JAEA-Review
2024-018
DOI:10.11484/jaea-review-2024-018

A Proposed Regulatory Framework for Small Modular Reactors

Nuclear System Technology Review Committee

Nuclear Plant Innovation Promotion Office
Sector of Fast Reactor and Advanced Reactor Research and Development

June 2024
Japan Atomic Energy Agency
日本原子力研究開発機構

JAEA-Review

国立研究開発法人日本原子力研究開発機構　研究開発推進部　科学技術情報課
〒 319-1112　茨城県那珂郡東海村大字村松 4 番地 49
E-mail: ird-support@jaea.go.jp

4-49 Muramatsu, Tokai-mura, Naka-gun, Ibaraki-ken 319-1112, Japan
E-mail: ird-support@jaea.go.jp

JAEA-Review 2024-018

A Proposed Regulatory Framework for Small Modular Reactors

Nuclear System Technology Review Committee

Nuclear Plant Innovation Promotion Office
Sector of Fast Reactor and Advanced Reactor Research and Development
Japan Atomic Energy Agency
Oarai-machi, Higashiibaraki-gun, Ibaraki-ken

(Received March 21, 2024)

In the R&D activities related to the Ministry of Education, Culture, Sports, Science and Technology's Innovative Nuclear R&D Program, "Development of Integrated Energy System Simulation Method Utilizing Small Modular Reactors for Enhanced System Decarbonization and Resilience," Japan Atomic Energy Agency (JAEA) established the "Nuclear System Technology Review Committee," consisting of experts in the subject areas, to obtain advice on the feasibility of deploying Design-standardized, Factory-built, Site-independent Small Modular Reactors (DFS-SMRs) in Japan and other countries.

The Committee met three times during the 2021–2024 project period to discuss proposals for a regulatory framework for the potential commercial deployment of DFS-SMRs in Japan. The starting point for the Committee's discussions was the view that Japan's nuclear regulatory framework, like most other countries with existing commercial nuclear power plants in operation, focuses on large Light Water Reactors. Another consideration was the Committee's view on the basic structure of the regulatory framework, consistent with other regulatory initiatives around the world. Specifically, that the most effective regulatory frameworks need to be less prescriptive, less technology-dependent, and more performance-based.

This report focuses on the United States, which has played a leading role in the deployment of SMRs and other advanced reactors, and summarizes the discussions regarding the proposal for a licensing framework for SMRs in Japan, an analysis of the gaps between Japan's current licensing framework and the proposed framework, and specific recommendations for closing the gaps. The Committee is hopeful that the changes to the regulatory framework proposed in this report will become a reality.

Keywords: Small Modular Reactor, Performance-Based Regulatory Framework, Gap Analysis

---

The contents of this report are part of the results of MEXT Innovative Nuclear R&D Program, “Development of Integrated Energy System Simulation Method Utilizing Small Modular Reactors for Enhanced System Decarbonization and Resilience.”
Committee secretariat:
Nuclear Plant Innovation Promotion Office, Sector of Fast Reactor and Advanced Reactor Research and Development, Japan Atomic Energy Agency

JAEA-Review 2024-018

小型モジュール型原子炉に対する規制枠組みの提案

日本原子力研究開発機構
高速炉・新型炉研究開発部門　プラント技術イノベーション推進室

原子力システム技術評価委員会

（2024 年 3 月 21 日受理）

日本原子力研究開発機構は、文部科学省・原子力システム研究開発事業「脱炭素化・レジリエンス強化に資する分散型小型モジュラー炉を活用したエネルギーシステムの統合シミュレーション手法開発」に係る研究開発活動の中で、日本および他国における設計標準化、工場製造、サイト独立型小型モジュール炉（DFS-SMR）の展開の可能性に関するアドバイスを得るために、対象分野の専門家からなる「原子力システム技術評価委員会」を設置した。

本委員会は 2021 年から 2024 年のプロジェクト期間中に 3 回開催され、日本における DFS-SMR の商業展開の可能性のための規制枠組みに関する提案が議論された。委員会での議論の出発点は、日本の原子力規制の枠組みは、既存の商用原子力発電所が稼働している他のほとんどの国と同様に、大型軽水炉に焦点を当てているという見解であった。もうひとつの考慮事項として、世界中の他の規制イニシアチブと整合性をもつ規制の枠組みの基本構造に関する委員会の見解が挙げられる。具体的には、最も効果的な規制の枠組みを実現するためには、規範性を減らし、テクノロジーに依存せず、パフォーマンスに基づいたものにする必要があるというものである。

本報告書では、SMR およびその他の先進的原子炉の配備に関して指導的役割を果たしている米国を取り上げ、日本における SMR に対応するライセンス枠組みへの提案に関する議論の内容および日本の現在のライセンス枠組みと提案されている枠組みとの間のギャップの分析並びにギャップを埋めるための具体的な推奨事項をまとめている。本委員会は、この報告書で提案された規制の枠組みの変更が現実になることに期待を寄せている。

本報告書の内容は、文部科学省・原子力システム研究開発事業「脱炭素化・レジリエンス強化に資する分散型小型モジュラー炉を活用したエネルギーシステムの統合シミュレーション手法開発」の成果の一部です。
原子力システム技術評価委員会事務局：
高速炉・新型炉研究開発部門　プラント技術イノベーション推進室
大洗研究所：〒311-1393　茨城県東茨城郡大洗町成田町 4002 番地

Contents

目　次

List of Tables

List of Figures

List of Committee Members

Michael Scott	Former United States Nuclear Regulatory Commission, USA
Sarbhpreet Sawhney	Federal Aviation Administration, USA (2021 JFY)
Daniel Elgas	Federal Aviation Administration, USA (2022 JFY)
Paul Devoti	Federal Aviation Administration, USA (2023 JFY)
John Yoo	Federal Aviation Administration, USA (acting for Mr. Devoti)
Kazuo Arie	Toshiba Energy Systems & Solutions Corporation, Japan
Akihito Otani	IHI Corporation, Japan
Masanori Tanihira	Mitsubishi Heavy Industries Ltd., Japan
Toru Nakatsuka	JAEA, Japan

List of Observers

Kenji Kimura	The Institute of Energy Economics, Japan
Satoru Kai	IHI Corporation, Japan
Larry Arima	Federal Aviation Administration, USA

Committee secretariat:

Xing L. Yan	JAEA, Japan
Hiroyuki Sato	JAEA, Japan
Naoaki Akasaka	JAEA, Japan

This is a blank page.

1. Introduction

There is currently substantial worldwide interest in small modular reactors (SMRs). While the definition of SMRs varies somewhat from country to country, for reference the International Atomic Energy Agency (IAEA) has used the following definition: (IAEA-TECDOC-2003) [1]

- Power typically <300 MW(e) or <1000 MW(th) per reactor
- For commercial use (including prototypes or demonstration plants), i.e. electricity production, desalination, process heat (as opposed to research and test reactors)
- Designed to allow addition of multiple modules
- Novel designs that have not been widely analyzed or licensed by regulatory bodies
- May be underwater, land-based or floating

Under the Ministry of Education, Culture, Sports, Science, and Technology (MEXT) Innovative Nuclear R&D Program, the Japan Atomic Energy Agency (JAEA) and its academic, research, and industry partners are doing research and development work in support of the design of SMRs that can potentially be entirely factory-built. The design or designs would be independent of site considerations. In other words, the design would be demonstrated to be safe irrespective of the characteristics of a site where it might be installed and operated. Deployment of SMRs in Japan would serve the objectives of converting the energy industry in Japan to being more carbon-neutral and more resilient, while also potentially reducing the cost of energy. Such reactors could be compatible with renewable energy generation. SMRs provide advanced operational safety and flexibility, including incremental capacity growth driven by demand, a relatively small initial investment, and standardization and serial (factory) production. They are much better suited for distributed deployment as compared to large reactors, and they have many potential applications such as cogeneration for district heating, hydrogen production, etc.

Under the purview of MEXT, JAEA has convened a Committee of subject matter experts to provide advice regarding potential deployment of the Design-standardized, Factory-built, Site-independent Small Modular Reactors (DFS-SMRs) in Japan and similarly in other countries. Several types of DFS-SMR design concepts including Light Water Reactor (LWR), High Temperature Gas-cooled Reactor (HTGR) and Sodium-cooled Fast Reactor (SFR) are currently under consideration and design development in JAEA and elsewhere in Japan.

The Committee is chaired by JAEA and comprised of representatives of JAEA, IHI, MHI, and Toshiba. The Committee also includes a representative of the Federal Aviation Administration (FAA) and a former senior executive of the United States Nuclear Regulatory Commission (NRC). The FAA perspective is being sought based on its experience and expertise in licensing complex, factory-built systems (commercial aircraft), for which safety is paramount, analogous to the situation with the proposed DFS-SMR. The NRC's expertise and advice were sought due to that agency's extensive nuclear regulatory experience, its initiatives to enhance effectiveness and efficiency of nuclear regulation, and the advanced status of its licensing of SMRs in the United States. Although the NRC declined to propose a member for the Committee, senior licensing management at the NRC endorsed the specific former senior executive with substantial NRC licensing experience to support the Committee.

The Committee has met three times, the first meeting held virtually and the most recent two in person, over the project period of 2021 through 2024. JAEA has requested that the Committee use its extensive expertise in Japan and the United States to develop and approve this document, which contains recommendations on an appropriate regulatory framework for licensing the DFS-SMR in Japan.

The Committee contributors are:

Members:

Michael Scott	Former NRC, USA
Sarbhpreet Sawhney	FAA, USA (2021 JFY)
Daniel Elgas	FAA, USA (2022 JFY)
Paul Devoti	FAA, USA (2023 JFY)
John Yoo	FAA, USA (acting for Mr. Devoti)
Kazuo Arie	Toshiba ESS, Japan
Akihito Otani	IHI, Japan
Masanori Tanihira	MHI, Japan
Toru Nakatsuka	JAEA, Japan

Observers:

Kenji Kimura	IEEJ, Japan
Satoru Kai	IHI, Japan
Larry Arima	FAA, USA

Secretariat:

Xing L. Yan	JAEA, Japan
Hiroyuki Sato	JAEA, Japan
Naoaki Akasaka	JAEA, Japan

1.1 Objective

The objective of this report is to present to JAEA, for its consideration and development within the MEXT R&D program, a proposal of top-level licensing framework for potential commercial deployment of DFS-SMRs in Japan. The Committee members believe the major aspects of this proposal, if adopted, will provide a licensing framework that will be both protective of public safety and supportive of substantially deploying DFS-SMRs to potentially make a major contribution to reducing greenhouse gas emissions in the production of energy in Japan, as well as to reduce the dependence of the electric grid and other energy infrastructure in Japan on import of large quantities of fossil fuels.

1.2 Scope

The Committee's starting point for development of this paper is its view that the nuclear regulatory framework in Japan, as in most other countries with existing commercial nuclear power plants in service, is focused on large LWRs. This focus is unnecessarily disadvantageous to successful deployment of SMRs in Japan, because it does not credit the safety and economic advantages of SMRs as compared to large LWRs. Another consideration is the Committee's view, consistent with other regulatory initiatives worldwide, regarding the basic structure of regulatory frameworks. Specifically, to be most effective, regulatory frameworks need to be less prescriptive, more technology-neutral, and performance-based. This paper uses the United States, which is in a leadership role as regards deployment of SMRs and other advanced reactors, as an illustrative example for the Committee's deliberations on recommendations for a corresponding licensing framework for SMRs in Japan. The paper describes the licensing framework currently being used in the United States for SMRs, as well as current initiatives there for revising the regulatory framework for all reactors to be less prescriptive, more technology-neutral, and performance-based. It also discusses the regulatory framework applied in the United States to factory production of commercial aircraft, a situation somewhat analogous to some proposed SMR production concepts. The Committee does not intend to fully endorse either concept currently in place in the United States, and there are useful analogs in regulatory concepts in other countries. But, as noted, the U.S. frameworks and related initiatives are both advanced and readily visible, so the Committee is using them as a starting point. The Committee is proposing a regulatory/licensing framework that is not identical to that in use or planned in the United States, and which recognizes the specific situation in Japan as regards nuclear regulation and licensing. The Committee believes an SMR licensing framework similar in concept to that proposed in this paper would be optimal for safely licensing the DFS-SMR.

The paper goes on to discuss the current nuclear reactor licensing framework in Japan. Building on these discussions, Section 6 of the paper makes recommendations for a proposed DFS-SMR licensing framework as discussed in Section 1.1. It also provides an analysis of gaps between the present licensing framework in Japan and the proposed framework, as well as specific recommendations for closing the gaps.

2. Design-standardized, Factory-built, Site-independent SMR (DFS-SMR) Concept

This section briefly discusses the DFS-SMR concept/definition and high-level design features, without getting into details that are neither available nor within the scope of this paper. The Committee believes its recommendations contained in this paper are valid, irrespective of any specific DFS-SMR design.

This section also focuses on the Committee's views on desirable features of a regulatory and licensing framework conducive to the safe deployment of the DFS-SMR. These are input parameters into the Committee's deliberations and recommendations discussed in Section 6 below.

2.1 DFS-SMR Definition

While there is no single definition of an SMR, a workable definition is provided in Section 1 above. This definition does not include any specification regarding site characteristics. Another term under wide use currently is "advanced reactor." There is no broadly accepted definition for this term, but it is reasonable to define an advanced reactor as what it is not – a large, LWR that characterizes almost all currently deployed commercial-scale nuclear reactors worldwide. Numerous advanced reactor designs are being proposed worldwide. An SMR is arguably an advanced reactor, though an advanced reactor may not be an SMR (e.g., it may not be small or modular).

JAEA and its partners intend to develop and support deployment of one or more SMR designs consistent with the definition of an SMR in Section 1. However, in addition to that definition, the intention for the DFS-SMR project is to deploy a reactor design or designs that will each have a single standardized design that will be wholly assembled in a factory and will be shown before deployment to meet applicable regulatory requirements for any reasonable candidate site. *[1]

2.2 General Features

The following subsections describe key aspects of the DFS-SMR concept. The concept is intended to incorporate all the advantages of SMRs, while adding additional benefits provided by design standardization and essential independence of site characteristics. Understanding these benefits supports recognition that the regulatory framework, while continuing to focus

*[1] The intent of the program is to make the design demonstrably deployable at many sites, including in an earthquake-prone nation such as Japan. No reactor design can be built on any site without exception (e.g., on top of an active volcano).

first on health and safety of the public, needs to allow the advantages of the DFS-SMR concept to be realized.

2.2.1 Design Standardization

The design standardization concept as applied to the DFS-SMR includes the following aspects:

- Regulatory approval of a design and manufacturing process for each reactor type, e.g. LWR, HTGR and SFR, based on regulations and standards
- Approval of complete reactor systems
- Use of a standard SPE (site parameter envelope) for site and external hazard conditions concerning seismic, tornados, etc.*2

The objective is to achieve a single design that will be replicated without change perhaps hundreds of times for multiple customers. Regulatory approval, once granted for the first of a kind, will be very much streamlined for following reactors of the same design. The SPE concept allows the design approval to specify a set of important site characteristics. As long as the actual site characteristics fit within the bounds of the SPE, the site is suitable and essentially pre-approved for the reactor design.

2.2.2 Factory Build

The factory build concept removes the disadvantages of building a reactor on site, which include complex construction activities performed often by large site-specific construction organizations and staff. Factory build is essential for obtaining the potential advantages of the DFS-SMR. Aspects of the regulatory concept applicable include:

- Manufacture of systems and components in a factory having a manufacturing license
- Fabrication of components in factories in compliance with the quality assurance and safety requirements for the original manufacturing license
- Inspection and oversight of the original manufacture license holder and regulators

2.2.3 Site Independence

Use of the SPE as discussed in Section 2.2.1 will help facilitate a very limited site review for application of the DFS-SMR to any reasonable site. In addition, the radiological dose consequences from normal and accident radiological releases are expected to be sufficiently

*2 A similar process could be used for early review of a site without specifying a design. The site could be shown acceptable to host any nuclear power plant whose relevant design parameters fit within a specified plant parameter envelope (PPE) used in analysis of site acceptability.

small to limit the PAZ (Precautionary Action Zone) for emergency planning to lie entirely within the limited access area. This will allow the DFS-SMR to be sited in locations not suitable for large LWRs.

Figure 1 graphically depicts these concepts.

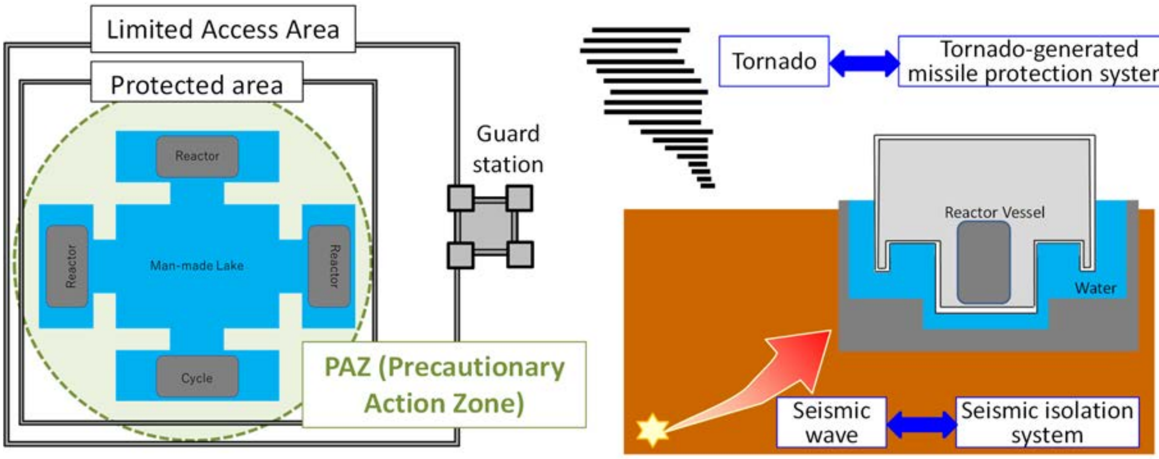

Figure 1: Conditions for site impact assessment

2.3 Deployment Model

Figure 2 depicts the conceptual deployment model for the DFS-SMR. It includes the following aspects:

- Verification of compliance with appropriate regulations and standards such as those encompassed in the framework proposed by the Committee and presented in this report
- Approval of a standard design type certificate
- Approval of a manufacture certificate for fabrication of components, modules, and systems and assembly into a completed SMR plant
- Site assessment confirming that the site and external hazard parameters established envelope the site and hazard bounding parameters used for the approval of the design type certificate
- Factory builds of components and assembly into a completed SMR plant
- Demonstration of safety and performance on the site (first-of-a-kind: FOAK only)
- Transport of the completed SMR plant to the site
- Installation of the SMR on the site
- Fuel loading and commissioning tests (nth-of-a-kind: NOAK) (by manufacturer or utilities)

- Approval of operation certificate for operation and maintenance (for manufacturer in the case of initial commissioning test performed by manufacturer or in the case of manufacturer being the operator of the plant, and for operators such as the utilities)
- Design modification and upgrade as needed, and ability to obtain the approvals for them in significantly simplified processes as compared to the initial approvals of the type design and manufacture.

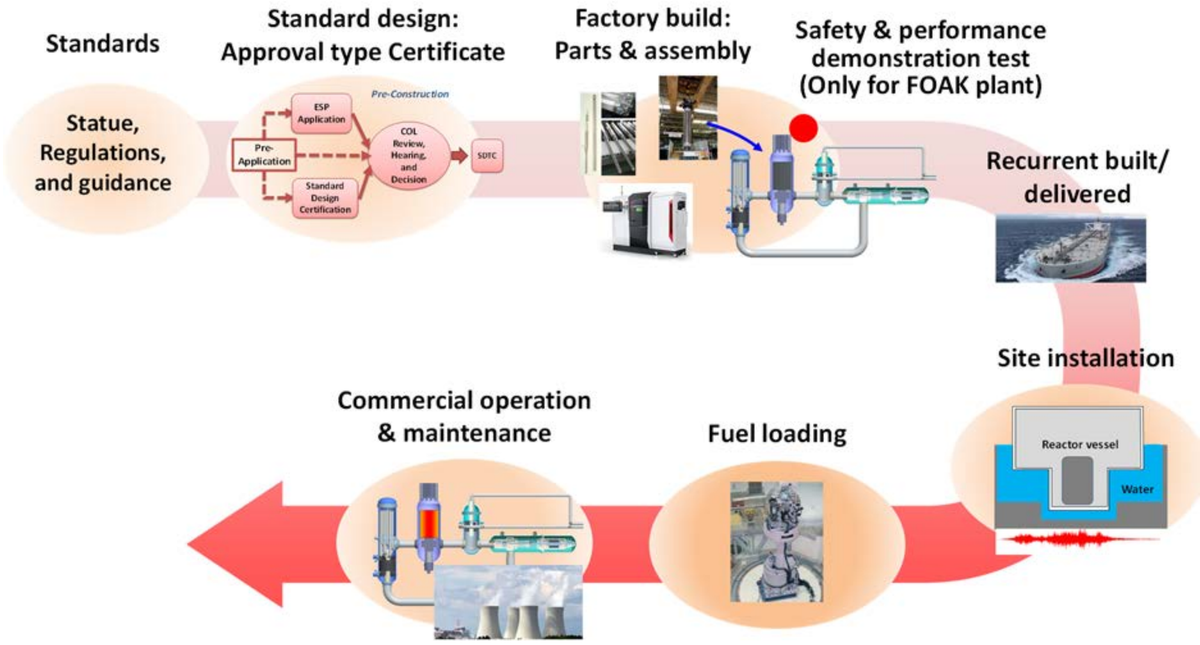

Figure 2: Deployment model for DFS-SMR

3. Desired Characteristics of Regulatory Framework for SMRs Including DFS-SMRs

The subsections below provide the Committee's views on the characteristics of a desirable regulatory and licensing framework for DFS-SMRs. With these characteristics in mind, Section 6 of this paper makes specific recommendations for a desirable licensing framework for the DFS-SMR. Such recommendations need to be based on general desirable characteristics of such a framework. Many of these characteristics apply to a desirable licensing framework for any reactor, while others address specific characteristics applicable to an SMR, and more specifically to the DFS-SMR concept.

3.1 General and Desirable Characteristics for a Nuclear Regulatory Framework

Discussed below are important characteristics of a nuclear regulatory/licensing framework supportive of both high levels of safety and furtherance of national policy goals that seek to implement a commercial nuclear power program to address priorities such as minimizing climate change. These characteristics were sourced in part from publicly available information from the NRC and the IAEA. [2), 3)]

- Regulator and licensees/applicants demonstrably focused on safety. Nuclear power is a controversial subject, and many members of the public worldwide distrust the technology and those involved in it. The successful national nuclear power program focuses first on safety because it is the right thing to do, and also because it is essential to building public trust in the program and the government's oversight of the program. Therefore, the very first, and most essential, aspect of a successful licensing framework is that the framework, and its participants, begin with safety as the incontrovertible and nonnegotiable first principal. Management and staff of the regulator and those of licensees/applicants always act with integrity and professionalism.
- Predictability/reliability. Potential investors in new nuclear technology need to perceive that the regulatory environment will not change over the lifetime of their investment, absent extremely unusual circumstances. Changes in the governing political party should not lead to major changes in the regulatory/licensing framework. In part this objective is met by having an independent regulator, as discussed below.
- Independent regulator. All parties to the licensing process need to perceive the regulator to be essentially independent of undue political influence. This does not mean the regulator is independent of national policy. Rather, it means that the national policy is implemented in the laws and regulations that define the regulatory process in ways that make it challenging for a new government to change the regulatory framework without adequate basis and national consensus. Within the regulatory framework, the regulator evaluates all relevant information and reaches its decisions objectively.

- Openness and transparency. Regulatory and licensing documents, meetings between regulator and licensees, and other interactions related to regulation and licensing need to be clearly visible to the public, and they must be open to input and participation from the public.
- No unnecessary regulatory burden. The regulatory framework should impose no burden on licensees and applicants beyond what is necessary to demonstrate and maintain safety. As long as a licensee demonstrates it is constructing and/or operating its facility safely and consistent with the terms of its license or permit, it should be free to do so.

3.2 Desirable Characteristics of a Regulatory Framework for SMRs Including DFS-SMRs

The existing regulatory and licensing frameworks for nuclear power plants in most or all countries operating nuclear power plants are based on the fact that almost all power reactors in service today are large (~1,000 MW(e)) LWRs that are largely assembled on site and often have design aspects particular to each site. These frameworks have evolved, and are continuing to evolve, to be more efficient in the task of licensing large LWRs. But there are features of SMRs that render the current licensing frameworks in most or all countries suboptimal for the task of licensing such SMRs.

To be effective and efficient for licensing SMRs, a country's licensing framework needs to optimally address these features, such as: (recognizing there is no single SMR design, and some SMRs or advanced reactors may not have all the features discussed here)

- Smaller size as compared to large LWRs, meaning smaller amount of radioactive material in each core, and therefore smaller potential worst-case release of radioactive materials to the environment
- Potential for deployment as a floating reactor
- Modular design, meaning potentially the entire nuclear power module can be assembled in a factory and shipped to the site via ship, rail, truck, etc. A power plant may be made up of multiple such modules.
- Potential for the manufacturer of an SMR to fuel and test it onsite before turning it over to the ultimate utility owner for commercial operation by the utility.
- Possibility that a selected SMR might not be an LWR (e.g. could be gas-cooled, sodium-cooled, etc.)
- Potential for a much less elaborate security/physical protection capability based on lower hazard and smaller site footprint
- Potential for much smaller emergency planning zone and much less complex offsite emergency response plan based on much lower radiological hazard posed by the SMR

- Potential for different siting criteria. As previously noted, the DFS-SMR includes design criteria that would greatly simplify siting reviews – in other words, a design that will be effectively independent of site criteria, beyond verifying that a site fits within the site-related design criteria. Many or most sites that would be unsuitable for a large LWR would likely be suitable for SMRs.
- Potential for much smaller numbers of required operating staffing due to simplicity of the SMR design
- Potential for a functional containment (e.g., coated, melt-resistant fuel) vs. the physical containment required for a large LWR
- Potential for varying aircraft impact assessment requirements due to smaller hazard and smaller reactor facility size that could render large aircraft impact incredible

The Committee is also aware, as discussed below in Section 4 below, that there are current regulatory initiatives (for example, in the United States) to make regulation of all power reactors less prescriptive, more performance-based, and more technology-neutral. Current regulations tend to include very specific requirements dependent on the technology involved (mostly large LWRs). For example, there may be requirements specific to emergency electrical power sources, reactor vessel integrity, etc. The current initiatives are attempting to remove such detailed requirements and replace them with more bottom-line performance requirements. For example, the offsite radiological dose that could occur as a result of credible accidents may not exceed specified limits. Requirements such as these are not technology-dependent. By focusing on the overall outcome, they limit the tendency of the regulator and licensee/applicant to focus on the specifics, sometimes to the detriment of overall performance of the plant under accident conditions. In addition, technology-specific detailed requirements are becoming impractical given the wide variety of reactor technologies currently being advanced worldwide. The Committee agrees with the rationale for moving toward less prescriptive, more performance-based, and more technology-neutral regulatory framework. This results therefore in a recommendation to move away from the current regulatory practice in Japan to attempt to develop specific, prescriptive regulatory frameworks for each reactor technology (e.g., LWR, HTGR, SFR, Molten Salt Reactor (MSR), etc.).

4. Learning from Other Regulatory Approaches

This section begins by discussing the existing nuclear regulatory framework in Japan. In subsequent subsections the paper provides perspective on the regulatory frameworks in the United States. As noted in Section 1.2 above, the Committee is using the commercial nuclear and commercial aviation regulatory frameworks in the United States as informative examples for developing recommendations regarding an appropriate regulatory framework for Japan. The Committee's recommended framework is not identical to any single regulatory framework in the United States. The subsections in this section briefly describe these frameworks.

4.1 Nuclear Regulation Authority (NRA) Existing Regulatory Framework

Aspects of the current nuclear regulatory framework in Japan relevant to optimum regulation of the DFS-SMR include the following:

- Regulatory approval of the basic reactor design, as well as approval of the construction plan, inspection plans, operational safety program and physical protection program, are required for every application for a new nuclear facility installation.
- A standardized design certification (approval) process is only institutionalized for specific components such as emergency diesel generators.
- Permission for siting is required for every application for a new nuclear facility installation.
- A lengthy and uncertain licensing process makes SMR applicants hesitate to introduce innovative technologies.
- The applicable NRA regulations are prescriptive in nature, with separate frameworks for each reactor technology for which regulatory approval has been sought.

Figure 3 depicts at a high level the current NRA regulatory framework.

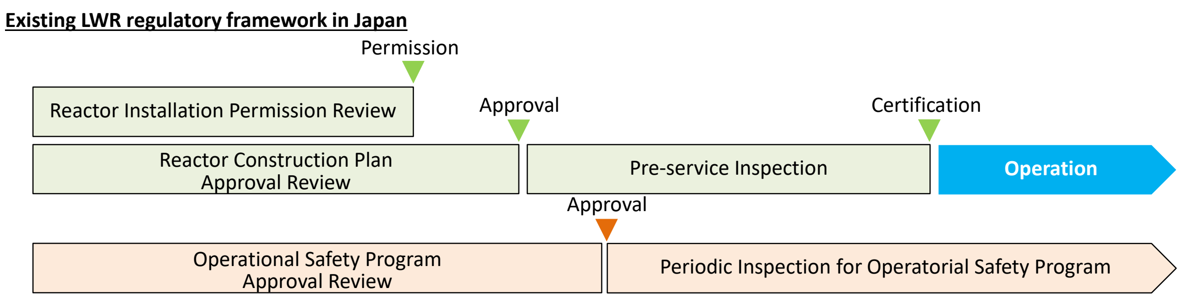

Figure 3. Existing NRA regulatory framework in Japan

As stated earlier, the existing NRA regulatory framework is focused on large LWRs. Future regulatory development should implement requirements more suitable for crediting the innovative features of SMRs. Changes could address measures such as:

- Avoiding a repeated review process for each reactor installation if the reactor design, construction plan, inspection plans, the operational safety program, and the physical protection program are certified
- Allowing the applicant to largely be exempt from a detailed site permission process if site parameters are bounded by the design parameters
- Incorporating a certification process for replaced and/or modified components without requiring a review of an entire plant

4.2 United States Nuclear Regulatory Commission (NRC) Regulatory Approaches

The Committee believes that valuable perspectives on an appropriate regulatory framework for the DFS-SMR in Japan may be found by examining the nuclear regulatory framework and the FAA regulatory framework in the United States. Both are discussed in the following subsections. In the United States, these frameworks operate essentially independent of each other, but an innovative regulatory framework for SMRs could combine aspects of both. The subsections that follow address the NRC nuclear regulatory framework, while Section 4.3 addresses the FAA framework.

Note: In the United States, in addition to a safety review of a proposed power reactor, a separate environmental review is required under Title 10 of the Code of Federal Regulations (10 CFR) Part 51, Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions. The Committee is not aware of significant planned changes in the U.S. nuclear regulatory framework regarding environmental regulations and reviews to address SMRs. Evaluation of environmental reviews for nuclear reactors in Japan (separate from nuclear safety reviews) is outside the scope of this document and not further discussed herein.

The NRC is the sole regulator of nuclear safety for power reactors in the United States. Neither other Federal agencies, nor any state or local unit of government, has any regulatory authority over nuclear safety of these facilities, though several Federal agencies (e.g., the Federal Emergency Management Agency) support the NRC in its regulatory role. The NRC has been in existence since the mid-1970s, or since the 1950s if its predecessor the Atomic Energy Commission is considered. Over that time the NRC has licensed over 100 power reactors. This subsection discusses the existing and potential future NRC regulatory framework, with focus on SMRs.

An applicant for a power reactor (including an SMR) in the United States may currently apply to the NRC under one of two regulatory frameworks. Both are contained in 10 CFR. Each is discussed in the following subsections, along with a likely future framework.

4.2.1 10 CFR Part 50, Domestic Licensing of Production and Utilization Facilities

Almost all power reactors in the United States have been licensed under 10 CFR Part 50, which has been in place for the entire existence of the NRC. [4] Licensing under Part 50 is referred to as a "two-step" process. The first step involves application for a construction permit (CP). Assuming one is granted, the second step is application for an operating license (OL) as plant construction nears completion.

Each application under Part 50 is effectively stand-alone; the applicant must submit a limited safety analysis to support issuance of a CP, and a complete safety analysis to support issuance of an OL. No two reactors licensed under Part 50 are identical, since each site is different and each applicant tends to vary its design somewhat from other utilities, even when starting with the same basic nuclear steam supply system (NSSS) design. There have been occasional efforts to implement standardized reactor designs (e.g., Combustion Engineering System 80), but very little power reactor standardization in fact exists in the United States.

Advantages to licensing under Part 50, from the applicant's perspective, include the regulator's substantial experience with that framework, and the ability to start construction without having fully developed the design. A major disadvantage, and the primary reason for development of the Part 52 regulations discussed below, is that it is possible the facility may be largely completed before all safety issues and contentions are resolved. [5] This presents the possibility that the plant may be built but not allowed to operate, a disastrous development from an investment perspective. Another scenario is the possibility the regulator might change the regulations or its interpretation of them during plant construction, and then "backfit" a required change to the plant design of a partially constructed plant. Such changes can add major expense and delays in completion of construction.

Part 50 is in general prescriptive, with often detailed requirements placed on reactor safety systems, structures, and components. There are some performance-based requirements, but the NRC is considering optional licensing regulations that are much less prescriptive and more performance-based than Part 50, as discussed in Section 4.2.3 below.

4.2.2 10 CFR Part 52, Licenses, Certifications, and Approvals for Nuclear Power Plants

The NRC developed and implemented regulations in Part 52 in the late 1980s in response to industry calls to allow resolution of licensing issues early in the licensing process for a given facility, and to better support standardization. The common thread under Part 52 is that an applicant to construct and operate a power reactor must apply for and receive a Construction and Operating License (COL). A holder of a COL may construct the facility and then demonstrate to the NRC that it has built the facility in accordance with the terms of the COL. Having done so, it may operate the plant without the need for a separate Operating License (OL).

Subparts of Part 52 provide the opportunity to resolve any licensing issues even before the COL is submitted, and/or provide for the possibility of innovations such as factory construction of reactors (rather than constructing them on site).*3 The Subparts of interest are:

- Subpart A, Early Site Permits – Allows resolution of siting issues, even absent a specific identified reactor design
- Subpart B, Standard Design Certifications – Provides for Commission approval of a given reactor design, providing substantial finality and confidence to an entity constructing the certified design that it will not be successfully challenged by the regulator or other stakeholders
- Subpart C, Combined Licenses – Discussed above
- Subpart E, Standard Design Approvals – Similar to Standard Design Certifications, but with only NRC staff approval of the design, not Commission approval; thereby conveying substantial finality but less than for a Standard Design Certification
- Subpart F, Manufacturing Licenses – Allows for approval of a reactor design to be manufactured and potentially installed at multiple sites, using site parameters postulated for the design and to be verified prior to installation and operation at a site. Note: A manufacturing license is not required to fabricate a reactor at a factory.

Worthy of special note is Appendix N to Part 52. This Appendix provides requirements to be addressed should an applicant or applicants for COLs at multiple sites wish to reference an identical reactor design. The Appendix is intended to streamline the licensing reviews for each proposed site by incorporating the single design – ideally, one certified under 10 CFR 52 Subpart B. This is therefore an initial attempt to support standardization, a key aspect of the DFS-SMR concept.

For any reactor to be operated under Part 52, the requirements of Subpart C must be met. The applicant for a COL may choose, but is not required, to reference any or all of a standardized design under Subpart B or E, an early site permit under Subpart A, or a manufacturing license under Subpart F. Choosing to reference an already-approved site or

*3 The NRC licensed factory construction at one facility of large floating LWRs to be factory-built under Part 50 in the early 1980s, but no reactors were actually constructed.

design limits the scope of information to be provided, and potential issues to be resolved, during the COL review.

The NRC has issued several Early Site Permits, Standard Design Certifications, and COL. Two reactors have been fully constructed under a COL.

Part 52 has the advantage of allowing for early issue resolution and encouraging standardized designs. It has the disadvantage, from the licensee's perspective, of making it harder to change the design during or after construction, particularly if a Standard Design Certification is used, because these Certifications are written into regulations. For example, Appendix D to Part 52 is the Design Certification Rule for the Westinghouse AP1000 reactor design.

Part 52 refers to or retains many specific requirements from Part 50. It therefore cannot be said to have progressed substantially over Part 50 in removing prescriptive requirements and being technology-neutral. It is a rule that was intended to regulate licensing of large LWRs but can be adapted (by exempting irrelevant or unnecessary requirements) to regulation of SMRs and other advanced reactors.

4.2.3 DRAFT 10 CFR Part 53, Risk-informed, Technology-inclusive Regulatory Framework for Advanced Reactors

There is currently substantial worldwide interest in advanced reactors. While there is no single accepted definition of an advanced reactor, they generally:

- Represent significant improvements over earlier reactors, though not necessarily improvement in safety
- Are not LWRs (could be HTGR, MSR, SFR, etc.)
- Are likely to be 300 MW(e) or less
- May or may not be modular

There is a subset under "Advanced reactors" – namely, "microreactors." The NRC has not explicitly defined microreactors. The U.S. Department of Energy has defined a microreactor as: [6)]

- Typically 1-20 MW(th) – very small
- Factory fabricated
- Transportable by rail, truck, ship/barge, or air
- Fully self-regulating and passive
- Higher enrichment than existing LWRs but still less than 20%

The NRC has recognized that its existing regulations (e.g., those in Parts 50 and 52) have been developed and issued primarily to regulate large LWRs. They have certified an SMR design (NuScale) under Part 52 through issuance of exemptions to requirements not applicable or not necessary for the NuScale SMR design. However, rather than continuing to license using exemptions to address gaps between the existing rules and an optimal rule for SMRs and advanced reactors, the NRC has been developing a new risk-informed regulation at 10 CFR Part 53. [7)] This proposed rule, which exists today in draft form, is intended to apply to new reactors viewed as "advanced." The new draft rule does not define or even mention "advanced reactor." In its explanatory text that accompanies the draft rule, the NRC staff states:

> Based on public discussions on the use of the (advanced reactor) term, the NRC determined that the NEIMA (U.S. Federal law tasking NRC to develop a suitable regulatory framework) definition, although broad, did not define "significant improvements" with enough specificity to implement in NRC regulations. Additionally, a number of stakeholders suggested that the descriptor, "advanced," implied enhanced safety, while the NEIMA definition includes "significant improvements" in areas other than safety enhancements. In response to this feedback, and to be technology inclusive, the NRC staff determined that the broader term "commercial nuclear plant" would be preferable. … The NRC proposes to allow use of part 53 by any "commercial nuclear plant."

The NRC staff submitted the draft rule to the NRC Commissioners on March 1, 2023, requesting approval to issue the proposed rule for public comment. The proposed rule is quite lengthy. It provides two top-level licensing frameworks, with Framework A largely based on probabilistic risk assessment (PRA), and Framework B using a more deterministic approach with PRA insights, similar to the existing Part 50/Part 52 approach. If approved, applicants under Part 53 could use either framework. The NRC Commissioners has not publicly opined on the Proposed Rule, so its primary value at this time is to indicate the NRC staff is focused on improving the existing regulations to more effectively license advanced reactors. In addition, it is important to recognize the NRC staff's intent to try to develop one rule that any applicant for a power reactor may use – and for any reactor design. Such a rule would of necessity need to be nonprescriptive and performance-based, given the wide variety of designs that could be submitted for regulatory approval. Until and unless a final Part 53 rule is issued (currently planned for mid 2025), the new rule has no regulatory force and may not be cited as basis for approval of a reactor application.

4.2.4 NRC "White Paper" Regarding Micro-reactors

In 2021, the NRC released a draft "white paper" entitled "Micro-reactors Licensing Strategies." [8)] This paper provided stakeholders insight into the NRC staff's thinking about how to streamline licensing of microreactors. Having issued the paper as a draft document and stated it had not been subjected to NRC management review, the staff made no commitment to updating it or finalizing it in the future. The perspectives therein have presumably been considered as part of the 10 CFR Part 53 rulemaking discussed in the prior subsection. Furthermore, the DFS-SMR may not ultimately be of a size consistent with what the NRC views as a micro-reactor. Nevertheless, a few points in the white paper are appropriate to highlight here as indicative at a high level of the NRC staff's thinking on optimal licensing a standardized reactor design deployable with little site review on a wide range of sites, consistent with the DFS-SMR concept.

The white paper is largely focused on suggestions for a reactor vendor and prospective COL applicant(s) to take within the existing Part 52 regulatory framework to enhance standardization and minimize the review scope at the COL stage. For example, operational programs could be standardized. However, the NRC staff also shares thoughts regarding changing the regulatory framework as regards micro-reactors that have likely been considered as part of the 10 CFR Part 53 rulemaking process.

The white paper addresses the logic the NRC staff would use to evaluate site impacts on a microreactor design. The process is already in use in Part 52; it focuses on identifying site parameters important to a given reactor design and listing those in the design certification. As long as the actual site parameters are within the envelope/boundaries specified in the certified design, no further site review is needed at the COL stage.

The white paper also notes that the staff is considering allowing for additional finality in operational programs such as in-service testing and inspection, which typically are included in technical specifications at the COL stage.

Other subjects addressed in the white paper include the potential to transport a reactor containing fresh fuel to a site, or for transporting a reactor containing spent fuel. The paper describes the set of regulations in the United States, issued by the NRC and the U.S. Department of Transportation, that would be invoked in considering such approaches. The paper does not propose a change to the regulatory framework. Rather, it discusses how approval can be sought under the existing framework, including possibly seeking an exemption from some requirements.

The white paper notes that a manufacturing license can eliminate the need for many site-specific inspections and verifications. It also states, regarding manufacturing licenses:

> While manufacturing licenses may provide some flexibility for designing and fabricating microreactors in a factory under the existing regulatory framework, separate licenses will be necessary for transporting a fueled reactor from a manufacturing facility to a preapproved site and for initial testing and performing preoperational testing of a reactor with fuel in a manufacturing facility. The NRC staff members involved in the 10 CFR Part 53 rulemaking are exploring ways to increase flexibility for manufacturing and transporting a fueled reactor to an approved site under a manufacturing license. However, scenarios involving starting and testing a reactor in the factory under a manufacturing license are beyond the current scope of the 10 CFR Part 53 rulemaking, because an OL or COL would be required for operation of a reactor at the manufacturing site.

4.3. Federal Aviation Administration (FAA) Regulatory Framework [9), 10)]

4.3.1 Aviation Product Lifecycle Regulatory Stages

The regulation for a lifecycle of aircraft, aircraft engine and propeller includes the major stages below:

- Standards: Title 14 CFR made by FAA as rulemaking actions with public procedure
- Design Approval (type certification): type certificate (TC), amended type certification/supplemental type certificate (ATC/STC), Parts Manufacturer Approval (PMA), Technical standard order authority (TSOA), Licensing agreement (LA)
- Production (aircraft, engines, and parts): initial airworthiness approval, and oversight
- Air carrier Operations (pilots, mechanics): approval and recurrent airworthiness
- Maintenance Approval
- Approval and Oversight of Individual Designees and Oversight of Organization Designation Authorization (ODAs)

Figure 4 illustrates these regulatory stages.

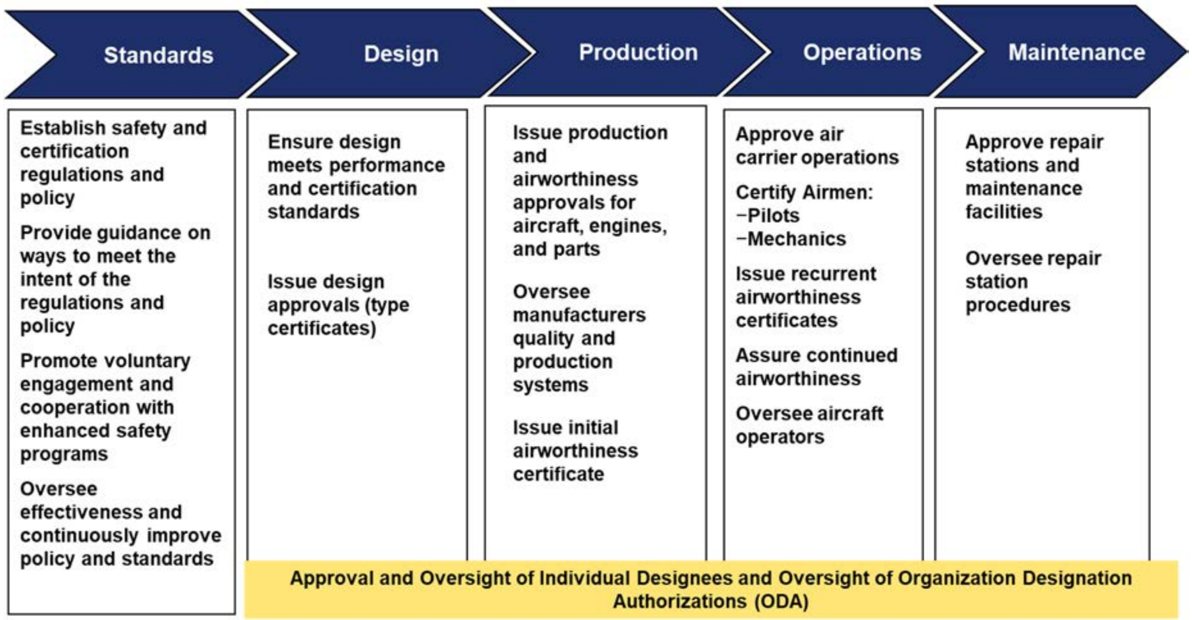

Figure 4: Aviation Product Lifecycle Regulatory Stages [11)]

4.3.2 Process for Design and Production Approval of a Type Certificate (TC)

Figure 5 illustrates the chronological stages of designing and building a transport airplane. Each stage has specific steps that the manufacturer and the FAA discuss and agree upon. Based on a specific design that a manufacturer develops, the pertinent FAA regulations are identified. These requirements must be met before an airplane is certified and approved for production.

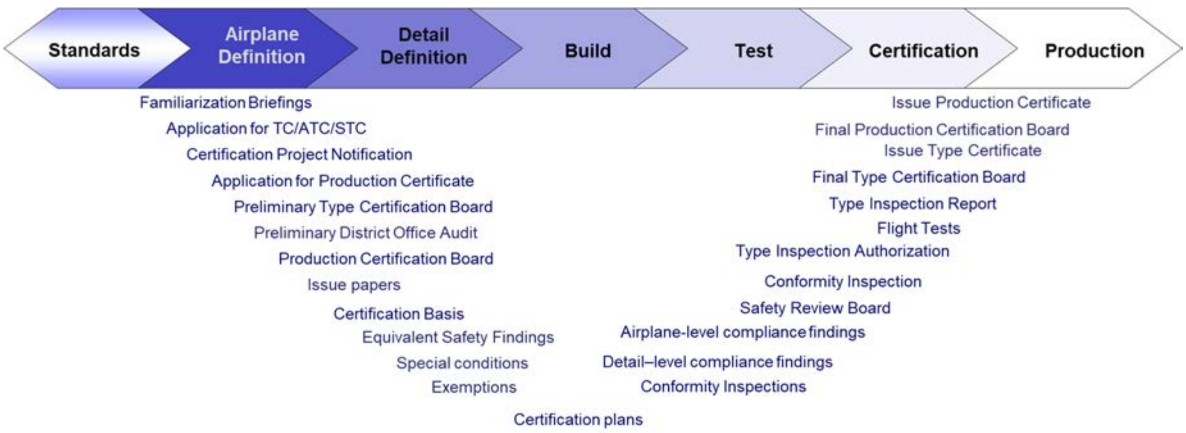

Figure 5: Design and Production Stages [11)]

4.3.3 Other Specific Details

A Licensing Agreement (LA) is a commercial agreement between a TC or STC holder and a Production approval holder (PAH) (or applicant, manufacturer and supplier) formalizing the rights and duties of both partners to use the design data for the purpose of manufacturing the product or article. Although not expressly written in this definition, a TSOA holder is included in this definition.

In accordance with 14 CFR 21.55, a TC holder must provide a written licensing agreement acceptable to the FAA in order to allow a person/entity to use the TC to manufacture a new aircraft, aircraft engine, or propeller. In accordance with 14 CFR 21.120, the same requirement for the submittal of a written licensing agreement applies to an STC holder that wants to allow a person to use the STC to alter an aircraft, aircraft engine, or propeller.

In practice as an example, the Boeing 787 Dreamliner is produced from components such as engines and fuselage manufactured in various facilities by suppliers worldwide, including Japan, and assembled in one final Boeing facility in the US state of South Carolina. The Boeing model that manufactures components at different facilities and assembles them in one final production facility is common in aviation. In this model, the FAA issues a production approval or certificate to Boeing, the applicant; and all of the suppliers that are supplying Boeing must come under Boeing's approved quality system and oversight. Boeing has approval for its facility in South Carolina as part of FAA requirements for a production certificate. Boeing as the production certificate holder is expected to extend its quality system and safety oversight to all its suppliers. The entire supply chain is required to be monitored by Boeing as the production approval holder to ensure it is producing parts consistent with the type design and quality system of the production approval holder. In addition to that, the FAA conducts oversight through risk-based audits of Boeing's suppliers around the world.

5. Gap Analysis Between Desired and Existing Regulatory Frameworks

The subsections of this section discuss differences between the NRA, NRC, and FAA regulatory frameworks, respectively, and the Committee's views as to the desirable characteristics of a regulatory framework for the DFS-SMR.

5.1 Gaps and Resolutions Between NRA Regulatory Framework and Desired Framework

As discussed in Section 4.1 above, the NRA regulatory framework involves prescriptive, technology-specific requirements. There is essentially no allowance for standardized factory production of reactors. Such a framework is fundamentally not consistent with effective and efficient licensing of the DFS-SMR. The table below describes in high-level terms the types of changes needed for a concept such as the DFS-SMR to be successful while continuing to protect health and safety of the public.

Table 1: Gaps from NRA frameworks and potential resolutions

Identified Gaps	Potential solutions to fill gaps
Differences in type of regulatory framework (Permission, Approval, Certification)	Changes to the "Act on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors" to provide for a performance-based, risk-informed, nonprescriptive regulatory framework that also specifically addresses standardization and the other aspects discussed in Sections 3.1 and 3.2 above
	Extension of the application range for "Design Certification for specific Component" that is stated in "Act on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors" to include certification and standardization of an entire reactor design
Review of site safety, environmental emission, site-specific design features are conducted using site dependent information	Changes to the "Act on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors" to allow essential independence of design approval from site characteristics if the design can be demonstrated sufficiently robust to justify this
	Inclusion of a regulatory process that allows permission and approval for siting the DFS-SMR using a hypothetical SPE

5.2 Gaps and Resolutions Between NRC Regulatory Framework and Desired Framework

As previously discussed, the Part 50 regulatory framework is prescriptive, focused on large LWRs, and not focused on factory production of reactors or standardization. The Committee does not therefore consider it a strong model for an appropriate regulatory framework for the DFS-SMR. The Committee finds that, conceptually, a regulatory framework in Japan similar to the NRC Part 52 regulatory framework would be reasonably supportive of licensing the DFS-SMR. Advantages of this framework include:

- Process for early resolution of siting, reactor design, and other technical issues
- Ability to certify a single design to be used at multiple sites
- Potential for manufacturing licenses for specific designs

However, this framework does not alone address all potential aspects of successful regulation. In part this is because Part 52 is a process-oriented (as opposed to technical) rule. Part 52 refers to Part 50 for many technical rules. The technical rules in Part 50 are often prescriptive and not risk-informed, and Part 50 largely applies to large LWRs. For these reasons the NRC has drafted Part 53. The draft regulation is both risk-informed and technology-neutral, so a framework similar to Part 53 would correct some of the less advantageous aspects of Part 52. However, the draft Part 53 is complex, and it will likely see substantial change before it is issued, if it is issued. Even if Part 53 is implemented, some power reactor applicants may continue to choose to be licensed under Part 50 or Part 52 if they prefer either of those frameworks to that in Part 53.

Were the Part 52 process to be considered a starting point for successful SMR regulation, the Committee believes it should be revised to include the considerations in Sections 4.1 and 4.2 above, including:

- Full risk-informed requirements (e.g., emergency planning, security, control room staffing, etc.)
- Allowance for manufacturer to fuel and operate plant as initial commissioning process or as operator of the plant on site
- Allowance for floating configuration
- Removal of all technology-specific requirements and references, to be replaced with technology-inclusive requirements where needed

The draft Part 53 language could be a useful reference in developing a risk-informed regulatory framework.

5.3 Gaps and Resolutions Between FAA Licensing Framework and Desired Framework

The Committee finds that, conceptually, some major elements of the FAA regulatory practice could be attractive to licensing SMRs, including DFS-SMRs, if appropriately modified and adapted to the differing nature of a power plant vs. a commercial aircraft. They include:

- Issue type certificate (TC) design approval for aircraft, engine, parts, regardless of each article itself
- Issue production and initial airworthiness approval for aircraft, engine, parts, regardless of each article itself
- Issue TSOA (Technical Standard Order Authorization) TC design and production approval as a streamlined process
- Early engagement and resolution starting as early as aircraft design conceptual stage in the process of TC.
- Flight test required for initial airworthiness certificate of a plane but not required of subsequent planes of that specific TC design.
- Issue production certificate to a manufacturer and/or a production facility for multiple TC designs
- Issue airworthiness certificate and operational approval of a TC design to manufacturer such as Boeing or recurrently to certain carriers or other approved organizations of that specific TC design, saying after overhaul.
- Issue Airport Operating Certificates under 14 CFR Part 139. [12] The certificate will dictate the airport requirements and denote the types of aircraft to be operated at those airports

While some elements like TSOA do not exist in the current regulatory frameworks of Japan and the United States, others may be found but with various degrees of gaps as identified in Table below.

Table 2: Similar features between FAA framework and NRC or NRA framework (1/2)

FAA Framework	Corresponding NRC or NRA Framework
TC (Type Certificate) - Approval of aircraft, engine or propeller design ATC/STC - Major change or modification to original TC PMA - Replacement or modified parts	NRC issues design certification (DC) or standard design approval (SDA) per 10 CFR 52 for a reactor design, not a reactor itself. In the case of Japan, NRA approves a reactor, instead of a design or type design, as "Reactor Installation Permission Review" or part of a reactor construction license.
Production approval to Manufacturer	NRC has a process for issuing a manufacturing (process) license (ML) to a manufacturer for a certified design in 10 CFR 52. However, a combined construction and operating license (COL) is further required in 10 CFR 52 of the end user for installation and operation of a manufactured reactor. NRA has no manufacture approval. It issues one-step construction plan approval for construction of a reactor
TSOA (Technical Standard Order Authorization) - Design and production approval - Intended to be a streamlined process – installation of the article is separate and examined in type design	No similar practice in the NRC or NRA frameworks
Airworthiness approval and operational approvals	NRA issues operating approval or license (OL) only after fuel loading and full power commissioning safety and performance test to owner utilities and users with liability
Operational approval and issuance of recurrent airworthiness to certain air carries or maintenance organizations and personnel	Operating License (OL) or COL, and restart, license renewal, life extension, etc. are issued to owner and operator of nuclear plant utilities. NRC does not require licensee to receive permission to restart as long as within the conditions of its license.

Table 2: Similar features between FAA framework and NRC or NRA framework (2/2; Cont.)

FAA Framework	Corresponding NRC or NRA Framework
Production Licensing Agreement (QA, Oversight) acceptable to FAA, under which - a TC holder as licenser may transfer the TC to suppliers as licensee for manufacturing a new aircraft, engine or propeller - Licensee inherits the same TC privileges (right to manufacture according to the TC) and duties (QA, safety for the products) of the licenser - FAA conducts oversight of the TC compliance by random visits to some of the suppliers (licensees) around the world	No written licensing agreement is required by NRC or NRA for a construction license (CL) holder or COL holder such as a utility or owner/user to contract suppliers for manufacturing equipment, system, or reactor. However, the holder of the CL or COL retains all privileges and responsibilities (such as QA, safety of the product, etc.) for compliance with the license requirements.
ODAs (Organization Designation Authorization), the ODA holders (currently about 140 organizations and companies) delegated to, and under oversight by, FAA for: • Type Certification, Supplemental Type Certification • Production Certification • Parts Manufacturer Approval • Technical Standard Order Authorization • Major Repair, Alteration, and Airworthiness • Air Operator	NRC holds each licensee responsible for the quality of all work performed on and in support of its reactors. The NRC issues applicable standards or refers to industry standards, and inspects on a sampling basis to provide assurance that licensees are consistent with the standards and in compliance with NRC's regulations.
Airport Operating Certificate - Dictate the airport requirements and denote the types of aircraft to be operated at those airports	Nuclear plant siting - Site assessment to establish site (seismic, environmental, and external hazards) parameters for construction and operation of a design or a reactor in the case of NRC, and of a reactor in the case of NRA. - Site permit by NRC or NRA

More detailed gap analyses are provided on selected aspects in the subsections that follow.

5.3.1 Siting

Site assessment by each applicant (owner and operator of a plant) and permitting by the nuclear regulator are required for installation and operation of the plant. A nuclear site is somewhat analogous to an airport in that the airport hosts airliners in the same way the site hosts a power plant. Thus a site may similarly be permitted for various designs (types) of SMRs to operate as is currently practiced in the United States but not in Japan (see the table above).

The FAA regulates U.S. domestic airports through Airport Operating Certificates issued under 14 CFR Part 139. The certificate will dictate different requirements under the airport certification manual elements and will also denote what types of aircraft can operate at those airports from Class I-IV with I being the largest. The list of U.S. airports and their classification can be found at "Part 139 Airport Certification Status List." [15)]

5.3.2 Operating License

The owner and operator of each nuclear plant is required to obtain an operating license from the nuclear regulator to operate and maintain that plant. The nuclear plant owner/operator is analogous to the air carrier, say Delta, United. Each such air carrier applies to and obtains from the FAA a certificate for it or its pilots and mechanics to operate, inspect and maintain each type of aircraft and for recurrent airworthiness of a plane after major maintenance and repair. The major aspects are as follows:

- Before an operator (airline) is allowed to operate, they must undergo rigorous certification under FAA 14 CFR Part 121 for regularly scheduled air carriers. They are required to outline their systems and operations in the following areas, each of which is highly regulated and has separate requirements:
    - Aircraft they will operate, the routes, limitations
    - Maintenance, preventive maintenance, and alterations
    - Airman and crewmember requirements
    - Training Programs
    - Crewmember qualifications
    - Dispatcher qualifications and duty time
    - Flight time and rest requirements
    - Flight time limitations
    - Record keeping
    - Medication equipment and training
    - Hazardous Materials training and operations
    - Continued airworthiness and safety improvements.

- Maintenance and Repair Organizations (MROs) are regulated by 14 CFR Part 145. These can be standalone operators. The airlines also have their own maintenance and repair stations. These MROs are given the authority to repair aircraft or products/articles back to the original type design and certify conformity to the type design and subsequently reissue an airworthiness certificate which states that it is airworthy. The FAA performs inspections of the Part 145 MROs to assure safety, and it also collects defect data through 14CFR21.3 from the manufacturer to monitor continued operational safety.

5.3.3 Operation by Manufacturer

While an operating license is granted only to users or operators of a reactor, an airworthiness certificate and operational approval is issued not only to air carrier (aircraft user or operator) but also manufacturers such as Boeing and Airbus of a type certificated design.

Furthermore, while an operational or commissioning test is required by regulations for each newly constructed nuclear plant to confirm the plant's operational safety as designed and procedure as specified, a flight test is required by the FAA in the type certification process but not for airworthiness certification for each subsequent plane. More specifically:

- Once a manufacturer, e.g. Boeing, Textron etc., has obtained a type certificate and a production certificate for a model of aircraft (products/parts/articles), new aircraft manufactured under a production certificate are eligible for issuance of an airworthiness certificate without further showing in accordance with 14CFR 21.183(a).
- There is a provision for manufacture of an aircraft with a type certificate only, which is utilized for demonstration models etc. The manufacturer would be required to follow 14CFR 21.183(b) which requires presentation of a statement of conformity (14CFR 21.130) which states that the aircraft manufactured conforms to the type design and is in a condition for safe operation.
- Flight testing is required during the type certification phase, but is not required by regulation for each subsequent aircraft that is produced or delivered, assuming one of the two paths listed above; however, prior to operation the manufacturers go through extensive flight tests for each delivery in conjunction with airline operators.
- Airworthiness approval for each aircraft is regulated by the FAA, though the airworthiness approval certificates may be issued by FAA Aviation Safety Inspectors, ODA or FAA designees.
- Safety regulations typically are the minimum necessary to ensure the level of safety required. The FAA is not the only entity that assures safety. Each aircraft undergoes a flight test once they come off the assembly line, but that process is dictated by the manufacturer and the purchasers. It is not governed by the type certificate process. Boeing and Airbus detail the very extensive quality check and delivery process to customers, which includes flight testing and delivery. [13), 14)]

Note that the scale (large number of aircraft under regulation) is an important factor in how the FAA layers in safety throughout the entire lifecycle from production to operations, maintenance, airspace controls, to build an airworthiness safety system.

In contrast, the number of nuclear plants is presently nowhere close to the volume of aircraft so individual conformity by test of each reactor could be the proper level of oversight. This might not be the case with a significantly larger number of SMRs that might deploy in future. A manufacturer of a SMR design might be issued a manufacturing license as well as an operating license to build and demonstrate the operation of a new type of design. It could be allowed to build, fuel, and start up a subsequent unit of the same type; and then to hand over the ownership and operation of the unit to its utility customer that has obtained an operating license for the reactor type.

6. Proposed Regulatory Framework for SMRs

Based on the Committee's deliberations and the points captured above, the Committee supports and recommends a proposed regulatory framework that, if appropriately implemented, will be both protective of public health and safety, and conducive to deployment of significant numbers of standardized small modular reactors such as DFS-SMRs. These reactors have the potential to make a major contribution toward climate goals and energy resiliency and reliability in Japan, while also reducing the cost of energy supply. This framework advances significantly from the current nuclear regulatory framework for commercial reactors in Japan. Presently, all commercial reactors are large size light water reactors. The Committee strongly believes that most or all the recommendations made herein are essential for success of a future SMR program in Japan.

Figure 6 depicts at a high level a comparison of the existing nuclear regulatory framework in Japan with the recommended frameworks for the FOAK and NOAK SMR. The existing framework, as discussed in this paper, treats every regulatory review as unique, required since all existing reactors vary from each other to some extent for numerous reasons. In contrast, the recommended regulatory framework that could be applied to SMRs in general (any other standardized design deployable at most potential sites) and to DFS-SMRs in particular involves a very streamlined review of NOAK installations. Both the FOAK and NOAK would include use of a single type design certified by the regulator for the FOAK reactor.

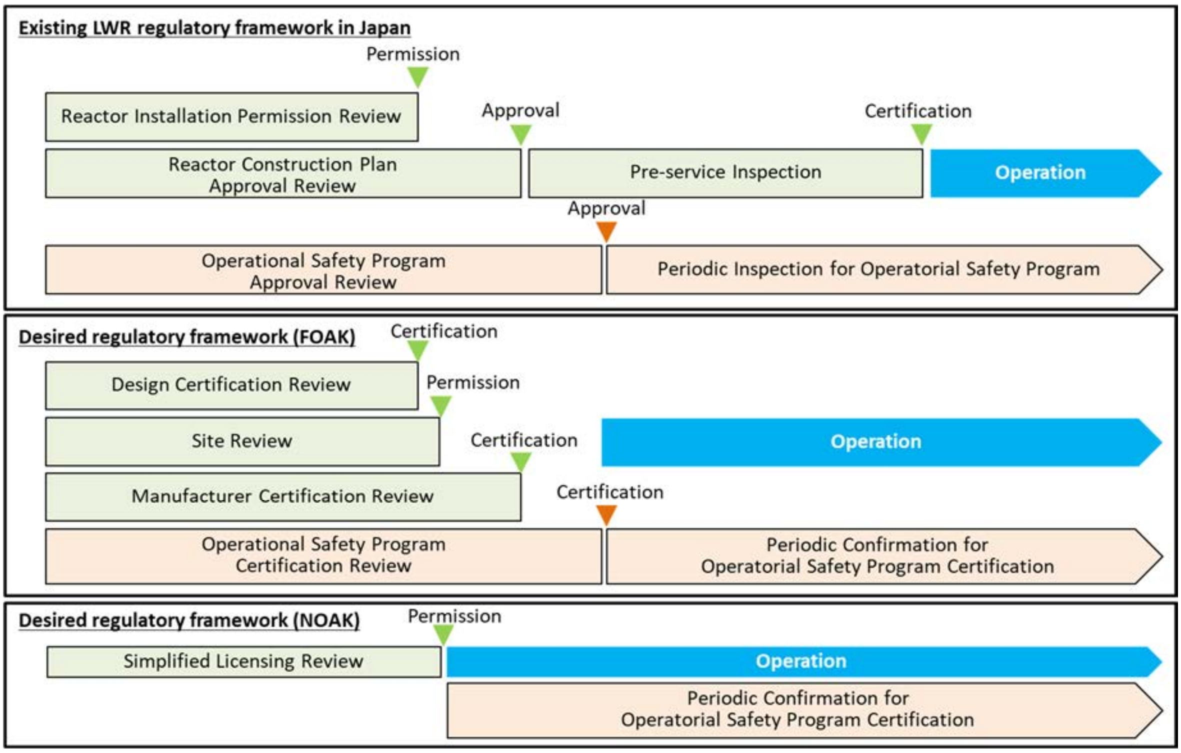

Figure 6: Desired regulatory frameworks for DFS-SMR and comparison with existing one

Differentiation between the two frameworks is based on the principle that the NOAK DFS-SMR design is identical to that of the FOAK. Therefore, there is no need for regulatory review of the NOAK reactor design beyond necessary verification that the manufacturer has constructed the reactor of high quality that meets applicable standards and consistent with the approved type design specifications. This process will be simplified by the regulator having certified the manufacturer's processes as adequate to ensure these outcomes. Similarly, the operational safety program will be identical for all SMRs. The regulator would review and approve the program for the FOAK, but no such review would be needed for following reactor plants. The site review will be limited for NOAK to verifying that the actual site conditions for a given NOAK SMR installation are bounded by the site parameter envelope specified in the certified type design.

Figures 7 and 8 provide additional details on the proposed licensing processes for FOAK and NOAK SMRs including DFS-SMRs.

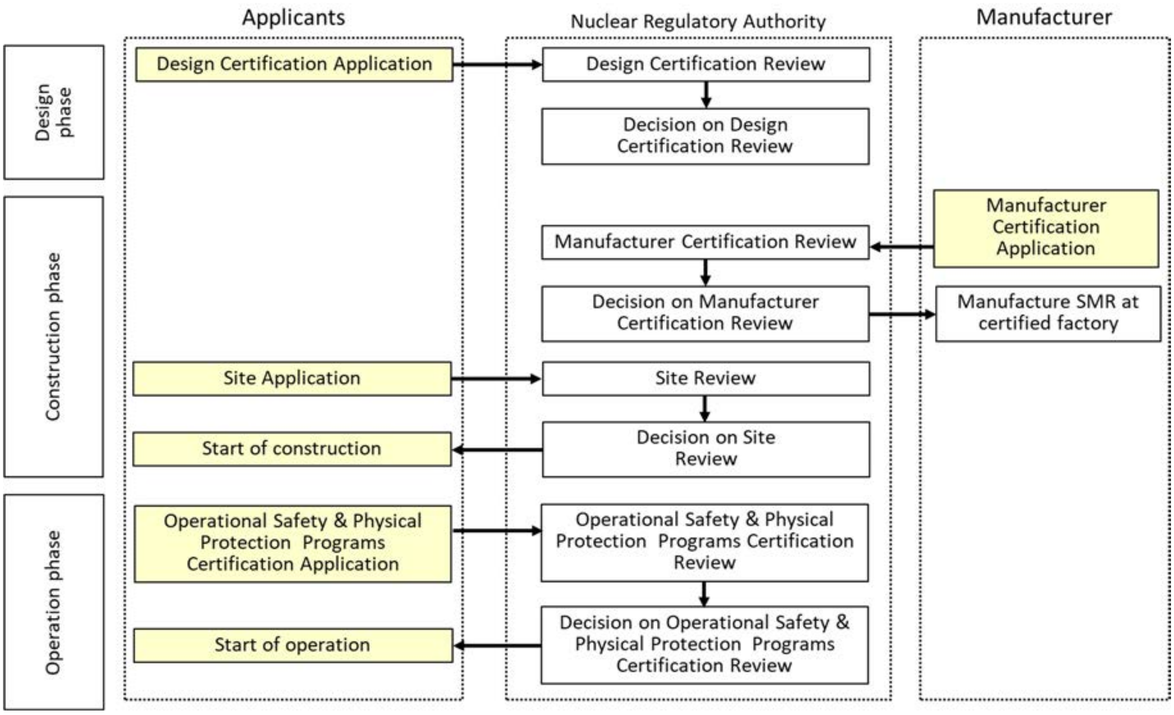

Figure 7: Desired regulatory framework for FOAK SMRs including DFS-SMRs

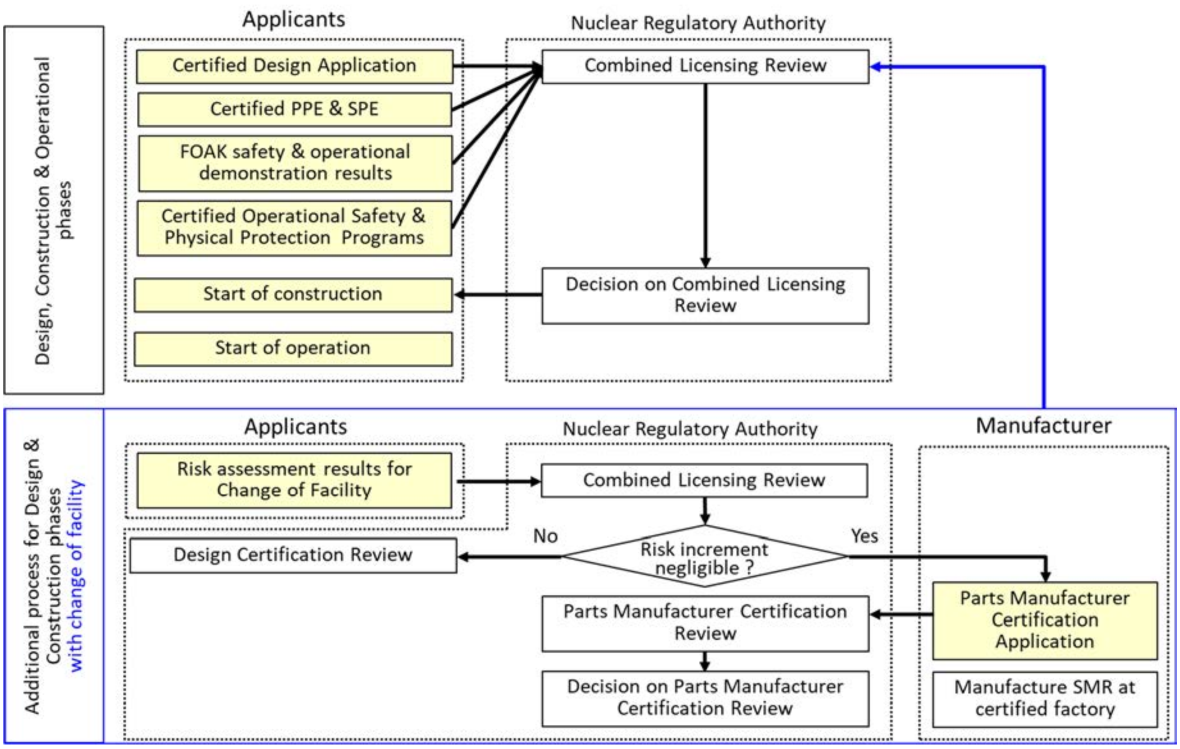

Figure 8: Desired regulatory framework for NOAK SMRs including DFS-SMRs

The Committee recommends that the regulatory framework*4 for standardized SMRs such as DFS-SMRs include the following features:

- The reduced regulatory reviews discussed above for NOAK standardized reactor designs, coupled with a focused and efficient process for demonstrating safety for any changes deemed necessary or desirable for a given NOAK reactor
- Flexibilities for licensing options, similar to the approach in 10 CFR Part 52 in the United States, especially those that allow approvals of standardized designs or manufacturing processes to be applied to multiple sites. The framework should include, but not require, a manufacturing license or certified design. As an example, an applicant seeking to construct a reactor that is not a certified design foregoes the prior-approval advantages of the design certification process.
- Option for a very limited site review for a standardized reactor whose safety levels can be shown in the design certification process to be sufficient for essentially any site characteristics
- A nonprescriptive, risk-informed, performance-based, technology-neutral framework, consistent with initiatives in other countries to use these types of frameworks to remove unnecessary regulations focused on detailed requirements that can lead to suboptimal outcomes. Instead, the regulations should be focused on the desired end-state outcome of protection of public health and safety rather than performance of a particular system, structure, or component.
- An option for licensing an SMR manufacturer to fuel its reactor on site and test it at power before turning it over to the ultimate utility customer. This process, similar to that approved by the FAA to test completed NOAK commercial airlines, conveys significant efficiencies in the process of validating readiness of each SMR for service because the seasoned manufacturer operating/test crew can go from site to site much more readily than a utility crew needing to complete the fueling/testing process for a much smaller number of reactors.
- The general desirable characteristics for a nuclear regulatory framework addressed in Section 3.1 above. Many or most of these features already exist in the Japan regulatory framework or in the U.S. reactor licensing and regulation processes. The existing framework should be reviewed against all these principles. Where they already exist, they should be retained or strengthened. Where they do not, they should be added or incorporated into the regulatory framework(s) available for licensing for all commercial reactors.
- Given the simplicity and higher safety margins possible with SMRs, the option to standardize operational programs such as emergency and planning and security, and to

*4 Some but not all of the proposed framework could be applied as options to large reactors. However, detail discussion is outside the scope of the Committee.

reduce the scope/magnitude of such programs if justified by meeting specified criteria related to the actual hazard (or lack thereof) posed by the SMR

- Reactor staffing flexibilities consistent with the relative simplicities in operating some SMRs
- Flexibilities in specific high-concern aspects of reactor design, such as containments and resistance to aircraft impacts, based on assessed needs for these features given specifics of given SMR designs and hazard assessments for them
- A process that provides for expedited review of changes with minimum risk impact during design upgrade, construction, or operation.

7. Conclusions and Recommendations

The Committee, as previously noted, believes that implementation of most or all the recommendations in Section 6 of this report is very important for Japan to achieve the many potential benefits of a standardized SMR program. For success, the Committee believes the Government of Japan will need to prioritize a substantial change to the regulatory approach currently in existence in Japan. This necessary change includes revision to the overall philosophical approach to nuclear power regulation, as discussed in Section 6. Such a change will be very challenging and potentially controversial among some stakeholders skeptical of the nuclear industry. Clear and open communication with all stakeholders is necessary with regard to how and why SMRs including DFS-SMRs are both safe and beneficial to the people of Japan, and why a new regulatory framework is needed to achieve these benefits.

The Committee recommends that the following actions be taken to enable and assist the Government of Japan in making decisions and taking actions related to this subject.

1) This report should be translated into Japanese and submitted to MEXT as the product of the Committee of the MEXT project.
2) The report should be submitted to JAEA senior management to achieve internal alignment on the recommendations. The report should be published and made available to the public, including entities such as professional societies.
3) Once aligned and in support of proposed changes to the regulatory framework, JAEA senior management should establish a Committee comprised of expert representatives of JAEA, NRA, industry organizations, and professional societies to develop a plan for sponsoring the proposed changes among all government and nongovernment stakeholders. This plan should include:
    - A plan for communicating with all stakeholders. The Agency should engage experts on public communication to advise the Committee on how to communicate with different stakeholders, including members of the public who have a variety of views on nuclear power. The objective is to communicate clearly and effectively with each stakeholder, including listening to them, and understanding and responding to any concerns each may have. The plan should include focus on social media as the place many people go for information on subjects of interest or concern to them.
    - A plan for obtaining alignment on the proposed changes among Government of Japan entities whose cooperation or encouragement is needed for the changes to occur.
    - A plan for drafting the proposed regulations and seeing them through the appropriate process to implementation

The Committee emphasizes that the success of its work on this report is not directly related to publishing the report itself.　Rather, it is based on the extent to which this report serves as a catalyst to significantly advance the regulatory framework for reasons discussed herein.　We look forward with great anticipation to the changes proposed herein becoming reality.

References

1) IAEA, “Lessons Learned in Regulating Small Modular Reactors”, IAEA-TECDOC-2003, 2003, 506p.
2) U.S.NRC, “Principles of Good Regulation”, https://www.nrc.gov/about-nrc/values.html#principles (accessed Oct., 2023).
3) IAEA, “Organization, Management and Staffing of the Regulatory Body for Safety”, IAEA Safety Standards Series No. GSG-12, 2018, 124p.
4) U.S.NRC, “Domestic Licensing of Production and Utilization Facilities”, Title 10 Code of Federal Regulations (CFR), Part 50, 2022, pp.845-1069.
5) U.S.NRC, “Licenses, Certifications, and Approvals for Nuclear Power Plants”, Title 10 Code of Federal Regulations (CFR), Part 52, 2024, pp.1-152.
6) U.S. Department of Energy, “What Is a Nuclear Microreactor?”, https://www.energy.gov/ne/articles/what-nuclear-microreactor (accessed Oct., 2023).
7) U.S.NRC, “Risk Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors”, DRAFT Title 10 Code of Federal Regulations (CFR) Part 53.
8) U.S.NRC, DRAFT White Paper “Micro-reactors Licensing Strategies”, Agencywide Documents Access and Management System (ADAMS) Accession Number ML21328A189.
9) FAA Regulations, https://www.faa.gov/regulations_policies/faa_regulations (accessed Oct., 2023).
10) Sarbhpreet Sawhney, Private Communication.
11) Danial Elgas, Private Communication.
12) FAA, “Airport Certification”, Title 14 Code of Federal Regulations (CFR), vol. 3, Part 139, 2023, pp.566-586.
13) Boeing, “Airplane Delivery Centers strive for perfection”, http://www.lb.boeing.com/news/frontiers/archive/2004/february/ts_sf.html (accessed Oct., 2023).
14) Airbus, “Delivery, Culminating the production process”, https://www.airbus.com/en/products-services/commercial-aircraft/the-life-cycle-of-an-aircraft/delivery (accessed Oct., 2023).
15) FAA, “Part 139 Airport Certification Status List”, https://www.faa.gov/airports/airport_safety/part139_cert/part_139_airport_certification_status_list (accessed Jan., 2024).

Abbreviations

ATC	Amended Type Certification
CFR	Code of Federal Regulations
CL	Construction License
COL	Construction and Operating License
CP	Construction Permit
DFS	Design-standardized, Factory-built, and Site-independent SMR
FAA	Federal Aviation Administration
FOAK	First-of-a-Kind
HTGR	High Temperature Gas-cooled Reactor
IAEA	International Atomic Energy Agency
JAEA	Japan Atomic Energy Agency
LA	Licensing Agreement
LWR	Light Water Reactor
MEXT	Ministry of Education, Culture, Sports, Science and Technology, Japan
ML	Manufacturing License
MRO	Maintenance and Repair Organization
MSR	Molten Salt Reactor
NEI	Nuclear Energy Institute
NOAK	Nth-of-a-Kind
NRA	Nuclear Regulation Authority
NRC	United States Nuclear Regulatory Commission
ODA	Organization Designation Authorization
OL	Operating License
PAH	Production Approval Holders
PAZ	Precautionary Action Zone
PMA	Parts Manufacturer Approval
PRA	Probabilistic Risk Assessment
QA	Quality Assurance
SDA	Standard Design Approval
STC	Supplemental Type Certificate
SFR	Sodium-cooled Fast Reactor
SMR	Small Modular Reactor
TC	Type Certificate
TSOA	Technical Standard Order Authority