and effective project management, we recommend that, as soon as a potential applicant initiates interaction with the NRC, the agency produce an initial LPP establishing guidelines that define the working relationship among the parties. This should help to ensure rapid resolution of conflicts and efficient progress. The NRC and potential applicants should discuss the appropriate contents of an LPP during this initial engagement period, and the LPP should be built up with additional detail as the project progresses and it is possible to foresee upcoming interactions. Much of the responsibility for designing an effective LPP lies with the applicant; the applicant will need to understand a project's design, development, deployment, and investment milestones in order to propose corresponding licensing milestones. At the same time, NRC expectations for the level of design detail must correspond to the particular milestone, and be clearly communicated to potential developers. (See Section IV.A for further detail.)

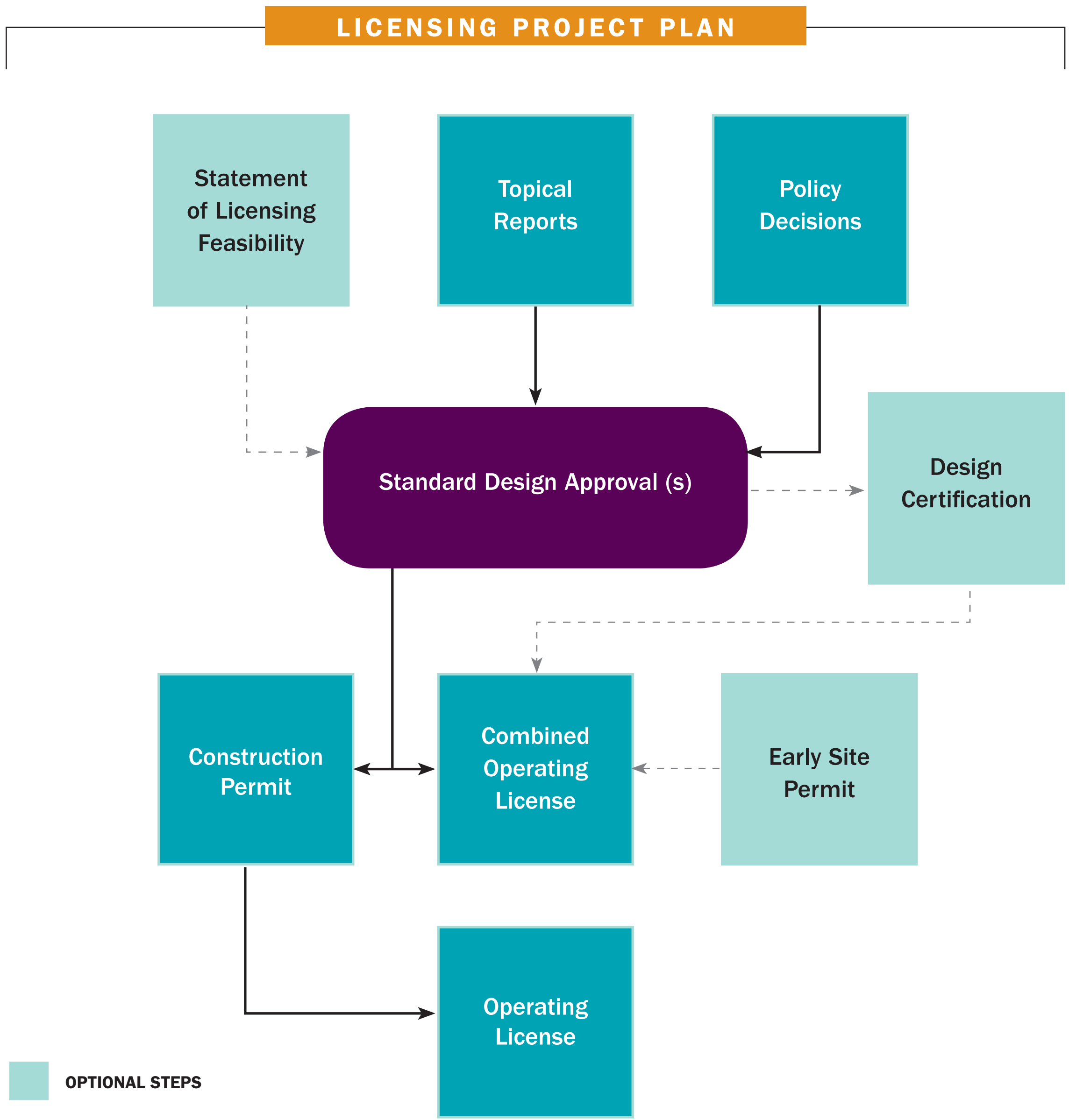
2. The NRC should promote and applicants should use topical reports and the standard design approval as tools to introduce stages into the advanced reactor licensing process, while emphasizing the need to achieve a level of finality that supports staged decision making. These tools can be employed under current regulations, if the proper staff guidance and policies are put in place; the proposed licensing project plan could structure their use. (See Chapter IV for further detail.)

3. The NRC should develop and employ an optional statement of licensing feasibility process with time frames and budgets to be agreed upon in the licensing project plan. This would permit it to more easily assess whether an applicant's design intent was conceptually aligned and consistent with established regulatory requirements. Doing so would offer important benefits: (i) it would standardize a review phase that, because of its limited cost and duration, could be used by stakeholders to compare available design options; (ii) it would provide early feedback to the applicant, allowing timely alterations in approach to better meet regulatory obligations; and (iii) it would provide useful structure to pre-application engagement. (See Section IV.D for further detail.)

   Figure ES-1 (p. 4) depicts the elements that could be used to support the staged licensing of an advanced reactor, structured by an LPP. This can be implemented under existing NRC authority; it would not require an Act of Congress.

4. The Commission and license applicants should work together to adapt the agency's light water

FIGURE ES-1
Available Stages for Licensing an Advanced Reactor



reactor (LWR)-centric requirements so that they are better suited to advanced reactors seeking licenses in the near term, while, wherever appropriate, increasing the use of risk-informed and performance-based techniques. For new technologies, alternative approaches to the exemption process should be considered. Recently, applicants have used the practice of seeking relief from certain inapplicable or partially applicable requirements. For example, during recent licensing activities for light water small modular reactors, applicants experienced increased cost and slower review due to difficulty in executing the NRC's exemption processes. Advanced reactor designers from both traditional industrial organizations and small start-ups are concerned with the cost and schedule uncertainty associated with the exemption process (as well as potential negative perception that applicants are trying to avoid stringent safety regulation). As a result, they are hesitant to submit applications without first being assured that exemption requests will be meaningfully processed. A means should be available earlier in the process for the NRC and the applicant to reach agreement on alternative compliance strategies for specific requirements that are only partially applicable or are not applicable at all. The LPP would be a natural place to do this, once the NRC and stakeholders have identified promising approaches. This will increase efficiency and effectiveness in the design and regulation of advanced technologies without sacrificing safety or security. (See Section IV.A for further detail.)

5. The NRC and DOE should continue to move forward with the DOE/NRC Advanced Reactor Licensing Initiative.[1] This will help to establish and clarify acceptable approaches for creating the underlying design criteria associated with these concepts, thereby removing a portion of the regulatory uncertainty associated with advanced non-LWRs. (See Section V.A for further detail.)

6. Given the substantial investments that have already been made by industry and DOE in pre-application reports and proposals for advanced reactors (including the Next Generation Nuclear Plant), and by NRC staff in evaluating them, the NIA recommends that (i) the NRC complete its evaluation and the Commission issue its decisions or opinions at this stage of the application, and (ii) generic issues raised by DOE and NRC be resolved through the issuance of guidance for advanced reactor applicants. (See Section V.A for further detail.)

7. At the same time that the NRC pursues the above initiatives, the NRC should designate a special technical team to develop a plan to implement a technology-inclusive licensing and regulatory framework for advanced reactors based on risk-informed and performance-based principles. The technical team should propose a roadmap for putting the new framework into practice by 2025, and then be given the administrative flexibility and resources to succeed. Because this framework will not be ready immediately, it should remain optional (similar to the Part 52 licensing processes as an alternative to the Part 50 process)—at least until it is fully demonstrated. That way, its development will not delay current projects. (See Section V.A for further detail.)

8. To provide a clear and achievable regulatory pathway for developing and deploying advanced demonstration reactors, the NRC should:
   i. In collaboration with stakeholders, clarify terminology and resolve discrepancies and gaps in statutes, regulations, and practice;
   ii. Using terminology revised pursuant to (i) above, clarify responsibility for reviewing potential applications;
   iii. Develop guidelines for advanced reactor demonstrations to support the review process; and
   iv. Provide or develop guidelines for prototype plant regulation (as defined in 10 CFR 50.2 and referenced in 10 CFR 50.43(e)) and conversion to commercial operation.

   (See Section V.B for further detail.)

9. The NRC should continue development and execution of advanced reactor technology knowledge management and training opportunities for NRC staff. Mid- and upper-level managers should be included in these programs. Funding will be needed to support this. (See Section V.B for further detail.)

B. Policy Recommendations

1. Congress should revise the NRC's budget structure so that, instead of a 90% fee-based, 10% public funding model, licensees and applicants reimburse the NRC for activities related to their regulation, with Congress funding other agency-related activities—including the development of new regulations for advanced technologies, R&D, international programs, and other initiatives not related to a specific licensee. The nuclear fleet operating today was licensed by an NRC that had been fully funded by Congress, before the advent of current fee-recovery rules. Unlike that earlier generation of reactors, licensing of the AP1000s now under construction has been supported by substantial cost-shared funding from DOE. To prepare for the licensing of advanced reactors, the NRC faces a greater

1. This was most recently described in the following report: US Department of Energy, Office of Nuclear Energy, Guidance for Developing Principal Design Criteria for Advanced (Non-Light Water) Reactors, December, 2014. *http://pbadupws.nrc.gov/docs/ML1435/ML14353A246.pdf*.

challenge that will require consistent public funding.

2. Congress should appropriate funds for the NRC to prepare for advanced reactor licensing, including but not limited to:
   - Development and implementation of strategies to stage and expedite the advanced reactor licensing process;
   - Development and implementation of a risk-informed, performance-based licensing framework for advanced non-light water reactors;
   - Efforts to prepare the process of licensing advanced demonstration reactors; and
   - Staff training or the hiring of experts.

3. To expand available financial resources for advanced reactor companies, Congress should continue to fund DOE to competitively award grants for early efforts to license advanced reactor companies, including but not limited to:
   - Pre-application engagement with the NRC;
   - Developing a licensing project plan; and
   - Applying for a statement of licensing feasibility or similar early-stage design review.

The DOE Gateway for Accelerated Innovation in Nuclear (GAIN) initiative's small business voucher program is one possible mechanism for this.

C. Industry Recommendations

Industry has an important role to play as a constructive participant in all of the above recommendations, but also has primary responsibility for several actions:

1. Industry stakeholders should cooperate to deliver a coordinated message to the NRC regarding technology-inclusive advanced reactor priorities.

2. Prospective applicants should proactively address the NRC's need for information about future projects by informing the agency as early as possible of their intent to request NRC review. By capturing this information in regulatory issue summaries, the NRC will have a stronger basis to support research, as well as budgetary estimates and requests.

3. Industry should take a more active role in communicating with the NRC, DOE, and other stakeholders on the challenges and opportunities associated with various advanced reactor designs, including R&D priorities.

4. Working with appropriate research and standards organizations, industry should pursue the development of codes, standards, and conventions for advanced nuclear power.

We intend these recommendations to serve as a foundation for appropriate deliberation and prioritization and, soon after, decisive action to improve the regulatory pathway for advanced nuclear energy technologies. This is critically important work that will enable society to capture the immense future benefits of advanced nuclear power.

CHAPTER I

INTRODUCTION

THE PURPOSE OF THIS REPORT is to propose strategies that facilitate efficient, cost-effective, and predictable licensing of advanced nuclear power plants in the United States. These are nuclear plants that will generate clean, safe, sustainable, reliable, affordable, proliferation-resistant energy through the use of innovative technologies, and that will improve the quality of our lives and the health of our environment—nationally and internationally.

Specifically, this report is intended to lay the foundation for a dialog among stakeholders that will result in an improved process for licensing advanced nuclear reactors. Such a process would incorporate discrete stages for project risk management and, where appropriate, risk-informed and performance-based strategies.

The need for such a process is urgent.

A. Nuclear Innovation: Importance and Potential

The world will double or triple its energy demand by 2050, driven by an emerging middle class in the developing world and the need to bring electricity to 1.4 billion people who lack it today. At the same time, many analyses point to the pressing need, by 2050, to reduce global carbon emissions by 80% or more if we are to avoid the direst impacts of climate change. This will require an enormous transformation of existing electricity generation capacity. Increasingly, analytic models projecting future global energy needs signal an important role for nuclear power, particularly given its low-carbon emission profile and its reliability.

But a more rapid expansion of nuclear technology faces stiff challenges. Accidents raise public fears about safety; large cost overruns and protracted schedules deter investors and owners; and concern over spent nuclear fuel disposal and weapons proliferation continues to block expansion in some parts of the world.

This network is ready to advance a generation of safer and more affordable nuclear energy.

Fortunately, nuclear technology is not standing still. In the US and elsewhere, dozens of innovative start-up companies and other stakeholders are pioneering new designs reliant on different fuels and reactor technologies—designs that emphasize inherent safety, lower cost, less waste, and reduced proliferation risk compared with existing reactors. Among these new approaches are reactors that (i) instead of being custom built, are centrally manufactured in smaller modules, potentially reducing both direct costs and financing; (ii) rely on such coolants as molten salts and gases; (iii) provide adequate passive cooling, even in the absence of an external energy supply; (iv) operate at or near atmospheric pressure, reducing the possibility of rapid loss of coolant; and (v) consume nuclear waste as fuel, addressing two problems at once.

Historically, the United States has led the world in nuclear technology innovation. Decades of public and private investment created a strong network of inventors, engineers, financiers, regulators, business interests, technologies, and experimental facilities. This network is ready to advance a generation of safer and more affordable nuclear energy.

But nuclear energy development in the US has stalled since late in the last century. The primary causes include political controversy, market factors, and project management failures, complicated by the scale and complexity of existing nuclear technologies.

Nuclear power is a key tool for meeting global environmental and public health goals.

Today, however, innovative reactor designs promise to lower risk and cost, and reduce deployment barriers. The challenge is to accelerate that innovation, while maintaining the important strategic and economic advantages of continued US leadership in this area. These advantages include:

- *Energy security*: reactor designs that use domestically available fuel rely on a secure energy source.
- *Price-stable reliable power*: nuclear power has low and predictable operating costs, unlike fossil fuels (particularly natural gas) and can operate as a baseload resource; many new designs are also meant to operate on-demand.
- *Domestic economic benefits*: in addition to providing price-stable power, the nuclear industry supports high-paying manufacturing and technology jobs.
- *Influence on global nuclear safety*: US involvement in the global nuclear power industry provides leverage in helping to set global standards for nuclear safety.
- *Influence on global nuclear security*: to maintain influence in international discussions about nuclear security and safeguards, the US must remain at the forefront of nuclear power technology.
- *Sustainability*: nuclear power is a key tool for meeting global environmental and public health goals, including decreased emissions of both greenhouse gasses and conventional pollutants, reduced land impacts, a smaller energy consumption footprint, and greater access to useful energy (particularly electricity).

B. Challenges to Nuclear Innovation

Despite the American talent for developing advanced nuclear energy technologies, the transition from design to commercialization and deployment, both in the US and globally, has been slow. Many hurdles exist, some of which relate to the regulatory system, while others do not. Although this report focuses on identifying and mitigating challenges posed by regulation, it is useful to recognize that other challenges exist as well.

1. CHALLENGES UNRELATED TO NUCLEAR REGULATION

- *Market Environment:* In the United States, low energy demand growth and low natural gas prices jointly contribute to a difficult environment for nuclear power. Power market structure in many regions also poses an obstacle. For example, subsidy and dispatch policies that favor intermittent renewables over more capital-intensive baseload generation lead to operating losses at existing nuclear plants.
- *Public Policy:* US clean energy policy is supported by tax incentives, renewable portfolio standards, carbon pricing in some markets and, most recently, the renewable incentive provisions of EPA's Clean Power Plan. In general, political and public discourse have focused exclusively on how incentives such as these will advance renewable resources like solar and wind. The discussion has not included nuclear energy, despite the fact that it currently provides about two-thirds of America's carbon-free electricity. Indeed, nuclear energy has the potential to decarbonize much of the power sector, and ultimately—through process heat applications and synthetic fuel production—other sectors as well.
- *Inaction on Nuclear Waste:* Lack of federal action to create a permanent nuclear waste repository or to implement an interim solution hampers nuclear power development in several ways. It erodes public confidence, creates complex legacy issues, demands much time and attention from policymakers and industry, and quite directly prevents the siting of new nuclear power plants in certain states.
- *Technological Challenges:* Although most advanced reactors under development are based on technologies originally tested many years ago, many also rely on new materials and technologies, or at least ones introduced in the intervening decades. Either way, these newer approaches often have not been tested in nuclear reactor environments. As a result, some advanced reactor designs will require lengthy fuel qualification testing in test reactors, others may require extensive materials tests or the development of new materials, and still others will have to await the refinement of chemical processes or the creation of new ones. Low levels of government R&D investment in advanced reactors and the lack of a fast neutron test reactor compound these technical challenges.

- *Supply Chain Limitations:* Due to lagging reactor construction, the nuclear energy supply chain in the US is eroding. As a result, the options for procuring many essential components are limited and skilled construction labor is in short supply. These issues are not likely to be resolved until US nuclear construction undergoes a resurgence.

2. CHALLENGES CONTAINING A NUCLEAR REGULATION COMPONENT

A critical obstacle to financing innovative nuclear power technologies is that there is no clear pathway for an initial demonstration project. At the dawn of the nuclear power age, demonstration reactors were heavily supported and often managed by the federal government. It is generally accepted that demonstration of today's advanced reactors will require coalitions backed by strong private-sector partners. Even so, government-owned sites and other public resources may prove to be indispensable. Either way, the demonstration project approach has yet to be endorsed by key stakeholders—and, even assuming it is, the private sector and DOE (or DOD) will have to work out the contractual details. By providing a policy, funding, and testing platform for qualified nuclear innovators, the risk, cost, and difficulty of initial demonstrations could be greatly reduced and the innovation process accelerated.

This demonstration challenge contains two components related to nuclear regulation:

1. It is possible that demonstration reactors could be built under DOE safety oversight authority or under existing NRC authority. In either case, NRC involvement early in the process will be essential to ensuring a tight connection between the expertise gained from the demonstration phase of a project and the technical substance of the commercial license application subsequently filed with the NRC. If the NRC plays the primary role in licensing and regulating a demonstration project, it might draw on older processes and practices that have not recently been used, or on new ones that are not currently well-defined or well-understood. Either way, the NRC and DOE will find it necessary to further develop their knowledge of advanced technology. This challenge is discussed further in Section V.B.

2. With no fast flux test reactor in the US and no practical and proven pathway for creating a demonstration reactor here, international partnerships are becoming increasingly valuable. In some cases, the US export control regime imposes burdens on these partnerships, resulting in delays, added cost, and missed opportunities. NRC involvement in quality assurance for international testing can be important for later use of test results in the US. There may be opportunities to smooth the process for regulating international nuclear energy cooperation and to enable greater NRC observation of international work.

3. CHALLENGES PRIMARILY RELATED TO NUCLEAR REGULATION

Current NRC regulation presents two major challenges to the licensing of advanced technologies. First, NRC design approval calls for enormous front-loaded investment during a protracted development and licensing phase; there is no staged design approval structure providing applicants with clear, early, and periodic feedback on an agreed schedule. Second, existing regulation has been designed primarily for light water technologies; it is not easily adapted to the features and performance characteristics of advanced reactors, which rely on substantially different fuels, cooling systems, and safety strategies, and also exhibit novel operating characteristics.

a. Need for a Staged Licensing Process

The development and commercialization of an advanced nuclear power technology can be a multi-billion-dollar investment played out over a decade or more. New technology investments this large are best made in graduated steps; with each infusion of investment, some of the project risk must be retired in order to attract new investors with a lower risk appetite. In many industries, the bulk of the risk lies in the technology (e.g., that it might fail to work), or the market (e.g., that no one will want to buy the product). Although both of these risks also are present in nuclear energy, another risk—regulatory risk—is seen as particularly inimical to innovation, because it is so difficult to predict and to manage. At present, little evidence exists that a non-light water reactor can be licensed in a time frame compatible with private-sector requirements. That makes it even more important that investments be stepwise—beginning with modest sums and increasing as risk is reduced. At a time when key stakeholders are working to better adapt nuclear regulation to the needs of technological innovation,

FIGURE I-1
Desirable Project Risk/Investment Profile Relative to Licensing

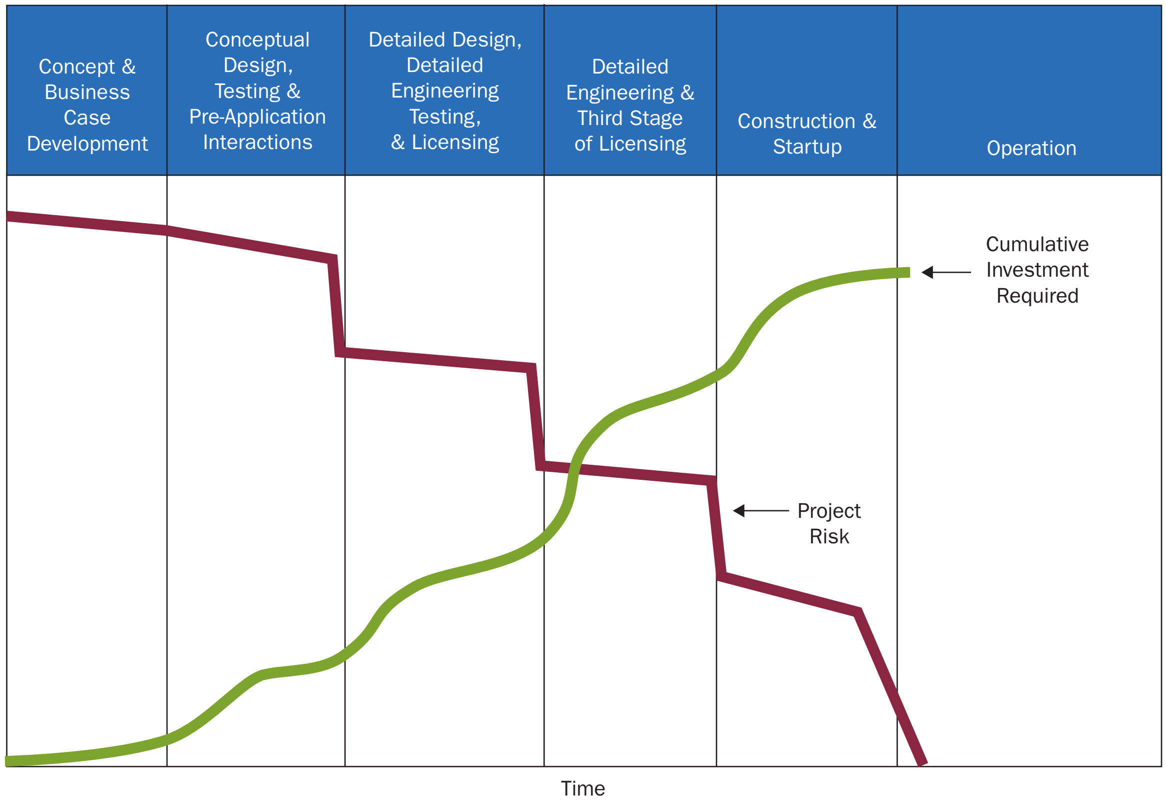
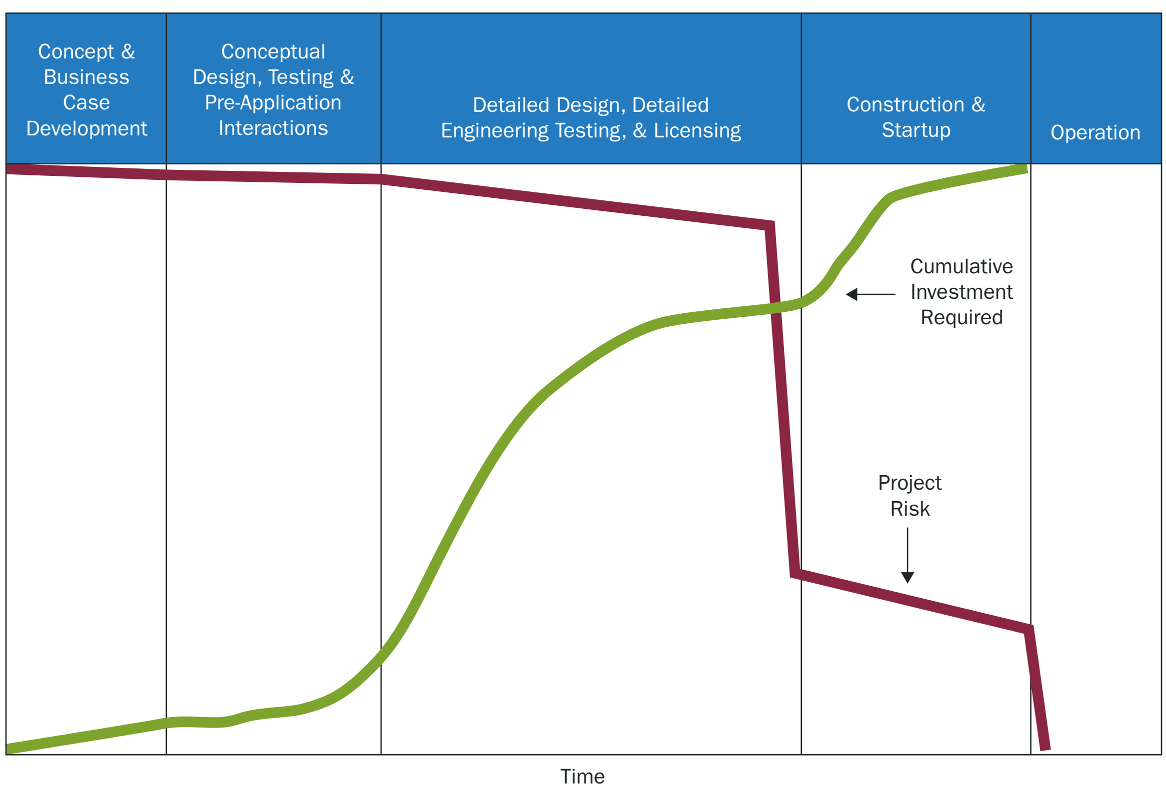


FIGURE I-2
Current Project Risk/Investment Profile Relative to Licensing



a staged licensing process should at least be an ideal to strive for. Figure I-1 provides a schematic illustration of this type of stepwise licensing invesment/risk profile. The picture today looks more like that illustrated in Figure I-2.

This state of affairs did not happen by chance. In the mid-to-late 1980s, the light water reactor industry and the NRC actually sought to develop, in 10 CFR Part 52, a licensing process with fewer stages, but clearer ones. They also sought a process that would reduce the number of adjudicatory hearings without decreasing their useful input. This process, described in more detail in Appendix B, is currently in use in the United States at the V.C. Summer and Vogtle projects.[2] The other NRC licensing approach, which is based on 10 CFR Part 50 and has been in use since the 1970s, is being applied to the reactivation of Watts Bar Unit 2.

The current system is best suited for applications that support a completed design and are backed by a commercial order. Here, the Part 52 process minimizes regulatory risk. Nonetheless, neither the Part 50 nor Part 52 process currently provides for design review and approval via a clear set of stages, with strong regulator feedback, during the licensing process—a necessary approach for advanced reactors with dramatically new designs. Although this is a barrier to significant private and venture-based investment, its impact is even broader. For a new technology to succeed, investments must be made in many forms by many parties. Entrepreneurs invest their time and energy in a project that they believe can succeed; industrial partners direct in-kind resources to building partnerships and developing aspects of plant design; potential suppliers devote resources to capacity building, while creating new parts for advanced technology; prospective owners must select sites and develop operations teams long before the design is licensed; even prospective employees dedicate their time and education in preparing to join innovative companies and industries. All of these contributions are burdened by a regulatory process that does not promote incremental progress through the achievement of defined milestones along the licensing path.

Adjusting the licensing process to establish distinct review stages, and better aligning these stages with those typical for the development of and investment in new technology would facilitate the commercialization of innovative reactor designs. Not only would this approach enable the current crop of innovators to move forward, it would also encourage more students, entrepreneurs, and companies to enter the development pipeline.

In this report, we suggest several mechanisms for achieving this type of staged process. They are not the ultimate answer, but can serve as starting points from which the NRC, advanced reactor developers, and other stakeholders can work to develop a new, more effective model.

Adjusting the licensing process to establish distinct review stages would facilitate the commercialization of innovative reactor designs.

b. Transition from LWR-centric to Advanced Reactor Guidelines

Current NRC regulations provide detailed guidelines for license applications for and approval of light water reactors (LWRs). Recently, the NRC offered a way to adapt this to advanced LWRs: the applicant can ask the NRC to collaboratively develop a design specific review standard (DSRS) keyed to its reactor technology.[3] With changes based on experience, a similar process could be useful for non-LWR advanced reactors—whether molten salt, high-temperature gas prismatic, sodium fast pool-type, or others. However, the task of developing the necessary inputs for a non-LWR DSRS would fall heavily on the first applicant, thus erecting a much higher regulatory barrier than what

2 The Part 52 process—consisting of a design certification (DC) followed by a combined operating license (COL) for construction and operation—provides a more predictable regulatory pathway for light water reactors built by large regulated utilities. It does so by resolving an issue that arose in the older Part 50 process. Under 10 CFR Part 50, a construction permit (CP) was issued before the design was complete; an operating license (OL) would be issued following construction and non-nuclear testing. However, an OL was not assured. This led to extremely costly delays after construction had been completed. Combining the CP and OL into a COL reduces the risk of this type of delay, but adds several requirements at the front end: (i) that a complete design be submitted prior to the start of construction; (ii) that any design changes be carefully presented and approved; and (iii) that a lengthy series of inspections and tests confirm that the plant is being built as designed and will operate as expected.

3 See NRC NUREG 0800 Standard Review Plan–Introduction–Part 2 Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: Light-Water Small Modular Reactor Edition. *http://pbadupws.nrc.gov/docs/ML1320/ML13207A315.pdf.*

LWR applicants must currently surmount.[4] Because the time and cost of completing that process is unknown, it represents a major barrier to investment in and development of new designs.

Two approaches exist for addressing this challenge, and they should be pursued in parallel:

i. The NRC can develop and adopt a risk-informed, performance-based regulatory framework. This would allow for consideration of advanced technology based primarily on risk and performance criteria, rather than on prescriptive specifications that must be crafted anew for each technology. Because entirely new regulatory guidance will not be required for each new design concept, this approach will reduce barriers to innovation. Although it may take several years to implement fully, immediate, meaningful progress is also possible: several key parts of the advanced reactor safety case can be rendered more technology neutral by incorporating risk information or performance-based techniques. Specific examples include the event selection process, containment requirements, and emergency planning. This work was initiated during the Next Generation Nuclear Plant Project, with parts pursued via the SMR program. The NRC could rapidly adopt a performance-based pathway by revising its policies.

ii. Given the limitations of the risk-informed framework (e.g., the long lead-time and the need to develop the framework at the same time that reactors are under review), some near-term changes can help to mitigate the challenges that today's advanced reactor developers face. For example, government support of and NRC resource allocation to development of regulatory guidance for advanced reactors would help to pave a pathway for innovation. This work could be performed via an expansion or extension of the current DOE/NRC Advanced Reactor Licensing Initiative. Nonetheless, these short-term strategies should not divert the NRC or the nuclear industry from pursuing the risk-informed framework as well.

As we make clear in this report, staging the licensing process will also help to establish a clear step-wise pathway for the successful licensing of advanced designs. This will in turn address a critical investor concern and facilitate commitment of additional private capital to advanced nuclear development.

C. Guide for the Reader

This report consists of ten sections:

Executive Summary

The Executive Summary provides an overview of key recommendations.

I. Introduction

The Introduction presents the context, explaining why advanced nuclear reactors are important, noting critical barriers that they face, and outlining the key changes required in the licensing process to enable advanced reactor innovations to reach the market.

II. Reactor Development and Deployment Process

This chapter describes how nuclear reactors are developed and deployed, an essential predicate to understanding how a project's staged licensing structure can be coordinated with a more organized approach to sequential risk reduction.

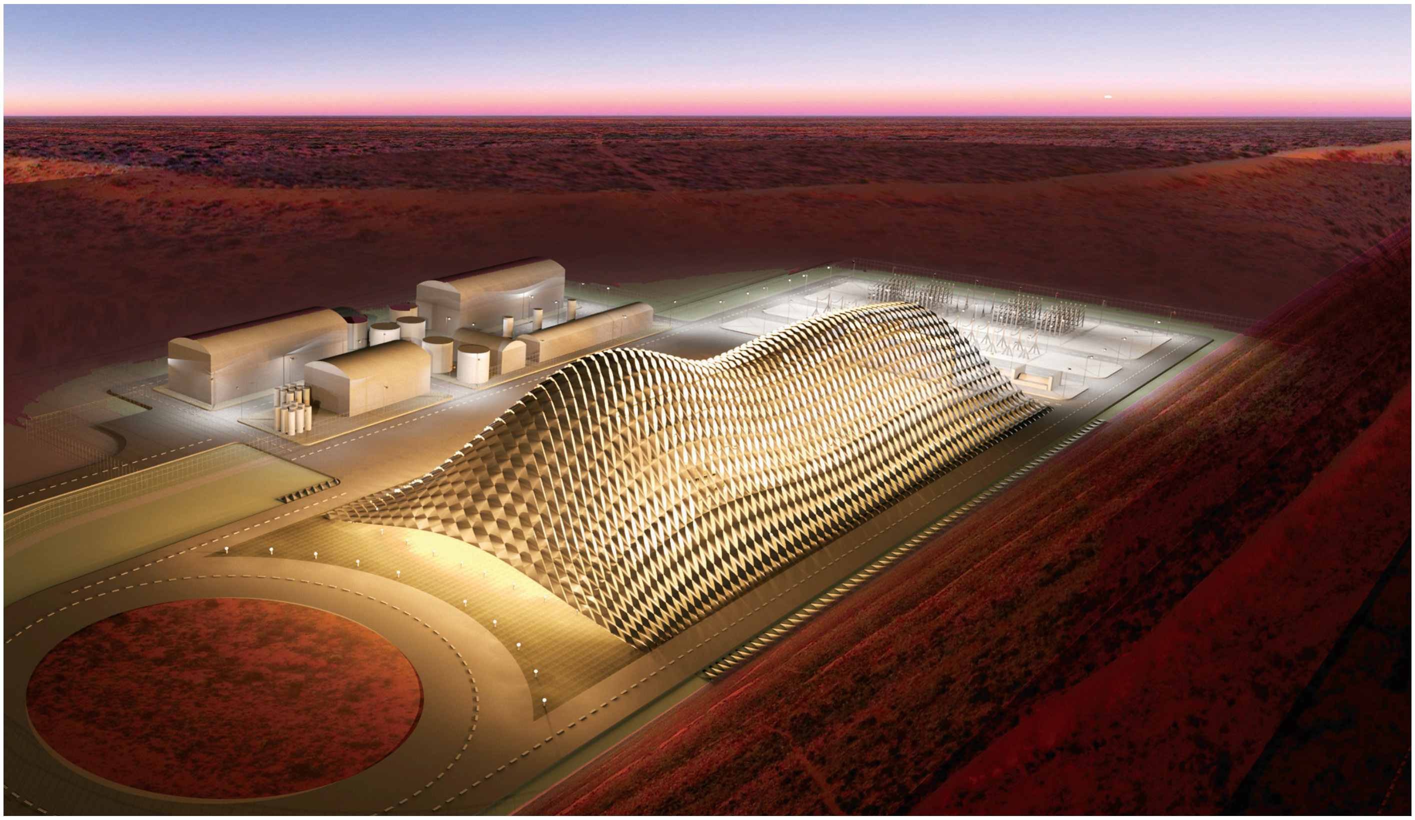
III. Useful Regulatory Models and Lessons

This chapter describes several regulatory models, nuclear and otherwise, that offer useful lessons for ways in which the advanced nuclear power plant licensing process may be improved in the United States.

IV. Mechanisms for Staging Advanced Reactor Licensing

This chapter outlines proposed mechanisms for introducing discrete stages to the licensing process, as a way to better align with innovation and deployment.

4 Although NRC developed a design specific review standard (DSRS) for the NuScale and a partial DSRS for the B&W mPower Small Modular LWR, a DSRS for a non-LWR will diverge far more from existing LWR guidance and thus present a far greater challenge.



Artist's rendition of the Transatomic Power Molten Salt Reactor plant. The Transatomic Power reactor, which is based on technology first developed at Oak Ridge National Laboratory in the 1960's, is walk-away safe and has the potential to run on spent nuclear fuel.

V. Other Potential Improvements in the Advanced Reactor Licensing Process

This chapter discusses additional improvements that would help to inspire nuclear innovation, including the development of a risk-informed, performance-based licensing framework and the drafting of clearer guidelines for the licensing of advanced reactor demonstration projects.

VI. Recommendations

This chapter sets forth detailed recommendations for the development of advanced reactor licensing strategies that encourage innovation.

Abbreviations

This section provides a guide to the abbreviations and acronyms used in the report.

Appendix A: Advanced Reactor Development and Deployment Process

Appendix A describes the advanced reactor development and deployment process, and recommends the introduction of distinct phases into the commercialization process, reducing program risk and increasing stakeholder alignment.

Appendix B: Legal Context

Appendix B provides the detailed legal context for the options explored in this report, as well as for its recommendations and conclusions.

CHAPTER II

REACTOR DEVELOPMENT AND DEPLOYMENT PROCESS

The licensing process for advanced reactors should not be considered in a vacuum. The creation of stages in the licensing process will be most effective if those stages are coordinated with logical phases in the design, development, deployment, and investment process (the "development process") for advanced reactors. Even independent of the licensing process, a more orderly and thoughtful execution of phases and coordination of stakeholders in the development cycle might serve to expedite the process.

In simplified form, this chapter lays out a typical development and deployment timeline for nuclear power plants, and identifies key stakeholder groups. More details, including a description of key stakeholder relationships and a conceptual layout of program phases that help to organize the process, are provided in Appendix A; a more detailed description of staged licensing will be presented in Chapter IV. The current chapter provides context for the entire project development cycle.

The existing design, licensing, and delivery process for new reactor designs costs too much and takes far too long.

The existing design, licensing, and delivery process for new reactor designs and specific reactor projects costs too much and takes far too long. To help the reader fully appreciate the complexity and interrelationships of the major phases and types of stakeholders, Figure II-1 graphically illustrates the current development and deployment pathway for an advanced light water reactor (ALWR). This figure reflects a composite of the various major activities that must be completed to bring a first-of-a-kind (FOAK) project from the pre-conceptual stage to full operation. The stakeholder groups include investors, designers, regulators, builders, operators, owners, and the public, and were chosen to represent the typical (and broad) range of institutions that participate in a FOAK program. Each has a distinct set of interests, including institutional motivation, risk tolerance, and time frame.

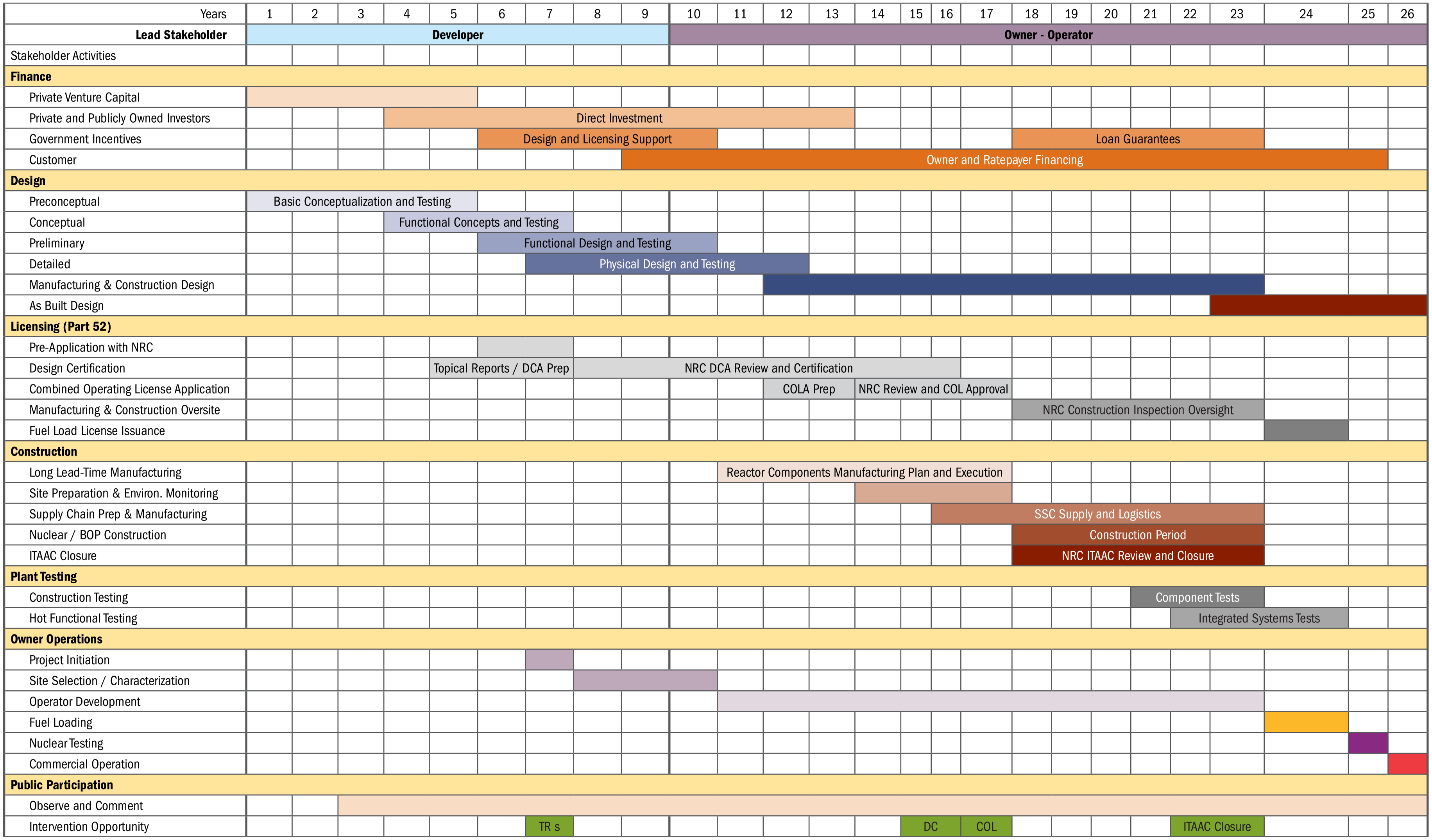
The stakeholders' primary involvement includes some or all of the following activities:

- Finance,
- Design,
- Licensing,
- Construction,
- Plant Testing,
- Owner Operations, and
- Public Participation.

The activities and sub-activities in Figure II-1 reflect current practices and expectations of the licensing process spelled out in 10 CFR Part 52. Based on actual experience with current ALWR designs (using averages derived from public data), it would take more than 25 years to complete the full set of sub-activities listed here. One reason for the lengthy development timeline is that initial NRC reviews take a long time, often reach widely varying conclusions, and require applicants to prepare extensive responses to agency comments. Delays have also arisen from unsteady funding, poor design execution and integration, limited pre-application engagement with the NRC, failure to incorporate construction methods into design, failure of the owner to adequately prepare for

FIGURE II-1

Stakeholder Activities and Timeline



operation, and protracted intervention proceedings. Indeed, the historical evidence suggests that, at one time or another, each of the stakeholders has negatively affected the development process. Lack of alignment on major points of decision can create a nearly continuous series of unanticipated or poorly timed results, leading to delays and cost overruns.

Regulatory experience shows that the need to establish a clear system of phasing and integrate it with discrete risk reduction applies not only to the regulatory process, but, analogously, to all stakeholders. That is, each party would benefit from a more organized development approach. Concrete phases with defined outcomes will enable stakeholders to more easily make rational long-term commitments to the program. This in turn could lead to faster commercialization and thus nearer-term deployment of technologies that address the global need for clean, reliable energy. Preliminary recommendations for introducing distinct phases into the commercialization process, reducing program risk, and increasing stakeholder alignment are detailed in Appendix A.

CHAPTER III

USEFUL REGULATORY MODELS AND OBSERVATIONS

Safety evaluations of advanced (non-light water) reactors are not a wholly new undertaking. The NRC and its predecessors have evaluated and even approved non-light water reactors, some of which were built and operated in the United States in the early days of nuclear power. A number of observations can be made about those efforts.

Similarly, guidance can be drawn from other regulatory authorities, both nuclear and non-nuclear. This chapter n looks to the US Atomic Energy Commission, the NRC, the Canadian Nuclear Safety Commission (CNSC), the United Kingdom's Office of Nuclear Regulation (ONR), the US Federal Aviation Administration (FAA), and the US Food and Drug Administration (FDA) for best practices and strategies that point to desirable adjustments in the NRC's processes, as well as changes to avoid.

A. Historical Practices at the NRC and the AEC

The United States has a long history of licensing a range of reactor types. Primary responsibility originally resided with the Atomic Energy Commission (AEC), as authorized by the Atomic Energy Act of 1954 (AEA). The Energy Reorganization Act of 1974 (ERA) divided the duties of the AEC between the NRC and the Energy Research and Development Administration (ERDA). ERDA—which in 1977 merged with another agency to become the DOE—was given authority over nuclear research, testing, and development. The NRC, on the other hand, took charge of licensing and regulating commercial reactor development, including prototype and demonstration reactors. Considerable precedent from the AEC era supports the licensing of non-light water reactors, although its current applicability may be limited. Still, a few precedents post-date the creation of the NRC and remain useful.

Key points that we take from this early experience include:

- ***The NRC and its predecessor have in the past reviewed advanced reactors, assigning dedicated teams to examine particular designs. Such a team may be the most effective way to develop a strategy to improve the review process for all advanced designs and to implement a more risk-informed process.***
- ***Further examination of the computer codes and other sources of knowledge that support past advanced reactor evaluations may assist the NRC in preparing to evaluate current advanced reactors.***
- ***Knowledge transfer from NRC staff involved in these early reviews should receive high priority.***

1. EARLY AEC PRACTICES

With construction starting in 1949 and power production following in 1951, the experimental breeder reactor (EBR)-1 in the United States ushered in the non-military era of nuclear development worldwide. US government policy was highly supportive of nuclear energy development, and the Cooperative Power Reactor Demonstration Program backed the development and demonstration of advanced reactor concepts for nearly two decades.

During this period, a wide range of reactors was developed and built, including many non-LWR reactor types.[5] Numerous one-of-a-kind research and test reactors were licensed and constructed, including those that generated electricity, produced isotopes, and powered space missions.

To support these programs, the Atomic Energy Act provided the AEC with licensing authority. A more complete discussion of the legal powers granted to the AEC and NRC is provided in Appendix B.

The practice during this period was to issue construction permits (CPs) following mandatory hearings, and then operating licenses (OLs), after the resolution of any issues raised in discretionary public hearings requested by third parties. For the earliest reactors, expert judgment was the primary method of evaluation. As time went on, more focused regulations were issued, based on prior experience in licensing, building, and operating the early reactors. At both the CP and OL stages, it was common for the AEC or NRC to attach conditions to a permit or license, and require the developer to meet those conditions by certain construction or operation milestones. The Atomic Safety and Licensing Board (ASLB) would conduct the hearings mandated prior to issuance of the CP. The ASLB would conduct a second hearing at the OL stage as well, but only if it had been requested by a person or entity whose interests might be affected by the operating license. Prior to issuance of the CP and OL, the Advisory Committee on Reactor Safeguards (ACRS) also would conduct an independent review of the permit and license applications, then provide an opinion to the Commission. On this foundation, the Commission would grant or deny a license. Many of these plants were licensed under §104(b) of the Atomic Energy Act, which set the review standards for research and demonstration reactors. There, the Commission followed the statutory directive that it impose "the minimum amount of such regulations and terms of license as will permit [it] to fulfill its obligations under" the AEA.

The non-light water reactors licensed and operated under the AEC included:

- Peach Bottom I, a 40-MWe High-Temperature Gas Reactor (HTGR) (OL issued in 1967);
- Fort St. Vrain, a 350-MWe HTGR (OL issued in 1973);
- Hallam Nuclear Generating Station, a 75-MWe Sodium Graphite Reactor (OL issued in 1963);
- Fermi I Nuclear Power Plant, a 69-MWe Sodium-Cooled Fast Breeder Reactor (OL issued in 1963); and
- Piqua Nuclear Power Facility, a 12.5-MWe Organically-Cooled and Moderated Reactor (OL issued in 1963).[6]

In some cases, provisional licenses were granted to first-of-a-kind demonstration plants.[7] Once the demonstration period was deemed complete, the provisional licenses would be converted to regular §103 operating licenses and regulated under the usual provisions applicable to all commercial reactors. Until this practice was stopped in the late 1960s, the AEC awarded provisional operating licenses to numerous electricity-generating reactors.[8]

From 1960–1970, as LWR experience grew, the regulatory framework was greatly expanded and refined. Late in the decade, the AEC began to develop and issue general design criteria (GDC). All of this activity reflected the needs of a growing LWR-centric industry, as well as an agency that required more stable and structured regulatory standards.

2. POST-ERA DOE AND NRC NON-LWR PRACTICES

Enacted in 1974, the ERA split the AEC into two parts in order to address several issues, among them concern about lack of regulatory independence, need for greater disclosure of safety issues, and desire to separate the AEC's promotional and oversight functions. Formed soon after, the NRC was given licensing authority for commercial, industrial, and medical nuclear facilities, as well as for some that were research-related. The promotional activities of the AEC were transferred to the Energy Research and Development Administration (ERDA).

One of the programs that the AEC and ERDA promoted involved the fast breeder reactor. The fast breeder program was the NRC's principal non-

5 Flanagan, G. F. "Previous Experience 'Licensing/Authorizing' Non-LWRs in the US—How It Was Done and Who Did What" September 2015. *http://pbadupws.nrc.gov/docs/ML1524/ML15245A643.pdf.*

6 Ibid.

7 Plants that initially operated under provisional licenses include Haddam Neck, Oyster Creek, Palisades, Ginna, Maine Yankee, and Indian Point.

8 See 10 CFR 50.57 footnote 1.

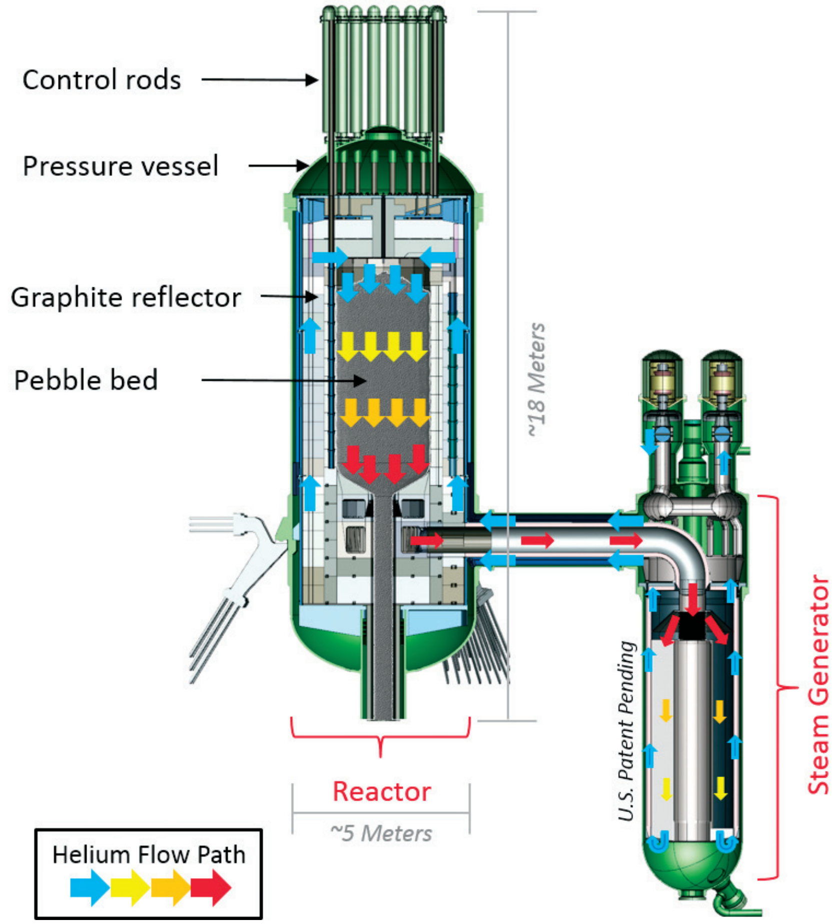
LWR licensing-related initiative in the early 1980s. In 1983, after review, the NRC granted the Clinch River breeder reactor a limited work authorization. But this did not lead to a construction permit. Instead, for reasons of cost and need, Congress canceled the project in 1983.[9]

By the mid-1980s, interest in the development of new reactor technology was growing. Several advanced LWR and non-LWR designs had progressed to the point that the NRC was accepting for review and comment preliminary design information documents. Although not so formal that it could result in a license, the process was extensive. Five non-LWR designs underwent this type of review, with the NRC issuing draft preliminary safety evaluation reports (SERs) for three of them. These were:

- Sodium Advanced Fast Reactor Liquid Metal Reactor (LMR) (3600 MWt) (NUREG-1369),
- GE-Hitachi PRISM Liquid Metal Reactor (LMR) (350 MWt) (NUREG-1368), and
- Modular High Temperature Gas Reactor (HTGR) (471 MWt) (NUREG-1338).

Each of these preliminary SERs provided developers with valuable feedback on the licensability of a given reactor design—as well as on the need for additional design, analysis, testing, and research before final design documents were considered substantially complete and ready for agency review. Although not binding on the NRC today, these agency reports (NUREGs) continue to serve as important reference points for developers of each of these technologies.

The reviews also identified a number of policy issues important to the licensing of advanced non-LWR reactors, and they proposed courses of action to address several specialized issues that these advanced reactor designs presented.[10] Although more recent pre-application programs—NGNP and NuScale—have succeeded in advancing the discussion, most of the policy issues from that earlier era remain.[11] These include licensing basis event selection criteria, use of mechanistic source terms, functional containment performance, and emergency preparedness. Resolving those issues would assist in reducing the uncertainties that surround the licensing of advanced reactors.



The Xe-100 nuclear reactor, being developed by X-energy, is a modular pebble bed high temperature gas reactor that uses helium coolant. © X-energy, LLC

B. UK Office of Nuclear Regulation and Canadian Nuclear Safety Commission

The NRC in the United States, the United Kingdom Office of Nuclear Regulation (ONR), and the Canadian Nuclear Safety Commission (CNSC)

9 Flanagan, G. F. "Previous Experience 'Licensing/Authorizing' Non-LWRs in the US—How It Was Done and Who Did What" September 2015. *http://pbadupws.nrc.gov/docs/ML1524/ML15245A643.pdf.*

10 SECY-93-092, "Issues Pertaining to the Advanced Reactor (PRISM, MHTGR, and PIUS) and CANDU 3 Designs and their Relationship to Current Regulatory Requirements," guided subsequent activities by providing specific guidance to NRC staff and useful feedback to advanced reactor developers. Today, many of the issues have been highlighted again, driven by continuing industry and DOE interest in advanced reactor development. See generally, PBMR, Toshiba 4S, NGNP, DOE, and generic and specific SMR work advanced by NEI, NuScale, and B&W/Generation mPower. See also SECY-10-034, "Potential Policy, Licensing, and Key Technical Issues for Small Modular Nuclear Reactor Designs."

11 SECY-015-0077: "Options for Emergency Preparedness for Small Modular Reactors and other New Technologies." *http://pbadupws.nrc.gov/docs/ML1503/ML15037A176.pdf.*

have a great deal in common. They share similar missions and principles, for instance. But they also differ in key respects, several of which offer useful examples of alternative ways to regulate nuclear technologies, while maintaining high safety standards. Here, we will highlight differences in (i) pre-licensing design review, (ii) cost control, (iii) prescriptive regulations, and (iv) public participation.

Staged approaches allow the regulator to provide key licensability information to reactor design vendors earlier in the licensing process.

Key points from the UK ONR and the CNSC include:

- ***Pre-licensing design reviews in the UK and Canada are more structured than in the US, and offer useful formal feedback based on earlier-stage design. Although positive findings in the UK's generic design assessment and vendor design review are necessarily provisional (they await further design detail, confirmatory analysis, and a full license application), this early feedback is of significant assistance to developers.***
- ***Canada's vendor design review offers a promising model for an optional NRC "statement of licensing feasibility" that could emerge from structured pre-license application interactions between NRC staff and developers.***
- ***The UK's generic design assessment provides for a staged process that could be instructive in developing a similar approach for the NRC's licensing process.***
- ***The UK will enter into a limitation of liability agreement during pre-licensing review that provides the vendor with certainty about its expenses. The NRC could take similar steps to increase transparency and cost-effectiveness.***
- ***The UK ONR has adopted a goal-setting approach to regulation that is less prescriptive than the NRC's framework. This provides a greater measure of flexibility to potential advanced reactor applicants—for example, by encouraging more innovative engineering techniques. It may be possible for the NRC to develop risk-informed or performance-based regulations for certain key areas integral to the licensing of advanced reactors. The design basis event selection process is one such area that would benefit from this approach.***

1. PRE-LICENSING DESIGN REVIEW

All three regulatory regimes offer formal pre-licensing reviews of reactor designs. The key difference among them, however, is that both the UK and Canadian pre-licensing reviews are structured and staged, whereas the NRC's is not. The Canadian Vendor Design Review (VDR) Program and the UK's Generic Design Assessment (GDA) Program consist of distinct phases or steps. At the end of each one, the regulator issues a public report stating whether the reactor design has met the requirements for that phase or step. If not, the design cannot proceed to the next one. These staged approaches allow the regulator to provide key licensability information to reactor design vendors earlier in the licensing process than is currently possible with the NRC.

In the US, the NRC's policy is to encourage early discussions with potential applicants, such as utilities and reactor designers. This helps to develop the agency's understanding of the technology, and to identify and resolve potential licensing issues. These discussions are conducted prior to the submission of a license application. Typically, the entity seeking to build a new reactor will meet with NRC staff to present technical details of the proposed design, as well as an overall schedule and plan. Then, agency staff will request that the entity provide a list of topical and technical reports on pertinent areas (e.g., quality assurance program description, design overview, and core nuclear design). These help to prepare the staff for the expected application submittal. They also are considered in scheduling staff resources.

Although the pre-license application process can be beneficial to the NRC and to the parties, it does not result in any formal statement from the NRC on the expected licensability of the proposed design.

The step-wise pre-licensing design review processes in Canada and the UK provide earlier opportunities for reactor vendors to demonstrate to their investors and potential investors that the reactor design technology will be licensable. This increases the likelihood of continued and perhaps greater investor funding of advanced reactor designs. A step-wise process will also increase assurances to investors that a reactor project is more likely to be constructed, particularly in light of the lengthy licensing processes developers face in all three nations.

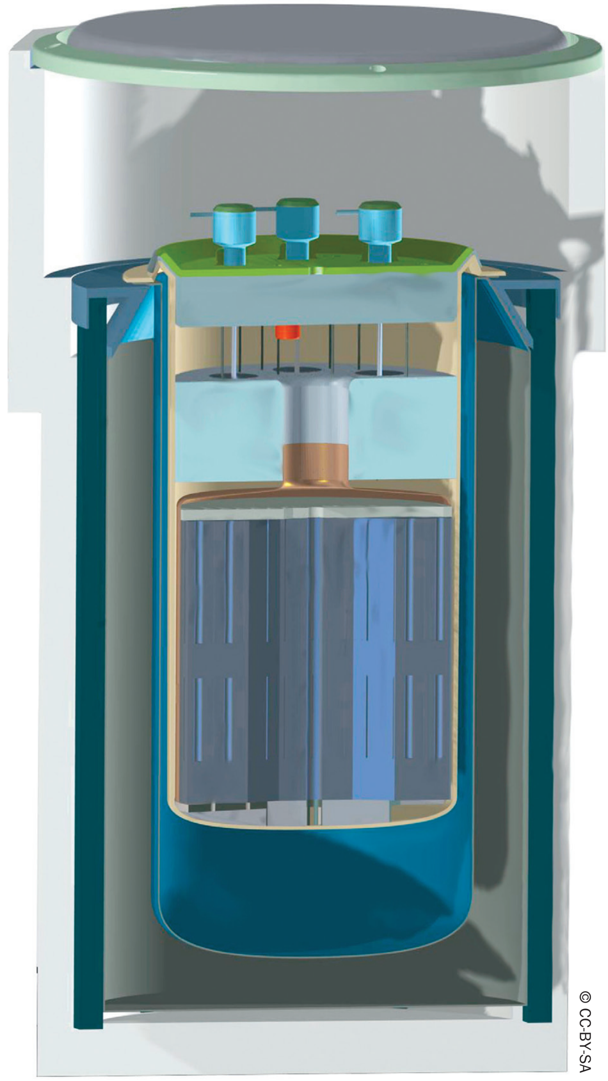
a. CNSC Vendor Design Review

CNSC offers reactor vendors the opportunity to participate in a pre-licensing vendor design review (VDR). The process is optional. Section 21(1)(a) of Canada's Nuclear Safety and Control Act (NSCA) gives CNSC the authority to "enter into arrangements, including an arrangement to provide training, with any person, any department or agency of the Government of Canada or of a province, any regulatory agency or department of a foreign government or any international agency" in order to achieve its objectives. Under this authority, at the request of a reactor design vendor and with a signed service agreement identifying a fixed scope of work, the CNSC will undertake a pre-licensing review of a vendor's reactor design. This process is described in CNSC guidance document GD-385, Pre-licensing Review of a Vendor's Reactor Design (May 2012).[12]

As an option, but not a licensing prerequisite, VDR serves as a tool to mitigate risk. Its primary purpose is to apprise the vendor of the overall acceptability of the reactor design. This standardized process evaluates whether fundamental barriers could prevent licensing of the design in Canada. It is available when the vendor's conceptual design is essentially complete and the basic engineering program has begun. VDR protects proprietary information, while providing data to the public through an executive summary.

This review allows for early identification and resolution of potential regulatory or technical issues arising in the design process, particularly issues that could result in significant changes to the design or safety case. Because it enables vendors and utilities to communicate, identify, and address regulatory issues sufficiently early to minimize delays in licensing and facility construction, a VDR produces license applications of higher quality. It also facilitates vendor-initiated discussions with potential licensees interested in the vendor's technology and with potential investors seeking greater assurance that the technology works. If a VDR finds that the design is not viable, this early determination saves the parties from needless development and licensing expense.

A VDR can begin once a vendor has made reasonable progress in preliminary design engineering. This means that the basic architecture of important safety systems conforms to the vendor's reactor design guides and requirements. At this time, the following should be nearing completion:



Terrestrial Energy has announced that it is submitting its Integral Molten Salt Reactor (IMSR) design to the CNSC for Phase I of its Vendor Design Review.

- Design guides that describe design philosophies, safety philosophies, and rules that designers must follow when performing their work, including safety requirements (e.g., applicable codes and standards);
- Design requirements for important safety systems that establish, among other things, minimum performance requirements and reliability targets;
- The vendor's overall management system as it applies to the design of the proposed plant's (or small reactor's) structures, systems, and components; and

12 "Pre-licensing Review of a Vendor's Reactor Design" (GD-385). CNSC. May 2012. *http://nuclearsafety.gc.ca/pubs_catalogue/uploads/May-2012-GD-385-Pre-licensing-Review-of-a-Vendors-Reactor-Design_e.pdf*

© TerraPower, LLC

TerraPower explores the features and performance characteristics of the fuel and fuel assemblies for their sodium-cooled reactor in their Bellevue, WA based laboratory.

- Design and safety analysis that approaches the level of information needed for a preliminary safety analysis report.

The outcome of the VDR process is not a detailed review nor does it involve certification of the entire design. Rather, it consists of a broad sample of key topics related to safety. The CNSC performs far more detailed design scrutiny when it reviews the license application for a specific site. Nevertheless, VDR results can inform licensing activities. Assuming that the vendor shares results with the interested utility, the latter can shape its own licensing submissions by drawing on information obtained from the VDR process.

The VDR pre-licensing process is accomplished in three phases of increasing levels of review, as follows.

Phase 1–Compliance with Regulatory Requirements. Requiring approximately 5,000 hours of CNSC staff time over the course of a year, this phase addresses whether the vendor design intent demonstrates an understanding of Canadian requirements. Nineteen focus areas can be examined, and the applicant chooses which focus areas to submit for review. A vendor can initiate a Phase 1 review once the conceptual design is complete, and the preliminary engineering program is either at an advanced stage or has been completed.

CNSC will provide the vendor with a Phase 1 summary report containing findings for each review focus area and the bases for those findings. For all focus areas successfully completing the review process, CNSC issues the following statement:

> Canadian Nuclear Safety Commission staff has completed a Phase 1 pre-licensing review of a vendor's reactor design for the [vendor/reactor design]. In the following key areas, CNSC staff has determined that the design intent is compliant with the CNSC regulatory requirements and meets the expectations for new nuclear power plant [small reactor] designs in Canada: [list of review focus areas].

CNSC will also identify any focus area in which the vendor must complete additional work in order to demonstrate its intent to meet applicable requirements.

CNSC treats the Phase 1 report as commercially sensitive information and thus does not disclose it to the public. However, CNSC also posts an executive summary on its public web site, communicating, in general terms, the results of the review.

Phase 2–Pre-licensing Assessment. This phase requires approximately 10,000 hours of CNSC staff time and takes roughly eighteen months to two years to perform. A vendor can initiate a Phase 2 review once the design's preliminary engineering program is either well under way or complete. Phase 2 follows up on issues identified in Phase 1, while assessing the design for fundamental barriers to licensing. In other words, Phase 2 examines whether the vendor is addressing Canadian design and safety analysis requirements for specific design aspects. The Phase 2 review also uses the 19 review focus areas, but it requires more detailed information for each focus area so staff can assess whether the reactor design and supporting analyses meet Phase 2 objectives. The results of a Phase 2 review assist the vendor's development of a preliminary safety analysis report, which in turn provides support for a site-specific construction license application.

CNSC will prepare a Phase 2 summary similar to the Phase 1 summary, with findings for each review focus area and the bases for those findings. CNSC issues the following statement for all compliant focus areas:

> Canadian Nuclear Safety Commission staff has completed a Phase 2 pre-licensing review of a vendor's reactor design for [vendor/reactor design]. This review provides a further level of assurance that [vendor] has taken into account regulatory requirements and expectations. Based on the Phase 2 review, CNSC staff concludes that there are no fundamental barriers to licensing the [design] design in Canada.

CNSC will also issue a statement identifying any focus area in which the vendor must complete additional work in order to demonstrate its intent to meet applicable requirements:

> This statement is subject to the successful completion of [vendor/reactor]'s planned activities, in particular those related to: [list of review focus areas].

As with the Phase 1 report, CNSC does not disclose to the public the contents of the Phase 2 report, but does post a non-confidential executive summary on its web site.

Phase 3–Pre-construction Follow-Up. Once Phases 1 and 2 are complete, and its detailed engineering program for non-site-specific design is underway, the vendor may initiate the Phase 3 process. This generally begins once the vendor is supporting an entity (e.g., a utility) that is preparing an application for a construction license. Phase 3 allows the vendor to follow up directly with CNSC in greater detail on one or more areas covered in Phase 1 or 2. The Phase 3 goal is to obtain thorough review of selected topics to avoid detailed CNSC reassessment of those areas during construction license review.

CNSC will deliver to the vendor a Phase 3 summary report at the end of the Phase 3 review period. The report will contain either a summary of the discussions or any additional findings for each focus area, along with the bases for those findings. As with the first two phases, the Phase 3 report is treated as commercially sensitive, but, again, CSNC posts a non-confidential executive summary on its web site.

The GDA process is intended to give the operator of a new nuclear plant a clear signal through a staged process.

b. UK Generic Design Acceptance

Under the licensing regime in the United Kingdom, it is anticipated that new nuclear power plant projects will be based on a design acceptance confirmation (DAC) obtained through the UK's generic design assessment (GDA) process. There, the Office of Nuclear Regulation (ONR) assesses the safety case for the generic design of a specific reactor. The GDA process is intended to give the operator of a new nuclear plant a clear signal—through a staged process—of whether the new reactor design would, in principle, meet regulatory requirements if a license were sought based on that design. Because of the advantages afforded to both reactor vendors and new reactor developers, ONR believes that new nuclear power stations in the UK will be based on a reactor design that has undergone a GDA. A GDA does not replace the site-specific licensing process, but it is expected to make a significant contribution to ONR's assessment of the license applicant's safety case.

As with most government agencies, ONR has limited resources. Obtaining a spot in the ONR review queue can be challenging for reactor developers, contributing to the uncertainty of cost and schedule.

The GDA process is carried out in four steps, with the assessment becoming more detailed with each step. ONR publishes an update at the end of each step, highlighting any concerns or technical issues that have been raised. In addition, the Environment Agency conducts both preliminary and detailed assessments, followed by a consultation. The GDA process is intended to offer a number of advantages over the existing approach, including (i) early involvement with reactor designers so that design changes can be addressed prior to construction; (ii) a staged process that allows ONR to identify key design issues early on, thus reducing a developer's financial and regulatory exposure; (iii) the separation of design issues from site issues; (iv) a level of transparency that allows the public to view detailed design information on a website and submit comments; and (v) regular feedback on how the agency's assessments are progressing.

After the reactor vendor has prepared the design, safety case, and security submissions (Step 1), the next three steps in the GDA process, ONR estimates, collectively take about 48 months. The breakdown is as follows: approximately 6–8 months for fundamental design, safety case, and security claims overview (Step 2); an additional 12 months for overall design, safety case, and security arguments review (Step 3); and an additional 28 months for the detailed design, safety case, and security evidence assessment (Step 4). After ONR has completed its assessments, additional steps may be required if one or more issues remain unresolved.

If ONR is satisfied with the submissions, it will publicly disclose after each step any fundamental safety or security concerns that might thwart the issuance of a DAC, or that might prevent the design from proceeding to the next step. For a recent example of a smoothly advancing process, which involved ONR review of Hitachi-GE's UK advanced boiling water reactor (ABWR) design, the agency issued the following announcement at the completion of Step 3: "ONR has concluded that sufficient progress has been made by Hitachi-GE to move into the final assessment stage, which Hitachi-GE expects to be complete in December 2017."[13]

The GDA process leads to generic (i.e., not site-specific) Pre-Construction Safety and Security Reports. After Step 4, it results in one of three potential outcomes: provision of a DAC, provision of an interim DAC identifying outstanding generic design acceptance issues, or provision of no DAC. A DAC issued by ONR is effective for a period of up to 10 years, absent significant new information undermining its issuance. A DAC implies that ONR is confident that the generic design is capable of being built and operated in a safe and secure manner on a site bounded by the generic site envelope. It follows that ONR gives weight to the DAC when assessing the adequacy of an applicant's request to construct and operate a nuclear reactor on a specific site. (Naturally, the reactor proposal itself would be subject to more specific assessment, as well as licensing.)

ONR will authorize an interim DAC if it is generally satisfied with the generic safety and security aspects of the submissions, even if certain issues remain. When additional information submissions are filed to resolve those issues, ONR will approve a full DAC. On the other hand, if ONR finds a significant, unacceptable shortfall in the design, safety, or security of the submissions it received, it will deny the DAC request and explain why it did so.

2. COST LIMITATION AGREEMENTS FOR PRE-LICENSING REVIEW ACTIVITIES

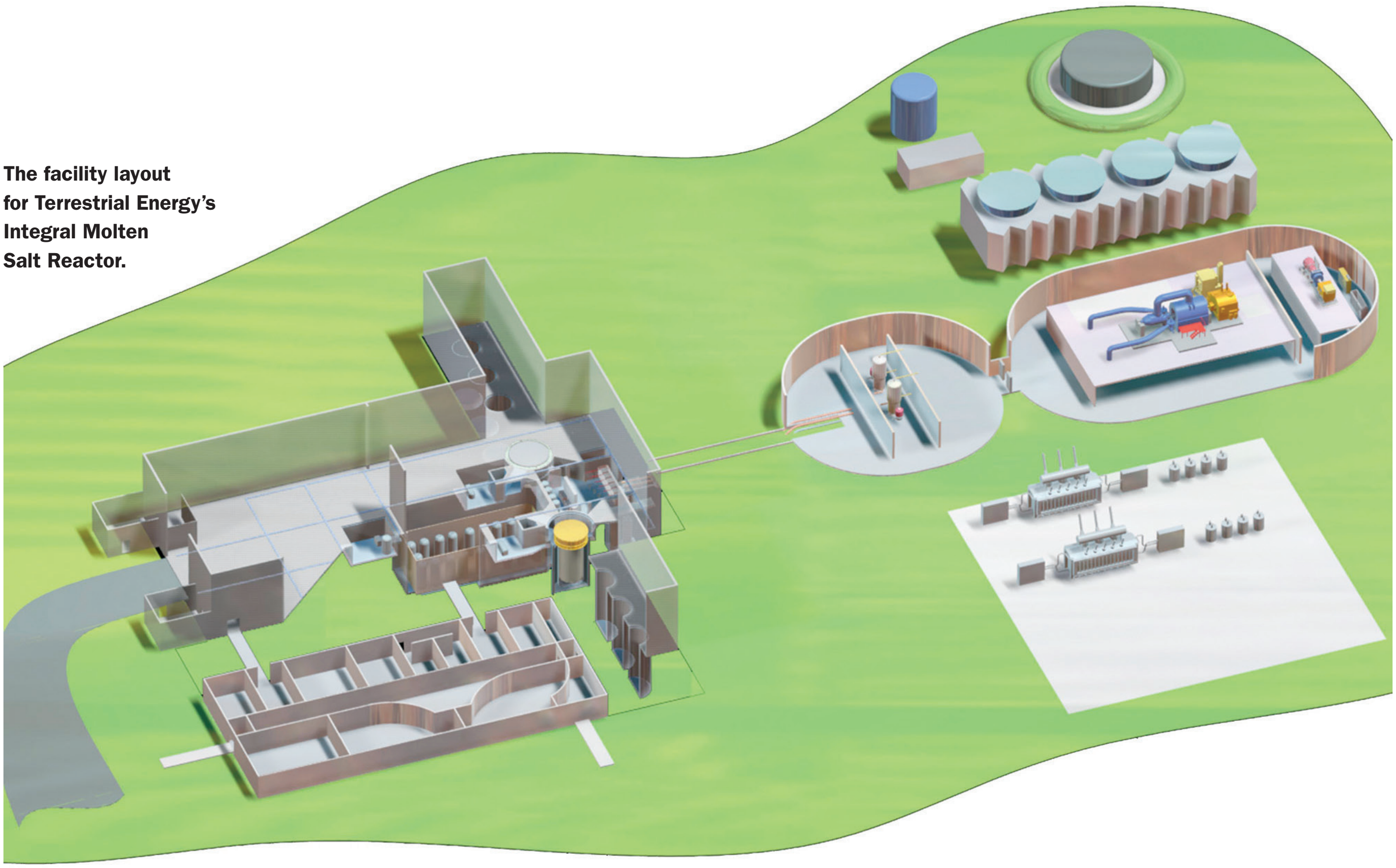
The UK's ONR will also enter into limitation of liability agreements with a reactor vendor or potential license applicant setting a ceiling on costs ONR can incur—and be reimbursed by the private party—for pre-license application review activities. It is typical for a reactor vendor or potential applicant to engage the UK regulator in pre-licensing discussions and information sharing aimed at identifying potential licensing issues early in the process. A cost limitation agreement provides the vendor or license applicant with certainty that pre-license application discussions will not exceed a specified cost. In the US, the NRC could take similar steps to increase the transparency and cost-effectiveness of its proceedings.

3. MORE FLEXIBLE REGULATION

NRC and CNSC reactor licensing regulations are far more prescriptive than the ONR's performance-based regulations. In the UK, the ONR sets objectives, and then license applicants must demonstrate that they meet them. The ONR prefers this strategy because it can achieve the required high levels of nuclear safety while allowing an operator greater access to innovation and to approaches better

13 "UK ABWR progresses to final stage of assessment." UK ONR. October 30, 2015. *http://news.onr.org.uk/2015/10/uk-abwr-progresses-to-final-stage-of-assessment*

The facility layout for Terrestrial Energy's Integral Molten Salt Reactor.



tailored to the operator's circumstances. It also encourages the adoption of sound practices and continuous improvement.

In the UK, the ONR trades more certain licensing guidelines for increased regulatory flexibility. With respect to design-basis accidents, for example, ONR does not follow the US practice of using as license criteria fault sequences and analytical assumptions that are defined by the agency. Rather, ONR sets more general regulatory expectations and then requires licensees to determine—and justify—how best to achieve them. This approach facilitates the use of probabilistic methods to identify key accident sequences and to ensure that the safety case is complete. That, in turn, creates room for innovative engineering approaches that may not be contemplated (or allowed) by a more deterministic set of limiting accidents. In short, an objective-setting approach provides a greater measure of flexibility to potential advanced reactor applicants. Although it is unlikely that the NRC would replace all of its prescriptive regulations with performance-based ones, it may be possible to introduce the latter approach in certain areas integral to the licensing of advanced reactors—especially non-light water technologies. The design basis event selection process is one key area that would benefit from this.

An objective-setting approach provides a greater measure of flexibility to potential advanced reactor applicants.

4. PUBLIC PARTICIPATION

All three regulatory regimes provide the public with multiple opportunities to participate in and provide input into the reactor licensing processes. The US licensing system provides public participation opportunities that are considerably more formal than those of the UK and Canada. In the United States, members of the public, state and local governments, and non-governmental organizations can become formal parties in nuclear licensing hearings and fully participate in the adjudicatory process. The level and extent of public participation in the US is often considered a major source of delay in the licensing process.

The UK licensing process provides no similar opportunity. Although the Canadian licensing process allows the public to participate in CNSC hearings, these hearings are more legislative than adjudicatory in nature, which means that they provide an opportunity for the public to submit evidence and testimony, but do not take a formal "trial-like" approach to contested issues.

All three licensing processes provide a variety of options for public involvement and public input in nuclear reactor licensing decisions. The sharpest distinction among them is the extent to which the public can directly challenge a proposal by becoming a full-fledged party to a formal adjudicatory proceeding. To participate in an NRC adjudication, members of the public, adverse state and local governments, and anti-nuclear interests must demonstrate that the construction or operation of the proposed reactor may adversely affect their interests. Upon such a showing, these individuals or entities may intervene, with the objective of demonstrating to the administrative law judges overseeing the proceeding that the reactor should not be licensed or, alternatively, that the application should be amended to address the concerns raised. Such interveners are empowered to submit their own evidence, cross-examine witnesses, and take other formal steps. In the UK and Canada, members of the public, local governments, and other interest groups also have the opportunity to express their opposition to the licensing of a nuclear plant, but not to the extent permitted in the US.

C. Federal Aviation Administration

A number of observations can be made about the Federal Aviation Administration's (FAA's) regulatory process, though it is important to note that the FAA, like the NRC, is not perfect and should not be held up as an ideal in every respect. The lessons presented here are drawn from areas where the FAA excels.

Key points from the FAA include:

- ***The FAA has established the values of safety, excellence, integrity, people, and innovation at the center of its regulatory work. The NRC's "Principles of Good Regulation" include independence, openness, efficiency, clarity, and reliability. The NRC could consider adding innovation to its core values and making it a key element of continual improvement.***
- ***The first step in the FAA regulatory process is to define the working relationship between the FAA and the applicant. This provides a foundation for effective communication and rapid resolution of conflicts. The nuclear regulatory process would benefit from a similar first step.***
- ***The FAA's project-specific certification plan (PSCP) is a possible model for our proposed licensing project plan (LPP). An LPP would help to establish a collaborative roadmap for licensing a given project with agreed upon milestones and deliverables.***
- ***Although the FAA has embraced some risk-informed regulation, its experience suggests that a level of prescriptive regulation will remain. This is likely to be the case in the nuclear energy sphere as well. It is important for both the NRC and industry to recognize that the transition to more risk-informed or performance-based regulation does not have to—and probably cannot—exclude all prescriptive aspects (nor will this transition happen overnight).***
- ***Standards development organizations are considered useful partners in the effort to develop new regulations, as they bring additional resources and expertise to bear.***

1. FAA REGULATORY PROCESS

The Federal Aviation Administration (FAA) exists to "provide the safest, most efficient aerospace system in the world" by striving to "reach the next level of safety, efficiency, environmental responsibility and global leadership."[14] The FAA has a dual mission that involves both regulating and promoting air travel. This is important to keep in mind when comparing the NRC and the FAA, because the NRC's role is not to promote nuclear energy, but rather to ensure that its use does not compromise public health and safety, or the common defense and security—in other words, to regulate it. DOE is charged with nuclear technology research, development, and promotion. This separation was established by the Energy Reorganization Act of 1974 and is considered essential to maintaining an independent regulator. To ensure the safety of planes flown in US airspace, the FAA employs approximately 7,000 people in aviation safety and has an annual budget of slightly more than $15 billion.[15] At the center of the FAA's regulatory work are the values of safety, excellence, integrity, people, and

14 *https://www.faa.gov/about/mission*

15 FAA Budget Estimate, FY2015. *https://www.transportation.gov/sites/dot.gov/files/docs/FAA-FY2015-Budget-Estimates.pdf*

innovation. The NRC should consider adding innovation to its core values, because it is a key element of continual improvement and connection to future nuclear technology developments. This is not to suggest that the NRC should promote technology innovation, but rather that it should strive to incorporate into its regulatory function innovation that enhances its effectiveness and efficiency.

a. The FAA Phased Process

The FAA's five-phase regulatory process is highly prescriptive, although it often bases its rules on industry standards.[16] Approval comes in the form of a type certification. A useful overview of the process can be found in *The FAA and Industry Guide to Product Certification, Second Edition* (CPI Guide).[17] As the NRC makes changes in the advanced nuclear reactor licensing process, it would serve both the agency and industry to develop a similar document, particularly one that outlines consensus guidelines for an effective and efficient regulatory process. The first part of the FAA's certification process requires the FAA and the applicant to agree upon a "Partnership for Safety Plan" (PSP).[18] Subsequent interactions are broken down into five phases:

i. Conceptual design,
ii. Requirements definition,
iii Compliance planning,
iv. Implementation, and
v. Post certification.

Certification is structured around the building blocks of the PSP, the project specific certification plan (PSCP), and phase evaluation checklists, each of which is further described below.

b. FAA Partnership for Safety Plan

The PSP is an umbrella agreement between the FAA and the applicant. The following excerpt from the CPI Guide describes the purpose and vision of the PSP:

> The purpose of this Partnership for Safety Plan (PSP) is to define a working relationship between the Aircraft Certification Service of the Federal Aviation Administration (FAA) and Applicant. It provides the foundation from which to build mutual trust, leadership, teamwork, and efficient business practices. This Plan enables the FAA, Applicant, and their staffs to expedite certification projects by focusing on safety significant issues. It is the mutual goal of the FAA and Applicant to meet or exceed the expectations of this agreement to achieve the following vision:
>
> **Vision of the Product Certification Process**
>
> A credible and concise product certification process that results in:
>
> - *Timely and efficient product type design and production approvals*
> - *Clearly defined and understood roles, responsibilities, and accountability of all stakeholders*
> - *Timely identification and resolution of the certification basis, potential safety issues, and business practice requirements*
> - *Optimal delegation using safety management concepts with appropriate controls and oversight*
>
> In the establishment of this PSP, it is understood that a cooperative working relationship is required for this process to be effective. To achieve this Vision, it is understood that the Applicant and FAA team members will work in accordance with the guidelines contained in this PSP.[19]

FIGURE III-1
The FAA's Five-phase Regulatory Process

1	2	3	4	5
Conceptual Design Phase	Requirements Definition Phase	Compliance Planning Phase	Implementation Phase	Post Certification Phase

16 T. Murphy in correspondence with K. Shield. 2015.

17 The FAA and Industry Guide to Product Certification Second Edition *http://www.faa.gov/aircraft/air_cert/design_approvals/media/CPI_guide_II.pdf.*

18 Ibid.

19 Ibid

The PSP contains guidelines for:

- Corporate planning,
- Communication and coordination,
- Delegation,
- Production quality system evaluation,
- Issues resolution process, and
- Performance measures.

The PSP is a tool for ensuring effective communication, clear protocols, rapid assessment of issues, and resolution of disagreements. A similar tool in the nuclear regulatory process could help to improve resource planning and effectiveness, while reducing delays and ill will caused by miscommunication, lack of communication, and uncertain responsibility. This could be the first section of the licensing project plan (LPP) that we propose.

c. FAA Project-Specific Certification Plan

The PSPC defines and documents a product certification plan between the FAA and the applicant. It is a living document, to which changes are made if the FAA and applicant agree they are needed. It is intended to be developed as soon as a project is considered viable and resources are committed to certification. It includes the following sections:

Purpose
Effectivity
Product certification

1. Project description
2. Project schedule
3. Certification basis
4. Means of compliance
5. Communication and coordination
6. Delegation
7. Testing plan (a.) General (b.) Flight test (c.) Conformity
8. Compliance documentation

Production certification
Post certification requirements
Project issues planning
Continuous improvement
Signatories

The PSPC is a useful model for the licensing project plan that we propose in Section IV.A.

2. FAA USE OF RISK-INFORMED AND PERFORMANCE-BASED REGULATION

Recent efforts by the aviation industry and the FAA to make regulation less prescriptive have resulted in incremental changes, but not a complete transition to a risk-informed model. Officials in the FAA's rulemaking office told the GAO that about 20% of the agency's regulations are performance-based.[20] The FAA seems to struggle with challenges relating to risk-informed and performance-based licensing in ways similar to those faced by the NRC.

The FAA conducted a review of its Part 23: Small Airplanes regulations in 2009 and found that the regulations have

> continually become more prescriptive in reacting to specific design features of the day. The result of the combination of all of these specific rules is the loss of the original intent of airworthiness design regulations and a lack of flexibility to quickly address today's airplanes.[21]

In 2013, a similar report by the Part 23 Reorganization Aviation Rulemaking Committee described these regulations as "prescriptive in nature, written to address out-of-date technologies and structured based upon broad assumptions, including airplane weight and propulsion type, which are becoming less accurate and more constraining as time progresses." The report expresses concern that numerous load requirements and materials regulations are overly prescriptive.[22]

The FAA experience may be taken as a note of caution to those working to reduce the prescriptive nature of NRC regulations: not all risk/reward formulae allow for risk-informed and performance-based regulation; thus, some level of prescriptive regulation is likely to remain. For new technologies, however, the FAA works closely with industry to determine how regulations need to be written or changed to incorporate innovation. Industry standards often evolve more quickly than agency regulations;

20 Government Accountability Office. Aviation Safety: Certification and Approval Processes Are Generally Viewed as Working Well, but Better Evaluative Information Needed to Improve Efficiency. GAO-11-14. October 2010.

21 Federal Aviation Administration. Part 23—Small Airplane Certification Process Study: Recommendations for General Aviation For the Next 20 Years. 2009 page 16 *https://www.faa.gov/about/office_org/headquarters_offices/avs/offices/air/directorates_field/small_airplanes/media/CPS_Part_23.pdf*

22 14 CFR Part 23 Reorganization Aviation Rulemaking Committee. Recommendations for increasing the safety of small general aviation airplanes certificated to 14 CFR part 23. 2013. p. iii *https://www.faa.gov/about/office_org/headquarters_offices/avs/offices/air/directorates_field/small_airplanes/media/P23_Reorg_ARCFINAL.pdf.*

by adopting these standards as regulations, the FAA allows industry to identify economical changes, while ensuring that they meet baseline safety goals. A similar approach in the nuclear industry would encourage standards-setting associations to play a more active role in the development of advanced nuclear technology requirements. It also could allow the NRC to more quickly adopt less prescriptive requirements while maintaining strong public health and safety standards. It may be worthwhile for the NRC to consult with the FAA to learn about the challenges the FAA has faced and successes it has achieved in increasing its use of risk-informed and performance-based regulation.

D. Food and Drug Administration

Not all aspects of the FDA regulation and approval process can or should be transferred to the NRC. There are significant differences between the two regulatory bodies, and between the types of products and activities they regulate. Similarities also exist, however, and these suggest that the FDA's experience can help to guide the NRC.

Key points from the FDA include:

- ***The FDA's staged approval process has proved to be compatible with innovation and with large high-risk investments. The stages provide transparency that helps all parties judge the likelihood that a product under development will be successfully approved. This lends support to the hypothesis that a staged process would enable greater investment and innovation in advanced nuclear energy.***
- ***A large set of different approval pathways can be confusing and counterproductive. It may be most effective to work to improve existing pathways, while developing entirely novel pathways only when a clear need exists and significant advantage is to be gained.***
- ***Given the many ways in which advanced reactors differ from traditional LWRs, the NRC should consider dedicating a special team to exploring the potential benefit of developing innovative licensing strategies for such reactors.***
- ***The FDA's budget is provided through fees (50%) and federal outlays (50%). At the NRC, the share of the budget furnished by fees—90%—is much higher. Providing timely cost sharing or grants from DOE to cover early interactions may help projects get off the ground in their initial stages. Beyond that, reducing the portion of the NRC budget that is covered by industry fees may enable the agency to focus more effort on important, forward-looking work that is of less immediate benefit to ratepayers, but paves the way for future evaluation of advanced nuclear technologies.***

The FDA underwent a significant effort in the 1960s and 1970s to increase its expertise in biologics; after that, the approval process for biologics became more efficient. The NRC may need to make a similar effort, increasing its expertise in advanced reactors in order to facilitate the advanced reactor licensing process.

1. FDA MISSION AND STRUCTURE

Like the FAA, the US Food and Drug Administration (FDA) has a dual-focus mission: to protect "the public health by assuring the safety, efficacy, and security of human and veterinary drugs, … [and to advance] public health by helping to speed innovations that make medicines more effective, safer, and more affordable."[23] Fundamentally, the FDA aims to prevent dangerous drugs from entering the marketplace, while it simultaneously promotes medical advances. As explained in Section IV.C, above, this is fundamentally different from the NRC's role, which is to regulate but not to promote. Comparisons should be drawn with an awareness of this distinction.

The FDA's size has been steadily increasing; in FY2015, the agency had 16,700 full-time equivalent employees and a budget of approximately $4.5 billion.[24] There are multiple offices within the FDA, but three are significant here because they evaluate product approvals. The Center for Drug Evaluation and Research (CDER), the largest of the FDA centers, approves chemically derived products, as well as some biologically derived therapeutic products. The Center for Biologics Evaluation and Research (CBER) regulates other biologics for human use, including blood-based, vaccine, tissue, and gene therapy products, as well as a small number of devices. Most devices, however, are regulated

23 FDA 2016. *http://www.fda.gov/AboutFDA/WhatWeDo*

24 HHS. (2015); FDA, "Executive Summary All Purpose Table," (2015).

by the Center for Devices and Radiological Health (CDRH), which approves medical devices and products that emit radiation.[25]

Unlike the FDA's Centers, the NRC evaluates reactors within two departments—the Office of Nuclear Reactor Regulation and the Office of New Reactors—without differentiating on the basis of reactor structure or type. Given the many ways in which advanced reactors differ from traditional LWRs and the potential benefits of developing innovative licensing strategies for them, the NRC may find it useful to dedicate a special team to this effort. It may also be useful to direct a team to develop a strategy for implementing a risk-informed, performance-based framework for advanced reactors. Recognizing that NRC staff size is decreasing as the number of licensees declines, Congress may need to be asked to budget funds for these teams, rather than relying on NRC fees.

The FDA's drug approval process incorporates discrete stages that have proved compatible with the development process and the investment needed to support it.

Of the FDA's budget, approximately half consists of federal outlays and half is derived from fees.[26] In contrast, as noted, 90% of the NRC's budget is fee based, with only 10% from outlays. Although in both cases industry shoulders a large share of the budget, the percentage at the NRC is especially high. Providing cost sharing or grants to cover early interactions with the NRC may help projects in their initial stages get off the ground. Beyond that, decreasing the part of the NRC's budget derived from fees may enable the agency to focus more effort on important, forward-looking work that is of less immediate benefit to ratepayers, but paves the way for future evaluation of advanced nuclear technologies.

2. DRUG APPROVAL PROCESS

The FDA approval process varies greatly, depending on the type of drug, the existence of similar drugs already in the marketplace, and the illness itself. The "normal" drug application process for new products requires two different applications: an investigational new drug (IND) application, followed by a new drug application (NDA) for drugs and biologics submitted to CDER, or a biologics license application (BLA) for those submitted to CBER. An IND application is usually filed following laboratory tests (in vitro and animal in vivo) that demonstrate a drug's probable safety for humans, and is required before clinical trials begin.[27] Clinical trials are conducted in three phases, and their design must be outlined in the IND. Upon completion of the clinical trials, the data are submitted in the form of an NDA or BLA. On average, the FDA approves drugs in two years, though approval can take up to seven years. Total development time—including R&D, clinical trials, and FDA approval—ranges from 8 to 15 years. Expedited pathways, which reduce FDA review time to one year, also exist (there are four of them). The FDA approves dozens of novel drugs and hundreds of slightly altered drug delivery processes (e.g., dosages and disease applications) annually.

As is true of nuclear power plants, the process of developing and commercializing a new drug is highly capital intensive. The FDA's drug approval process incorporates discrete stages that have proved compatible with the development process and the investment needed to support it. Table III-1 shows typical investment requirements for each stage of the approval process.

The FDA has created a multitude of pathways through which products may be approved; while each of these provides a more convenient route for a specific subset of products, variety can cause problems. For example, confusion regarding which types of biologics are regulated by which center—and the fact that different centers apply different regulations for similar or even identical products—can unnecessarily complicate the approval process. Although it is sometimes advantageous to recommend new approval pathways that are cheaper or faster, it also is important to realize that having a multitude of pathways can increase confusion around approval of emerging technological advances. This should instill caution in NRC staff and stake-

25 FDA. *How Drugs are Developed and Approved.* August 18, 2015. *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/default.htm*

26 HHS, FY2016 Budget in Brief. 14 (2015).

27 FDA. *Drug Study Progression.* CDER World. *http://www.accessdata.fda.gov/scripts/cderworld/index.cfm?action=newdrugs:main&unit=2&lesson=1&topic=6.*

holders working to develop new licensing pathways. It may be most effective to focus on improving existing pathways, while developing entirely new ones only when a clear need exists.

3. DEVELOPMENT AND REGULATION OF NEW TECHNOLOGIES

In representing related but significantly different products that require new specialization within the regulatory agency, advanced reactor technologies in many ways mirror the emergence of biologics at the FDA. From the mid-1960s to the late 1970s, the number of FDA employees technically capable of analyzing biologics research rapidly increased; this was followed by improvements in the efficiency of the approval process itself. Similarly, increasing the number of NRC employees with engineering backgrounds relevant to advanced reactor technologies may prompt the agency to work more closely, competently, and confidently with its counterparts in the private sector.

FIGURE III-2

Phases in the Drug Development and Approval Process

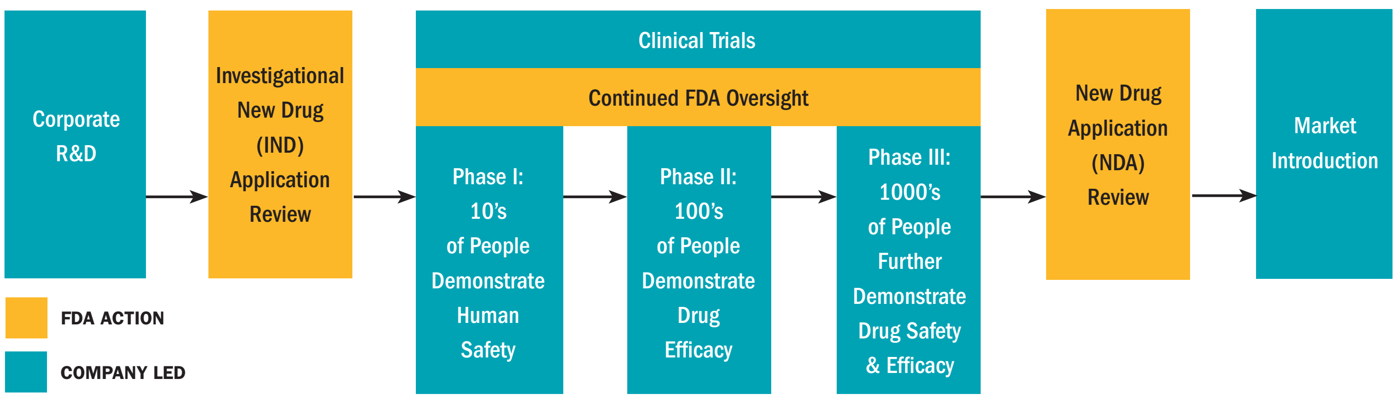


TABLE III-1

Drug Approval Stages and Investments[28]

Stage	Elapsed Time (years)	Capital Required (millions)	Purpose and Objective	Market Value (millions)	Historical Success (probability)
Pre-clinical	1 to 5	\$10 to \$50	Pre-human validation	\$10 to \$20	10%
Phase I	1–2	\$5 to \$20	Safety	\$10 to \$50	65%
Phase II	2–3	\$20 to \$50	Efficacy and dose	\$50 to \$100	50%
Phase III	3	\$40 to \$100	Registration Trial	\$200 to \$400	65%
New Drug Application	1	\$20 to \$50	Manufacturing Approval by FDA	\$500 to \$1000	90%

28 Rothrock, Ray. Testimony before Blue Ribbon Commission on America's Nuclear Future, Subcommittee on Reactor and Fuel Cycle Technology. August 30, 2010.

CHAPTER IV

MECHANISMS FOR STAGING ADVANCED REACTOR LICENSING

A CENTRAL RECOMMENDATION OF this report is that topical reports and the standard design approval should be used as tools to introduce more progressive stages into the advanced reactor licensing process. To provide the foundation for effective project management and to structure the licensing and pre-licensing stages, we propose that a licensing project plan (LPP) be introduced. Since the primary purpose is to achieve a rapid evolution that provides greater certainty, delivers early concrete feedback, and complements the overall development and deployment schedule discussed in Chapter II, it is important to work within the existing regulatory framework if at all possible. This chapter first proposes and describes the licensing project plan; discusses the legal context for the use of topical reports, and explains what they are; and then sets forth a proposal to create a staged system to apply these tools. Next, the potential use of the standard design approval (SDA) is considered, along with a proposal for integrating it into a staged licensing process. Finally, the development of a statement of licensing feasibility is discussed, with a side note on the finality of staged licensing decisions.

A licensing project plan will improve communications, efficiency, and project execution.

A. Developing a Licensing Project Plan

Commission Chairman Stephen G. Burns has made the point on several occasions that effective communication is important—that the NRC's independence does not require total isolation.[29] We recommend the development of a licensing project plan (LPP) that will improve communications, efficiency, and project execution. The LPP should set out communication protocols and lay out a detailed roadmap for a licensing project—including a schedule, milestones, defined deliverables, and NRC review budgets. It should be a living document, to be updated with progressively more detailed and precise plans as upcoming activities become clear.

To establish open and effective lines of communication between the regulator and the applicant, we recommend that, at the outset, the NRC adopt the FAA's practice of establishing guidelines for the working relationship between the regulator and the applicant.[30] The FAA's mechanism for this is the partnership for safety plan (PSP). More details on the FAA's PSP are contained in Section III.C and in *The FAA and Industry Guide to Product Certification, Second Edition*.[31] We recommend that the NRC implement this recommendation in the first chapter of the licensing project plan.

The FAA's PSP is intended to define the working relationship between the regulator and the applicant, including communication protocols, roles, responsibilities, accountability, and other

29 *http://www.nrc.gov/reading-rm/doc-collections/commission/speeches/2015/s-15-008.pdf.*

30 The precise time for developing the LPP is something that the NRC and industry should further discuss, but it should be early in the pre-application phase.

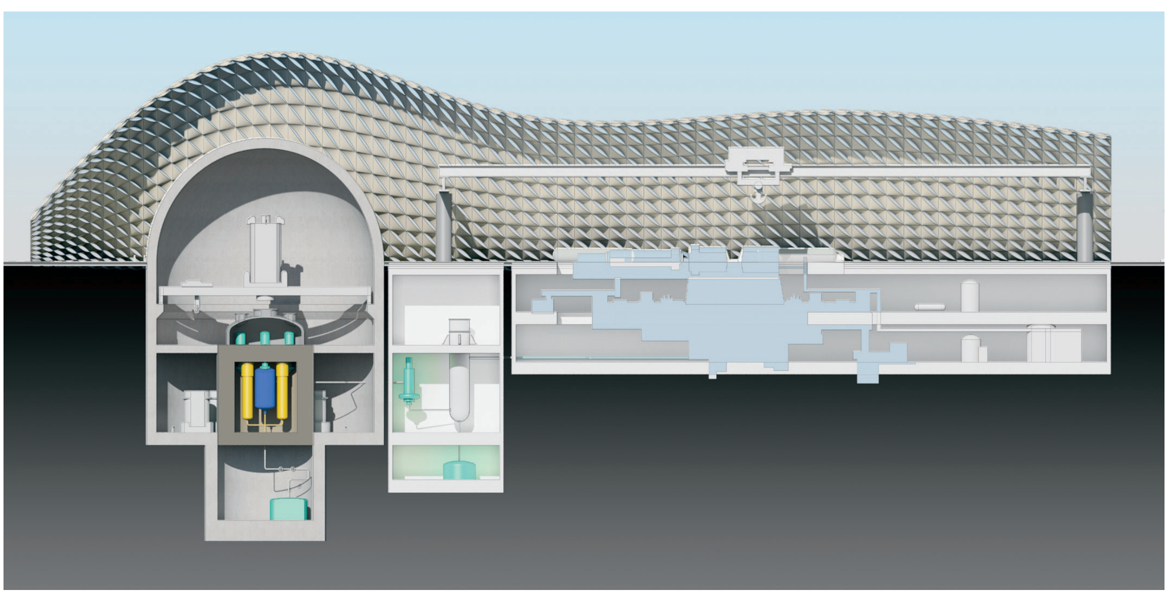
31 *http://www.faa.gov/aircraft/air_cert/design_approvals/media/CPI_guide_II.pdf.*

important aspects of their interaction. The goal of that document is to provide the "foundation from which to build mutual trust, leadership, teamwork, and efficient business practices." A similar agreement in the LPP would enable the NRC and the applicant to develop a cooperative working relationship, supportive of a more efficient and harmonious regulatory process. But even with best efforts and intentions, conflicts occur. In the past, many opportunities to take swift corrective action have been missed because communication channels were impaired; the early establishment of communication protocols should help to ensure that in the future these opportunities are recognized and seized—with the result being effective forward momentum.

As discussed in Chapter II and in Appendix A, the development, licensing, and deployment of advanced reactors is complex, with the phases interrelated. Uncertainties and delays in one area can reverberate, causing problems and magnifying delays in other phases. In the past, licensing delays have been caused by poor planning and execution on both sides. Still, a great deal of responsibility lies with applicants, who must try to manage their licensing deliverables in coordination with their engineering, testing, and investment demands, as well as their customer relationships—all of which interact in ways that can be challenging to anticipate. Notwithstanding that difficulty, the applicant must still make a concerted effort to predict the schedules of key stakeholders—particularly the schedules of their design, engineering, and licensing teams—so that it can approach the NRC in an informed manner.

The details of each nuclear power project are different, but with advanced reactors this difference is amplified. Many designs are currently under development. Each has particular R&D needs and requires distinctive strategies for delivering the final product to market, while simultaneously navigating an exceptionally challenging investment environment. To make the strongest business case and safety case, each project may rely on a different set of key design features. This diversity has value. It increases the likelihood that some projects will succeed. However, it also means that no "one-size-fits-all" set of stages will optimally align with the needs of all applicants (or even with many). At the same time, the readiness of the NRC and its contractors to evaluate particular designs displays considerable variation across topic areas and designs.

For these reasons, the most effective approach will be for the applicant and the NRC to design a joint licensing project plan that is specific to a given project. The LPP would establish milestones that correspond to meaningful stage-gates for a project's specific situation and that reflect awareness of the NRC's readiness to review certain design aspects. By using topical reports, standard design approvals, and perhaps a statement of licensing feasibility, a project team and the NRC will be in a position to agree on an LPP that establishes clear, useful project stages, and makes it easier to coordinate them with



Cross-section of Transatomic Power's proposed Molten Salt Reactor plant design. The company's reactor, which is based on technology first developed at Oak Ridge National Laboratory in the 1960's, is walk-away safe and has the potential to run on Spent Nuclear Fuel.

parallel stages in the design, development, deployment, and investment processes.

The LPP should provide a roadmap similar to the FAA's PSCP.[32] It should be a living document, one that will be revised by mutual agreement of the applicant and the NRC as the project progresses and more information becomes available. The LPP should describe the project, and define the schedule and deliverables in as much detail as possible. This would include a plan to perform the testing and analysis necessary for licensing. Other features may be useful as well; the NRC and industry should consider these as a more detailed LPP conceptual outline is created. An LPP that carefully supports the NRC's and developer's long-range planning is essential to the efficient and timely execution of the licensing program.

B. Using Topical Reports to Create a Staged Approach

The use of topical reports in a more structured manner can be accomplished under existing rules without need for additional rulemaking. Nonetheless, substantial interaction with the NRC staff will be required to set up this more structured process, as it will include sequences and schedules for submittals, staff review timetables, and resource allocations. Elements of this reorientation will likely bring the agency's budget into play, along with related policy issues, and this in turn will require staff consultation with the Commission.[33] It also will likely involve changes in internal staff procedures (office letters, for example) and this, too, will require consultation.

1. HOW TOPICAL REPORTS WORK

Topical reports (TRs) are one mechanism that the NRC employs to make the licensing process more efficient. Topical reports can be used as a supplemental mechanism to document technical nuclear plant safety topics. TRs are submitted to the NRC for review and approval, either in advance of a design certification, combined operating license, standard design approval, or construction permit application, in parallel with them, or even after a COLA has been submitted. The reports become part of the official basis for issuing a DC, COL, SDA, or CP—in which they are incorporated by reference. They allow the NRC to review submittals from a license applicant or licensee on a proposed methodology, design feature, operational requirement, or other safety-related subject. When a TR has been approved, the applicant can reference it in the licensing petition. The purpose of a TR is to reduce licensing time and effort by streamlining the review and approval of a particular safety topic. Incorporating an approved TR by reference avoids repeated reviews of the same subject in multiple applications. Topics typically addressed in TRs include:

- Systems and plant assessment reports, including those that examine security, fire, and aircraft impact;
- Safety analysis code reports needed for a complete description of the evaluation models used in the safety analysis;
- Analyses or documentation of select design aspects, such as equipment qualification methods, and seismic and environmental qualification; and
- Vendor data reports.

In regard to timing, the earliest TRs required are those that the NRC has not previously evaluated and that are intended to address long lead-time items.[34] These are submitted prior to the application.

The NRC's internal process for reviewing and approving TRs can be found in its licensing instruction on the TR process.[35] The licensing

32 More details on the FAA's PSCP are contained in Section III.C of this report, and in The FAA and Industry Guide to Product Certification Second Edition. See *http://www.faa.gov/aircraft/air_cert/design_approvals/media/CPI_guide_II.pdf*.

33 NRC Chairman Burns recently indicated in a speech and in a written statement to the Subcommittee on Energy of the U.S. House Committee on Science, Space, and Technology, that, although the NRC generally supports the idea of moving forward with a revised regulatory framework for advanced reactors, the agency will "be able to optimize its planning processes and resource expenditures to conduct licensing reviews when a complete and technically sufficient non-LWR application is presented for consideration." Written Statement at 10. From this, it may readily be inferred that any move by NRC staff to devote significant resources to early advanced reactor design assessments will first require that staff consult with the Commission.

34 Technical reports may also be utilized during the pre-application or application period. These documents are similar to a topical report but do not receive a separate NRC safety evaluation report. But, like TRs, they may be incorporated by reference into the application. "White papers" are a form of pre-application documentation used to address a more general issue—for example, summarizing existing regulatory requirements or guidance to provide context, or describing the strategic approach required to address a particular issue.

35 LIC-500, Revision 4, Topical Report Process, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission (December 21, 2009, ML091520370). Note that, although the licensing instruction was issued by the Office of Nuclear Reactor Regulation, it also is applicable to and used by the Office of New Reactors.

instruction identifies four criteria[36] that should be met before the NRC will accept a proposed TR for review:

- The TR must deal with a specific safety-related subject that requires a safety evaluation by NRC staff—for example, component design, analytical models or techniques, or performance testing of components or systems that can be evaluated independently of a specific license application (Section 4.1.1A);
- The TR is likely to be used by multiple licensees in a number of requests for licensing actions (Section 4.1.1B);
- The TR contains complete and detailed information on the specific subject presented. Conceptual or incomplete preliminary information will not be reviewed (Section 4.1.1C);[37] and
- NRC approval of the report will increase the efficiency of the review process for applications that reference the report (Section 4.1.1D).

The licensing instruction states that exceptions to the above criteria may be allowed on a case-by-case basis, if NRC staff determines that an exception is in the "public interest." According to the instruction, this finding is particularly common for Criterion B (Section 4.1.1B)—that the TR is likely to be used by multiple licensees for a number of licensing requests. This is especially relevant for advanced reactors planning to seek standard design approval or design certification under 10 CFR Part 52 or Part 50. Although the TRs pertinent to these processes typically will not be applicable to "multiple licensees," the main goal of seeking NRC approval is to improve the efficiency of the licensing process —for instance, by referencing a TR in a future application for standard design approval, for design certification, or for a construction permit. The NRC readily accepts and approves TRs submitted in anticipation of design certifications or construction permits, and the same would be expected for applications seeking standard design approval under Subpart E of 10 CFR Part 52.[38] Another exception to Criterion B could involve a TR's helping to resolve a safety-related issue, to advance a technology that reduces an operational burden, or to achieve significant cost savings for industry.

Section 4.2 of the licensing instruction sets forth the steps for the TR review process. These cover the pre-submittal meeting between the applicant and NRC staff, any fee exemption request submitted with the TR, the NRC acceptance review period, staff requests for additional information, and the issuance of the safety evaluation approving the TR. All of these steps are discussed in further detail in the licensing instruction, as well as on the NRC's website.

The NRC safety evaluation report is the key approval document relevant to a TR. No environmental reviews are required. Any deviations from an approved topical report will result in a plant or site-specific review.

The first step in the TR approval process is the pre-submittal meeting. This is particularly important for a standard design approval request under 10 CFR Part 52. Such a request may consist of a series of linked TRs, although the overall plan to which these TRs relate should be discussed with the NRC early in the TR approval process (and, ideally, during development of the licensing project plan). This will provide some protection against an unexpected derailment or delay during the TR approval process. As noted in an NEI position paper on pre-application engagement for small modular reactors:

> An applicant should develop a proposed listing of the topical reports anticipated for technical support of an application that is shared with the NRC. In addition, overall licensing effort should be developed and reviewed by the NRC staff during the pre-application program interactions.[39]

In the course of detailed physical design development, equipment qualification testing, manufacturing, or construction, or as a result of industry events, topical report revisions may be required if assumptions, methods, or acceptance criteria change materially as a result of new information. Well-understood criteria exist for revising approved

36 Ibid. at page 2.

37 In this regard, the licensing instruction refers to the criteria in LIC-109, "Acceptance Review Procedures" (2009, ML0918100088).

38 Examples of topical reports in anticipation of a certified design application can be found in the quality assurance program for the design certification of the B&W mPower Reactor (July 12, 2011, ML11216A165) and the NuScale Topical Report: Quality Assurance Program Description for Design Certification of the NuScale Power Reactor (October 27, 2010, ML103210261).

39 "SMR Pre-application Engagement," a position paper, Nuclear Energy Institute (January 2011).

applications when new material information becomes available. Examples of such criteria can be found in 10 CFR 21 and 10 CFR 50.55. The possibility of future changes should not necessarily preclude submission of TRs that are fully prepared for NRC review—although the probability of a major change might be an exception.

In the early stages of design and licensing, certain topics may be sufficiently complete that they can be addressed in TRs, even though final design information is not available for all topics.[40] These TRs and their associated safety evaluation reports can then be incorporated by reference into subsequent license applications or related procedures (including SDA, DCA, and COLAs). Topical report approvals "represent a good-faith commitment on the part of the NRC to accept the conclusions of the topical report and the NRC's associated safety evaluation during future licensing reviews, subject to changes in regulations or NRC guidance." This process provides the applicant with substantial authoritative feedback. An ACRS review can be conducted as well, providing further assurance that the full license application will be approved.

2. EXECUTION OF A STAGED TOPICAL REPORT PROGRAM

Initial NRC engagement should include an overview of a licensing project plan (LPP), as described in Section IV.A, which defines the review components to be submitted to the NRC during each stage of licensing. As discussed in Section IV.A, we recommend that the specifics of each stage as well as the overall review plan be customized to each project. That way, the LPP can account both for the applicant's key concerns and design and development schedule, and for the NRC's review resources, which may require a brief period of adjustment to support review of a novel design.

Below we provide one example of what a staged topical report program might look like, with the caveat that this is not a proposal, but rather an illustration to make this concept more concrete. Brackets reference associated chapters in a standard review plan that would be supported by the individual topical reports (TRs) listed here.[41] Relevant technical reports that might be included in each stage are also shown.

1. Conceptualization Stage
   - Quality Assurance Plan Topical Report [Ch. 17]
   - Reactor Design Technical Report (initial concept description) [Ch. 1]
   - Regulatory Gap Analysis Technical Report (initial assessment) [Ch. 1]
   - PIRT, Test Facilities and IET/SET Plans Technical Report [Ch. 15]

2. Licensability Stage
   - Fuel Design and Testing Plan Topical Report [Ch. 4]
   - Safety Analysis Development Plan Topical or Technical Report [Ch. 4, 5, 15]
   - Codes and Methods Qualification Plan Topical Report [Ch. 4, 5, 15]
   - Human Factors Development Plan Topical Reports (early plans and methods) [Ch.18]
   - Preliminary PRA Technical Report [Ch. 19]
   - Risk-Informed SSC Classification Methodology Topical Report [Ch. 3, 19]
   - FOAK Safety Component Qualification Plan [Ch. 3, multiple]
   - Setpoint Methodology Topical Report [Ch. 8, 16]
   - Normal Source Term and Release Methodology (GALE equiv.) Topical Report [Ch. 11, 12, 15]
   - Accident Source Term Methodology [Ch. 15]
   - Containment Performance Topical Report [Ch. 6, 15]
   - Emergency Planning Zone Size Topical Report [ESP and Ch. 6, 15, 19]
   - Standard Design Approval (SDA SAR) [Ch. Multiple]

3. Technology Approval Stage
   - Specific Safety Analysis Code Qualification Topical Reports (multiple) [Ch. 4, 5, 15]
   - IET/SET Testing Program Result Topical Reports (multiple) [Ch. 3, 4, 5, 6, 7, 15]
   - Human Factors Engineering Topical Reports (multiple) [Ch. 18]
   - Fuel Design and Performance Topical Reports (multiple) [Ch. 4]
   - Safety Analysis Topical Reports (multiple) [Ch. 6, 15]

40 TR approval would be subject to regulatory requirements addressing an applicant's duties regarding the completeness and accuracy of information. See, for example, 10 CFR 50.9(b) and 10 CFR 52.6(b).

41 See NUREG-0800 for chapter details.

3. TOPICAL REPORT BENEFITS

Generic findings for all licensing applications and project types: A TR is a fungible product if the boundary definitions and conditions of use are set at appropriate points. This allows various generic design features, methods, and capabilities that fit the boundary conditions of the TR and related SER to be referenced in a license application or related procedure (SDA, DCA, COLA, CP, or OL).

Timing: TRs can be submitted at any time, with the timing dependent on applicant needs. The timing of NRC review is subject to the agency's priorities and resources, as well as the completeness of the TR application. Other considerations also may help determine when a TR is accepted for review.[42] Applicants should inform the NRC of their intention to submit topical reports with as much notice as possible, by responding to the NRC's regulatory issue summary (RIS) to enable NRC to plan its resources appropriately.[43] The applicant can request that the NRC treat this information as proprietary in accordance with 10 CFR 2.390, and this is a routine practice.[44]

Finality: TRs are considered final until amended or withdrawn. Finality has two elements: (i) the degree to which, absent new information or direction from higher authority, the reviewing entity's decision is considered to be the entity's last word on the subject; and (ii) the degree to which the reviewing entity's decision is binding on others. In the case of TRs, the staff's decision is final (element (i)) and binding (element (ii)) on the staff and the applicant, but not on the Commission or on adjudicatory bodies that may consider the TR as part of a future application. A TR has no expiration date, although its applicability may be subject to technical conditions. (Some topical reports referenced in major applications of recent vintage were initially approved in the early days of commercial nuclear power.)

Incorporation into other Part 50 or Part 52 applications: TR findings can be incorporated by reference into Part 50 or Part 52 applications, so long as the TR is considered relevant to the application.[45] To use TR findings in a major application, any departure from the report's conditions or its stated applicability will require a detailed explanation and, if necessary, a persuasive defense.

Program credibility (technical, performance, schedule assurance, cost confidence): Developing an application and, more importantly, securing its review by the NRC confers significant credibility in the eyes of a wide variety of stakeholders—particularly regarding whether the remaining work will be completed on time. It also reinforces confidence that the reviewed portion of the design is stable, and this in turn increases comfort with stated cost and scope. In particular, it substantially boosts the credibility of new entrants who have little or no experience with nuclear development and delivery, and it also establishes a key milestone for project team members who, during what can be a lengthy regulatory process, might begin to feel that their work was not moving forward.

Reduced execution risk for applicants: TRs are stand-alone documents that may be submitted for NRC review and approval at any time. Because they can be precursors to a complete review of a major application, they have the capacity to reduce both the risk that the application will not be accepted and the length of the review period, particularly if the complexity or novelty of the TRs calls for extensive scrutiny. Additionally, TRs can protect proprietary information from disclosure to competitors or to the public. Finally, TRs can serve to summarize a much larger body of work that supports NRC review findings and references, and thus can make it unnecessary to include in an application exhaustive, detailed design and engineering data. If appropriate, the NRC will employ design audits

42 See NRC Office Instruction LIC-500 "Topical Report Process" for a full description of NRC TR process management. NRC Office Instruction LIC-109 "Acceptance Review Procedures" provides guidance for accepting a TR for technical review.

43 For example, see NRC Regulatory Issue Summary 2015-07. *http://pbadupws.nrc.gov/docs/ML1410/ML14101A166.pdf.*

44 See, for example, Southern Nuclear Operating Company's "Response to NRC Regulatory Issue Summary 2015-07." *http://pbadupws.nrc.gov/docs/ML1516/ML15166A530.pdf.*

45 According to the NRC, "plant-specific concerns must always be taken into account when actually using an approved topical report in a specific licensing action. For this reason, the NRC verifies relevant criteria for approved topical reports during each licensing action to ensure that the topical report's conclusions are both valid and applicable to the particular licensing action under review." *http://www.nrc.gov/about-nrc/regulatory/licensing/topical-reports/requirements.html.*

and independent analyses to confirm the validity of the work underlying a TR.

4. TOPICAL REPORT REVIEW DURATION

Several significant stages in the NRC's review of topical reports add value and credibility to an application. They are listed below, along with nominal time frames from initial submittal to the milestone noted. The range of outcomes varies depending on the complexity of the issues, agreed milestone dates, timeliness of the applicant's response, and the speed with which the NRC closes open items following its initial review of request for additional information (RAI) responses.

- Initial receipt for review based on completeness [2 months]
- Initial review comments and requests for additional information (RAIs) [8 months]
- Draft safety evaluation report (SER) [14 months]
- ACRS review if required [16 months]
- Final SER and approval [20–24 months]
- Incorporation of final approval conditions [3–6 months from date of SER]

The NRC should evaluate and suggest options for expediting topical report review to support a more efficient advanced reactor licensing process.

5. LIMITATIONS OF TOPICAL REPORT CONCLUSIONS

A topical report is bounded by its context, the adequacy of its technical information, and the applications for use it defines. TRs can be amended or corrected over time. This may be necessary if new information comes to light, errors are found, or, to extend the TR's value, a broader set of applicable uses is sought. The NRC can also impose limitations as a result of its review. After a TR's draft SER is reviewed and accepted by the NRC, the final SER is issued. The applicant incorporates any required changes into the TR. At that point, the composite document can serve as a final reference in future licensing actions.

6. ACTIONS BY NRC NEEDED TO IMPLEMENT THIS APPROACH

Although a change of this nature would not likely be reviewed as a formal policy matter, it does represent a significant modification and one that may be of interest to the nuclear industry, congressional oversight bodies, and the public. Typically, it would come to the Commission's attention when NRC staff informed the Commission that they were using the TR process in a new way, and then sought concurrence for one or more initial license applications. In this situation, Commission approval normally is secured when the NRC's executive director of operations submits a SECY memorandum to the Commissioners, which describes the proposed change. At times, the latter may schedule a public meeting and ask the staff to outline the proposal and answer questions. In the SECY, the staff would summarize the reason for the request, available resources, proposed schedule, legal and management implications, alternatives, and implementation strategy. The Commission's response to such a request is typically in the form of a staff requirements memorandum (SRM). It should be noted, however, that this process generally happens only if one or more members of the NRC staff serve as advocates for an applicant's request.

Once the Commission provides direction, the next significant step is the initial engagement letter from the applicant agreeing to the type of approach advocated here.

As suggested, incremental resolution of specific topics via TR review cumulatively creates confidence that the underlying design will be licensed. Moreover, several TR review steps provide other benefits to the applicant. Acceptance review completion demonstrates that a valid safety issue with generic applicability has been competently presented. Requests for additional information (RAIs) improve project planning and opportunities for risk reduction by identifying areas of additional work within or outside the scope of the TR, work that can be either completed prior to a major application or obviated by adopting alternative approaches. In a major application, the draft SER previews the safety findings of the final SER, while confirming the generic issues to be resolved in advance of the NRC's findings. If an ACRS review is conducted, its technical conclusions—set forth in a letter to the NRC—add credibility to the project and bolster the stakeholders' confidence. These conclusions also increase the likelihood that the issue in question will not be further explored by the ACRS if it reviews the major application. The final SER approval letter and published TR can be fully referenced in future applications.

C. Using the Standard Design Approval to Create a Staged Approach

Standard design approval (SDA) is a mechanism identified in Subpart E of 10 CFR Part 52. The

SDA process is currently in place and usable "as is" under existing NRC regulations, so rulemaking would not be required to incorporate it into staged licensing.

1. HOW STANDARD DESIGN APPROVAL WORKS

Subpart E states that any person—including a vendor, or a future applicant for design certification or a reactor license—may file an application for standard design approval of a proposed nuclear reactor design. The SDA application can cover the entire proposed reactor or a "major portion" of it. The latter option may be most useful in the staged licensing context, because it provides an opportunity to secure NRC review of that portion of the design most critical to the new product's business case or technology case. Successful NRC review of such a key segment of the design will reduce the overall risk of project failure. It also will provide assurance to investors, prospective owners, suppliers, and technology partners that the new technology is viable, and worth the continued investment of time and money.

An approved SDA can be referenced in any of the following: (i) a combined license under Subpart C of 10 CFR Part 52, (ii) a standard design certification under Subpart B of 10 CFR Part 52, (iii) a construction permit under 10 CFR Part 50, or (iv) a manufacturing license under Subpart F of 10 CFR Part 52. Thus, like a topical report, an approved SDA becomes part of the formal record supporting the final, full license application.

Technical information that a standard design approval applicant must submit for NRC review is set forth in 10 CFR 52.137. Pursuant to that section, an application for a standard design diverging significantly from the light water reactor designs licensed and commercially operating prior to the promulgation of Part 52 in 1989, or one accomplishing its safety functions through simplified, inherent, passive, or other innovative means, must meet the requirements of 10 CFR 50.43(e). Those mandate that the performance of each safety feature of the design be demonstrated through "either analysis, appropriate test programs, experience, or a combination thereof," or that "there has been acceptable testing of a prototype plant." Notably, although standard design approval requires ACRS review, neither an adjudicatory hearing nor Commission review is compulsory. Design approval is conducted at the NRC staff level and, via 10 CFR 51.22(c)(22), is categorically excluded from environmental review. As with topical reports, this does not curtail public participation, Commission review, or later environmental review, but it does allow a vendor to submit to design review prior to securing a specific site, project, or owner. At this initial stage, there may be insufficient project-level detail to support site-specific reviews, and the long delays and extensive labor associated with those reviews could severely hamper early-stage project design at a time when they are not yet necessary to ensure public health and safety.

Successful NRC review of a key segment of the design will provide assurance to investors, prospective owners, suppliers, and technology partners.

2. EXECUTION OF A STANDARD DESIGN APPROVAL WITHIN A STAGED PROCESS

In this section, we suggest a starting point for defining a "major portion" of the design, discuss the importance of early coordination for establishing the content of the SDA, and, as a useful example, outline the general scope of an SDA covering a hypothetical nuclear island.

a. Defining a "Major Portion" of the Design

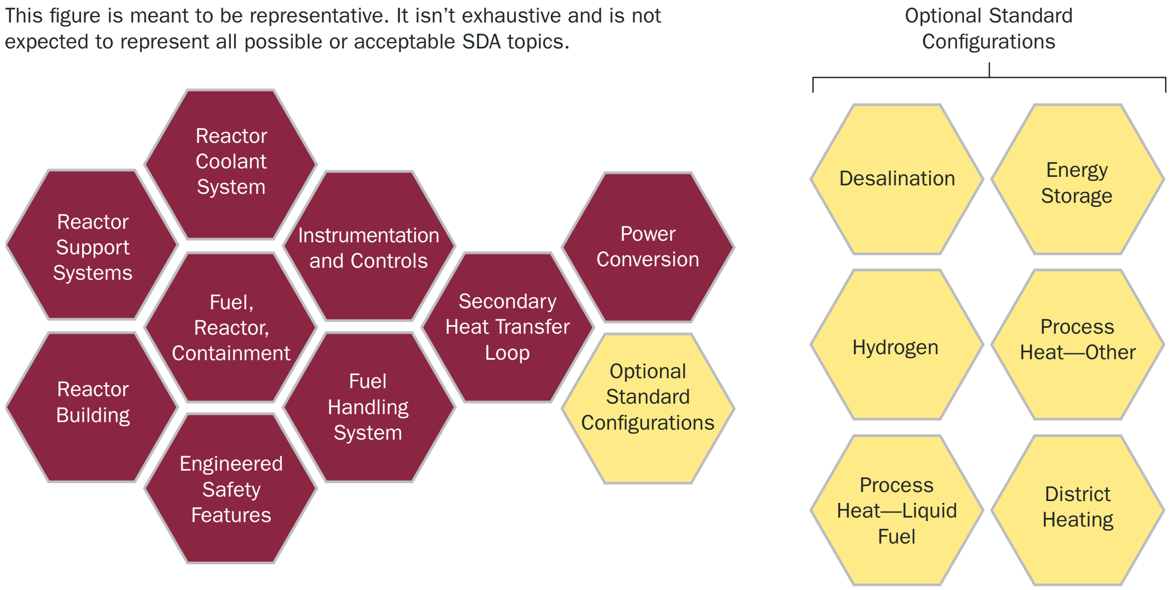
In contrast to topical reports, experience with SDAs is limited. Few helpful precedents exist that describe the use of SDAs in the context of advanced reactors. As a result, it can be difficult to determine what qualifies as a "major portion" of the design. Subpart E is silent on the matter. 10 CFR 52.137 provides some clues, but ultimately this is a question that will need to be resolved through discussions with the NRC.

10 CFR 52.137 states that "items such as the reactor core, reactor coolant system, instrumentation and control systems, electrical systems, containment system, other engineered safety features, auxiliary and emergency systems, power conversion systems, radioactive waste handling systems, and fuel handling systems shall be discussed insofar as they are pertinent." Each of these items could be considered a major portion of the design, but there is not yet precedent for that determination. Multiple SDAs are not prohibited in Part 52 Appendix E.

10 CFR 52.137 also requires a "description, analysis, and evaluation of the interfaces between the standard design and the balance of the nuclear

FIGURE IV-1
Flexible Use of Standard Design Approvals

This figure is meant to be representative. It isn't exhaustive and is not expected to represent all possible or acceptable SDA topics.



Each of the Standard Design Approvals must satisfy the interfacing boundary conditions for safety and licensing.

Possible SDA scope; multiple topics could be combined.

Once SDAs are in place, a variety of end-use applications are possible, provided they meet appropriate boundary conditions.

power plant." The careful evaluation of these interfaces will be a crucial element of a successful SDA approach. Proper definition of interfaces can enable the insertion of an SDA into an overall plant design that could include a variety of end uses for the produced energy, particularly after initial licensing of the baseline configuration. If an electricity generation plant serves as the baseline, the SDA process could be a useful way to confirm the licensability of, for example, a process heat application for petrochemical facilities, for desalination facilities, or for hydrogen production facilities.

The potential flexible use of the SDA is illustrated in Figure IV-1.

b. Establishing an Agreed Content Outline with the NRC

Successful use of the SDA as an element of a fully staged licensing strategy should begin with early agreement between the applicant and the NRC on what the SDA, as part of a licensing project plan, must contain.

Whether one or multiple SDAs are envisioned, it is essential to thoroughly understand how the SDA's content relates to topical and technical reports, as well as to DCA, CP, and COLA submittals and reviews. As with a DCA, COLA, CP, or topical report, the first step in a successful SDA review is to make sure that the application is accepted for review. This requires either a clear precedent or a specific agreement governing the scope of the submittal.

The following list highlights some of the important topics on which agreement with the NRC must be reached if the SDA is to support the development process. Here, we assume that a standard nuclear island constitutes the "major portion" of the design, as defined by the SDA.

- ***Standardized nuclear island definition.*** This establishes the boundary conditions around the nuclear reactor, the interfaces with the secondary heat transfer systems, the emergency core cooling systems, the containment structure, the normal supporting systems for safe reactor operation, the electrical and controls systems, the ultimate heat sink description, and the functional interface conditions for all other systems and components necessary to support nuclear island structures, systems, and components.
- ***Identification of design specific review standard sections or partial sections to be included in an SDA.*** This is an explicit listing of all standard review plan sections for which a design-specific

review application is made. This listing should be a product of early pre-application engagement, starting at the conceptualization stage. Early resolution helps to shape the developer's technical work sequence and provide information that allows the NRC to allocate resources for an efficient review.

- ***Use of referenced topical reports.*** Topical reports are integral to the licensing plan. Relevant TRs will be incorporated by reference into the SDA's scope and, later, the findings. Submission of complete topical reports before or with the SDA—and the SDA's justifiable reliance on those reports—should be a priority of the project management dialogue between the developer and the NRC.
- ***Boundary conditions with CP, DCA, or COLA.*** The SDA essentially encapsulates a bounded discussion of safety management for part of the nuclear facility. To conduct an effective safety review, agreement is needed on the assumed physical boundaries of the structures, systems, and components (SSCs) addressed in the SDA, the performance requirements across boundary points, and any safety interactions that should be included in the safety analysis.
- ***Safety analysis sufficiency for functional design.*** The level of detail available to complete a design safety analysis increases as the design evolves from initial conceptualization to its final as-built form. A review can be conducted at several points to draw conclusions about safety.[46] For the SDA safety review, the functional design should be well advanced. This implies that margins and uncertainties will be sufficiently understood to support definitive NRC findings. Nonetheless, later updates may be required to complete the development of technical specifications, operational limits, and other elements that depend on the final or even the as-built design data. The limitations of the NRC findings must be fully described in the application and agreed to in the safety evaluation report.
- ***One issue, one review, one position strategy.*** In 2006, NRC staff developed a design-centered review approach (DCRA), which later was approved by the Commission and described in RIS 2006-06. The DCRA applies to design certification (DC) and combined operating license (COL) applications. It is based on the practice of industry's standardizing COL applications (COLAs) that reference a particular certified design. In an effort to optimize the review process—including needed resources and review schedules—this approach adopts, to the maximum extent feasible, a "one issue, one review, one position" strategy. Specifically, NRC staff will conduct a technical review of each reactor design issue and release one set of findings to support its subsequent decisions on the DC and on multiple COLAs. For the process to be effective, it is essential that applicants referencing a particular design make every effort to standardize their applications. In this way, the NRC staff's technical review and findings can be conducted and crafted using concepts and language that align with the standard application, known as the reference COLA or R-COLA. If this is done, those findings become applicable to later COLAs or S-COLAs that reference the standard. Thus, the use of SDAs meets the Commission's objective of "one issue, one review, one position" in a new manner. Confirmation of the utility of SDAs in R-COLA and S-COLA applications would add confidence to this process.

46 See discussion of "safety finding" as used in final NRC SERs before approval of a DCA or COLA.

c. Example of an SDA Scope

To better understand what an SDA might look like, the major topical areas relating to the nuclear island hypothetical are organized in the following table, which generally illustrates the scope of agreement that an applicant must reach with the NRC on an SDA. In actual practice, the specificity of details would increase two or more levels (i.e., on the order of 300–400 line items).[47]

SDA Application Chapter	Coverage*	Comments
1 – Introduction	Some	Providing design overview and gap analysis results; SDA boundary description and interfaces with ESP, DCA, COLA, Topical Reports
2 – Site Characteristics	Some	Defining environmental conditions for safety analysis
3 – Design of SSC Criteria	Most	Providing design information consistent with boundary definitions
4 – Reactor	All	Setting forth full reactor design
5 – Reactor Coolant System	All	Setting forth full reactor cooling design up to agreed boundary
6 – Engineered Safety Features	All	Describing passive and active features plus containment
7 – Instrumentation and Controls	Most	Providing design for safety and reactor controls; automation plan
8 – Electric Power	Some	Providing design for 1E power required for safety (AC or DC) and offsite power functional designs
9 – Auxiliary Systems	Some	Providing design for risk significant SSC functional designs supporting PRA
10 – Steam and Power Conversion	Limited	Providing design for secondary heat exchanger to agreed boundary
11 – Radioactive Waste Management	Limited	Setting forth bounding source terms
12 – Radiation Protection	Limited	Setting forth functional requirements and boundary conditions
13 – Conduct of Operations	Limited	Providing detail needed to understand concept of operations, and instrumentation & controls (I&C) and human factors engineering (HFE) requirements
14 – ITAAC / Initial Plant Testing	Limited	Providing information for reactor design topics only; general ITAAC approach
15 – Accident Analysis	Most	Providing analysis for reactor-island events
16 – Technical Specifications	Limited	Providing safety parameter limits for nuclear island SSCs
17 – QA and RA	Some	Providing QA plan only
18 – Human Factors Engineering	Some	Providing initial plans, functional analysis, PRA and human reliability analysis items
19 – Probabilistic Risk Assessment	Most	Establish to the extent Level 1, 2, 3 needed to support SSC classification and develop margins and uncertainty bounds for plant safety and siting
Safeguards Information	None	
Environmental Report	None	
Tier 1 and ITAAC	None	
***Legend**		
Limited		Only narrow topics included where development of information occurs early in the design process and is necessary to complete SDA review
Some		Select portions of the design require review in order to issue safety findings within the scope of the SDA
Most		A substantial portion of the chapter is required to support SDA findings. Some interfacing system features or events can be omitted from the SDA and reviewed in the DCA/COLA when the corresponding information is submitted
All		All portions of the chapter are required
None		No development of the chapter needed

47 If a regulatory gap analysis has been prepared early in the pre-application process, this task can be simplified greatly. A gap analysis should already have contributed to the development of a design specific review standard (DSRS), if one is used. It is also a typical work product of any design and licensing process that seeks to minimize regulatory surprises of the type inimical to efficient engineering workflow. The detailed outline of DSRS sections included in the FSAR ensures that all subsequent sections are developed and included within the DCA or COLA.

3. STANDARD DESIGN APPROVAL BENEFITS

Generic findings for all licensing applications and project types: The SDA is a fungible product if the boundary definitions and conditions of use are set at appropriate points. That allows various plant application selections to reference the SDA, if they fit the SDA's boundary conditions. These plant application selections could include such topics as process heat use, cogeneration products, and plant configuration (e.g., single or multi-module). The value of this approach is greatest for reference plant configurations in R-COLAs developed within 15 years of SDA approval.

Timing: The timing of an SDA is driven by the development timeline of the entire nuclear plant program. The functional development of the nuclear island dictates functionality of the remainder of the plant. Using an SDA focused on core nuclear SSC design and performance may allow the NRC to perform an early integrated review of the essential elements of the nuclear design. This in turn has the potential to expedite the review process and reduce regulatory risk in later stages.

Finality: The staff's safety findings based on their review of an SDA, which are documented in a final design approval, are similar to the findings made by the staff in the SERs issued in conjunction with the review of topical reports. When an SDA or topical report is incorporated by reference in a later application for a construction permit, operating license, design certification, or combined license, the staff's safety findings are subject to further review during public hearings and rulemaking processes, as may be required based on the specific permit, license, or certification being sought. (See Section IV.B.3 and finality provisions in 10 CFR 52.145.)

Incorporation into other Part 50 or Part 52 applications: As with topical reports, SDA findings can be incorporated by reference into Part 50 or Part 52 applications so long as the SDA is considered active. The existing practice of incorporating ESP or DCA results into a COLA, CP, or OL should be considered precedents that also apply to an SDA.

Program credibility (technical, performance, schedule assurance, cost confidence): Developing a major application and, more importantly, securing its review by the NRC accords a project substantial credibility in the eyes of a wide variety of stakeholders, particularly regarding whether the remaining work will be completed on time. It also provides substantial confidence that the reviewed portion of the design is stable, which in turn increases comfort with stated cost and scope. Finally, it adds significant credibility to new entrants who have little or no experience with nuclear development and delivery, and provides a key milestone for project team members.

Reduced execution risk for COLA applicants: The SDA resolves certain issues in much the same way as a DCA. By substituting for significant sections, the SDA simplifies both development and review of the full COLA. This can decrease COLA review time, particularly if it reduces the number of requests for additional information (RAIs) or eliminates extended reviews of narrow COLA-related topics. Pursuing an SDA also has the potential to identify critical issues at a much earlier point in the licensing process. For example, if additional testing or analysis becomes necessary, discovering this one or two years earlier may allow the developer to maintain the original program schedule.

Confirmation of direction and scope for future applications: The results of the SDA review shed light on the efficacy of future applications that vary from the baseline configuration. For example, if the successful review of a nuclear island concludes that its back-end applications will have little or no impact on its design, alternative application projects can proceed with higher confidence of licensability. This is particularly useful for advanced designs seeking to provide services other than electric power (e.g., use of nuclear energy as a heat supply).

4. STANDARD DESIGN APPROVAL REVIEW DURATION

Several significant stages in the NRC's review of a major application can individually add value and credibility to a development program. The nominal time frames for each stage, from initial submittal to completion, are shown in brackets below. The range of outcomes varies, depending on the complexity of the issue raised, the applicant's timeliness in responding, and the NRC's closure of open items after it reviews initial RAI responses.

- Initial receipt for review based on completeness [2 months]
- Initial review comments and requests for additional information (RAIs) [8 months]
- Draft SER [14 months]
- ACRS review [16 months]
- Final SER and approval [20–24 months]

The NRC should evaluate and suggest options for expediting SDA review to support a more efficient advanced reactor licensing process, especially in cases where the SDA covers a major portion of the design that has a more limited scope than the nuclear island used as an example here.

Each milestone offers different benefits. The initial acceptance for review confirms that the scope and content of the work warrants application of NRC resources. It also confirms that the pre-application plan is ready for submittal. If on schedule, it underscores the developer's delivery capability. The initial round of RAIs highlights any gaps or flaws in the design that require remedial action. If gaps or flaws are identified, the major application submission arrives at a relatively early point, allowing changes to be more readily accommodated in subsequent work plans. The draft SER and independent ACRS review confirm the adequacy of the design in the areas reviewed and increase assurance that NRC staff review has been thorough. Completion of the ACRS review also strengthens certainty that the design is sound in the areas reviewed. The final SER finalizes review of the SDA. This is highly significant for future prospects of the design, as it removes a large number of issues from further staff review, absent a new, material fact that would alter the original findings.

Developing an optional preliminary NRC review milestone analogous to the VDR Phase 1 would offer important benefits.

5. SPECIFIC CONCLUSIONS FROM STANDARD DESIGN APPROVAL

Not all of the results of the SDA are final safety findings. Certain specific conclusions from the review may signal conditional approval subject to further testing or analysis—steps that would be met in the DCA or COLA, or by satisfying an ITAAC during construction. Of these, some conditional authorizations may highlight areas of uncertainty or, for operational reasons, call for more conservative margins than typical. These results can then be re-addressed and refined in the COLA in a manner that improves operational flexibility without undermining safety findings.

6. LIMITATIONS OF SDA CONCLUSIONS

NRC conclusions will necessarily be limited by the state of design and testing. As a result, caveats regarding incomplete design or pending confirmatory tests should be expected. In some cases, safety findings covering reviewed portions of the design will be contingent on the acceptable performance of the overall plant or support system. In the case of advanced reactors, for example, used fuel storage or fuel handling events outside of the reactor could limit siting conditions, even though reactor operations are considered to be extremely safe.

In consequence, some residual risk of incomplete or conditional approval remains, much in the same way that design acceptance criteria, ITAAC or commissioning testing pose a slight risk of failure late in the delivery process. It may nonetheless be useful in some instances to have preliminary findings in hand before expensive tests are completed. The interim feedback may help the applicant to justify—prior to final application and approval—the additional tasks required to validate that certain design features or chemical/physical processes operate as expected, and thus support the application. If interim feedback will not be of assistance, the applicant need not incorporate that step in its licensing project plan (LPP). Nonetheless, identification of residual open items can help a broad range of stakeholders assess their continued or future involvement in the program.

D. Providing a Statement of Licensing Feasibility

One regulatory product that many US advanced reactor developers have requested is an early-stage optional pre-application review akin to that issued by the Canadian Nuclear Safety Commission (CNSC) in the vendor design review (VDR) process (see Section III.B.1.a for more details on the VDR). One option to explore involves the NRC's designing and developing a process like the CNSC's VDR Phase 1, with defined focus areas and a limited scope of review. The applicant and the NRC would agree upon the selected focus areas for review, timeframes, and review budgets in the licensing project plan. The product of such a program might serve as a statement of licensing feasibility.

Developing an optional preliminary NRC review milestone analogous to the VDR Phase 1, which assesses whether design intent is compliant with regulatory requirements, would offer important benefits—it would: (i) standardize a review phase that, because of its limited cost and duration, could be used by stakeholders to compare available design options; (ii) provide early feedback to the applicant, allowing timely alterations in approach to better meet regulatory obligations; and (iii) provide useful structure to pre-application engagement.

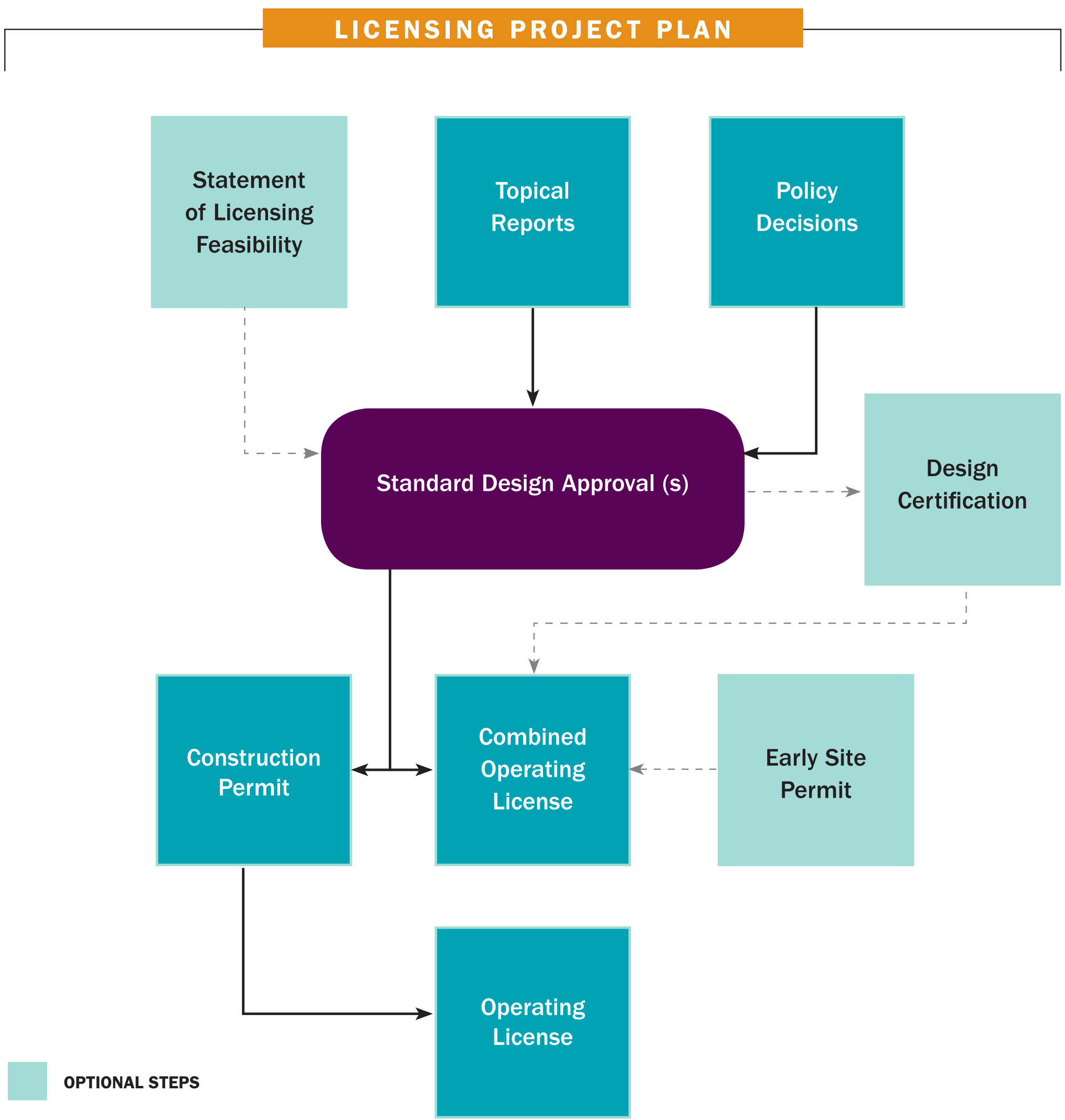
E. Staged Licensing Results

1. BENEFITS AND CHALLENGES

Opportunities for multistage licensing exist in current NRC regulations. Options are illustrated in Figure IV-2. If these are pursued, the most significant changes will occur in the internal processes and planning of both the applicant and the NRC. The development of a licensing project plan will require both parties—but especially the applicant—to consider timelines and resources carefully. For the most effective planning, the applicant will need to understand the timelines of the various stakeholders (with progressively increasing detail and precision) and then implement a level of coordination that has been lacking in past development efforts. For effective execution, both the applicant and the NRC must be held accountable to the agreed-upon schedule and deliverables.

The net benefit of this will be considerable. The LPP will enable more effective communication and quicker resolution of issues, while clarifying regulatory requirements and interpretations, and serving

FIGURE IV-2
Available Stages for Licensing an Advanced Reactor



as a project's roadmap. It will enable both the applicant and the NRC to plan resource allocation in accordance with the content and volume of upcoming submissions and reviews. If the applicant is able to integrate its design and licensing plans, it can avoid surprises of the type that can lead to design change delays or protracted agency reviews. In short, by exposing problems early, time will remain to fix them.

Realization of advanced nuclear energy production in the next decade is a strong possibility if proper policies are enacted.

The individual milestones created by a staged licensing process will provide a clear signal to applicants, investors, strategic partners, customers, employees, and other stakeholders that a project is moving forward according to plan. These also will help new entrants establish earlier credibility, will reduce the perceived likelihood of failure in licensing, and will diminish the actual likelihood of schedule slip by identifying critical issues and gaps promptly.

2. IMPROVED TIMELINE POTENTIAL

Many factors are expected to shorten the development cycle for advanced nuclear reactors. Shortening this cycle is a must if nuclear innovation is to move forward at a productive pace. Factors that will help speed things along include new reactor designs, modern design tools, factory fabrication and field assembly, and the incorporation of licensing considerations in integrated project planning. Figure IV-3 illustrates the potential benefits, which should be compared with the existing process in Figure II-1. Even greater efficiency may be possible for smaller designs or designs that accommodate faster construction schedules. This illustration represents a first of a kind project; later projects would proceed more rapidly. Further schedule reduction would be possible for projects electing not to participate in pre-licensing activities or electing to pursue technology approval and project specific approval more in parallel. Where the current ALWR commercialization timeline has been on the order of 25 years, this improved approach yields a process, from pre-conceptual design to commercial operation, of 15 years or less. Many advanced reactor designs have already advanced several years along this path, so realization of advanced nuclear energy production in the next decade is a strong possibility if proper policies are enacted in the US as a whole and at the NRC. These polices would include the regulatory adjustments discussed in this chapter, but also corresponding funding support to enable NRC's development of new methods and hiring of advanced reactor experts and consulting expertise. A revision to the NRC's current fee recovery structure would be needed to fully enable this.[48] Funding support to reduce the burden of costly NRC fees on license applicants will also be needed. Industry and policymakers as a whole will need to deliver a coordinated message to the NRC to enable swift change, and should take a more active role in communicating with the NRC, DOE, and other stakeholders on the challenges involved in licensing and technology development to support the broader policy development. Another opportunity for industry to drive faster progress lies in coordination with research and standards organizations to develop codes, standards, and conventions for advanced nuclear power, some of which could be adopted by the NRC.

48 The FY2017 appropriation of $5 million for NRC work to develop regulatory infrastructure for advanced reactor technologies is an excellent interim measure, but long-term support for this work will likely require a more systematic division of funding responsibilities between taxpayers and licensees.

FIGURE IV-3

Improved Timeline for Advanced FOAK Reactors with Staged Licensing Approach

F. Finality of Decisions in a Staged Licensing Process

Staging the licensing process under current regulation will involve the use of a variety of regulatory mechanisms and processes to issue decisions and findings on (i) discrete technical issues (involving, for example, the design, analysis, and expected performance of specific structures, systems, or components (SSCs) of a reactor facility); (ii) necessary boundary conditions and interface requirements for the SSCs being examined; (iii) integration and interaction of one or more SSCs to form larger and more complex elements of a reactor system; (iv) the design of the entire nuclear power reactor or major portions thereof (using a standard design approval (SDA) under 10 CFR Part 52, Subpart E); and (v) ultimately, combining all of the necessary elements of a complete facility design into an application for a license (DC, COL, or CP and OL).

The review mechanisms at each stage will differ. As a result, the nature and finality of the findings will vary, depending on the review mechanism. For example, the topical report (TR) mechanism can be applied to obtain findings on matters covered in (i), (ii), and (iii) above. Topical report results can also be used or referenced to obtain findings on matters covered in (iv)[49] above. In the case of SDAs under Subpart E of Part 52, applications will be reviewed for compliance with the standards set out in 10 CFR Parts 20, 50 and its appendices, 73, and 100. (See 10 CFR 52.139.) The findings of acceptability are "subject to appropriate terms and conditions" (10 CFR 52.143) and will not be relied upon by NRC staff or the ACRS if there is "significant new information that substantially affects the earlier determination or other good cause" (10 CFR 52.145). As to finality, NRC staff findings in topical report reviews and SDAs can be used and relied upon by NRC staff (and, in the case of an SDA, the ACRS) in the review of any individual facility license application that incorporates them by reference, absent these exceptions: (i) if significant new information later comes to light, (ii) if a new regulation substantially affects the earlier determination, or (iii) if other good cause exists. At the same time, the determinations and reports by staff do not constitute a commitment to issue a permit or license, or in any way affect the authority of the Commission, the Atomic Safety and Licensing Board (ASLB), or a presiding officer in any proceeding under 10 CFR Part 2. (See 10 CFR 52.145.)

49 Topical report results can also be part of the application for any of the licenses described in (v), but the findings will not be binding on the Commission.

CHAPTER V

OTHER POSSIBLE IMPROVEMENTS TO ADVANCED REACTOR LICENSING

A. Providing a More Technology-Inclusive Licensing Process

TECHNOLOGY-INCLUSIVE LICENSING approaches provide important safety and economic benefits.[50] Prescriptive requirements are necessarily developed around the regulator's expectations, and these tend to be based on past experience. Because they cannot easily incorporate novel approaches, these requirements tend to place regulatory impediments and delays in the path of innovation. That is a great disservice when innovation incorporates the state of the art—including decades of progress in materials science, computing, manufacturing, and creative thinking—and encompasses developments that can make reactors safer and more economical. Society has much to gain from a regulatory process that expedites, rather than delays, the introduction of advanced technologies.

Both at a high level and on a detailed level, the use of technology-inclusive approaches can reduce barriers to innovation by ensuring that no new design concept or engineering approach is held back by the absence of extensive regulatory guidance. At a high level, the NRC should develop and implement a risk-informed, performance-based framework that relies less on prescriptive requirements. Even though this can build on work already finished, the full framework will take years to complete. Thus, it has to begin now. At the same time, the NRC can move more expeditiously to increase its use of risk-informed, performance-based (RIPB) techniques in circumstances offering particular benefit. Industry will need to work with the NRC to identify appropriate situations, provide the necessary analysis and justification, and help engineer this change. Examples of fully-formed and nascent RIPB approaches, at both the framework level and for situational use, exist today. Efforts should build upon these.

The next sections of this report discuss the use of probabilistic risk assessment (PRA) as a safety analysis tool, previous efforts by the NRC to develop a risk-informed licensing framework, current uses of RIPB regulation, and recommendations for increasing the use of such regulation going forward.

1. PROBABILISTIC RISK ASSESSMENT AS A REGULATORY TOOL

A method key to accurate risk-informed decision-making is probabilistic risk assessment, or PRA. PRA assesses: (i) what can go wrong, (ii) how likely that is, and (iii) what the probable consequences will be.[51] By attempting to include all "initiating events" (causes of accident scenarios), PRA can be more thorough than expert judgment. However, because PRA is limited by the quality and completeness of the PRA model used and its inputs, a combination of PRA and traditional engineering

50 Here, "technology-inclusive" means using methods of evaluation that are formulated in a way that is as flexible as practicable for application to a variety of reactor technologies. This can include the use of risk-informed and performance-based techniques, probabilistic risk assessment, and other tools and methods, with the aim of minimizing prescriptive aspects of standards and evaluation techniques.

51 Apostolakis, G.E. Lecture Notes for MIT course 22.39 "Elements of Reactor Design, Operations, and Safety." Fall 2006. *http://ocw.mit.edu/courses/nuclear-engineering/22-39-integration-of-reactor-design-operations-and-safety-fall-2006/lecture-notes/lec7_ga.pdf.*

analysis may be optimal for high-level analyses or where the model is incomplete.

The first major use of PRA in the commercial nuclear industry was a 1975 study, described in "Reactor Safety Study: An Assessment of Accident Risk in US Commercial Nuclear Power Plants."[52,53] The Reactor Safety Study was undertaken in an effort to quantitatively assess the risk posed by reactor accidents, to develop approaches for such assessments, and to identify areas for future safety research.[54] The NRC's assessment of plant safety at the time focused in part on a set of postulated severe accident sequences (called design basis accidents, or DBAs) that were thought to provide adequate insight into a plant's ability to respond to safety threats. These accident sequences were developed based on engineering judgment supported by experiments and computer codes.

What the quantitative probabilistic analysis of the study suggested—and what received reinforcement following the Three Mile Island nuclear accident in 1979—was that design basis events, although severely testing a plant's safety response, were not necessarily the most *safety-significant* events. In fact, using a more systematic evaluation process (that is, early PRA), it was possible to identify beyond-design basis accident sequences that were more important from a public safety perspective than the traditional sequences used in NRC assessments. A key lesson was that these accident sequences deserved particular attention, and that designers should employ safety systems or design approaches to mitigate them. The Reactor Safety Study also revealed that the likelihood of core damage was higher than previously thought, and that the public safety consequences of that damage were lower than previously thought.[55]

A lesson from the many industry sponsored, plant-specific PRAs that followed the Reactor Safety Study was that each nuclear power plant has a different set of vulnerabilities, requiring special attention to operating procedures, maintenance programs, and incident response strategies. For advanced reactors that adopt novel ways to address operation and safety, a strong case can be made for using PRA to identify the most safety-significant systems, structures, components, initiating events, and accident scenarios. Experience suggests that this approach will yield a more realistic picture than deterministic approaches (e.g., engineering judgment) can, standing alone. PRA will also decrease costs by focusing resources and attention on the systems that are the most crucial for safety, and by enabling more elegant design and engineering solutions than those mandated by deterministic methods—which are based on past experience and thus are less adept at incorporating new ideas. The most thorough safety analysis will come from the combined use of a design-specific PRA, traditional engineering analysis, and performance-based monitoring.

2. PAST AND CURRENT NRC INITIATIVES AND PRACTICES

The NRC has undertaken several initiatives to develop a more technology-neutral licensing process. One involves the so-called "Part 53" program, focusing on the development of a risk-informed, performance-based (RIPB) regulatory framework for advanced reactors. This effort began in the early 2000s, in part due to growing interest in non-LWR reactors and the related recognition that existing regulations and guidance were generally LWR-centric.[56] The Part 53 development program was terminated several years later due to waning interest in advanced reactors and the substantial cost and time required to implement such a program. The most recent examination of RIPB practices was performed by the Risk Management Task Force, which outlined a risk management regulatory framework that would incorporate RIPB regulation.[57] This effort, led by then-Commissioner George Apostolakis, culminated in the publication in 2012 of NUREG-2150: *A Proposed Risk Management*

52 It is alternately referred to as "The Reactor Safety Study," WASH-1400, or "The Rasmussen Report," as it was directed by Professor Norman Rasmussen of MIT. *http://www.osti.gov/scitech/servlets/purl/7339389*.

53 Knief, R.A. Nuclear Engineering Theory and Technology of Commercial Nuclear Power Second Edition. 1992.

54 Ibid.

55 Apostolakis, G.E. Lecture Notes for MIT course 22.39 "Elements of Reactor Design, Operations, and Safety." Fall 2006. *http://ocw.mit.edu/courses/nuclear-engineering/22-39-integration-of-reactor-design-operations-and-safety-fall-2006/lecture-notes/lec7_ga.pdf.*

56 See NUREG-1860 "Feasibility Study for a Risk-Informed and Performance-Based Regulatory Structure for Future Plant Licensing, Volumes 1 and 2 (NUREG-1860)", October 2007. *http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1860/*.

57 See NUREG-2150 "A Proposed Risk Management Regulatory Framework" April 2012, *http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr2150*. NUREG-2150 is the most recent examination of the use of RIPB practices. The recommendations of the report have not been adopted and continue to be studies by industry and NRC staff.

Regulatory Framework. At present, the Commission has not provided guidance on whether it intends to move forward in the direction that NUREG-2150 recommends. However, on December 18, 2015, NRC staff issued a memorandum, SECY-15-0168, recommending that the Commission "use its existing regulatory framework to continue to make risk-informed regulatory improvements in an incremental manner."[58] In other words, staff recommended that the Commission not seek to design a new RIPB regulatory framework. However, the staff also stated:

> The staff believes that the adoption of a risk-informed regulatory framework, similar in concept to an RMRF, would provide the greatest benefits for new reactor designs that employ non-traditional technologies (e.g., Generation IV designs). The staff will continue to engage stakeholders interested in pursuing such a risk-informed framework.[59]

At the situational level, examples involving proposals for or use of RIPB approaches can be found in applications for operating reactors, in the recent Small Modular Reactor Licensing Program, and in the Next Generation Nuclear Plant (NGNP) Program. The NRC has also built a set of policy positions and implementation plans for both PRA and risk-informed decision-making. These include a major 1995 policy statement on the "Use of Probabilistic Risk Assessment Methods in Nuclear Activities" that encouraged increasing reliance on PRA in conjunction with the defense-in-depth philosophy.[60]

Through Regulatory Guides 1.174, 1.175, 1.176, 1.177, and 1.178, the NRC has provided guidance for using PRA to support changes in the licensing basis (design, operation, and other modifications) for operating plants.[61]

In 1999, the NRC promulgated 10 CFR 50.65, commonly referred to as "the maintenance rule." The maintenance rule requires that licensees use risk information to guide their maintenance activities, thus helping to ensure that plant safety is not inadvertently degraded by a maintenance action. Regulatory Guide 1.160, "Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," provides methods for complying with 10 CFR 50.65.[62] A related regulation is 10 CFR 50.69, "Risk-informed categorization and treatment of structures, systems, and components for nuclear power reactors."

The success of these efforts demonstrates that probabilistic risk assessments have matured to the point that the NRC and industry fundamentally agree on methods for applying PRA and, in limited circumstances, for using those methods.[63,64]

The most recent efforts to introduce risk-informed methods have centered on small modular light water reactors. Industry has proposed that risk-informed approaches be used to set emergency planning zones and control room staffing, and manage security. The NRC is in the process of reviewing the proposal for revised emergency planning zones. These approaches will also have direct relevance to many advanced non-light water reactors, so their development is of prime importance.

Even more relevant to advanced reactors have been past efforts to employ risk-informed techniques in the reactor evaluations in the 1980s and 1990s and in the Next Generation Nuclear Plant (NGNP) Project, as described in Section III.A. The NGNP Project involved a high temperature, gas-cooled reactor, an advanced design dramatically different from an LWR. The project proposed to use PRA for several applications, including:

- Input to selection of licensing basis events (accident sequences);

58 SECY-15-0168: "Recommendations on Issues Related to Implementation of Risk Management Regulatory Framework" *http://pbadupws.nrc.gov/docs/ML1530/ML15302A135.html.*

59 Ibid.

60 USNRC, "Use of Probabilistic Risk Assessment Methods in Nuclear Activities: Final Policy Statement," Federal Register, Vol. 60, p. 42622 August 16, 1995.

61 For example, Regulatory Guide 1.174: "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis." *http://pbadupws.nrc.gov/docs/ML0037/ML003740133.pdf.*

62 *http://pbadupws.nrc.gov/docs/ML1136/ML113610098.pdf.*

63 NRC Review of "Electric Power Research Institute's Advanced Light Water Reactor Utility Requirements Document Vol. 3 Part 1 Passive Plant Designs" NUREG-1242 August 1994 *http://pbadupws.nrc.gov/docs/ML1006/ML100610048.pdf* provides useful insight into the rationale for using risk-informed decisions for advanced passive LWRs.

64 Industry consensus standards have been and are being developed by the ANS and ASME Joint Committee on Nuclear Risk Management (JCNRM). As these standards are completed, the NRC has endorsed them for use—sometimes with certain limitations—in individual regulatory guides and review standards. Technology-independent standards are included in the library of standards under JCNRM's purview.

- Input to safety classification of structures, systems, and components; and
- Risk-informed evaluation of defense-in-depth.

Because the NGNP project has not proceeded on schedule, licensing has not been completed and the Commission has not made core policy decisions on how to approach these PRA applications. Issues raised in the NGNP review as well as earlier reviews are relevant to many other advanced reactors under development today. Their resolution would significantly reduce the uncertainty that surrounds the licensing of advanced reactors.

3. RECOMMENDATIONS

The NRC should designate a special technical team to develop a plan to implement a technology-inclusive licensing and regulatory framework for advanced reactors based on risk-informed and performance-based principles. The technical team should propose a roadmap for putting the new framework into practice by 2025, and then be given the administrative flexibility and resources to succeed. Because this framework will not be ready immediately, it should remain optional (similar to the Part 52 licensing processes as an alternative to the Part 50 process)—at least until it is fully demonstrated. That way, its development will not delay current projects.

At the same time, for advanced reactors pursuing commercialization and licensing in the immediate future, the NRC and license applicants should work together to adapt the agency's light water reactor (LWR)-centric requirements so that they are better suited to advanced reactors seeking licenses in the near term, while, wherever appropriate, increasing the use of risk-informed and performance-based techniques. The recent formation of the NRC Risk Informed Licensing Initiatives team provides a central place to pursue efforts to expand RIPB strategies for currently operating reactors. Either forming such a team for advanced reactors, or expanding the size and responsibility of the current team to include advanced reactor issues would enable rapid progress.

For new technologies, alternative approaches to the exemption process should be considered. Recently, applicants have used the practice of seeking relief from certain inapplicable or partially applicable requirements. For example, during recent licensing activities for light water small modular reactors, applicants experienced increased cost and slower review due to difficulty in executing the NRC's exemption processes. Advanced reactor designers from both traditional industrial organizations and small start-ups are concerned with the cost and schedule uncertainty associated with the exemption process (as well as potential negative perception that applicants are trying to avoid stringent safety regulation). As a result, they are hesitant to submit applications without first being assured that exemption requests will be meaningfully processed. A means should be available earlier in the process for the NRC and the applicant to reach agreement on alternative compliance strategies for specific requirements that are only partially applicable or are not applicable at all. The LPP would be a natural place to do this, once the NRC and stakeholders have identified promising approaches. This will increase efficiency and effectiveness in the design and regulation of advanced technologies without sacrificing safety or security.

Another activity to lighten the burden of LWR-centric regulations is the DOE/NRC Advanced Reactor Licensing Initiative, described in "Guidance for Developing Principal Design Criteria for Advanced (Non-Light Water) Reactors,"[65] a report issued in December 2014.

Finally, given the substantial investments that industry and the DOE already have made in developing and submitting the NGNP and earlier advanced reactor proposals (and that the NRC has made in evaluating those proposals), we recommended that NRC staff complete their evaluation of the policy issues identified in those submittals, and that the Commission review those evaluations and issue its decisions.

B. Preparing and Clarifying an Advanced Reactor Demonstration Licensing Process

A critical obstacle to commercializing innovative nuclear power technologies is that there is no clear pathway for a first demonstration. Here we use the term demonstration to encompass prototypes, test reactors, pilot-scale reactors, research reactors, and other first-of-a-kind projects that may be needed to propel a new technology to commercialization.[66]

65 *http://pbadupws.nrc.gov/docs/ML1435/ML14353A246.pdf*

66 Confusion about terminology is also a problem in this area.

Although many early demonstration reactors were heavily supported and often managed by the federal government, it is generally accepted that advanced reactors under development today will be demonstrated by coalitions backed by major private-sector partners. Nonetheless, as discussed in the Introduction, a significant component of this challenge continues to relate to regulation.

The procedure for licensing a demonstration reactor is not well understood, partly because such a reactor has not been built in the recent past. The NRC should provide a clear and achievable regulatory pathway for developing, licensing, and deploying advanced reactor prototypes, demonstration reactors, and test reactors, with provisions for both power generating and non-power types.

The NRC and DOE will each play important roles in advanced reactor demonstrations, but neither DOE, nor NRC, nor the advanced reactor community appears sufficiently prepared at this point to support such a demonstration. The following sections summarize the authority of DOE and the NRC regarding demonstration facilities, and highlight issues that will need to be addressed to ready the licensing process for advanced demonstration reactors.

1. SUMMARY OF CURRENT DOE AND NRC RESPONSIBILITIES

In brief, DOE is authorized to oversee research and test its own reactors, if the purpose is to advance R&D; NRC is authorized to license research and test reactors that are privately owned and operated, or are operated "for the purpose of demonstrating the suitability for commercial application of such a reactor."[67]

To be specific, NRC is responsible for (i) all non-military reactors developed for commercial or industrial power purposes, (ii) AEA §103-authorized research and development involving nuclear materials, (iii) research reactors and prototype reactors, and (iv) non-power reactors and nuclear testing facilities for commercial or industrial purposes, pursuant to AEA §104. NRC also is authorized to make arrangements to conduct research and development activities relating to the regulation of reactors within its jurisdiction.[68] The distinction between commercial reactors and test facilities, set forth in 10 CFR 50.22, defines the former as a facility for which more than 50% of the annual cost of owning and operating the reactor is devoted to the production of materials, products, or energy for sale or commercial distribution, or is devoted to the sale of services—other than research and development, or training. Commercial reactors are licensed under AEA §103. If a testing facility falls under the 10-MW threshold, it could be licensed under AEA §104c. This would generate more flexibility in licensing, given that the Commission is directed under AEA §104c "to impose only such minimum amount of regulation of the licensee as the Commission finds will permit the Commission to fulfill its obligations under [the AEA] to promote the common defense and security and protect the health and safety of the public…."[69]

For its part, DOE is responsible for all military reactors and has authority over all DOE-owned reactors that collect research data, or test fuels or materials. DOE is authorized to make arrangements —via contracts, agreements, and loans—to conduct research and development activities for reactors within its jurisdiction. In its energy development role, DOE holds the sole authority to use its own facilities to conduct research "for others."[70]

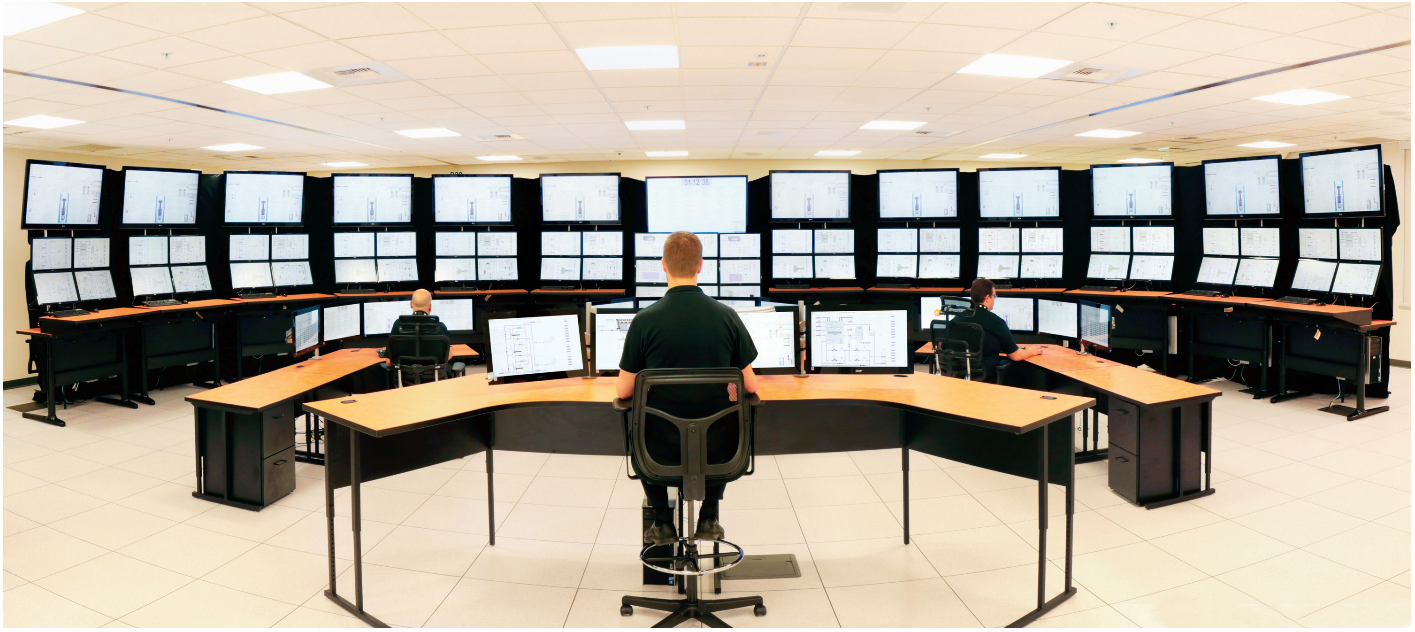
Whichever agency oversees a given demonstration reactor, the other agency will likely provide technical support. Thus, it is important for the NRC to be closely involved in either role so that

67 Energy Reorganization Act of 1974 §202(2)

68 Since the ERA, R&D under the AEA is divided by intent and purpose: (i) DOE is authorized to perform nuclear developmental (i.e., promotional) work and to conduct research that will support that work; (ii) NRC R&D cannot be promotional, but rather is to focus on confirming the adequacy of the agency's regulations and guidance, as well as the safety analysis codes and processes used in nuclear regulation and licensing. R&D to develop materials, components, and processes for advanced reactors would likely be deemed promotional, and thus a job for DOE.

69 This same flexibility exists under 104b for demonstration reactors of the type developed prior to 1970, but specific legislation is required to use this provision today. Authorization for the NGNP Program in the Energy Policy Act of 2005 specifically assigned to the NRC responsibility for NGNP licensing activities, eliminating any ambiguity regarding the authority of the NRC and DOE over that program.

70 AEA §33 – Research for Others specifically provides that, "where the [Atomic Energy] Commission [here, DOE] finds private facilities or laboratories are inadequate for the purpose, it is authorized to conduct for other persons, through its own facilities, such of those activities and studies of the types specified in section 31 as it deems appropriate to the development of energy." AEA §31 addresses R&D related to nuclear processes; the theory and production of atomic energy; processes, materials and devices related to such production; and many other topics.



The NuScale Power Control Room Simulator is designed to simulate the operation of a 12-module NuScale power plant.

it becomes more familiar with advanced technology, and ensures that the quality assurance program is sufficiently robust to produce testing results able to support a commercial license application. Continuing development and execution of advanced reactor technology knowledge management and training opportunities for NRC staff would be useful both for demonstration projects and for commercial projects.

2. KEY ISSUES

Confusion about the licensing of advanced demonstration reactors exists around terminology, responsibility, and requirements.

Terms are not generally used consistently among industry or the NRC, or even within the relevant statutes. Although there have been some efforts to improve this, we suggest that the NRC and stakeholders identify which terms are useful, determine which ones are defined by statutes and regulations, resolve discrepancies where possible, and identify any gaps that may need to be filled by additional policies, regulations, or legislation. In particular, definitions of production and utilization facilities should be resolved; breeder reactors that are not used for defense purposes may not have been contemplated by otherwise-relevant statutes and regulations. As a result, their classification may be unclear, hindering efficient processing of applications.

NRC responsibility for licensing non-power reactors lies with the Research and Test Reactor Branch of the Office of Nuclear Reactor Regulation, but the locus of responsibility is less obvious when the full spectrum of possible demonstration reactors is considered. A clarification of responsibility may follow naturally from a clarification of terminology.

Regulatory guidelines have been developed for only a few advanced reactor types. As potential demonstration reactor applicants approach readiness, it would facilitate agency evaluation if NRC guidelines were expanded to address additional advanced reactor types. These guidelines could be developed using funds appropriated specifically for this purpose, outside of the fee base. Other improvements could include the development of regulatory guidance for a demonstration that is significantly smaller, less hazardous, or with a shorter operating life than a commercial unit. It would also be useful to develop guidelines addressing how a prototype plant (as defined in 50.2 and referenced in 50.43(e)) could be used to support the design certification or licensing of a first-of-a-kind plant. The method for authorizing the operation of the prototype and for converting it to a regular commercial license after completion of testing should be explained as well.

CHAPTER VI

RECOMMENDATIONS

THE PURPOSE OF THIS REPORT has been to propose strategies that facilitate the efficient, cost-effective, and predictable licensing of power plants in the United States. These are nuclear plants that would generate clean, safe, sustainable, reliable, affordable, and proliferation-resistant energy through the use of innovative technologies, and that would improve the quality of our lives and the health of our environment.

Specifically, this report has set forth the foundation for a consultation among stakeholders that results in an improved process for licensing the next generation of nuclear reactors. Such a process would incorporate discrete stages for improved project risk management and, where appropriate, risk-informed and performance-based strategies. Our major recommendations are set forth below in three categories: regulatory, policy, and industry recommendations.

A. Regulatory

1. To structure a staged review of advanced reactors and support long-range resource planning by the agency and the applicant, the NRC and industry should develop and employ guidelines for a licensing project plan (LPP). The LPP would be a living document that serves as a roadmap for the entire process, defining—in as much detail as possible—project schedules, testing requirements, deliverables, and NRC review budgets. The most effective approach will be for the applicant and the NRC to design a licensing project plan that establishes milestones corresponding to meaningful stage-gates along a given project's development pathway and that take full advantage of the NRC's readiness to review specific aspects of the design. To provide the foundation for open communication and effective project management, we recommend that, as soon as a potential applicant initiates interaction with the NRC, the agency produce an initial LPP establishing guidelines that define the working relationship among the parties. This should help to ensure rapid resolution of conflicts and efficient progress. The NRC and potential applicants should discuss the appropriate contents of an LPP during this initial engagement period, and the LPP should be built up with additional detail as the project progresses and it is possible to foresee upcoming interactions. Much of the responsibility for designing an effective LPP lies with the applicant; the applicant will need to understand a project's design, development, deployment, and investment milestones in order to propose corresponding licensing milestones. At the same time, NRC expectations for the level of design detail must correspond to the particular milestone, and be clearly communicated to potential developers. (See Section IV.A for further detail.)

2. The NRC should promote and applicants should use topical reports and the standard design approval as tools to introduce stages into the advanced reactor licensing process, while emphasizing the need to achieve a

level of finality that supports staged decision making. These tools can be employed under current regulations, if the proper staff guidance and policies are put in place; the proposed licensing project plan could structure their use. (See Section IV for further detail.)

3. The NRC should develop and employ an optional statement of licensing feasibility process with time frames and budgets to be agreed upon in the licensing project plan. This would permit it to more easily assess whether an applicant's design intent was conceptually aligned and consistent with established regulatory requirements. Doing so would offer important benefits: (i) it would standardize a review phase that, because of its limited cost and duration, could be used by stakeholders to compare available design options; (ii) it would provide early feedback to the applicant, allowing timely alterations in approach to better meet regulatory obligations; and (iii) it would provide useful structure to pre-application engagement. (See Section IV.D for further detail.)

Figure VI-1 depicts the elements that could be used to support the staged licensing of an advanced reactor, structured by an LPP. This can be implemented under existing NRC authority; it would not require an Act of Congress.

4. The Commission and license applicants should work together to adapt the agency's light water reactor (LWR)-centric requirements so that they are better suited to advanced reactors seeking licenses in the near term, while, wherever appropriate, increasing the use of risk-informed and performance-based techniques. For new technologies, alternative approaches to the exemption process should be considered. Recently, applicants have used the practice of seeking relief from certain inapplicable or partially applicable requirements. For example, during recent licensing activities for light water small modular reactors, applicants experienced increased cost and slower review due to difficulty in executing the NRC's exemption processes. Advanced reactor designers from both traditional industrial organizations and small start-ups are concerned with the cost and schedule uncertainty associated with the exemption process (as well as potential negative perception that applicants are trying to avoid stringent safety regulation). As a result, they are hesitant to submit applications without first being assured that exemption requests will be meaningfully processed. A means should be available earlier in the process for the NRC and the applicant to reach agreement on alternative compliance strategies for specific requirements that are only partially applicable or are not applicable at all. The LPP would be a natural place to do this, once the NRC and stakeholders have identified promising approaches. This will increase efficiency and effectiveness in the design and regulation of advanced technologies without sacrificing safety or security. (See Section IV.A for further detail.)

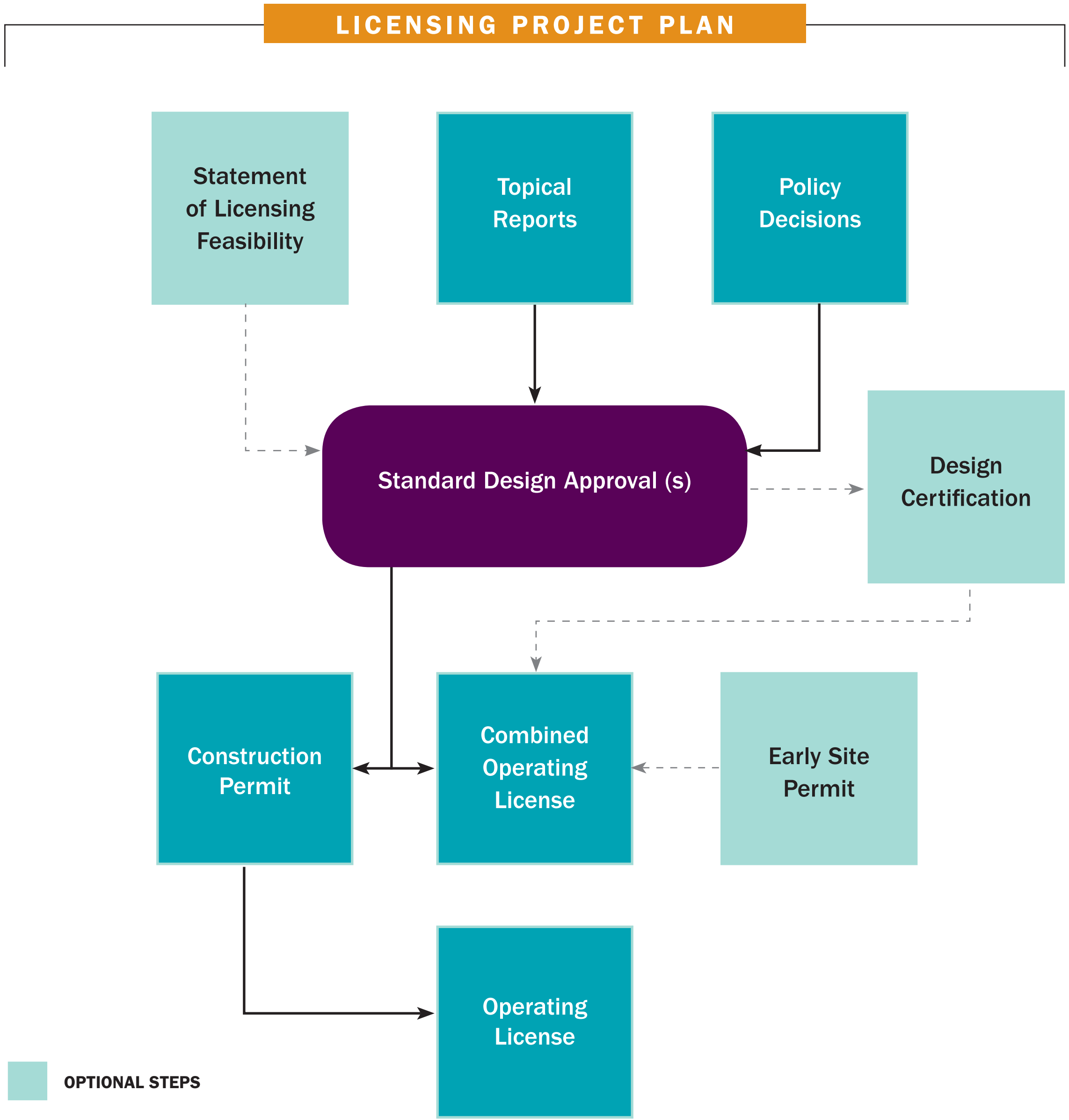
5. The NRC and DOE should continue to move forward with the DOE/NRC Advanced Reactor Licensing Initiative.[71] This will help to establish and clarify acceptable approaches for creating the underlying design criteria associated with these concepts, thereby removing a portion of the regulatory uncertainty associated with advanced non-LWRs. (See Section V.A for further detail.)

6. Given the substantial investments that have already been made by industry and DOE in pre-application reports and proposals for advanced reactors (including the Next Generation Nuclear Plant), and by NRC staff in evaluating them, the NIA recommends that (i) the NRC complete its evaluation and the Commission issue its decisions or opinions at this stage of the application, and (ii) generic issues raised by DOE and NRC be resolved through the issuance of guidance for advanced reactor applicants. (See Section V.A for further detail.)

7. At the same time that the NRC pursues the above initiatives, the NRC should designate a special technical team to develop a plan to implement a technology-inclusive licensing and

71 This was most recently described in the following report: US Department of Energy, Office of Nuclear Energy, Guidance for Developing Principal Design Criteria for Advanced (Non-Light Water) Reactors, December, 2014. *http://pbadupws.nrc.gov/docs/ML1435/ML14353A246.pdf.*

FIGURE VI–1
Available Stages for Licensing an Advanced Reactor



regulatory framework for advanced reactors based on risk-informed and performance-based principles. The technical team should propose a roadmap for putting the new framework into practice by 2025, and then be given the administrative flexibility and resources to succeed. Because this framework will not be ready immediately, it should remain optional (similar to the Part 52 licensing processes as an alternative to the Part 50 process)—at least until it is fully demonstrated. That way, its development will not delay current projects. (See Section V.A for further detail.)

8. To provide a clear and achievable regulatory pathway for developing and deploying advanced demonstration reactors, the NRC should:
   i. In collaboration with stakeholders, clarify terminology and resolve discrepancies and gaps in statutes, regulations, and practice;
   ii. Using terminology revised pursuant to (i) above, clarify responsibility for reviewing potential applications;
   iii. Develop guidelines for advanced reactor demonstrations to support the review process; and

iv. Provide or develop guidelines for prototype plant regulation (as defined in 10 CFR 50.2 and referenced in 10 CFR 50.43(e)) and conversion to commercial operation.

(See Section V.B for further detail.)

9. The NRC should continue development and execution of advanced reactor technology knowledge management and training opportunities for NRC staff. Mid- and upper-level managers should be included in these programs. Funding will be needed to support this. (See Section V.B for further detail.)

B. Policy

1. Congress should revise the NRC's budget structure so that, instead of a 90% fee-based, 10% public funding model, licensees and applicants reimburse the NRC for activities related to their regulation, with Congress funding other agency-related activities—including the development of new regulations for advanced technologies, R&D, international programs, and other initiatives not related to a specific licensee. The nuclear fleet operating today was licensed by an NRC that had been fully funded by Congress, before the advent of current fee-recovery rules. Unlike that earlier generation of reactors, licensing of the AP1000s now under construction has been supported by substantial cost-shared funding from DOE. To prepare for the licensing of advanced reactors, the NRC faces a greater challenge that will require consistent public funding.

2. Congress should appropriate funds for the NRC to prepare for advanced reactor licensing, including but not limited to:
   - Development and implementation of strategies to stage and expedite the advanced reactor licensing process;
   - Development and implementation of a risk-informed, performance-based licensing framework for advanced non-light water reactors;
   - Efforts to prepare the process of licensing advanced demonstration reactors; and
   - Staff training or the hiring of experts.

3. To expand available financial resources for advanced reactor companies, Congress should continue to fund DOE to competitively award grants for early efforts to license advanced reactor companies, including but not limited to:
   - Pre-application engagement with the NRC;
   - Developing a licensing project plan; and
   - Applying for a statement of licensing feasibility or similar early-stage design review.

   The DOE Gateway for Accelerated Innovation in Nuclear (GAIN) initiative's small business voucher program is one possible mechanism for this.

C. Industry

Industry has an important role to play as a constructive participant in all of the above recommendations, but also has primary responsibility for several actions:

1. Industry stakeholders should cooperate to deliver a coordinated message to the NRC regarding technology-inclusive advanced reactor priorities.

2. Prospective applicants should proactively address the NRC's need for information about future projects by informing the agency as early as possible of their intent to request NRC review. By capturing this information in regulatory issue summaries, the NRC will have a stronger basis to support research, as well as budgetary estimates and requests.

3. Industry should take a more active role in communicating with the NRC, DOE, and other stakeholders on the challenges and opportunities associated with various advanced reactor designs, including R&D priorities.

4. Working with appropriate research and standards organizations, industry should pursue the development of codes, standards, and conventions for advanced nuclear power.

We intend these recommendations to serve as a foundation for appropriate deliberation and prioritization and, soon after, decisive action to improve the regulatory pathway for advanced nuclear energy technologies. This is critically important work that will enable society to capture the immense future benefits of advanced nuclear power.

ABBREVIATIONS

ABWR	Advanced Boiling Water Reactor
ACRS	NRC Advisory Committee on Reactor Safeguards
AEA	Atomic Energy Act of 1954 (US)
AEC	Atomic Energy Commission, forerunner to the NRC and ERDA/DOE
ALWR	Advanced Light Water Reactor
ANS	American Nuclear Society
ASLB	Atomic Safety and Licensing Board
ASME	American Society of Mechanical Engineers
BLA	Biologics License Application (FDA)
CBER	Center for Biologics Evaluation and Research (FDA)
CDER	Center for Drug Evaluation and Research (FDA)
CDRH	Center for Devices and Radiological Health (FDA)
CFR	Code of Federal Regulations (US)
CNSC	Canadian Nuclear Safety Commission
COL	Combined Operating License (Part 52 Appendix C) (NRC)
COLA	Combined Operating License Application (Part 52 Appendix C) (NRC)
CP	Construction Permit (Part 50) (NRC)
CPI	Certification Process Improvement (CPI) Guide (FAA)
DAC	Design Acceptance Confirmation (UK)
DBA	Design Basis Accidents (NRC)
DC	Design Certification (Part 52 Appendix D) (NRC)
DCA	Design Certification Application (Part 52 Appendix D) (NRC)
DCRA	Design Centered Review Approach (NRC)
DOD	Department of Defense (US)
DOE	Department of Energy (US)
DSRS	Design Specific Review Standard (NRC)
EP	Emergency Preparedness (NRC)
ERA	Energy Reorganization Act of 1974, which created ERDA and the NRC as successors to the AEC (US)
ERDA	Energy Research and Development Administration, created by the ERA of 1974 and forerunner to DOE (US)
ESP	Early Site Permit (Part 52 Appendix A) (NRC)
ESPA	Early Site Permit Application (Part 52 Appendix A) (NRC)
FAA	Federal Aviation Administration (US)
FDA	Food and Drug Administration (US)
FOAK	First Of A Kind

FSAR	Final Safety Analysis Report (NRC)
FSER	Final Safety Evaluation Report (NRC)
GAIN	Gateway for Accelerated Innovation in Nuclear (DOE)
GAO	Government Accountability Office (US)
GDA	Generic Design Acceptance (UK)
GDC	General Design Criteria (10 CFR 50, Appendix A) (NRC)
HFE	Human Factors Engineering (NRC)
HRA	Human Reliability Assessment
I & C	Instrumentation & Controls (NRC)
IET	Integral Effects Test (NRC)
IND	Investigational New Drug application (FDA)
ITAAC	Inspections, Tests, Analyses, and Acceptance Criteria (NRC)
JCNRM	Joint Committee on Nuclear Risk Management (US)
LPP	Licensing Project Plan
NDA	New Drug Application (FDA)
NEI	Nuclear Energy Institute
NEPA	National Environmental Policy Act of 1969 (US)
NGNP	Next Generation Nuclear Plant
NRC	Nuclear Regulatory Commission (US)
NSCA	Nuclear Safety and Control Act (Canada)
NUREG	NRC-published reports or brochures on regulatory decisions, on the results of research and incident investigations, and on other technical and administrative matters (acronym is derived from "nuclear regulation")
OL	Operating License (Part 50) (NRC)
ONR	Office of Nuclear Regulation (UK)
Part 50/ Part 52	Title 10 of the US Code of Federal Regulations, Part 50 or 52
PIRT	Phenomena Identification and Ranking Table (NRC)
PRA	Probabilistic Risk Assessment
PSCP	Project-Specific Certification Plan (FAA)
PSP	Partnership for Safety Plan (FAA)
QA	Quality Assurance
RA	Regulatory Affairs
RAI	Request for Additional Information (NRC)
R-COLA	Reference Combined Operating License Application (NRC)
RIPB	Risk-Informed Performance-Based
RIS	Regulatory Issue Summary
RTR	Research and Test Reactor
SAR	Safety Analysis Report (NRC)
S-COLA	Subsequent Combined Operating License Application (NRC)
SDA	Standard Design Approval (Part 52 Subpart E) (NRC)
SECY	Memorandum to the Secretary of the Commission or the Commission from various NRC offices that report to the Commission
SER	Safety Evaluation Report (NRC)
SET	Separate Effects Test (NRC)
SMR	Small Modular Reactor
SRM	Staff Requirements Memorandum from the Commission to NRC Staff
SSC	Systems, Structures, and Components (NRC)
TR	Topical Report (NRC)
VDR	Vendor Design Review (Canada)

APPENDIX A

The Advanced Reactor Development and Deployment Process

The licensing process for advanced reactors cannot be considered in a vacuum. The introduction of stages to advanced reactor licensing will be most effective if those stages are coordinated with appropriate phases in the design, development, deployment, and investment process (put simply, the development process) for those reactors. Conversely, a more orderly and thoughtful execution of phases and coordination of stakeholders in the development process would serve to expedite the deployment of advanced reactors, particularly if steps in that process were coordinated with staged licensing.

This appendix sets forth a simplified representation of the development and deployment timeline, as well as key stakeholder relationships. It also provides a conceptual layout of the major program phases, emphasizing the possibilities for more effective "alignment"—that is, close coordination—of stakeholder interests. Details of a staged licensing approach are discussed in Chapter IV; this appendix provides context by describing how staged licensing fits into the overall project development process. A central theme in this report is the need for early planning and collaboration among stakeholders, so that the parties can develop an execution plan that accounts for all stages in the development (and licensing) process. This appendix provides examples of how early coordination resolves key issues sooner and more rapidly.

A. Development Process Stakeholder Timelines

The current duration and cost of the design, licensing, and delivery process for new reactor designs and specific projects is both uncertain and far too lengthy. To fully appreciate the complexity and interrelationships of the major phases and types of stakeholders, Figure A-1 (p. 63) is a representation of the current overall development and deployment cycle for an advanced light water reactor (ALWR). This reflects a composite of the various major activities that must be completed to bring a first-of-a-kind (FOAK) reactor design from the pre-conceptual stage to full operation. The stakeholder groups include investors, designers, regulators, builders, operators, owners, and the public, and were chosen to represent the wide range of institutions and entities that typically participate in a FOAK program. All have differing time frames with regard to interest, motivation, and risk tolerance.

The stakeholders' primary activities are as follows:

- Finance,
- Design,
- Licensing,
- Construction,
- Plant testing,
- Operations, and
- Public participation.

The sub-activities in Figure A-1 (p. 63) reflect practices and expectations observed in the NRC's current licensing process, described in 10 CFR Part 52. Extrapolating averages from publicly available data, actual experience with certain existing ALWR designs would generate timelines *exceeding three decades*, if all listed activities were completed. A major driver of this protracted development timeline is the wide variation in outcomes that arise from prolonged NRC review, further extended by the applicant's effort to resolve the issues that the NRC has raised. Delays are also caused by unsteady funding, mothballing and reactivation decisions by plant owners (e.g., Watts Bar Unit 2), poor design execution and integration, failure to incorporate construction methods into design, and failure of the owner to adequately prepare for operation. The historical evidence suggests that every stakeholder, at one time or another, has negatively affected the development cycle. Lack of alignment on major decisions can result in a nearly continuous series of unanticipated or poorly timed actions that lead to delay.

It is clear from past experience that the need to institute clear phases with discrete risk reduction does not solely apply to nuclear regulators. All stakeholders would benefit from a more organized development process. The benefits flow outward: efficient alignment of the regulatory and private development processes would enable faster commercialization and deployment of nuclear technologies, which in turn would address a growing global need for clean, reliable energy.

B. Reducing Program Risk

The prospects for advanced nuclear technology will be bleak if the delays historically associated with nuclear energy development persist.

Fortunately, the adoption of logical program phases can increase alignment of stakeholder expectations, enhance coordination, and help to reduce delays. Figure A-2 (p. 64) illustrates one possible phase delineation that strengthens coordination of financing, design, licensing, construction, testing, owner operation, and public participation. Concrete phases with defined outcomes will enable parties to more easily make rational long-term commitments to the program. As a result, the time frame from conceptualization to full operation can be shortened appreciably. The following phases are recommended:

1. ***Conceptualization:*** Initial phase of reactor concept development and start of functional design. Includes proof-of-principle testing in integrated and separate effects facilities. By the end of the stage, formal engagement with the NRC has been initiated.

2. ***Licensability:*** The transition from conceptualization to fully developed organization of design and licensing products, focusing on functional design, preliminary safety analysis, and licensing. An agreed-upon NRC pre-application program scope and schedule—as well as a preliminary licensing project plan (LPP), as described in Section IV.A—are in place. This could include an optional statement of licensing feasibility. At the end of this phase, initial topical reports should be under review, with some approved. The design stage should be progressing from functional design and the completion of design trade-off studies to the physical design of nuclear systems and structures.

3. ***Technology Approval:*** At this point, the NRC receives additional topical reports and possibly a standard design approval (SDA) application for "a major portion" of the common standardized design. This initiates the first phase of the integrated review process that precedes DCA and COLA submittals (or that could be incorporated by reference in a Part 50 application). The DCA, if applicable, is then submitted, referencing the SDA. This completes the description of the standard design to be certified.

4. ***Project-Specific Approval:*** The site-specific submittal and review of an application to build a plant. This would include submittal of a COLA, ESP (if desired), or a CP.

5. ***Construction Period:*** The period during which equipment is manufactured (e.g., factory fabrication of major assemblies, as well as individual components and parts) and the plant is constructed, consistent with the approved COL or CP. If a Part 50 approach had been taken, this period also would include submittal and review of the FSAR, followed by the OL hearing.

6. ***Licensed Operation:*** The period encompassing license issuance, delivery of fuel to the site, initial fuel loading, start-up of the nuclear unit, and testing operations.

7. ***Commercial Operation:*** The operating period that follows satisfaction of all initial testing and operational conditions of the license.

Retrospective redefinition of existing phases cannot by itself address the lack of coordination that hampers the prospects of future advanced reactor development. However, the process can be expedited by changing the way in which key stakeholders perform and align their portions of the work.

FIGURE A-1

Stakeholder Activities and Timeline

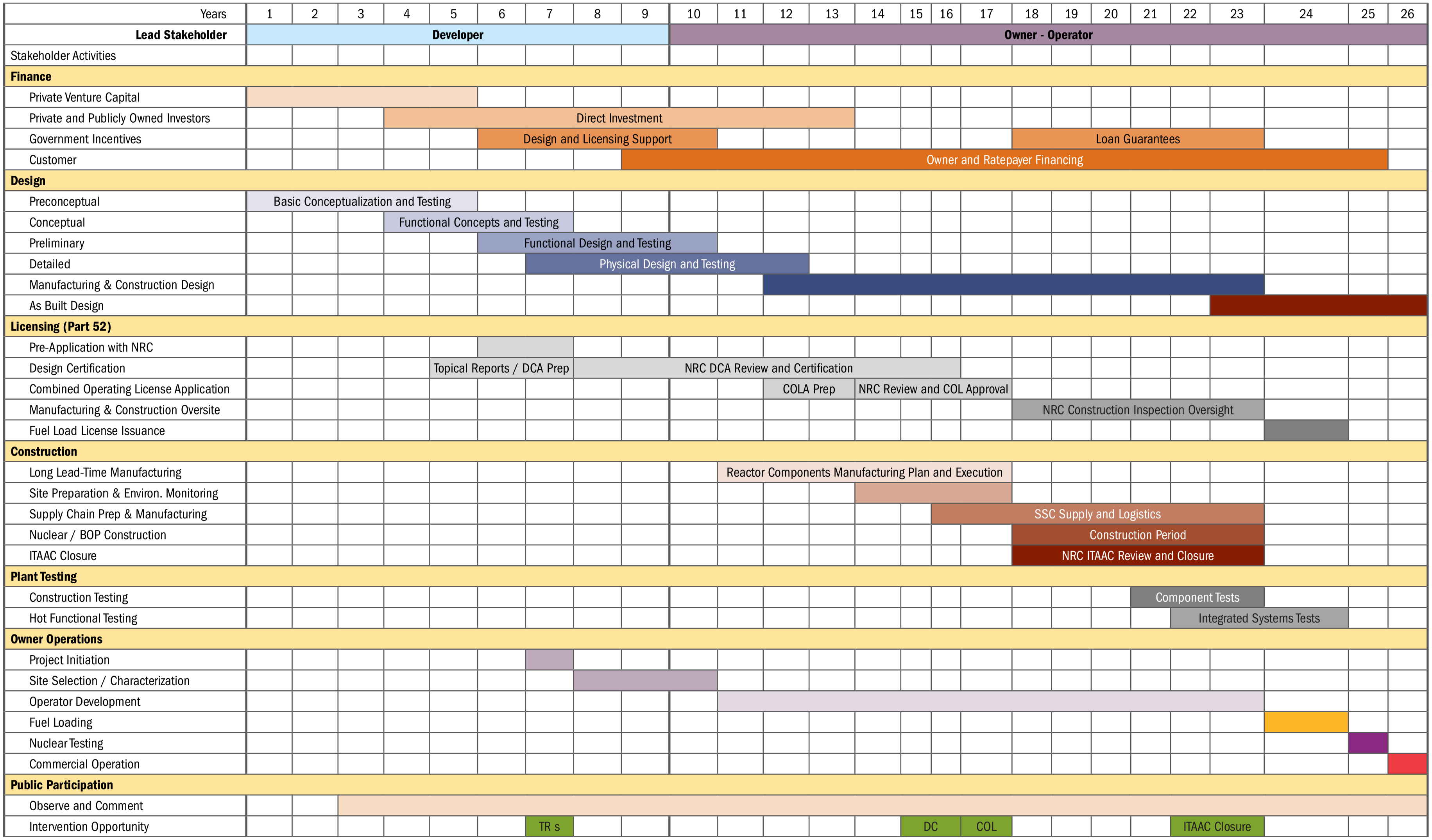
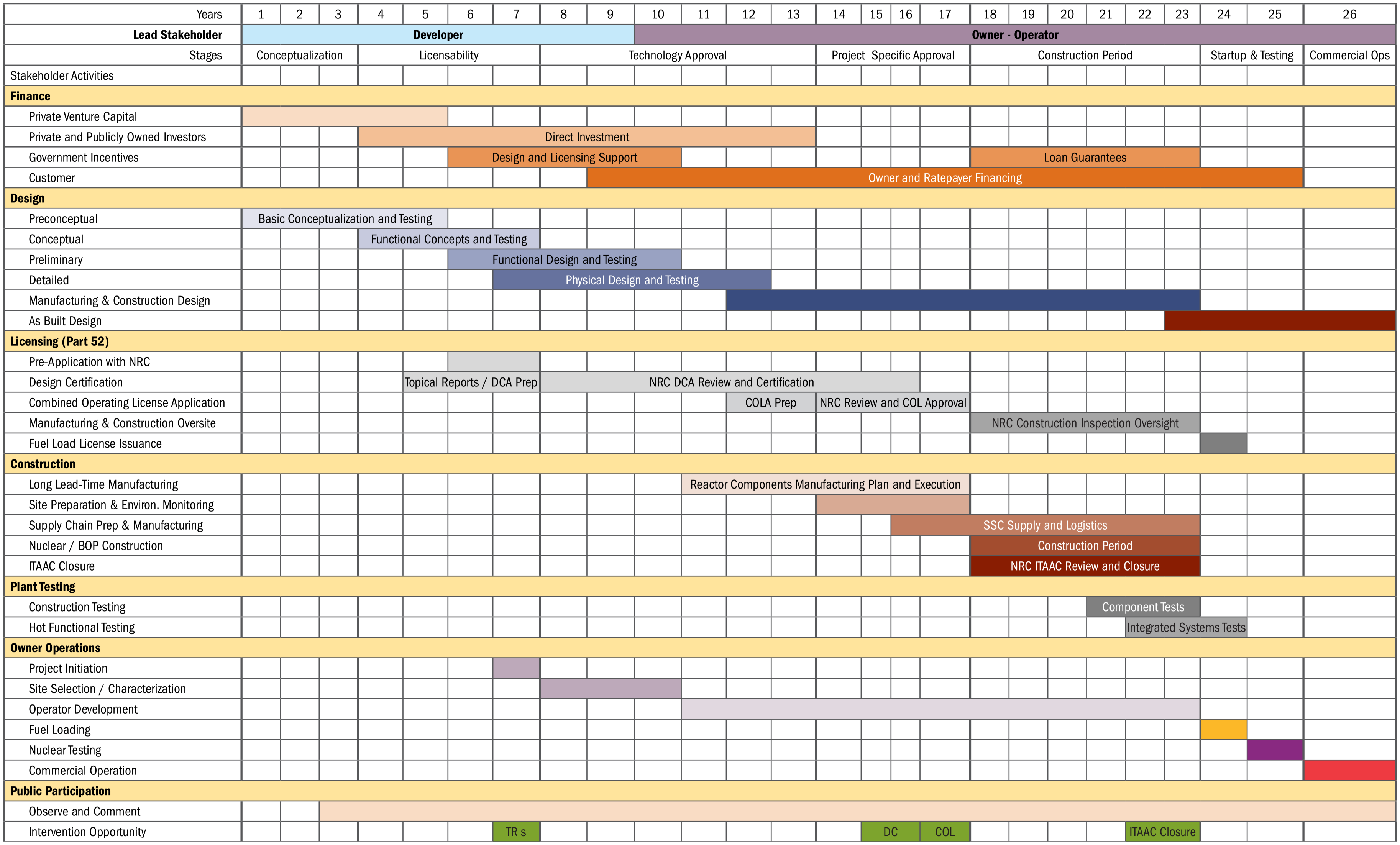


FIGURE A-2

Stakeholder Activities and Timeline with Conceptual Program Stages



C. Enhancing Stakeholder Alignment

To confirm the value of establishing and describing clearer program phases, it is helpful to understand the needs and interdependencies of the various stakeholders. Provided below are relevant examples of the types of issues that in the past have interfered with stakeholder alignment and coordination.

1. DESIGN AND LICENSING ALIGNMENT

To proceed effectively, designers and engineers must possess a clear understanding of their program objectives, technology choices, regulatory constraints, and prospective user needs. Historically, license applications were submitted late in the development process, often when the design work was nearing completion. As a result, licensing deliverables and design development proceeded as sequential, rather than parallel, objectives—sometimes requiring design changes in areas that had been misunderstood or overlooked. This negatively affected cost, schedule, and technical choices. To avoid this result, the applicant must receive clear guidance from the outset concerning the regulator's expectations. This is particularly important—but also particularly hard to obtain—for advanced designs that have not yet been licensed.

For the NRC to undertake licensing review in an efficient and timely way, the applicant must give the agency advance notice of any new technologies, analytical methods, materials, and approaches that the applicant intends to rely on. NRC staff also needs access to a sufficiently detailed design and schedule to plan for needed reviews—including reviews, if any, by outside experts. As part of the process, the applicant should identify any gaps it perceives in the existing regulatory framework. The agency should do the same, while also assessing the adequacy of existing resources.

2. FINANCIAL AND PROGRAM ALIGNMENT

A variety of financial stakeholders participate in the creation of a new nuclear plant. To support its decision to invest, each stakeholder requires reasonable assurance of success. When integrated program milestones provide clear entrance and exit points, investors are better able to make rational decisions on whether to move forward.

To avoid uncertainty and disruption, the development plan and program require continuous, or at least predictable, funding. Identifying explicit deliverables along the development timeline is critical to establishing program credibility and attracting progressively larger investment, consistent with efficient capitalization.

Early venture capital creates value in the developer's portfolio of intellectual property rights and previously completed work. This can produce a financial return: (i) when the developer, as a standalone entity, is sold to a later-stage funder; (ii) when the developer is taken public to benefit its original owners; or (iii) when the developer garners substantial additional private or government investment to support subsequent, increasingly more capital-intensive project phases. To assure program continuity, government funding often is essential—as much to signal political support as financial commitment. As with any emergent, capital-intensive technology, government policy can have a strong impact on progress and ultimate viability.

At some point, development progress must be sufficient to attract commitment from a public utility or similar end-use investor. But even before that, licensing progress acts as a critical indicator of on-time delivery and, thus, serves as a magnet for initial or continuing investment. In sum, licensing progress is as important as progress in the design delivery program—but even more so is their alignment and coordination.

3. OWNER/OPERATOR AND DEVELOPER PROGRAM ALIGNMENT

The ultimate owner/operator must maintain a substantial internal development program to assure its readiness to operate the completed nuclear facility. In addition to possessing sufficient project management capacity to support construction or on-site assembly, the owner/operator must assemble NRC-licensed programs for operations and maintenance, public engagement, and emergency response. All of these programs tend to be interdependent, but the operation and maintenance program is particularly dependent on facility design. There, procedures and staff training will require close coordination with the overall design of the plant. I&C design, HFE design, and simulator fidelity, for example, need to be carefully coordinated and completed in a time frame that strengthens initial licensed operator training.

4. PUBLIC AND DEVELOPMENT PROGRAM ALIGNMENT

Early, extensive, and continuous public outreach and involvement begins in the earliest phases of the development program. Generally, final responsibility for public outreach rests with the owner/operator. However, before an owner/operator has been identified, the vendor performs this task. At the federal level, the preparation, review, and approval of an early site permit (ESP) is a meaningful way to attract early public involvement.

Similar points of coordination among the site owner, the NRC, and state and local regulatory agencies should be described in the licensing project plan (see Section IV.A). This will provide an opportunity for state and local regulators to review the proposed technology and discuss their own requirements.

APPENDIX B

The Legal Context

This appendix provides the specific legal context that supports this report's recommendations and conclusions. It addresses (i) legal requirements for the development of a reactor; (ii) differences and similarities in the regulation of existing and advanced commercial reactors; and (iii) licensing prototype, demonstration, research, and test reactors.

Legal Requirements for the Development of a Reactor

The controlling statutes are the Atomic Energy Act of 1954, as amended (AEA), and the Energy Reorganization Act of 1974 (ERA). The NRC has broad discretion under the AEA to establish safety/security and licensing standards for industrial and commercial, medical therapy, and research and development reactors, and to establish licensing/administrative processes for agency reviews, hearings, and public input and participation.

Significant Atomic Energy Act and Energy Reorganization Act Sections

AEA §31 stipulates that the Commission is to ensure the continued conduct of research and development, and training in the theory and production of nuclear energy. Currently, after the division of the AEA's responsibilities between the NRC and DOE, DOE is charged with ensuring the conduct of research and development, and training in the theory and production of nuclear energy, while the NRC is authorized to conduct research and development, and training in the theory and production of nuclear energy as needed for safety and security regulation.

AEA §101 and §102 provide that a license is required for any person to manufacture, produce, transfer, acquire, possess, use, import, or export any reactor. Any reactor to be used for industrial or commercial purposes must be licensed pursuant to AEA §103. Reactor licenses for medical therapy and R&D are issued pursuant to §104.

AEA §103 authorizes the NRC—under the terms of an agreement for cooperation (a "123 agreement")—to issue licenses to persons applying to manufacture, produce, acquire, possess, use, import, or export any reactor for industrial or commercial purposes.

Applicants must be equipped and agree to follow all standards to protect health and safety, and to promote the common defense and security, and they must provide the NRC with all related information it deems necessary. Each §103 license is to be issued for a specified period not to exceed 40 years from the date of authorization, although it may be renewed. An advanced reactor developed for commercial or industrial purposes—for example, the generation of power for sale—would be licensed under AEA §103.

AEA §103b. establishes the fundamental standards for commercial reactor licensing: to protect health and minimize danger to life or property, to promote the common defense and security, and to protect the health and safety of the public.

AEA §104 authorizes the Commission to issue reactor licenses for medical therapy, and research and development ("Class 104" licenses). These

R&D reactors should not be confused with certain DOE research and test reactors (e.g., those located at certain national laboratories), which are not regulated by the NRC and are not "demonstration reactors" subject to NRC licensing and regulation under ERA §202.

AEA §104b. provides licenses "for utilization and production facilities for industrial and commercial purposes."

AEA §104c. considers "utilization and production facilities useful in the conduct of research and development activities of the types specified in section 31 and which are not facilities of the type specified in subsection 104b."

AEA §182 provides the Commission with broad powers to request and obtain all information it deems necessary for licensing and regulation.

AEA §185 establishes the license application processes, now commonly referred to as Parts 50 and 52 (see below, 10 CFR Part 50 and 10 CFR Part 52).

AEA §189 establishes the procedures for hearings and judicial review. The NRC must grant a hearing at the request of any person whose interest may be affected. Hearings are mandatory for issuance of construction authorization (CP or COL), and an opportunity for a hearing must be provided before operation is authorized or commences.

ERA §2 defines the separation of functions and authorities of the original Atomic Energy Commission. ERDA (now, DOE) maintains authority and responsibility for military aspects of atomic energy, as well as for research and development, and promotion of all forms of energy for commercial and industrial purposes. The NRC maintains authority and responsibility for licensing and regulation of the non-military production and use of atomic energy, as well as possession and use of AEA materials (source material, byproduct material, and special nuclear material).

ERA §103 conveys to DOE responsibility for, among other things, the research and development of nuclear energy sources, and the demonstration of their commercial feasibility and practical applications.

ERA §202(2) establishes that the NRC maintains the authority to regulate all demonstration reactors (except those in existence prior to the ERA's enactment) "when operated as part of the power generation facilities of an electric utility system, or when operated in any other manner for the purpose of demonstrating the suitability for commercial application of such a reactor," including those owned and operated by DOE.

Implementing Regulations

The reactor licensing and oversight requirements of the AEA are implemented by regulations and orders developed over time by the AEC and the NRC. The NRC may specify the information that an applicant must provide for licensing. The agency is authorized to combine licenses; to incorporate earlier findings, information contained in previous applications, statements, or reports; and to build on previous submittals (e.g., topical reports). The primary regulations specifically applicable to reactor licensing are set forth in 10 CFR Parts 50 and 52.

Other requirements and processes central to reactor licensing and oversight are found in the following sections, among others: 10 CFR Parts 2 (domestic licensing proceedings), 20 (standards for protection against radiation), 21 (reporting of defects and noncompliance), 51 (environmental protection), 55 (operators' licenses), 100 (reactor site criteria), 140 (financial protection requirements and indemnity agreements), 170 (fees for licenses and other regulatory services), and 171 (annual fees).

10 CFR Part 50 establishes the two-step licensing program—construction permit (CP) followed by operating license (OL)—envisioned in the AEA. It is oriented to light-water reactors, but is not limited to any one type of reactor technology. The AEA requires a mandatory adjudicatory hearing (even if no one whose interest may be affected requests one) before issuing a COL.

§50.12 permits the Commission to grant a specific exemption from the regulations, if (i) special circumstances, as defined in 50.12, are shown to exist; (ii) the exemption is in accordance with law; (iii) it will not present an undue risk to the public health and safety; and (iv) it is consistent with the common defense and security.

§50.21 defines the types of medical therapy, and research and development facilities that can be granted Class 104 licenses.

§50.22 states that a Class 103 license (for a commercial facility) is to be issued to a reactor for which more than half the annual cost of owning/operating the facility is allocated to the sale or commercial distribution of energy or other products, or the sale of services.

Under Part 50, a complete design is reviewed and a CP issued. When construction is completed in compliance with the CP, an OL will be issued.

10 CFR Part 52 combines the two steps of Part 50 into a combined license (COL). It includes definitions of prototype plants and testing facilities, and governs the issuance of early site permits (ESPs), standard design certifications (DCs), and standard design approvals (SDAs).

Subpart B defines a standard design certification (DC) as a nuclear reactor design embodied in a rule developed through the federal Administrative Procedures Act's traditional notice and comment rulemaking process. A DC will not be modified or changed by the Commission except in specified circumstances. The AEA does not require a hearing for issuance of a DC, although an environmental assessment is required.

Subpart C defines a combined license (COL), which can be thought of as a "one-and-a-half step" process. It serves as a construction permit and assures subsequent authorization to operate, if construction is adequate. The COL may reference a DC, SDA, or an early site permit (ESP). The AEA requires an adjudicatory hearing (even if no one whose interest may be affected requests one) before issuing a COL. A second proceeding (possibly a legislative-style "hearing") may be held to consider operating authorization after construction is completed.

Subpart E defines standard design approval (SDA) as a review of a final standard design or a "major portion" thereof. It is, in essence, an NRC staff statement regarding the licensability of the design, but not a commitment to issue a permit or license. An SDA is effective for 15 years, but may not be renewed. The SDA application does not trigger the hearing process and is not binding on the Commission.

Note that, where the proposed standard design differs significantly from the light water reactor designs of plants that were licensed and entered commercial operation before April 1989, 10 CFR 50.43(e)'s requirements for the demonstration of safety features (i.e., analyses, testing, experience, a combination thereof, or acceptable performance of a prototype plant) must be met. The SDA process under 10 CFR Part 52 is currently in place and useable, and the NRC has stated that it expects advanced reactor designs to follow it "as is."

Adequate Protection of Health and Safety

The AEA uses various terms ("not inimical to the health and safety of the public"; "protect health"; "adequate protection"; "reasonable assurance of adequate protection") to establish regulatory standards for safety requirements. The US Supreme Court has used the phrase "adequate protection" to describe the statutory benchmark. As authorized by the AEA, the NRC's application of its scientific and technical judgment to regulations and guidance further specifies that the "adequate protection" standard encompasses a level of safety sufficient for adequate protection of public health and safety, and the common defense and security.

Although current regulations and guidance do not completely describe the acceptance criteria for non-light water reactor designs, the NRC has determined that its current reactor licensing regulations are adequate for conducting reviews of advanced reactor applications. In exercising its licensing authority, the NRC has the discretion to determine—on a case-by-case basis, using its expert engineering and scientific judgment—what constitutes adequate protection; recently, it stated that it intends to do so via an exemption process initiated by advanced reactor applicants.[72]

Environmental review is required at various stages of the licensing process. The environmental review process for new reactors grows progressively more rigorous as development advances towards the siting of a reactor. There are no environmental review requirements for an SDA. Specified environmental reviews must be conducted for the DC (which requires, at least, an environmental assessment (EA)), with more rigorous, site-specific reviews (including the preparation of an environmental impact statement (EIS)) undertaken for ESPs, CPs, OLs, and COLs. These reviews are the responsibility of the NRC, but the Commission requires

72 Written Statement to the Subcommittee on Energy of the House Committee on Science, Space, and Technology, July 29, 2015, at 4–5, see *http://www.nrc.gov/about-nrc/organization/commission/comm-stephen-burns/burns-07292015-testimony.pdf).*

that the applicant prepare an environmental report (ER) encompassing the same information; the more information that the applicant provides to the NRC in its ER on topics to be addressed in the NRC's EA/EIS, the more expeditious it can expect the license application process to be.

Statement of Licensing Feasibility

For SDAs, the manner in which the required findings are expressed—"whether or not the design is acceptable, subject to appropriate terms and conditions"—clearly implies that, in essence, the NRC staff will be looking for compliance with the basic licensing standards set forth in 10 CFR Parts 20, 50, 73, and 100. This should be seen as a conditional finding of licensability and thus influential with the Commission, but it does not constitute a commitment to issue a permit or license. As a result, it does not bind the Commission or adjudicatory boards. A statement of licensing feasibility or a finding of no major impediments to licensing can be, and has been, issued under current rules. Developing a process analogous to the CNSC's VDR Phase 1 will require Commission policy decisions, at a minimum.

NRC Fee Recovery

The NRC is required by Congress, pursuant to Section 6101 of the Omnibus Budget Reconciliation Act of 1990, to recover approximately 90% of its budget through fees. These fees are assessed in accordance with 10 CFR Parts 170 and 171. Part 170 assesses fees for regulatory services (reviews, inspections, and evaluations), while Part 171 assesses annual fees on entities holding licenses and permits. Fee valuations are set annually in a formal rulemaking and, as noted, are designed to recover some nine-tenths of the agency's budget.

Regulation of Non-Light Water Reactors

In creating regulatory avenues, the AEA itself generally expresses no preference for light water over non-light water technology. In view of the commercial (primarily power) reactor industry's development path, the AEC/NRC has focused mainly on light water reactors. Nonetheless, the agency has some experience with non-light water reactors. For the most part, these have been reviewed on a case-by-case basis (e.g., Peach Bottom 1 and Ft. St. Vrain (gas cooled, graphite moderated) and the Clinch River breeder reactor (liquid metal)).

The NRC has indicated that it expects advanced reactors to follow similar review pathways—namely, via Part 50 or Part 52. For example, SDAs and topical reports can easily be applied to non-light water technologies and small modular reactor (SMR) designs. The need for exemptions from existing regulations has been recognized and exemptions may be granted, if it can be shown that the regulation does not apply to the advanced reactor design.

Standard Design Approvals

Any person (e.g., vendor, future applicant for a design certification or reactor license, etc.) may file an application for standard design approval (SDA) of a proposed nuclear reactor under Subpart E of 10 CFR Part 52. The application may cover the entire proposed reactor or a "major portion" of it.

At the conclusion of the NRC staff's review of an application for approval of a standard reactor design (applying 10 CFR Part 52 Subpart E—Standard Design Approvals), the staff will issue a final safety evaluation report (FSER). If the FSER demonstrates that the design is acceptable, the staff, if requested, may issue a final design approval with appropriate terms and conditions. An applicant for a construction permit filed under 10 CFR Part 50 or a combined license filed under Subpart C of 10 CFR Part 52 may reference the FDA in those applications.

Notably, although standard design approvals require ACRS review, they do not require an adjudicatory hearing or Commission review, and are categorically excluded from environmental review. The design approval occurs at the staff level. It provides an indication of the licensability of the design, and is "final" insofar as the same design/major portion cannot be re-reviewed by the staff or ACRS, unless significant new information comes to light. An SDA is not binding on the Commission or adjudicatory boards.

An SDA is valid for 15 years and cannot be renewed. It continues beyond that period for the duration of any related proceeding docketed before its expiration. The SDA process is in place and usable "as is" under existing NRC regulations, and can become part of a staged licensing process without the need for agency rulemaking.

Topical Reports

An important part of a staged licensing approach involves topical reports (TRs). TRs are a supplemental mechanism to document and obtain NRC staff approval of technical nuclear plant safety topics in advance of, in parallel with, or even after the submittal of an SDA, DC, or COL application.

A TR can involve a proposed analytical methodology, an SSC design, SSC performance testing, operational requirements, or other safety-related subjects. TR approval can be referenced in the desired licensing action application.

Typically, a TR is expected to be referenced by multiple licensees in multiple requests for licensing action, but TRs also are frequently used to protect proprietary information. In all cases, a TR must address a specific safety-related subject and contain complete and detailed information, thus increasing the efficacy of the NRC's review of future applications that reference the report. No environmental reviews are associated with TRs.

As the process exists today, the use of topical (and technical[73]) reports does not require formal rulemaking, but their use in creating a more structured (i.e., staged) licensing process would require substantial interaction with NRC staff. Such a process would call for submittal sequences and schedules, staff review timetables, and structured resource allocation. Implementing these changes would likely require staff consultation with the Commission.[74]

Exemptions

The NRC itself has indicated that it will use an "exemption" approach to establish the regulatory framework for advanced reactors if specific regulations do not suffice. Generally, this case-by-case method of setting design requirements and criteria is expected to provide adequate protection. In the specific area of emergency preparedness (EP), the NRC has indicated that it will consider modifying parts of the EP requirements applicable to large power reactors to apply to small modular reactors (SMRs).

For a DC, the exemptions will be incorporated into the DC rule. For a CP or OL under Part 50, and a COL under Part 52, the exemptions will be written into the license requirements by means of a license condition. For example, a COL applicant contending that specified regulations do not apply to its advanced reactor design must seek an exemption from the regulation in question and must establish that (i) the regulation as written does not fit its design, and (ii) the alternative means of accomplishing a safety function in the context of its design meets the intent of the regulation in question. This establishes a technical safety standard for this particular design in lieu of the regulation from which the exemption is sought. Typically, in such exemption requests, the NRC publishes a notice of proposed exemption, requests public comments (a mini-rulemaking), and applies 10 CFR Part 51 to address the agency's obligations under the National Environmental Policy Act (NEPA). Public comments can occur in conjunction with otherwise required hearings.

This process replaces the application of specific regulations, which in any event will be non-existent for many parts of a non-light water reactor design. Although this case-by-case process will be more tedious, it is a legally sound and workable alternative. The absence of regulations setting specific technical standards for non-light water reactors constitutes a limitation, but it is not a fatal one. A rulemaking to set specific standards is not required.

Licensing Prototype, Demonstration, Research, and Test Reactors

The basic standard is set by 10 CFR 50.43(e), which states that an application for design certification (DC), a combined construction and operating license (COL), an operating license (OL) or a manufacturing license that proposes a reactor design that differs significantly from light water reactors licensed before 1997 will be approved only if: (i)(A) the performance of each safety feature is demonstrated through analyses, appropriate test programs, and experience, or a combination of them; (i)(B) interdependent effects are shown to be acceptable by the same means; and (i)(C) sufficient safety feature data exist to assess the analytical

73 "Technical reports" may also be utilized during the pre-application or application period. These documents are similar to topical reports, but do not receive a separate NRC safety evaluation report. They are, like topical reports, incorporated by reference into the application. "White papers" are a form of pre-application documentation used to discuss a general topical area, provide context for an issue by reference to existing regulatory requirements or guidance, or propose a strategy to address a specific issue.

74 NRC Chairman Stephen G. Burns has recently indicated in a speech and in a July 29, 2015 written statement to the Subcommittee on Energy of the U.S. House Committee on Science, Space, and Technology, that, although the NRC is generally supportive of and receptive to the idea of moving forward with a regulatory framework for advanced reactors, the agency will "be able to optimize its planning processes and resource expenditures to conduct licensing reviews when a complete and technically sufficient non-LWR application is presented for consideration." Written Statement, at 6 (*see http://www.nrc.gov/about-nrc/organization/commission/comm-stephen-burns/burns-07292015-testimony.pdf*). From this, it may readily be inferred that any move by NRC staff to devote significant resources to early advanced reactor design assessment would require staff consultation with the Commission.

tools used in safety analyses over a sufficient range of normal operating conditions, transients, and accident conditions; or (ii) there has been acceptable testing of a prototype to demonstrate (i)(A)–(i)(C) above.

As a result, advanced reactor applicants must identify those structures, systems, and components (SSCs) that require research and development to confirm their adequacy, and provide a description of and schedule for the R&D program that will resolve safety questions (10 CFR 50.34(a)(8)). Before authorized to operate, the applicant must provide a description and evaluation of the results of the R&D programs to demonstrate that identified safety issues have been resolved (10 CFR 50.54(b)(5)). As noted, the NRC's experience has focused on light water reactors, but there is no restriction on the type of reactor technology for which a license can be sought or granted. R&D reactors are licensed by the NRC. If licensed under AEA §104c. (research-oriented but not commercial), they are to be subject to no more than the minimum level of regulation that, in the NRC's view, will permit the Commission to promote the common defense and security, and protect public health and safety.

The responsibility for oversight throughout the R&D process is shared between the NRC and DOE. DOE makes arrangements for the conduct of research and development activities relating to nuclear processes for purposes that include "industrial and commercial uses, the generation of useable energy, and the demonstration of advances in commercial or industrial applications of atomic energy."[75] In its energy development role, DOE alone was given the authority to use its own facilities to conduct research "for others."[76] If DOE determines that private facilities or laboratories are inadequate, and that DOE's facilities, or scientific or technical resources have the potential to provide significant assistance to others involved in protecting public health and safety, DOE may also assist at its own facilities by conducting research and development, training activities, or studies.

The NRC, on the other hand, is authorized to issue licenses for reactors for industrial or commercial purposes, as well as licenses for reactors for medical therapy and for industrial/commercial R&D (known as research and test reactors, or RTRs). ERA §202(2)'s definition of "demonstration" reactor includes the type of prototypes over which the agency exercises regulatory and licensing authority. However, the NRC would not have authority over reactors located at DOE-owned facilities that collect data for research, test fuels, or test materials.

ERA §202(2) specifies that the NRC exercises licensing and related regulatory authority over demonstration nuclear reactors, except (i) those that existed on the effective date of the ERA (January 19, 1975), (ii) when operated as part of the power generation facilities of an electric utility system, or (iii) when operated in any other manner for the purpose of demonstrating the suitability for commercial application of such reactor. ERA §202(2) clearly establishes that DOE reactors intended to demonstrate the suitability of a reactor for commercial application must be licensed and regulated by the NRC. However, DOE can avoid NRC licensing and oversight by exercising its authority under AEA §31 and §33 to find that private facilities or laboratories are inadequate for the types of studies and activities (i) which are specified in AEA §31, and (ii) which DOE deems appropriate to the development of energy resources. In such situations, DOE may conduct such activities for others at its own facilities. This may allow DOE to use those facilities (e.g., national laboratories) to perform studies, irradiate fuel, and conduct other discrete tasks—and to charge private parties for the work. This provision may even allow DOE to construct and operate a research-focused, non-power reactor to assist in some aspects of the evaluation of related systems and the development of supporting analysis codes. If this work is not governed by ERA §202, the NRC would not have the authority to license or regulate DOE's research for others. On the other hand, if DOE were to build and operate a demonstration reactor for commercial purposes—including the suitability for commercial use of advanced reactor designs—its action would (i) appear on its face to fall within the confines of ERA §202(2), and (ii) require Congressional authorization clarifying whether NRC licensing and oversight are required.

In sum, the extent to which DOE has sole authority over commercial testing and use of prototype and research reactors, and the extent to

75 Atomic Energy Act §31

76 Atomic Energy Act §33

which the NRC has the authority to regulate those reactors remains unclear.

Although the NRC suggests in 10 CFR 50.43(e) that prototype testing may be required for certification of some advanced non-light water reactor designs, the NRC's regulations do not require the use of a prototype plant for qualification testing. It may be possible to use existing test facilities or reactors (e.g., reactors owned and operated by DOE for R&D purposes)—and thus avoid the need to seek authorization to construct and operate a new facility—but such an approach would demand careful planning, as well as incremental development and testing. The written testimony of NRC Chairman Burns expresses the Commission's view that a privately funded R&D reactor constructed and operated at a DOE site would fall within the NRC's regulatory purview—"if such a facility would likely be used ultimately as a basis for commercial power reactor technologies."[77]

77 See page 3 of *http://www.nrc.gov/about-nrc/organization/commission/comm-stephen-burns/burns-07292015-testimony.pdf*.

Enabling Nuclear Innovation

Strategies for Advanced Reactor Licensing

NUCLEAR INNOVATION ALLIANCE

The purpose of this report is to propose strategies that facilitate the efficient, cost-effective, and predictable licensing of advanced nuclear power plants in the United States. These are nuclear plants that would generate clean, safe, sustainable, reliable, affordable, and proliferation-resistant energy through the use of innovative technologies, and that would improve the quality of our lives and the health of our environment.

Recommendations include the establishment of discrete stages for enhanced project risk management and, where appropriate, the use of risk-informed and performance-based techniques. Implementation of these and other policy changes will enable society to capture the immense future benefits of advanced nuclear power.

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