Micro-reactors Licensing Strategies

This draft white paper outlines optional strategies for streamlining licensing of anticipated micro-reactors. Its goal is to identify ways to standardize licensing and maximize regulatory finalities, as permitted under existing laws and Commission policies. The NRC staff has prepared this draft white paper and is releasing it to support an upcoming advanced reactor stakeholder public meeting. The NRC staff intends this draft white paper to facilitate discussion at the meeting but is not soliciting written comments on it.

This paper has not been subject to NRC management and legal reviews and approvals, and its contents are subject to change and should not be interpreted as official agency positions.

PURPOSE

The U.S. Nuclear Regulatory Commission (NRC) staff is providing this draft white paper to facilitate the development of optional strategies to streamline the licensing of micro-reactors.

SUMMARY

This effort will leverage flexibilities in existing regulations and identify options for changes to regulatory requirements that could provide additional flexibilities, to the extent permitted under Commission policy and existing laws (e.g., the Atomic Energy Act of 1954, as amended (AEA)). The NRC staff is considering strategies to streamline the license review process by maximizing standardization and finality through the use of design certification, standard design approval, and topical report approvals. For the purpose of this white paper, the term “standardization” refers to a micro-reactor design that could be deployed to the majority of sites in the U.S. without the need for site-specific features where the majority of safety issues could be resolved as part of a design certification and/or manufacturing license. One example would be to have a set of parameters developed as part of a variety of micro-reactor designs that can bound corresponding parameters of multiple sites without the need for customizing the design for each of these sites. The staff is focusing on the following areas:

- enhanced standardization of the design (e.g., through the use of bounding design parameters in early site permits, bounding site parameters in design certification, and a minimal set of site-specific design features).

- use of manufacturing license to gain potential efficiencies at the combined license (COL) stage; and use of other regulatory requirements, such as possession of special nuclear material and transportation.

- strategies for review of operational matters (e.g., technical specifications and operational programs) at the design stage, either as part of the design approval (to the extent allowed under Commission policy), through topical reports, or through a design-centered review approach,[1] in which the staff would review operational matters for the first micro-reactor application of a particular design and the review would be applied to

[1] Regulatory Issue Summary 2006-06, “New Reactor Standardization Needed to Support the Design-Centered Licensing Review Approach,” dated May 31, 2006 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML053540251).

subsequent applications that use the same approach to operational matters as the first application.

- rulemaking efforts to streamline the environmental reviews of advanced reactor applications.

BACKGROUND

There is growing interest in micro-reactor design and development. Micro-reactors are a subset of advanced non-light water reactor (non-LWR) designs. For licensing purposes, micro-reactors are commercial power reactors licensed under Section 103 of the AEA. Micro-reactors are expected to have power levels on the order of tens of megawatts thermal, and they may be fabricated in a factory, may also be fueled, and moved to a fixed site for deployment (i.e., they may be transportable). They are generally understood to have small site footprints, low potential consequences in terms of radiological releases, and they may have increased reliance on passive systems and inherent characteristics to control power and heat removal.
On November 13, 2019 (ADAMS Package Accession No. ML19319C449), the Nuclear Energy Institute (NEI) submitted a white paper titled "Micro-reactor Regulatory Issues", "to discuss changes in the way micro-reactors are licensed and regulated." The NRC staff considered this input and, on October 6, 2020 (ADAMS Package Accession No. ML20254A363), issued SECY-20-0093, "Policy and Licensing Considerations Related to Micro-Reactors", which addressed stakeholder-identified regulatory issues and other relevant regulatory and policy matters. Specifically, SECY-20-0093 informed the Commission of licensing topics related to micro-reactors that may necessitate departures from current regulations, related guidance, and past precedents; identified potential policy issues related to licensing micro-reactors; and described the staff's approach to facilitating licensing submittals for near-term and future deployment and operation of micro-reactors.

In January 2021, the Idaho National Laboratory (INL) issued INL/EXT-21-61275, "Fission Battery Initiative," the purpose of which is as follows:

> ...to define, focus, and coordinate research and development of technologies that can *fully* achieve battery-like functionality for nuclear energy systems. The notion of a "fission battery" conveys a vision focused on realizing very simple "plug-and---play" nuclear systems that can be integrated into a variety of applications requiring affordable, reliable energy in the form of electricity and/or heat and function without operations and maintenance staff. To formalize the desired functionality, the initiative has adopted the following key attributes to be achieved: economic, standardized, installed, unattended, and reliable.

In addition, INL held a workshop in early 2021 where it presented the concept of fission batteries to a variety of stakeholders and noted that the industry has expressed considerable interest in this topic. INL/EXT-21-61847, "Regulatory Research Planning for Microreactor Development," dated July 2021, states the following:

> [a] limited-scope Regulatory Research Development Plan (RRDP) is being developed to link important advanced non-light-water nuclear microreactor technology research and development (R&D) activities sponsored by the U.S. Department of Energy (DOE)'s Office of Nuclear Energy to regulatory requirements and critical licensing needs likely to impact the deployment of a domestic commercial microreactor fleet. More specifically, this plan will examine

R&D needs, opportunities, and status relative to increased autonomous reactor operations, remote monitoring and control, and other key factors concerning microreactor operations, particularly concerns associated with anticipated microreactor transportation and mobility capabilities.

To support potential commercial deployment of micro-reactors, including so-called fission batteries as described in INL/EXT-21-61275, the NRC staff is exploring approaches for standardizing and simplifying the licensing of micro-reactors. This would allow for the deployment of large numbers of such reactors, as envisioned in some commercialization scenarios.

SCOPE

The scope of this white paper is limited to the following:

- exploring licensing strategies using the existing regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 52, "Licenses, certifications, and approvals for nuclear power plants," that support licensing of stationary micro-reactors.

- exploring 10 CFR Part 52, Subpart F, "Manufacturing Licenses," to identify potential efficiencies that could be gained at the COL stage by using manufacturing licenses, as well as other regulatory requirements outside the scope of reactor licensing (e.g., transportation).

- informing the rulemaking working group on 10 CFR Part 53, "Risk-informed, technology inclusive regulatory framework for advanced reactors," for consideration of potential changes to the design certification, standard design approval, manufacturing license, and COL licensing processes that could further streamline micro-reactor licensing.

- describing the NRC staff's rulemaking efforts to streamline advanced reactor environmental reviews required by the National Environmental Policy Act of 1969, as amended (NEPA).

DISCUSSION

This paper describes strategies to streamline the license review process for micro-reactors through leveraging flexibilities in existing regulations and identifying possible changes to regulatory requirements that could increase flexibilities to the extent permitted under existing laws.

As discussed below, the NRC staff has identified certain areas for enhanced standardization in the licensing process for micro-reactors. Broadly, the staff has explored the question of licensing micro-reactors under the existing regulations and has identified potential efficiencies to be gained by resolving many items before the COL stage.

To license micro-reactors under the existing regulations in 10 CFR Part 52, applicants should consider following the process described below. Because of the significant differences between large light-water reactors (LWRs) and micro-reactors, as discussed in SECY-20-0093, the staff is receptive to requests for exemptions from the existing regulations and would evaluate such exemptions case by case using existing agency processes.

With respect to a potential streamlined micro-reactor licensing approach, the NRC staff anticipates that:

- Reactor design is standardized, so that all site characteristics for most or all specific locations are bounded by the site parameters postulated for the design.

- Reactors may be manufactured in a factory and transported to a site, with or without fuel. The licensing strategy may include an optional manufacturing license (10 CFR Part 52, Subpart F).[2]

- Operational programs are standardized (e.g., reviewed and approved as part of design certification or using topical reports, a design-centered working group approach, or templates). (See below for a list of operational programs.)

- No site-specific departures are anticipated.[3]

- No spent fuel storage at the installation site is anticipated. At the end of service, refurbishing or disposing of the reactor could be handled at the manufacturing site or other location if and as specified in the license.

- The advanced nuclear reactor generic environmental impact statement (ANR GEIS) will be used to streamline the site-specific environmental review. The staff also envisions other environmental review efficiencies.

- The Advisory Committee on Reactor Safeguards reviews and mandatory hearings will be conducted in accordance with the AEA.

To initiate a streamlined licensing review, the applicant should consider submitting a design certification, which will allow it to maximize standardization by using bounding site parameters, eliminating or reducing the need for site-specific safety features, and resolving certain operational programs. Applicants should engage the NRC staff in preapplication interactions to understand NRC staff guidance and to facilitate a more informed application, with the goal of minimizing the issues for acceptance of the application for docketing. Applicants should consider the staff's recent draft white paper encouraging robust preapplication engagement and explaining how such engagement can benefit prospective applications.[4] Applicants can also review "Detailed Pre-Application Readiness Assessment Observations of the NuScale Power, LLC Design Certification Application" issued on November 3, 2016 (ADAMS Package Accession No. ML16287A718). In this document, the staff elaborated its findings from the preapplication readiness review of the design certification application that NuScale was preparing to submit to the NRC. In addition, both the industry and the NRC have published lessons learned from the reviews of several licensing applications. The most recent of these reports, concerning the NuScale design certification application, was issued by the NRC Advisory Committee on Reactor Safeguards on October 2, 2020 (ADAMS Accession No. ML20267A655).

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2 Fuel may be loaded into the reactor at the factory given appropriate licenses for possession and transport of special nuclear material; however, this paper does not consider scenarios in which a reactor is operated in the factory for testing or other purposes.

3 While a COL applicant may still propose departures from the postulated site parameters at a specific site, such departures would complicate the review of the application for that particular application.

4 Draft white paper, "Pre-application Engagement to Optimize Advanced Reactors Application Reviews," issued May 2021 (ADAMS Accession No. ML21145A106).

NuScale Power, LLC, issued a separate one on February 19, 2021 (ADAMS Accession No. ML21050A431).

The standardization achieved through design certification would allow the NRC staff to reduce the scope of its safety review at the COL stage to verification of site characteristics and any other remaining site-specific matters. The enclosure to this paper contains a series of figures that the staff has developed to show how the standardization strategies discussed here can reduce the scope of the information required to be submitted by a COL applicant and in turn, the scope of the staff's review and associated cost and schedule.

Design Certification

Through the design certification, standardization can be maximized under the following conditions:

- No site-specific design features are relied on for safety (e.g., offsite power, water sources).
- COL action items are not used (i.e., the applicant is not deferring items that could be resolved at the design stage).
- Bounding site parameters, including hazard parameters, are selected during design to minimize review at COL stage.
- Operational programs are reviewed, if appropriate, at the design stage (through templates, topical reports, or a design-centered review approach if they cannot be resolved as part of the design certification in accordance with Commission policy) (see next section).

Combined Licenses

The staff can achieve COL review efficiencies through maximum standardization as follows:

- COL applications are fully standardized (maximizing the use of a design-centered review approach).
- The ANR GEIS is leveraged to streamline the environmental review.

The NRC staff review of COLs involving multiple fixed sites could be standardized by using 10 CFR Part 52, Appendix N, "Standardization of Nuclear Power Plant Designs: Combined Licenses to Construct and Operate Nuclear Power Reactors of Identical Design at Multiple Sites." This appendix sets out the particular requirements and provisions applicable to situations in which applications for combined licenses under Part 52, Subpart C are filed by one or more applicants for licenses to construct and operate nuclear power reactors of identical design ("common design") to be located at multiple sites.

Operational Programs

Current NRC regulations require the following 18 operational programs (summarized from NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear

Power Plants: LWR Edition," Section 13.4, "Operational Programs," draft Revision 4, issued September 2018 (ADAMS Accession No. ML18131A304), Attachment, "Sample final safety analysis report Table 13.4-x—Operational Programs Required by NRC Regulations"):

(1) inservice inspection program (10 CFR 50.55a(g))

(2) inservice testing program (10 CFR 50.55a(f); 10 CFR Part 50, Appendix A)

(3) environmental qualification program (10 CFR 50.49(a))

(4) preservice inspection program (10 CFR 50.55a(g))

(5) reactor vessel material surveillance program (10 CFR 50.60; 10 CFR Part 50, Appendix H)

(6) preservice testing program (10 CFR 50.55a(f))

(7) containment leakage rate testing program (10 CFR 50.54(o); 10 CFR Part 50, Appendix A (General Design Criterion 32); 10 CFR Part 50, Appendix J)

(8) fire protection program (10 CFR 50.48; also 10 CFR 70.22, 10 CFR 30.32, 10 CFR 40.31)

(9) process and effluent monitoring and sampling program (10 CFR 20.1301 and 20.1302; 20.1301(e) for 40 CFR Part 190; 10 CFR 50.34a; 10 CFR 50.36a; 10 CFR Part 50, Appendix I, Sections II, III, and IV)

(10) radiation protection program (10 CFR 20.1101; 10 CFR 20.1406; 10 CFR Parts 30, 40, and 70; 10 CFR Part 37)

(11) nonlicensed plant staff training program (10 CFR 50.120, 10 CFR 30.32, 10 CFR 40.31, 10 CFR 70.22)

(12) reactor operator training program (10 CFR 55.13, 10 CFR 55.31, 10 CFR 55.41, 10 CFR 55.43, 10 CFR 55.45)

(13) reactor operator requalification program (10 CFR 50.34(b), 10 CFR 50.54(i), 10 CFR 55.59)

(14) emergency planning (10 CFR 50.47; 10 CFR Part 50, Appendix E)

(15) security program (10 CFR 73.1; 10 CFR 73.67; 10 CFR 73.55(b); 10 CFR 73.55(c)(3); 10 CFR 73.56; 10 CFR 73.57; 10 CFR 73.55(c)(5); 10 CFR 73.55(k); 10 CFR Part 73, Appendix C; 10 CFR 73.55(c)(4); 10 CFR 73.55(d)(3); 10 CFR Part 73, Appendix B; 10 CFR 26.3(c); 10 CFR 26.4(c)(3); 10 CFR 26.4(c); 10 CFR 26.4(a) and (b); 10 CFR 73.54(b); 10 CFR 73.55(b)(8); 10 CFR 73.55(c)(6); 10 CFR Part 74, Subpart B (10 CFR 74.11–10 CFR 74.19, excluding 10 CFR 74.17); 10 CFR 37.41(a)(1))

(16) quality assurance program—operation (10 CFR 50.54(a); 10 CFR Part 50, Appendix A (General Design Criterion 1); 10 CFR Part 50, Appendix B)

(17) maintenance rule (10 CFR 50.65)

(18) motor-operated valve testing (10 CFR 50.55a(b)(3)(ii))

Notes:

1. Additional final safety analysis report (Standard Review Plan) sections may be identified under broad operational programs required by regulation (e.g., inservice inspection and inservice testing).

2. If the COL applicant submits a request for 10 CFR Part 30, 40, and 70 licenses within the 10 CFR Part 52 application, the applicant should identify implementation milestones related to these licenses.

The use of standardized operational programs would help streamline the COL review. Standardization could be achieved through the use of topical reports, NRC approved templates,[5] or staff review and approval of operational programs included in the scope of the certified design, to the extent permitted under Commission policy.

Operational programs fall into two broad groups. For the purpose of discussion in this paper, the staff refers to these as Group 1 and Group 2. Group 1 programs are those that are material to the adequacy of design (e.g., technical specifications, design quality assurance, and portions of the American Society of Mechanical Engineers Boiler and Pressure Vessel Code inservice inspection and inservice testing programs). Group 2 programs are those that are not material to the adequacy of design, such as emergency planning and security programs.

Group 1 Operational Programs

Neither 10 CFR Part 52 nor the AEA precludes resolution of Group 1 requirements through design certification. For operational requirements that are material to the findings on the design, 10 CFR 52.47(a) only requires the application to include information on technical specifications and design quality assurance design requirements. However, the NRC staff has not historically accorded finality under 10 CFR 52.63 to technical specifications at the design certification stage. The regulations in 10 CFR Part 52 do not require the design certification to include information on the inservice inspection or inservice testing programs.

The NRC staff decided not to accord the same degree of finality to Group 1 requirements when it completed the advanced boiling-water reactor (ABWR) and System 80+ design certification reviews in the mid-1990s. The Commission approved this approach in the ABWR and System 80+ design certification rules (10 CFR Part 52, Appendices A and B, respectively). As part of the ongoing 10 CFR Part 53 rulemaking efforts, the staff is exploring options to provide finality to technical specifications at the design certification stage to further streamline the COL review. This would be feasible if the design does not rely on any site-specific safety features. A change to the degree of finality provided in a design certification for Group 1 programs would constitute a policy change and would require Commission approval.

[5] The NEI has previously prepared generic template guidance for operational programs for NRC review and approval (e.g., NEI 06-13A, "Template for an Industry Training Program Description," Revision 2, issued March 2009 (ADAMS Accession No. ML090910554)).

Group 2 Operational Programs

While not precluded by the AEA, in order to resolve Group 2 requirements through design certification, the Commission would need to settle several significant policy questions. The NRC staff is considering addressing these policy issues as part of the ongoing 10 CFR Part 53 rulemaking efforts. Under the current regulatory framework, to streamline micro-reactor licensing, a vendor may address Group 2 programs in a topical report(s) proposing standardized operational programs. A COL applicant could incorporate the approved topical report(s) by reference into its application.

Manufacturing Licenses

Some stakeholders have expressed interest in pursuing a manufacturing license as part of their licensing strategies. The NEI submitted a white paper titled "NEI Paper on Manufacturing License Considerations for Part 53, Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors," on July 16, 2021 (ADAMS Accession No. ML21197A103), "to discuss potential approaches for establishing [manufacturing license] requirements in 10 CFR Part 53, with the intent to inform the NRC's ongoing Part 53 rulemaking." The paper is based on the NEI's understanding that several potential vendors intend to pursue manufacturing licenses to design, develop, fabricate, and operate micro-reactors at multiple sites that the NRC has licensed for this purpose, and that in some cases, vendors wish to move these reactors from one site to another when necessary.

Manufacturing license regulations appear in 10 CFR Part 52, Subpart F. A manufacturing license applicant may reference a standard design certification or a standard design approval in its application. The Commission imposes the following key requirements, as summarized from 10 CFR 52.167, "Issuance of manufacturing license":

- There is reasonable assurance that the reactor(s) will be manufactured, and can be transported, incorporated into a nuclear power plant, and operated at sites having characteristics that fall within the **site parameters postulated for the design** of the manufactured reactor(s) without undue risk to public health and safety.

- The proposed inspections, tests, analyses, and acceptance criteria are necessary and sufficient, within the scope of the manufacturing license.

- The findings required by 10 CFR Part 51, Subpart A, "National Environmental Policy Act—Regulations Implementing Section 102(2)," have been made.

- Each manufacturing license issued under this subpart shall specify **technical specifications** for operation of the manufactured reactor, as well as site parameters and design characteristics for the manufactured reactor.

- A holder of a manufacturing license **may not transport** or allow to be removed from the place of manufacture the manufactured reactor except to the site of a licensee with either a construction permit under 10 CFR Part 50 or a COL under 10 CFR Part 52, Subpart C, "Combined Licenses."

The regulations in 10 CFR 52.151, "Scope of subpart," set out the requirements and procedures applicable to Commission issuance of a license authorizing manufacture of nuclear power

reactors to be installed at sites not identified in the manufacturing license application. To install and operate a micro-reactor at a specific site would also require an operating license (OL) or COL.

Manufacturing licenses could be incorporated into licensing strategies that cover stationary micro-reactors built in a factory and transported to a licensed site, with no fuel loaded at the manufacturing site. This would reduce the need for site-specific inspections and verifications.

While manufacturing licenses may provide some flexibility for designing and fabricating micro-reactors 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.

It should be noted that a manufacturing license is an optional licensing process that some applicants may find desirable for their business model; however, a manufacturing license is not required for factory fabrication of reactor modules or micro-reactors.

Possession and Transportation of Special Nuclear Material

Some vendors are considering the option of manufacturing and assembling reactor components, fueling the reactor in a factory, transporting the fueled reactor to approved sites (e.g., sites with approved COLs), with the possibility of transporting the reactor containing spent nuclear fuel back to the factory for refurbishment. This section addresses the requirements for possession and transportation of nuclear material that would apply in these scenarios.

Applicants wishing to fuel reactors in a factory and then transport the pre-fueled units may also be subject to other regulations, including those in the following 10 CFR parts:

- 10 CFR Part 30, “Rules of general applicability to domestic licensing of byproduct material”
- 10 CFR Part 40, “Domestic licensing of source material”[6]
- 10 CFR Part 70, “Domestic licensing of special nuclear material”[7]
- 10 CFR Part 71, “Packaging and transportation of radioactive material,” for transport of fissile material and Type B packages (see below)

[6] At this time, the NRC is not aware the use of source or byproduct material licenses in any of the scenarios discussed in this paper.

[7] Title I of the AEA (§ 11aa.) defines special nuclear material as plutonium, uranium-233, or uranium enriched in the isotopes uranium-233 or uranium-235 but does not include source material.

An applicant proposing to receive and possess enriched uranium in activities such as fueling a micro-reactor in a factory will need to address the requirements of 10 CFR Part 70, specifically those in 10 CFR 70.22, "Contents of applications."[8] The applicant should also consider physical protection of special nuclear material, as required in 10 CFR Part 73, "Physical protection of plants and materials"; material control and accounting of special nuclear material, as required in 10 CFR Part 74, "Material control and accounting of special nuclear material"; and information to be provided to the NRC on management organization, administrative programs, and financial qualifications to ensure the safe and secure receipt, possession, inspection, and storage of special nuclear material in the form of fresh fuel.

An applicant proposing to transport either a fueled micro-reactor that has not been operated or a micro-reactor that has been operated will need to address the package performance requirements in 10 CFR Part 71 for the type of package that it proposes to ship. A fueled micro-reactor that has not been operated and contains uranium enriched to less than 20 weight percent of uranium-235 would be classified as a Type AF (fissile) package if the determination is based only on the fissile material present in the package. However, if the fuel contains other radioactive material (i.e., fission products or plutonium isotopes), then the package may be classified as a Type B package, depending on the quantity of other radioactive material and the A_1 or A_2 value[9] for the mixture.

The NRC and the U.S. Department of Transportation (DOT) co-regulate transportation of radioactive material, with the NRC regulating transportation for its licensees and issuing certificates of compliance for both fissile (Type AF, Type B(U)F) and nonfissile (Type B(U)) packages.[10] The DOT regulations in 49 CFR 173.416, "Authorized Type B packages," and 49 CFR 173.417, "Authorized fissile materials packages," which apply to shippers and carriers, authorize shipment of any Type AF, B(U), or B(U)F package that the NRC has approved.

The regulations in 10 CFR Part 71 contain prescriptive requirements (i.e., neither risk-informed nor performance-based requirements) for packaging and transportation of radioactive material, which have been harmonized with the International Atomic Energy Agency standards in the 2009 Edition of TS-R-1, ''Regulations for the Safe Transport of Radioactive Material," to facilitate international transport. However, under the current regulatory framework, the Commission may approve alternate standards for packages that may not meet all of the transportation requirements in 10 CFR Part 71. Specifically, 10 CFR 71.41(c) provides for tests and conditions different from those in 10 CFR 71.71 and 71.73 if the shipper's controls provide safety of the shipment equivalent to that provided by meeting the regulations. Further, 10 CFR 71.41(d) provides for special package authorization if the application demonstrates that compliance with the regulations is impracticable and the safety standards established by the regulations have been met through alternative means. Finally, an applicant may request an exemption as specified in 10 CFR 71.12, "Specific exemptions." Each of these alternatives has limitations, as described in more detail below.

The requirements in 10 CFR 71.41(c) provide for alternate environmental and test conditions for a package that, when subjected to the environmental conditions required by the regulations, in

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8 Depending on the proposed activities involving special nuclear material, the applicant may need to address the requirements in 10 CFR Part 70, Subpart H, "Additional Requirements for Certain Licensees Authorized To Possess a Critical Mass of Special Nuclear Material."

9 Appendix A, "Determination of A_1 and A_2," to 10 CFR Part 71 contains the A_1 and A_2 values for individual radioisotopes and the method for calculating the aggregate A_1 and A_2 value for a mixture of radionuclides.

10 Type B packages contain a quantity of radioactive material greater than a Type A quantity. The NRC defines a Type A quantity of material in 10 CFR 71.4, "Definitions."

conjunction with one or more of the tests for normal conditions of transport or hypothetical accident conditions, cannot meet the post-test criteria. Use of the alternate test criteria in 10 CFR 71.41(c) has several limitations. An applicant for package approval cannot eliminate the test but rather can reduce the severity of the test (e.g., the applicant can use a 20-foot drop instead of 30-foot drop but cannot substitute a different test) so that the package can meet the post-test criteria. In addition to the alternative environmental conditions or test criteria, the applicant must submit additional controls that the shipper can exercise to provide an equivalent level of safety for the shipment. The regulations in 10 CFR 71.41(c) do not offer alternate post-test criteria; therefore, the applicant would still need to meet the regulatory limits for dose rate, containment, and criticality safety. Differing post-test criteria can only be approved through exemption.

After its experience with issuing the exemption for the Trojan reactor vessel (see ADAMS Package Accession No. ML20155E053 and SECY-98-0231, "Authorization of the Trojan Reactor Vessel Package for One-Time Shipment for Disposal," dated October 2, 1998), the NRC noticed a need for a provision for a special package authorization for one-time shipment of large components that do not meet the criteria for shipment as low specific activity packages or surface contaminated objects.[11] In the 2002 proposed rulemaking (Volume 67 of the *Federal Register* (FR), page 21390 (67 FR 21390), Issue No. 12, "Special Package Authorizations"), the NRC added the special package authorization option in 10 CFR 71.41(d) for limited circumstances involving large packages for which it is not practical to fabricate an authorized packaging. In particular, the NRC limited this alternate approval method, among other things, to one-time shipments of large components "for which compliance with the other provisions of these regulations [i.e., 10 CFR Part 71] is impracticable." It could therefore be feasible to ship a micro-reactor using a special package authorization if it were only for a shipment back to a refurbishment facility.

If neither Section 71.41(c) nor Section 71.41(d) can be used, licensees can request an exemption to the regulations pursuant to 10 CFR 71.12. Through exemption, licensees can provide alternate environmental conditions and tests and alternate post-test criteria. The exemption request must contain sufficient technical information for the NRC staff to determine that the request is authorized by law and will not endanger life or property or the common defense and security. The exemption request should be accompanied by an environmental report, since the categorical exclusion in 10 CFR 51.22(c)(13) does not apply. In addition, each licensee making a shipment needs to request a separate exemption, since an exemption cannot be made generically applicable to multiple licensees. In addition, the DOT's regulations do not specifically authorize NRC-issued exemptions as a package approval; therefore, each licensee would need a DOT-issued special permit for its shipment.

External Hazards and Siting

Design certifications must contain site parameters postulated for the design and an analysis and evaluation of the design in terms of those site parameters. Site parameters are the postulated physical, environmental, and demographic features of an assumed site. Under 10 CFR 52.79(d)(1), a COL applicant that references a design certification is required to demonstrate that the actual characteristics of the proposed site fall within the site parameters in the design certification to ensure that the analysis of the certified reactor design remains valid. Because

[11] For the definitions of low specific activity and surface-contaminated object, see 49 CFR 173.403, "Definitions." For the exemption from most of the requirements in 10 CFR Part 71 for low-specific-activity packages and surface-contaminated objects, see 10 CFR 71.14(b)(3).

site parameters were used in bounding evaluations of the design certification applicant's design, they define the requirements that the characteristics of a proposed site must meet. Examples of site parameters that a design certification application should address appear in NUREG-0800, Chapter 2, "Site Characteristics and Site Parameters." These examples include external hazards such as the ground motion response spectra (GMRS) and meteorological conditions such as temperatures and atmospheric dispersion factors. They were developed based on the typical factors that influence site safety for large LWRs. Their impact on safety depends on the specific reactor design.

To meet the siting requirements under 10 CFR 100.21, "Non-seismic site criteria," and 10 CFR 100.23, "Geologic and seismic siting criteria," with respect to external hazards, the applicant must evaluate the physical characteristics of the site, including meteorology, geology, seismology, and hydrology, and must establish site characteristics such that potential threats from such physical characteristics will pose no undue risk to the proposed type of facility. Section 100.21 requires the evaluation of site atmospheric dispersion characteristics, the establishment of an exclusion area and a low population zone, and whether radiological release limits associate with normal operation can be met, as well as the evaluation of potential man-made hazards. To meet the requirements in 10 CFR 100.23, the applicant must conduct siting investigations commensurate with the footprint and risk profile of the facility to determine the physical properties of the material underlying the site in order to support the evaluation of the soil and rock response to vibratory ground motion, soil and rock stability, liquefaction potential, and slope stability. To support development of the site GMRS for comparison with the design-basis ground motion, regional probabilistic seismic source and ground motion models previously approved by the NRC staff are available for many locations in the United States. These models were developed jointly with other government agencies and the industry and used the Senior Seismic Hazard Analysis Committee (SSHAC) methodology described in NUREG-2213, "Updated Implementation Guidelines for SSHAC Hazard Studies," issued October 2018 (ADAMS Accession No. ML18282A082), to capture the uncertainty inherent in parameters such as fault slip rates and geometry, earthquake recurrence, and predicted ground motions. Section 6, "Geology, Seismology, and Geotechnical Engineering," in Chapter 2, "Site Information," of the proposed Advanced Reactor Content of Application Project (ARCAP), issued in draft in July 2021 (ADAMS Accession No. ML21189A031), specifies a graded risk-informed, performance-based approach for developing the site GMRS based on the seismic design category of the proposed facility. Chapter 2 of the proposed ARCAP also provides further detail on the factors to be considered when evaluating sites, including seismic and non-seismic parameters.

If a design certification identifies parameters that the design is insensitive to or that can be bounding for a number of predetermined COL sites, then this will eliminate or reduce the level of effort required at the COL stage.

The NRC staff can use a hazard screening flow diagram, such as the one for volcanic hazard assessment (refer to Figure 1, "Flowchart for an acceptable volcanic hazards assessment," of Regulatory Guide 4.26, "Volcanic Hazards Assessment for Proposed Nuclear Power Reactor Sites," issued June 2021 (ADAMS Accession No. ML20272A168)) to determine that some external hazards (e.g., ice effects) have no impact on the design and do not exceed regulatory limits.

Pre-identified sites that are not vulnerable to volcanism or other hazards can be licensed to use micro-reactors that are certified when these hazards are excluded (see Figure 1 below). The

staff can verify these hazards to be within the design parameters without significant effort at the COL stage.

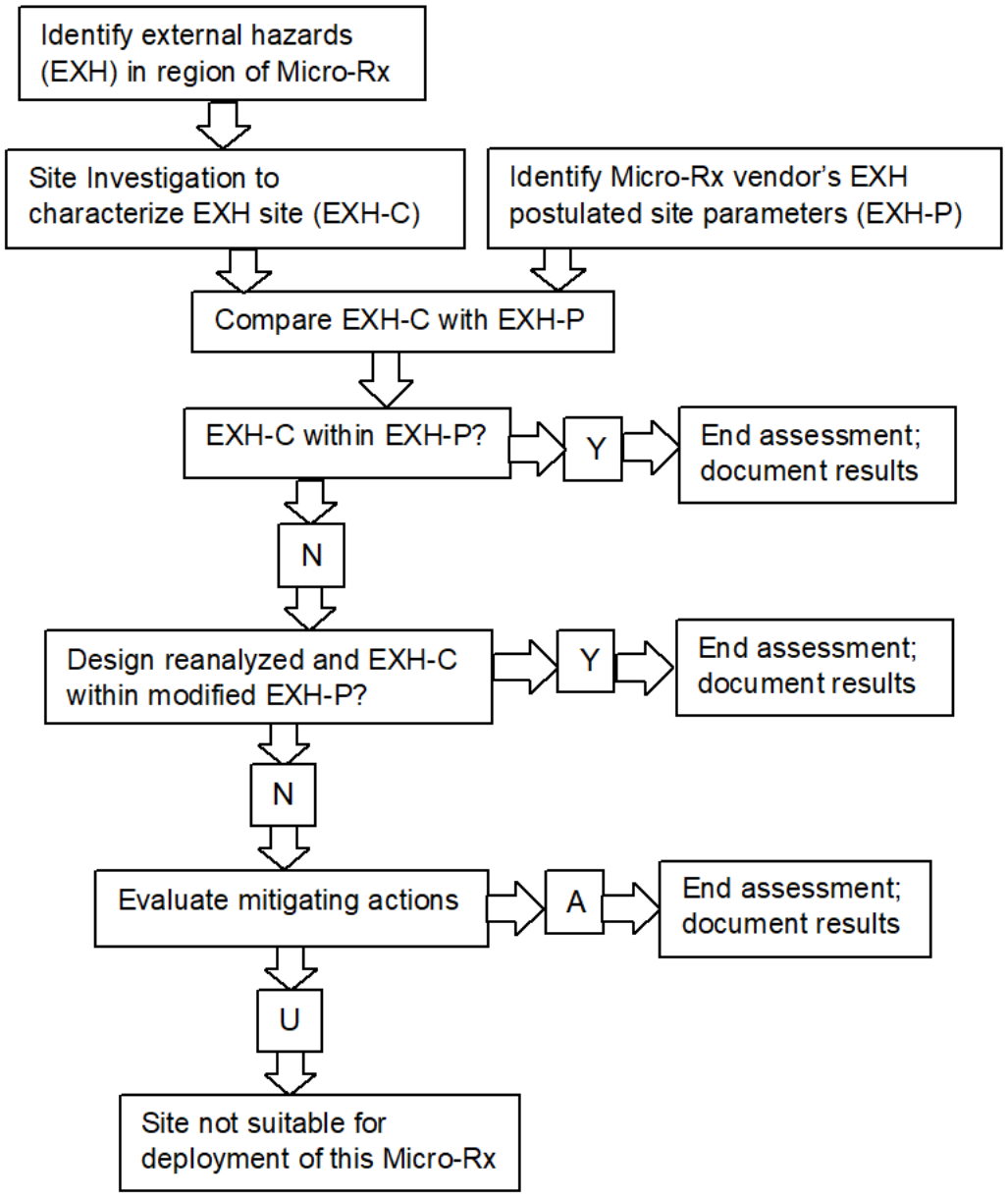

Figure 1 Flowchart for an acceptable site hazard parameters assessment in the micro-reactor design process (Y = yes, N = no, U = unacceptable performance, A = acceptable performance)

Environmental Review

To meet NEPA requirements, the NRC staff evaluates the environmental impacts of proposed licensing actions. The NRC's NEPA implementing regulations are codified in 10 CFR Part 51. They take account of the NEPA regulations promulgated by the Council on Environmental Quality in 40 CFR Parts 1500-1508. In addition to its obligations under NEPA, the NRC staff is

also required to conduct consultations under other environmental statutes (e.g., the Endangered Species Act and the National Historic Preservation Act), or otherwise demonstrate compliance with various environmental statutes (e.g., the Coastal Zone Management Act).

In performing its evaluations in conformance with 10 CFR Part 51, the NRC staff may (1) adopt a previously established categorical exclusion (listed in 10 CFR 51.22), (2) prepare an environmental assessment (EA), or (3) prepare an environmental impact statement (EIS). A Federal agency may establish categorical exclusions for classes of actions that the agency has determined, on the basis of past experience and after review by the Council on Environmental Quality, do not individually or cumulatively have a significant effect on the human environment and for which; therefore, neither an EA nor an EIS is normally required. An EA is prepared to determine whether a Federal action may cause significant environmental effects. If a proposed action is determined to significantly affect the quality of the human environment, then the Federal agency is required to prepare an EIS. In its regulations at 10 CFR 51.20(b), the NRC has presumptively determined that the issuance of a limited work authorization, construction permit, early site permit, OL, or COL for a nuclear power reactor requires the preparation of an EIS.

The NRC staff has identified several actions that could streamline the environmental review of micro-reactor applications. These actions include the recent issuance of guidance to applicants and NRC staff on the conduct of environmental reviews for advanced non-LWRs and micro-reactors, development of a GEIS for advanced nuclear reactor applications, a proposed rulemaking that would codify the generic findings of the advanced nuclear reactor (ANR) GEIS, and a potential rulemaking that would streamline 10 CFR Part 51, including a potential revision to 10 CFR 51.20(b) that would allow the NRC to prepare an EA for certain types of reactor applications (e.g., micro-reactors) rather than an EIS.

Environmental Review Guidance

Regulatory Guide 4.2, “Preparation of Environmental Reports for Nuclear Power Stations,” Revision 3, issued September 2018 (ADAMS Accession No. ML18071A400), provides guidance for preparing environmental reports in support of reactor licensing applications. Appendix C to this regulatory guide provides supplemental guidance on environmental reports prepared to support licensing applications for small modular reactors and non-LWRs.

In October 2020, the NRC issued interim staff guidance (ISG) COL-ISG-029, “Environmental Considerations Associated with Micro-reactors” (ADAMS Accession No. ML20252A076), to modify existing guidance and provide supplemental guidance to help the NRC staff determine the scope and scale of environmental reviews of micro-reactor applications. The ISG highlights unique considerations for micro-reactors in each resource area typically covered in the staff’s environmental review. It also offers guidance on scaling the analyses to streamline the environmental review and documentation where appropriate. The ISG focuses on better aligning the environmental reviews to the unique aspects of micro-reactors relative to the NRC’s previous environmental reviews for other nuclear facilities such as large LWRs. The ISG outlines what the NRC staff considers to be an appropriate scope and level of detail for the specific aspects of an environmental review needed to document a micro-reactor licensing action.

Generic Environmental Impact Statement for Advanced Nuclear Reactors

The NRC staff is currently developing an ANR GEIS for the generic assessment of the environmental impacts of constructing and operating advanced nuclear reactors. The staff is using a technology-neutral, performance-based approach to allow the use of the ANR GEIS by as wide a range of future applicants as possible. The draft ANR GEIS identifies a range of specific environmental issues for evaluation. Similar to the operating reactor license renewal GEIS (NUREG-1437), the ANR GEIS divides the identified environmental issues into two categories, Category 1 issues and Category 2 issues. The Category 1 issues are those for which the associated potential environmental impacts can be bounded for all plants that meet a set of values and assumptions in defined plant parameter envelopes (PPE) and site parameter envelopes (SPE). Additionally, the NRC staff has preliminarily determined that the potential environmental impacts associated with each Category 1 issue are small (as opposed to moderate or large). The Category 2 issues are those for which the associated potential environmental impacts cannot be bounded generically, and as such, require a site-specific analysis. The potential impacts of Category 2 issues could range from small to large. The ANR GEIS will support a proposed rule that would codify the Category 1 issues to permit an applicant for an advanced nuclear reactor permit or license to use the ANR GEIS in preparing its environmental report. If an applicant chooses to rely upon one or more of the Category 1 findings, the applicant's environmental report must be prepared in accordance with the proposed rule. Similarly, the proposed rule would require the NRC staff to prepare a site-specific draft and final supplemental EIS (SEIS) that is a supplement to the ANR GEIS. Applicants could rely upon the ANR GEIS in preparing their environmental reports and the staff would rely upon it in preparing the site-specific draft and final SEIS. Together, the ANR GEIS and the SEIS will constitute the NEPA analysis for a given ANR project.

Provided that an ANR applicant can demonstrate that it meets the PPE and SPE values and assumptions for a given Category 1 issue, and that neither the applicant nor the NRC staff has identified any new and significant information pertaining to that issue, both the applicant and the NRC staff can rely upon the generic findings for that issue. The ability to rely upon the generic findings for a given Category 1 issue will obviate the need for the applicant and the NRC staff to conduct a site-specific analysis for that issue, thereby streamlining the environmental review of licensing applications for advanced reactors, including micro-reactors. Codification of the generic findings in the NRC regulations will also restrict challenges to such issues to circumstances justifying a waiver of the rule in 10 CFR 2.335, which prohibits challenges to regulations in licensing proceedings absent a waiver.

Alternative Environmental Review Approach

Historically, the NRC has licensed nuclear facilities, including large LWRs, that involved the construction of dozens of buildings and other structures occupying hundreds of acres. Large LWR projects could transform surrounding landscapes, stream and river systems, and rural communities. The NRC therefore determined that EISs assessing the potential impacts of these facilities represented the appropriate level of review to meet the agency's obligations under NEPA, as codified in 10 CFR 51.20(b).

As described in the staff's proposal to revise and update 10 CFR Part 51 and associated guidance (SECY-21-0001, "Rulemaking Plan—Transforming the NRC's Environmental Review Process," dated December 31, 2020 (ADAMS Accession No. ML20212L393)), the staff has identified 10 CFR 51.20(b) as a candidate for potential streamlining revisions. In 10 CFR 51.20(b), the NRC lists several categories of licensing actions that the Commission has determined require an EIS, including issuance of permits and licenses for power reactors. Based upon over 40 years of NRC regulatory experience, the staff has determined that an EA

may suffice to meet NEPA requirements for the evaluation and disclosure of environmental impacts for some categories of licensing applications that currently fall within the scope of 10 CFR 51.20(b). The staff would then prepare an EIS only for applications in which it could not make a finding of no significant impact (FONSI). Based on its experience with environmental reviews of large LWRs, the staff has determined that an EA may be appropriate for some advanced reactor applications with limited expected environmental impacts, such as those involving the deployment and operation of micro-reactors.

The NRC anticipates that the construction footprints for micro-reactors will be small, that water consumption may be zero or limited to a small amount per day for potable purposes, and that construction and operation may involve a limited number of site staff. Furthermore, many micro-reactors may be sited within existing developed areas (such as retired fossil-fueled generating stations) that lack sensitive environmental resources. Therefore, compared to a large LWR, a micro-reactor is likely to require less data and analysis for most environmental issues. These characteristics make it more likely that siting and operation of a micro-reactor may have the potential for no significant environmental impact.

Thus, with the proper rulemaking change, the staff could prepare an EA for a micro-reactor project in accordance with 10 CFR 51.30, “Environmental assessment,” to determine whether a FONSI could be issued pursuant to 10 CFR 51.32, “Finding of no significant impact.” Such an EA could potentially be streamlined through incorporating by reference applicable analyses contained in the ANR GEIS. If, while preparing such an EA, the NRC staff determined that the proposed action may have one or more significant environmental impacts, then the staff, in accordance with 10 CFR 51.31(a), would prepare an EIS. If there are no such significant environmental impacts, however, the staff could then prepare an EA and FONSI, which would reduce both the environmental review time and avoid the costs associated with preparing a more complex EIS.

CONCLUSION

Because prospective vendors are interested in fabricating micro-reactors in factories and transporting them to preapproved sites, with the possibility of transporting them from one site to another, the NRC staff has explored strategies to streamline the review of such applications within existing regulations, Commission policy, and public laws. The areas explored by the staff include design certification, COLs, manufacturing licenses, siting and external hazards, and environmental reviews.

While a manufacturing license could provide flexibility for designing and fabricating micro-reactors, fuel loading and transportation would require a number of other licenses. Addressing operational programs through a topical report at the design phase could streamline the review at the COL stage. Applicants may be able to adopt certain measures to enhance standardization at the design phase; for example, they could provide design parameters that would bound the actual site characteristics at the COL stage, thereby reducing the staff review to simple verification. In addition, if the design does not depend on certain site -specific features, such as water and the need for external power, the scope of the COL application and the staff’s review will be substantially reduced. The environmental review could be streamlined by adopting the ANR GEIS, which will reduce the effort required for environmental review to the extent that the ANR GEIS parameters bound the plant and site, and absent any new and significant information. Additionally, because micro-reactors may have limited environmental impacts, a site -specific EIS may be unnecessary; if the Commission approves the staff’s rulemaking plan, the staff may be able to establish a FONSI through an EA. The staff therefore concludes that

future rulemaking efforts could explore the streamlining of site hazards, operational programs, manufacturing licenses for fabrication and transportation, and environmental review.

Scope of Combined License Safety Review with Varying Degrees of Standardization

The NRC staff has prepared the following figures to demonstrate how enhanced standardization of the design can significantly reduce the scope of the information required to be submitted by a combined license (COL) applicant and in turn, the scope of the staff's review and associated cost and schedule. Figure 1 shows the typical COL review scope. In Figure 2, the scope of the COL is reduced by enhancing standardization through strategies such as eliminating deviations or departures from the certified design and reducing the number of site-specific features. Further, the use of standard operational programs can lead to review efficiencies. Figure 3 shows further efficiencies that could be realized by providing finality for standard operational programs as part of the design certification.

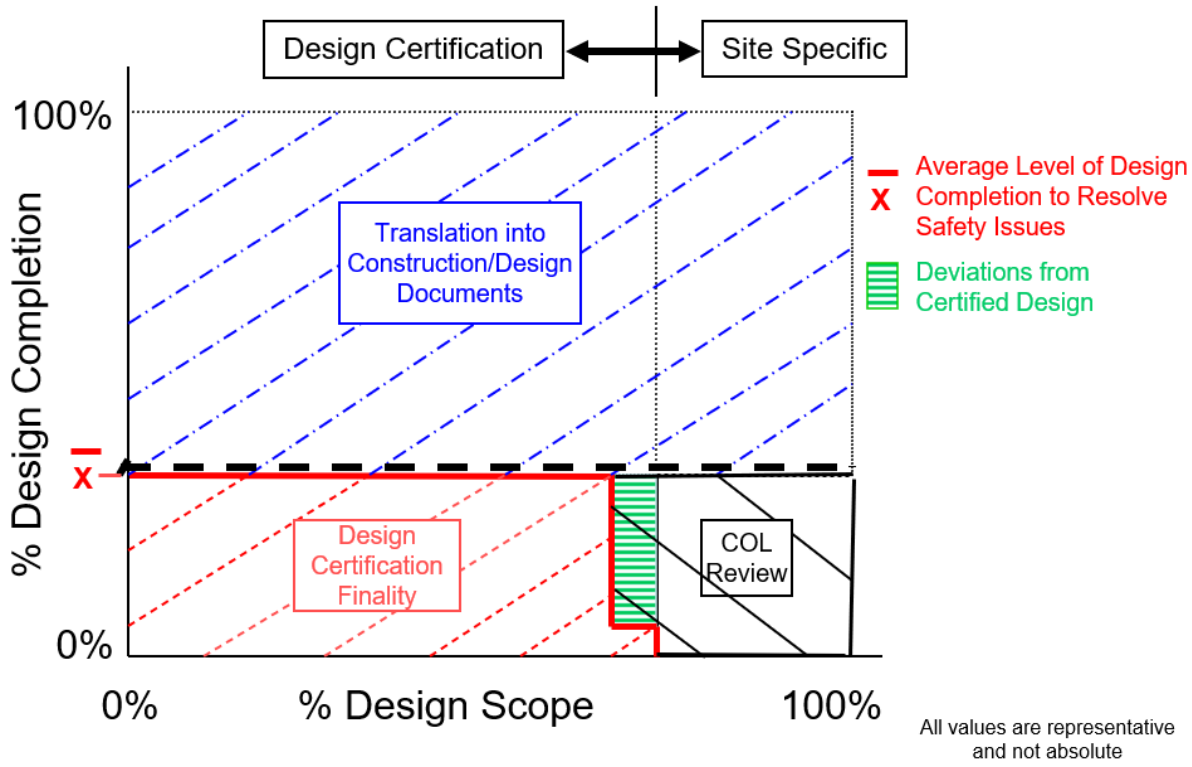

Figure 1 COL application referencing a certified design

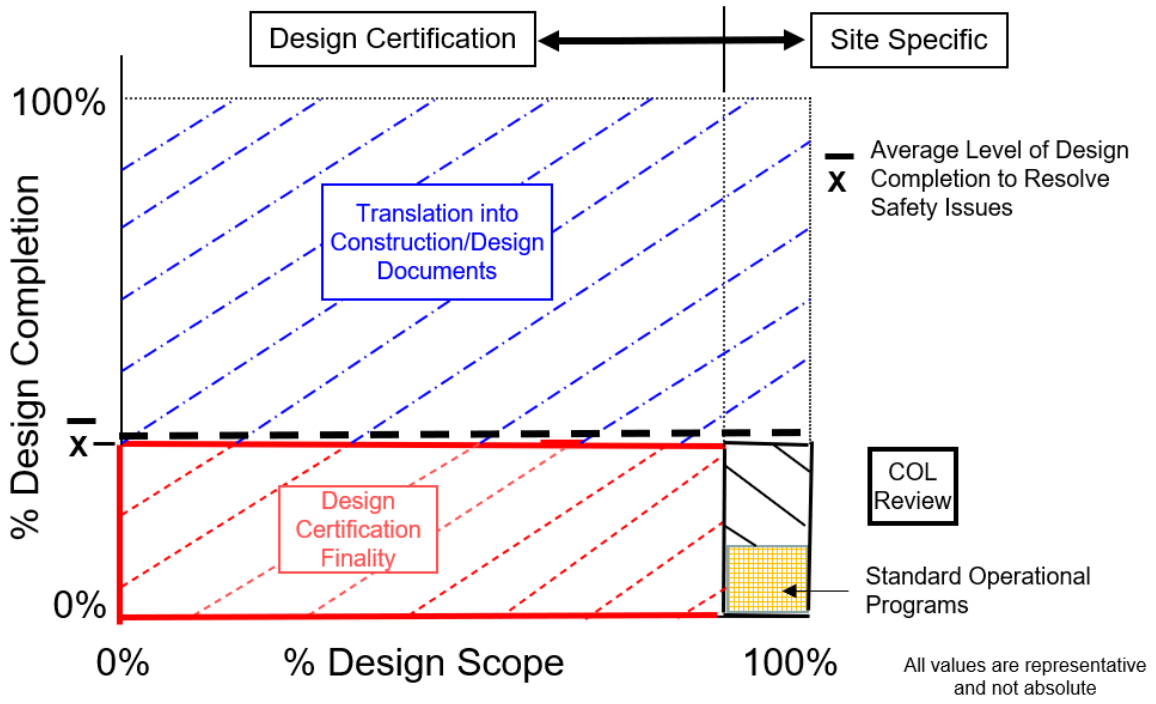

Figure 2 COL application referencing a certified design with enhanced standardization

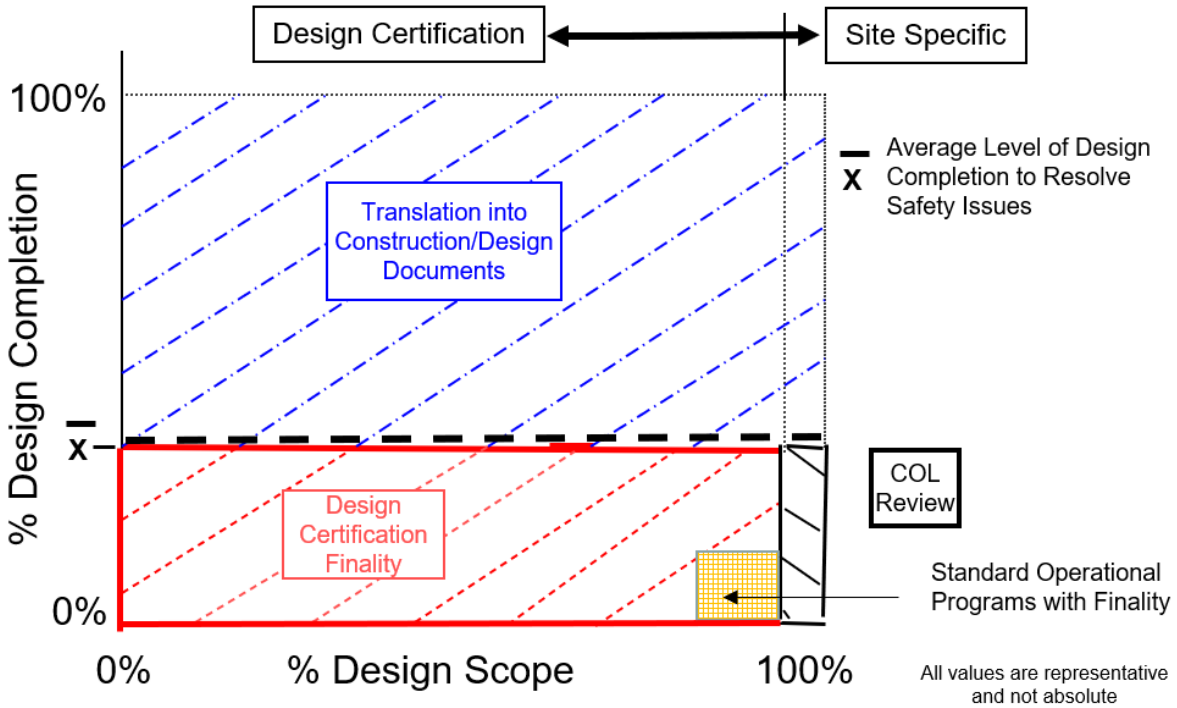

Figure 3 COL application referencing a certified design with enhanced standardization and finality for operational programs