Standardization of Operational Programs for Nth-of-a-Kind Microreactors

To facilitate efficient licensing of nth-of-a-kind (NOAK) microreactors, the U.S. Nuclear Regulatory Commission (NRC) staff has developed two options for staff review of standardized generic operational programs.[1] Option 1 would maintain the status quo, in which the staff may review measures proposed to satisfy operational programs through topical reports or through a design-centered review approach. For the design-centered review approach, the staff would review measures to satisfy operational requirements or entire operational programs for the first microreactor application of a particular design and that review would be applied to subsequent microreactor applications of the same design that use the same approach as proposed in the first application. Option 2 would provide for the review of measures proposed to satisfy operational requirements (e.g., technical specifications (TS) and operational programs) in either a design certification (DC) or a manufacturing license (ML) application. This enclosure discusses the NRC staff's reasoning regarding the review and approval of standardized operational programs as part of the DC or ML application review.

Background

Approaches that rely on topical reports or a design-centered review can be implemented under the current regulatory framework without a change to Commission policy. However, current Commission policy restricts review of operational requirements proposed in the context of a DC or ML application to those that are material to the finding on the safety of the design (e.g., TS). The Commission would have to change this policy to accommodate strategies that would allow an option to resolve all operational matters during the DC or ML review to accord finality or enhanced regulatory stability to requirements that are not material to the safety of the design. If the Commission changed its policy to allow complete review and approval of all operational requirements in connection with a DC or ML application, maximal issue resolution could be achieved through rulemaking.

Historically, the Commission has approved operational requirements proposed in a DC application only if they are material to the safety of the design. In the context of the completion of the advanced boiling-water reactor (ABWR) and System 80+ DC reviews in the mid-1990s, the NRC staff addressed this issue. Specifically, in the draft final rules the NRC staff sent to the Commission to certify these designs, the staff included provisions that would accord only limited finality to operational requirements, even if approved in a DC review, by applying the standards of Title 10 of the *Code of Federal Regulations* (10 CFR) 50.109, "Backfitting." See SECY-96-077, "Certification of Two Evolutionary Designs," dated April 15, 1996 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML003708129). In SECY-96-077, the NRC staff stated that not providing finality for TS and other operational programs "is not inconsistent with [10 CFR] Part 52's focus on design finality and it preserves NRC's flexibility to backfit future rules on operational matters such as steam generator tube plugging criteria even though such rules may affect the design incidentally." The staff also

1 Although this Enclosure focuses on programs required for reactor operation, some program elements, such as quality assurance for construction required in a combined license or construction permit application, do not govern operation or design and are therefore not required in an application for design certification, standard design approval, or a manufacturing license. The staff could apply the options stated in this enclosure and the SECY paper for operational programs to such program elements. The language of "operational" programs or requirements as employed in this Enclosure should not be understood as excluding program elements that apply neither to operation nor design from approval under the options stated in this Enclosure. The staff plans to apply the Commission's direction on the policy questions presented in the SECY paper to such programs.

stated that “[m]ost importantly, a provision has been included in Section 4 [of the ABWR design certification rule (DCR) in 10 CFR Part 52, Appendix A] to provide that the final rules do not resolve any issues regarding conditions needed for safe operation (as opposed to safe design),” which the Commission quoted in the ABWR Final Rule in Volume 62 of the *Federal Register* (FR) on page 25806 (62 FR 25800, 25806; May 12, 1997). The Commission approved this approach for the ABWR and System 80+ DCs in the staff requirements memorandum (SRM) for SECY-96-077, dated December 6, 1996 (ML003754873) and the ABWR and System 80+ final rules.

Further, in the preamble to the ABWR Final Rule, the Commission specifically rejected a comment on the ABWR proposed rule that requested that all design control document (DCD) requirements be accorded finality, including operational-related and other nonhardware requirements. In rejecting that comment, the Commission stated the following:

> The Commission has determined that NEI’s [Nuclear Energy Institute’s] proposal to assign finality to operational requirements is unacceptable, because operational matters were not comprehensively reviewed and finalized for design certification (refer to section III.F of this SOC [Statements of Consideration (rule preamble)]). Although the information in the DCD that is related to operational requirements was necessary to support the NRC’s safety review of the standard designs, the review of this information was not sufficient to conclude that the operational requirements are fully resolved and ready to be assigned finality under § 52.63. Therefore, the Commission retained the former Section 4(c), but reworded this provision on operational requirements and placed it in Section VI.C of this appendix with the other provisions on finality (also refer to Section VIII.C of this appendix).

The Commission also excluded from finality the information voluntarily provided in the economic simplified boiling-water reactor (ESBWR) DC application regarding operational requirements. In the preamble to the ESBWR Final Rule (79 FR 61944; October 15, 2014), the Commission stated the following:

> [General Electric-Hitachi included] in the DCD details on two HFE [human factors engineering] operational program elements (procedures and training) that are not used to determine the adequacy of the HFE design. In keeping with the established Commission policy of not approving operational program elements through design certification except where necessary to find design elements acceptable, the NRC is excluding these two HFE operational program elements in the ESBWR DCD from the scope of the design approved in the rule.

In contrast, an applicant for a combined license (COL) must describe all operational requirements specified in NRC regulations in the COL application. In SRM-SECY-02-0067, “Staff Requirements—SECY-02-0067—Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC) for Operational Programs (Programmatic ITAAC),” dated September 11, 2002 (ML022540755), the Commission determined that a COL applicant is not necessarily required to have ITAAC for an operational program with the exception of emergency planning. The Commission stated the following:

> [ITAAC] for a program should not be necessary if the program and its implementation are fully described in the application and found to be acceptable by the NRC at the COL stage. The burden is on the applicant to provide the

> necessary and sufficient programmatic information for approval of the COL without ITAAC.

The Commission defined “fully described” in SRM-SECY-04-0032, “Staff Requirements—SECY-04-0032—Programmatic Information Needed for Approval of a Combined License Without Inspections, Tests, Analyses, and Acceptance Criteria,” dated May 14, 2004 (ML041350440). The Commission stated the following:

> In this context, “fully described” should be understood to mean that the program is clearly and sufficiently described in terms of the scope and level of detail to allow a reasonable assurance finding of acceptability.

In SECY-05-0197, “Review of Operational Programs in a Combined License Application and Generic Emergency Planning Inspections, Tests, Analyses, and Acceptance Criteria,” dated October 28, 2005 (ML052770257), the NRC staff described its plan for implementing the Commission’s position on operational programs for COL applications. In SECY-05-0197, the NRC staff defined operational programs for new nuclear power plants as programs required by regulation; reviewed by the NRC staff for acceptability, the results of which are documented in the safety evaluation report; and inspected by NRC inspectors to verify implementation. In the SECY, the NRC staff also listed operational programs required by regulation. The Commission endorsed the NRC staff recommendations on operational programs in SRM-SECY-05-0197, dated February 22, 2006 (ML060530316). NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition” (SRP), Section 13.4, Revision 4, “Operational Programs,” issued March 2019 (ML18344A032), addresses review and implementation of operational programs required by regulations for a COL, and includes a table identifying a list of operational programs.[2] As described below, for a DCR or ML proceeding to finally resolve operational programs, the DCR or ML application would need to “fully describe” the programs in accordance with Commission direction for COL applications.

Design finality under 10 CFR 52.63, “Finality of standard design certifications,” is premised on an applicant providing an essentially complete design for the DC review to justify a finding that the vendor’s design; structures, systems, and components (SSCs); and justifications, for example, are sufficient and that additional or alternative designs, SSCs, and justifications are not necessary (see section VI.A of each DCR). A DC application does not have to include “essentially complete” operational requirements; however, 10 CFR Part 52, Subpart B, “Standard Design Certifications,” requires the applicant to provide some information, such as a design quality assurance (QA) program and proposed TS. Under section VIII.C of each DCR, the NRC has included additional procedures for changes to those operational requirements that were completely reviewed and approved as documented in the safety evaluation report on the DC application (e.g., generic changes to operational requirements that do not require a design change would be subject to 10 CFR 50.109).

The regulations in 10 CFR Part 52, Subpart F, “Manufacturing Licenses,” are similar to those for a DC application, and require an ML application to include information related to the design of

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[2] The SRP has been prepared to establish criteria that the NRC staff responsible for the review of applications to construct and operate nuclear power plants intend to use in evaluating whether an applicant or licensee meets the NRC's regulations. The SRP is not a substitute for the NRC’s regulations, and compliance with it is not required. However, an applicant is required to identify differences between the design features, analytical techniques, and procedural measures proposed for its facility and the SRP acceptance criteria and evaluate how the proposed alternatives to the SRP acceptance criteria provide an acceptable method of complying with the NRC regulations.

the reactor and controls for manufacturing but not information relating to operational requirements that are not material to the adequacy of the design. To the extent 10 CFR Part 52, Subpart F, requires an ML application to describe operational requirements, the staff plans to apply the Commission direction described above for DCRs to that information. An applicant for a COL under 10 CFR Part 52 or a construction permit (CP) and subsequent operating license (OL) under 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities,” can currently reference DCRs or other NRC approvals, including MLs.

The review of a DC application also addresses COL action items, which identify matters outside the scope of a DCR that remain to be resolved in a proceeding on a COL application referencing the DCR (proceedings on a CP/OL referencing the DCR would also need to resolve such matters). The NRC staff will review this information to verify that the referencing application includes all required information outside the scope of the DCR. This process currently applies in the case of operational programs that are not material to the adequacy of the design, as well, and that information could instead be included within the scope of a DC or ML application and review. If the Commission approves the NRC staff recommendation in Option 2, and a DC or ML applicant chooses to pursue additional regulatory stability by submitting operational program(s) with the DC or ML application, the applicant would need to provide sufficient information to “fully describe” the program such that the NRC staff could determine whether the program description is adequate to satisfy the relevant NRC regulations. If so, the staff could then approve the program in conjunction with the DC or ML for reference by future COL or CP/OL applicants.

If the Commission approves Option 2, the staff is also considering several regulatory vehicles to provide DC and ML applicants the option to submit proposed measures to satisfy operational programs as part of a DC or ML. Specifically, the DC would be codified through the rulemaking process, which would provide for Commission engagement on each individual DC application. A rule of particular applicability for an ML would allow for a set of operational requirements and programs to be tailored to a specific ML application, with consideration of the type of technology employed, and could be referenced in a COL or CP/OL application for NOAK licensing. Such a rule would be particularly useful for establishing definitions unique to a particular design and for treating issues common to several programs. A case-specific order, which would define the applicable license review standards and any special standards or instructions, would provide a focused regulatory structure and perhaps offer the most flexibility. However, there is uncertainty about the value or practicality of a case-specific order in conjunction with an ML as there is little precedent for that approach in similar contexts. Additionally, it would require substantial time and interaction between the applicant and the staff before submittal and acceptance of an application and approval of the approach (including issuance of a case-specific order) by the Commission. This approach also carries a risk of future litigation over the standards applied to each program, to the extent that the programs or standards differ from those in current NRC rules.

A rule of particular applicability carries a lower risk of litigation because it provides for the public notice-and-comment process associated with a rulemaking. Potential drawbacks to a rule of particular applicability include a substantial upfront time cost to both the staff and the applicant, as the rule would need to be promulgated before the COL or CP/OL application is submitted.

Another approach to implementing Option 2 for ML applications is rulemaking to amend 10 CFR Part 52, Subpart F, to generically authorize an alternative for an ML applicant to propose operational programs that are not material to the safety findings on the design in the application. Such a rulemaking could also amend 10 CFR Part 52, Subpart B, to allow the generic resolution of operational program issues in the context of DC applications. In the context of an ML or DC application, the advantage of this approach is that it would resolve all issues associated with operational program review in one NRC action.

The approach described in Option 2 would afford the NRC staff the flexibility to approve operational requirements proposed in a DC or ML application if they are adequately detailed such that the NRC staff can perform a comprehensive review and determine whether they satisfy NRC regulations. The completeness of operational programs at the design stage in a DC or ML may also depend on a COL or CP/OL applicant having few site-specific or owner-specific features. Under the approach described in Option 2, the NRC could, upon a comprehensive review, determine that the information provided by the DC or ML applicant is sufficient to describe a program that meets the relevant regulations, with the staff verifying site-specific aspects during the COL or CP/OL review. Also under Option 2, the staff intends to continue leveraging the tools discussed under Option 1 to provide for more efficient reviews. The NRC staff also notes that guidance to applicants may still be warranted to address the many possibilities for novel deployment models of microreactors for both Option 1 and Option 2.

For the purposes of this SECY, the NRC staff used the guidance in SRP section 13.4 to inform the list of operational programs the staff considered. The NRC staff notes that the operational programs referenced in this SECY may not be all inclusive or applicable with respect to every microreactor or advanced reactor design. The NRC developed Advanced Reactor Content of Applications Project (ARCAP) guidance (ML23277A105), including DANU-ISG-2022-01, “Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications—Roadmap—Interim Staff Guidance,” issued March 2024 (ML23277A139), to support near-term advanced reactor applicants. Appendix B to DANU-ISG-2022-01 describes the regulations that are generally applicable to a non-light-water reactor (non-LWR) application for a CP and OL under 10 CFR Part 50 and DCs, COLs, and standard design approvals under 10 CFR Part 52. The applicant should identify the operational programs that apply to its design and deployment models.

Summary of the Operational Programs and NOAK Considerations

This section summarizes and describes NOAK considerations related to the following operational programs: Inservice Inspection, Inservice Testing, Preservice Inspection, Preservice Testing, Motor-Operated Valve Program, Containment Leakage Rate Testing, Reactor Vessel Material Surveillance, Equipment Qualification, Fire Protection, Quality Assurance, Maintenance Rule, Reliability Assurance, Process Effluent Monitoring and Sampling Program, Radiation Program, Non-Licensed Plant Staff Training, Reactor Operator Training, Operator Requalification Programs, Technical Specifications, Security, Material Control and Accounting, and Emergency Preparedness. The NOAK considerations include information related to standardizing the programs for microreactors and the possibility of reviewing and approving standardized operational programs in connection with a DC or ML application, through a topical report, or in a first-of-a-kind (FOAK) review ahead of submission of a CP/OL or COL application for NOAK microreactors.

Inservice Inspection, Inservice Testing, Preservice Inspection and Testing, and Motor-Operated Valve Programs

Current Framework

The purpose of the inservice inspection (ISI), inservice testing (IST), preservice inspection and testing, and motor-operated valve (MOV) programs is to provide assurance of the integrity and capability of SSCs that perform a safety or risk-significant function.

The ISI program provides data on the condition of such SSCs necessary for a licensee to adequately manage deterioration and aging effects. This is achieved by periodically monitoring and tracking degradation (e.g., defects, corrosion, erosion) in welds and base metal (and/or graphite or composite inspection for non-LWRs) of components and their supports within the program's scope to determine their suitability for continued operation. The current ISI programs for LWRs include inspections of American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code (BPV Code) Class 1, 2, and 3 piping; safety-related pressure-retaining components; and component supports. Non-safety-related but safety-significant components are typically inspected as part of reliability assurance or maintenance programs. The staff review guidance for the ISI program can be found in SRP Section 5.2.4, Revision 2, "Reactor Coolant Pressure Boundary Inservice Inspection and Testing," issued March 2007 (ML070550066); Section 5.4.2.2, Revision 2, "Steam Generator Program," issued March 2007 (ML070380194); and Section 6.6, Revision 2, "Inservice Inspection and Testing of Class 2 and 3 Components," issued March 2007 (ML070550071).

The purpose of the IST program is to periodically measure, assess, and track the performance of components within the program's scope. The NRC incorporates by reference the ASME Operation and Maintenance of Nuclear Power Plants, Division 1, Operations and Maintenance (OM) Code, Section IST (OM Code), in 10 CFR 50.55a, "Codes and standards," for IST programs in LWRs. The IST program is intended to verify the operational readiness of certain components to perform their safety functions. The current IST programs for LWRs include components consisting of pumps, valves, and dynamic restraints (snubbers) that perform safety functions. SRP Section 3.9.6, Revision 4, "Functional Design, Qualification, and Inservice Testing Programs for Pumps, Valves, and Dynamic Restraints," issued March 2017 (ML16134A116), and SRP section 5.2.4 contain the staff review guidance for the IST program.

The preservice testing and inspection program includes testing and the examination of certain components to assess their structural integrity and operational readiness before plant startup. Applicants or licensees use the test results to determine reference values for the acceptable performance of applicable components in the IST program. Both the ISI and IST program documents include the staff review guidance for the preservice program.

As mentioned in Generic Letter 89-10, "Safety-Related (1) Motor-Operated Valve Testing and Surveillance Results of the Public Workshops," the Commission called for implementation of a program to demonstrate the capability of MOVs to perform their safety functions because the previous ASME OM Code requirements for testing MOVs in nuclear power plants were not sufficient in light of the design of the valves and the conditions under which they must function. ASME has since modified the testing requirements for MOVs to include diagnostic performance testing as part of the IST program specified in the ASME OM Code. For new reactors, the IST program includes diagnostic testing of MOVs to ensure that those components continue to be capable of performing their design-basis safety functions. SRP section 3.9.6 provides staff guidance for the review of MOVs as part of the IST program.

The NRC regulatory requirements for ISI and IST programs (which include preservice and MOV testing) are described in 10 CFR 50.55a, which incorporates by reference specified editions and addenda of the ASME BPV and OM Codes. The ISI and IST programs are required to be implemented before initial plant startup.

As discussed in the ARCAP roadmap guidance, the requirements in 10 CFR 50.55a apply only to LWRs. With the increased use of probabilistic risk assessment (PRA) information in the design and regulation of nuclear power plants, the NRC staff anticipates that applications for future nuclear plants will include risk-informed programs. The NRC staff has developed guidance that covers the methods acceptable to the staff for the content of an application describing risk-informed ISI and IST programs for a non-LWR design. That guidance is described in DANU-ISG-2022-07, "Risk-Informed Inservice Inspection/Inservice Testing Programs for Non-LWRs," issued March 2024 (ML23277A145), which also references Regulatory Guide (RG) 1.246, "Acceptability of ASME Code, Section XI, Division 2, 'Requirements for Reliability and Integrity Management (RIM) Programs for Nuclear Power Plants,' for Non-Light Water Reactors," issued October 2022 (ML22061A244). Additionally, DANU-ISG-2022-06, "Advanced Reactor Content of Application Project, Chapter 12, 'Post-manufacturing and construction Inspection, Testing and Analysis Program,'" issued March 2024 (ML23277A144), includes guidance on the content of the portion of a non-LWR application associated with the development of a risk-informed postconstruction (or post manufacturing for an ML application) inspection, testing, and analysis program. In addition, as described in RG 1.232, "Guidance for Developing Principal Design Criteria for Non-Light-Water Reactors," issued April 2018 (ML17325A611), the NRC has developed a set of non-LWR design criteria (Advanced Reactor Design Criteria (ARDC)), based on the general design criteria (GDC) in Appendix A, "General Design Criteria for Nuclear Power Plants," to 10 CFR Part 50, for application to and insights for the development of principal design criteria for non-LWRs.

With respect to future IST programs, ASME finalized the new OM-2 Code, "Code on Component Testing Requirements at Nuclear Facilities," in October 2024, which includes IST provisions for new and advanced water-cooled and non-water-cooled reactors. The NRC staff is considering whether to endorse the ASME OM-2 Code with appropriate regulatory positions. ASME is also preparing a reformatted version of its QME-1 Standard, "Qualification of Active Mechanical Equipment Used in Nuclear Facilities," to allow its more efficient use for new and advanced water-cooled and non-water-cooled reactors. The NRC staff will consider whether to revise RG 1.100, Revision 4, "Seismic Qualification of Electrical and Active Mechanical Equipment and Functional Qualification of Active Mechanical Equipment for Nuclear Power Plants," issued May 2020 (ML19312C677), to endorse, with appropriate regulatory positions, ASME Standard QME-1-2023 and the reformatted QME-1 version when available. Similar to the approach for ISI programs for non-water-cooled reactors described in RG 1.246, applicants may propose a license condition to implement the ASME OM-2 Code if endorsed in a new RG for the IST activities for components in non-water-cooled reactors.

Program Standardization Considerations and NOAK Strategy

Current regulations for a DC or ML do not require a detailed description of these inspection and testing programs. However, the regulations do not preclude an applicant from providing that information for a DC or ML application. Depending on the COL application, some site-specific information may be required to be verified during the COL stage. The NRC regulations in 10 CFR 52.79(a)(11) require COL applicants to address the ASME BPV Code and OM Code in accordance with 10 CFR 50.55a for water-cooled reactors. As stated in DANU-ISG-2022-07, the scope of a risk-informed inspection program for non-LWRs should be based on a plant-specific PRA. The applicant should identify which NRC regulations are applicable to its design.

Containment Leakage Rate Testing Program

Current Framework

The purposes of the containment leakage rate testing program, as defined by Appendix J, "Primary Reactor Containment Leakage Testing for Water-Cooled Power Reactors," to 10 CFR Part 50, are the following:

> assure that (a) leakage through the primary reactor containment and systems and components penetrating primary containment shall not exceed allowable leakage rate values as specified in the technical specifications or associated bases; and (b) periodic surveillance of reactor containment penetrations and isolation valves is performed so that proper maintenance and repairs are made during the service life of the containment, and systems and components penetrating primary containment.

Several GDC also require testing and inspection of containment, if applicable. SRP Section 6.2.6, Revision 3, "Containment Leakage Testing," issued March 2007 (ML070620007), provides the staff guidance for the containment leakage testing program review. Section III of Appendix J to 10 CFR Part 50 requires leakage testing before initial fuel load.

As described in ARCAP DANU-ISG-2022-01, Appendix J to 10 CFR Part 50 only applies to LWRs; however, there are GDC in Appendix A to 10 CFR Part 50 related to containment testing, such as GDC 53, "Provisions for containment testing and inspection." As discussed in DANU-ISG-2022-07, the GDC are generally applicable to and provide guidance for establishing the principal design criteria for reactors other than water-cooled reactors governed by the GDC. In addition, as described in RG 1.232, the NRC has developed the ARDC as a set of non-LWR design criteria, based on the GDC, for application to and insights for the development of principal design criteria for non-LWRs.

Program Standardization Considerations and NOAK Strategy

An applicant could provide a detailed testing program for containment or a containment-like structure, as applicable, in a DC or ML application. The NRC staff notes that some microreactors may be self-contained or have limited containment penetrations, which could reduce the scope of the program. Also, some designs may rely on other barriers and less on a containment or a containment-like structure. The staff encourages early engagement with the NRC to identify program applicability and treatment of SSCs in such cases.

Reactor Vessel Material Surveillance Program

Current Framework

The purpose of the reactor vessel material surveillance program, as required by 10 CFR 50.60, "Acceptance criteria for fracture prevention measures for light-water nuclear power reactors for normal operation," and Appendix H, "Reactor Vessel Material Surveillance Program Requirements," to 10 CFR Part 50, is, in part, to monitor changes in the properties of the reactor vessel that result from exposure to neutron irradiation and the thermal environment. As stated in the ARCAP roadmap, these 10 CFR Part 50 requirements are only applicable to LWR technologies. The regulations in 10 CFR 52.79(a)(13) also require the reactor vessel surveillance program for COL applicants for LWR designs and reference Appendix H to 10 CFR Part 50. SRP Section 5.3.1, Revision 2, “Reactor Vessel Materials,” issued March 2007 (ML063190007), provides the staff guidance for reviewing this operational program.

Program Standardization Considerations and NOAK Strategy

An applicant could provide a detailed surveillance program for the reactor vessel at the design stage in a DC or ML application, if applicable to the design. The design would assume certain operating parameters and a life cycle, which could then be used to define a standardized reactor vessel material surveillance program. Much of the program description may be known at the design stage for a DC or ML application, such as material specifications used for the reactor vessel or housing, or special processes used for the manufacture or fabrication of vessel components.

Equipment Qualification Program

Current Framework

The purpose of the equipment qualification program is to ensure that all items of equipment that are important to safety (i.e., mechanical, electrical, and instrumentation and control equipment) can perform their design safety functions under all normal environmental conditions, anticipated operational occurrences, and accident and post-accident environmental conditions for each component’s design life or for a specified period. The program includes all environmental conditions that may result from any normal mode of plant operation, anticipated operational occurrences, design-basis events (as defined in 10 CFR 50.49(b)(1)(ii)[3]), post-design-basis events, and containment tests.

GDC 1 of Appendix A to 10 CFR Part 50 requires that SSCs important to safety be designed, fabricated, erected, and tested to quality standards commensurate with the importance for the safety functions to be performed. GDC 4, “Environmental and dynamic effects design bases,” states, in part, that “[s]tructures, systems, and components important to safety shall be designed to accommodate the effects of and to be compatible with the environmental conditions associated with normal operation, maintenance, testing, and postulated accidents, including loss-of-coolant accidents.” General requirements associated with equipment qualification for SSCs important to safety appear in GDC 1, “Quality standards and records”; GDC 2, “Design bases for protection against natural phenomena”; and GDC 23, “Protection system failure modes.” The regulations in 10 CFR Part 50, Appendix B, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,” require, in part, that the pertinent requirements of Appendix B apply to all activities affecting the safety-related functions of the SSCs that prevent or mitigate the consequences of postulated accidents that could cause undue risk to public health and safety. These activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying. Further, 10 CFR Part 50, Appendix B, Criterion III, “Design Control,” discusses the verification of the adequacy of designs:

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[3] By its terms, 10 CFR 50.49 applies only to electric equipment important to safety, as defined in 10 CFR 50.49(b).

> The design control measures shall provide for verifying or checking the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of a suitable testing program…. Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, it shall include suitable qualifications testing of a prototype unit under the most adverse design conditions.

In 10 CFR 50.49, "Environmental qualification of electric equipment important to safety for nuclear power plants," the NRC further established specific requirements for environmental qualification of certain electric equipment important to safety located in a "harsh" environment. This regulation is also referenced in 10 CFR Part 52, Subpart C, "Combined Licenses," for contents of applications for COLs. The implementation milestone for the environmental qualification program is to have all qualification requirements met before the loading of fuel. SRP Section 3.11, Revision 3, "Environmental Qualification of Mechanical and Electrical Equipment," issued March 2007 (ML063600397), provides guidance to the NRC staff on reviewing the program to meet the relevant requirements and other applicable regulations, as appropriate.

Additionally, 10 CFR 50.55a(h) states that protection and safety systems must meet the requirements of the Institute of Electrical and Electronics Engineers Standard 603-1991, "Criteria for Safety Systems for Nuclear Power Generating Stations, (IEEE Std. 603-1991). The design-basis criteria identified in IEEE Std. 603-1991 include the range of transient and steady-state environmental conditions during normal, abnormal, and accident conditions when the equipment must perform its safety functions.

Program Standardization Considerations and NOAK Strategy

The regulations and the Atomic Energy Act of 1954, as amended (AEA), do not preclude an applicant from providing the information necessary to describe the equipment qualification program at the DC or ML stage. Specifically, both 10 CFR 52.47(a)(13) (for a DC application) and 52.157(f)(6) (for an ML application) require that the application include a list of electric equipment within the scope of the design that will require qualification but neither one requires the application to include a description of the environmental qualification program. With respect to an ML, however, 10 CFR 50.49 states the following:

> Each holder of or an applicant for an operating license issued under this part, or a combined license or manufacturing license issued under 10 CFR Part 52 of this chapter…shall establish a program for qualifying the electric equipment defined in paragraph (b) of this section. For a manufacturing license, only electric equipment defined in paragraph (b) which is within the scope of the manufactured reactor must be included in the program.

Under this provision, an ML holder must establish a program to qualify electric equipment important to safety, as defined in 10 CFR 50.49(b), for electric equipment within the scope of the design of the manufactured reactor. For the staff to approve that program, the ML applicant must describe the program in the final safety analysis report for the ML, i.e., in the ML application. That program description could also be adequate for qualification of electric equipment important to safety that is not within the scope of the design of the manufactured reactor, to the extent any such equipment exists, and the applicant could request approval of the program in that regard. For a DC application, in addition to providing the list of electrical equipment important to safety required in a DC application for the environmental qualification program, an applicant for a DC could discuss performance specifications under conditions existing during and following design-basis accidents and the method for qualifying these SSCs, or other information required by 10 CFR 50.49 for a CP/OL or COL.

An applicant for a DC could also choose to provide, for NRC staff review and approval, qualification program information regarding other equipment, such as mechanical or instrumentation and control systems. NRC staff review and approval would be dependent on the detail and specificity of the information provided by the DC applicant. As is the case for electric equipment important to safety, the staff will be able to make a safety finding on the ML regarding SSCs within the scope of the manufactured design for which other types of qualification are required only if the ML application adequately describes programs for accomplishing those types of qualification during manufacture of the reactor. The ML application could also request approval of those programs for qualification of SSCs outside the scope of the design of the manufactured reactor. The staff also notes that the amount of plant design standardization and site-specific information will impact the standardization of the equipment qualification program.

Fire Protection

Current Framework

The regulations in 10 CFR 50.48, "Fire protection" (also referenced in the regulations in 10 CFR Part 52), require applicants for a power reactor CP, OL, COL, DC, standard design approval, or ML to have a fire protection plan or a description and analysis of the fire protection design features that satisfy GDC 3, "Fire protection." The fire protection plan must describe the overall fire protection approach for the facility and outline the programs for fire protection, automatic fire detection and suppression capability, and limitation of fire damage. The fire protection plan must also describe specific features necessary to implement the program, such as administrative controls (e.g., policies and procedures) and personnel requirements for fire prevention and manual fire suppression activities, and the means to limit fire damage to SSCs important to safety, including those that are safety related, so that the capability to safely shut down the plant is ensured. In general, nuclear power plant SSCs "important to safety" are those required to provide reasonable assurance that the facility can be operated without undue risk to public health and safety.

A fire protection program (FPP) implements a fire protection plan and includes design and operational aspects. Fire protection design includes detection and suppression systems and features to assure postfire safe shutdown. The operational aspect of fire protection includes procedures, staffing, and administrative controls.

The regulations in 10 CFR 50.48(a) require the FPP to protect all equipment important to safety. The postfire safe-shutdown analysis should demonstrate compliance with 10 CFR 50.48(a)(2) to ensure that the fire protection features provided for SSCs important to safe shutdown are capable of limiting fire damage to systems required to achieve and maintain postfire safe-shutdown conditions. The NRC does not prescribe a specific method for meeting regulatory requirements governing postfire safe-shutdown capability. The goals are to clearly define a safe and stable end state, identify the set of SSCs credited to reach the safe state, and provide a list of safe-state SSCs and their locations. An analysis of the capability to safely shut down the plant after a fire evaluates the effects of a fire in the fire areas of the plant and identifies a safe-shutdown success path that is free of fire damage. Procedures for effecting a safe shutdown should reflect the results and conclusions of the safe-shutdown analysis.

Fire protection for nuclear power plants uses the defense-in-depth concept to achieve the required degree of reactor safety. This concept integrates administrative controls, fire protection systems, and safe-shutdown capability to achieve the following objectives:

- Prevent fires from starting.
- Rapidly detect, control, and extinguish those fires that do occur, thereby limiting fire damage.
- Provide an adequate level of fire protection for SSCs important to safety, so that a fire that is not promptly extinguished by the fire suppression activities will not prevent the safe shutdown of the plant.

Defense-in-depth is an approach to designing and operating nuclear power plants in a manner that prevents and mitigates accidents that release radiation or hazardous materials. The key is to create multiple independent and redundant layers of defense to compensate for potential human and mechanical failures so that no single layer, no matter how robust, is relied upon exclusively. The defense-in-depth approach includes the use of access controls, physical barriers, redundant and diverse key safety functions, and emergency response measures.

RG 1.189, Revision 5, “Fire Protection for Nuclear Power Plants,” issued October 2023 (ML23214A287), describes an approach that is acceptable to the staff for licensees to meet the regulatory requirements of 10 CFR 50.48(a). SRP Section 9.5.1.1, “Fire Protection Program,” issued February 2009 (ML090510170), provides guidance for staff review of the fire protection program.

The guidance in DANU-ISG-2022-09, “Risk-Informed, Performance-Based Fire Protection Program (for Operations),” issued March 2024 (ML23277A147), includes one way in which non-LWR applicants and staff reviewers can ensure compliance with NRC regulations for the operational aspects of an FPP. In 10 CFR 50.48, the NRC requires each holder of an OL or COL to have a fire protection plan (also referred to in DANU-ISG-2022-09 as a program description) that satisfies GDC 3. However, the GDC in 10 CFR Part 50, Appendix A, are considered only guidance for those applying for licenses for non-LWRs. These applicants must propose principal design criteria in accordance with 10 CFR 50.34, “Contents of applications; technical information,” or 10 CFR 52.79, “Contents of applications; technical information in final safety analysis report.” However, because Criterion 3 is technology neutral, the NRC staff anticipates that any proposed principal design criteria would be identical or at least similar to Criterion 3.

Program Standardization Considerations and NOAK Strategy

The regulations do not require a complete FPP at the design stage for a CP, DC, or ML, but they do require a description and analysis of the fire protection design features for the standard plant and for the reactor for a DC and CP or ML, respectively.

The staff notes that site-specific information may not be available at the design stage for a DC or ML application. For example, in accordance with DANU-ISG-2022-09, the program should address the administrative controls and personnel requirements for manual fire suppression activities, to include offsite manual firefighting resources. This information, if applicable, may not be known until a site is selected. Additionally, information traditionally contained in prefire plans, such as staging of fire equipment and assembly locations, may also be site specific. However, the NRC could review a generic fire program in a DC or ML application that could also include COL action items. The staff could then verify that the information about the program is included during the COL application review.

The staff also notes that the fire protection plan requirements will depend heavily on the microreactor plant design, and the applicant should identify which requirements relate to its specific design. An applicant could determine, at the DC or ML application (design) phase, that a certain requirement is not relevant due to that specific, standardized plant design, which could then potentially further streamline the COL review for a NOAK reactor. The staff encourages early preapplication engagement with the NRC to identify the appropriate regulations and requirements.

Quality Assurance, Maintenance Rule, and Reliability Assurance Programs

Current Framework for the Quality Assurance Program

The QA program comprises all those planned and systematic actions necessary to provide adequate confidence that an SSC will perform satisfactorily in service. QA also includes quality control, which comprises those QA actions related to the physical characteristics of a material, structure, component, or system that provide a means to control its quality to predetermined requirements. The QA requirements are set forth in Appendix B to 10 CFR Part 50 and must be implemented for activities affecting safety-related plant equipment.

Multiple regulations require an applicant for an OL to have a QA program. As stated in 10 CFR 50.54, “Conditions of licenses,” each nuclear power plant subject to the QA criteria in Appendix B to 10 CFR Part 50 must implement a QA program under 10 CFR 50.34(b)(6)(ii) or 10 CFR 52.79, and a holder of a COL must implement the QA program for operation 30 days before the scheduled date for the initial fuel loading. Additionally, GDC 1 requires that a QA program be established and implemented.

The regulations in 10 CFR Part 52 also detail requirements for DC and ML applicants to provide QA program descriptions. A DC applicant is required to provide a QA program description applied to the design of the SSCs within the scope of the standard design. An ML applicant is required to describe the QA program applied both to the design and to the manufacture of the reactor SSCs within the scope of the design. A QA program description submitted by a DC applicant may be a QA topical report or part of a safety analysis report. The ML and DC regulations do not require an operational QA program.

A QA program description submitted by a COL applicant covers all phases of a facility’s life, including design, construction, and operation. The NRC may not issue a COL without finding that the descriptions of these QA activities satisfy the requirements of 10 CFR Appendix B. As discussed in section C.1.10 of RG 1.206, Revision 1, “Applications for Nuclear Power Plants,” issued October 2018 (ML18131A181), a COL applicant can incorporate by reference a QA program description previously submitted to the NRC for review (e.g., prior submittal as a topical report).

SRP Section 17.1, Revision 2, “Quality Assurance During the Design and Construction Phases,” issued July 1981 (ML052350349); Section 17.2, Revision 2, “Quality Assurance During the Operations Phase,” issued July 1981 (ML052350361); Section 17.3, Revision 0, “Quality

Assurance Program Description," issued August 1990 (ML052350376); and Section 17.5, Revision 1, "Quality Assurance Program Description—Design Certification, Early Site Permit and New License Applicants," issued August 2015 (ML15037A441), provide staff guidance for reviewing the QA program related to different standards but all ensuring compliance with 10 CFR Part 50, Appendix B. The ARCAP roadmap also provides guidance for the staff and non-LWR design applicants regarding QA.

Current Framework for the Maintenance Rule Program

The purpose of the maintenance rule (MR) program is to help ensure proper plant maintenance and enhanced plant safety. RG 1.160, Revision 4, "Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," issued August 2018 (ML18220B281), states the following:

> As discussed in the [preamble] for the Maintenance Rule, there is a clear link between effective maintenance and safety when considering such factors as the number of transients and challenges to safety systems, and the associated need for operability, availability, and reliability of safety equipment. In addition, good maintenance is also important to ensure that failure of other than safety-related SSCs that could initiate or adversely affect a transient or accident is minimized.

The MR program is based on 10 CFR 50.65, "Requirements for monitoring the effectiveness of maintenance at nuclear power plants." For a COL review, the staff reviews the description of the operational program and proposed implementation milestones for the MR program in accordance with 10 CFR 50.65. The implementation milestones are plant specific, except that 10 CFR 50.65 requires that the program be fully implemented before the 10 CFR 52.103(g) finding (i.e., before fuel load).

SRP Section 17.6, Revision 2, "Maintenance Rule," issued July 2014 (ML14099A044), provides guidance for the staff to review the MR operational program. The guidance in section 17.6 also notes that, in meeting the MR requirements, the applicant may incorporate, by reference, an NRC-approved generic final safety analysis report (FSAR) template that provides a complete generic MR program description for developing the COL FSAR (e.g., NEI-07-02A, Revision 3, "Generic FSAR Template Guidance for Maintenance Rule Program Description for Plants Licensed Under 10 CFR Part 52," issued September 2007). The staff notes that the Maintenance Rule program is not related to the design of the reactor and is not required by regulation to be submitted with a DC or ML application.

Current Framework for the Reliability Assurance Program

The reliability assurance program (RAP) applies to those SSCs (referred to as "RAP SSCs"), both safety related and non-safety related, identified as risk significant (or significant contributors to plant safety) as determined using a combination of probabilistic, deterministic, or other methods of analysis to identify and quantify risk, including PRA, severe accident evaluation, assessment of industry operating experience, and expert panel deliberation. Not all items subject to the RAP are required by regulation. The purpose of the RAP is to provide reasonable assurance of the following:

- A plant is designed, constructed, and operated in a manner that is consistent with the risk insights and key assumptions (e.g., SSC design, reliability, and availability) from the probabilistic, deterministic, and other methods of analysis used to identify and quantify risk.

- The RAP SSCs do not degrade to an unacceptable level of reliability, availability, or condition during plant operations.

- The frequency of transients that challenge the RAP SSCs is minimized.

- The RAP SSCs will function reliably when challenged.

The RAP is implemented in two stages. The first stage is the design reliability assurance program (D-RAP), which encompasses reliability assurance activities conducted before initial fuel load. The objective of the D-RAP is to ensure that the plant is designed and constructed in a manner that is consistent with the risk insights and key assumptions (e.g., SSC design, reliability, and availability) from the probabilistic, deterministic, and other methods of analysis used to identify and quantify risk. The key features of the D-RAP include the following:

- Programmatic controls ensure the risk insights and key assumptions are consistent with the plant design and construction. These controls address organizational responsibilities, design control activities, procedures and instructions, records, and corrective action and assessment plans and ensure that the list of RAP SSCs is appropriately developed, maintained, and communicated to the appropriate organizations.

- QA programs related to design and construction activities provide control over activities affecting the quality of the RAP SSCs.

The second stage comprises activities that occur during the operations phase (after initial fuel load). The objective of the RAP during the operations phase of the plant's license is to ensure that the reliability and availability of RAP SSCs are maintained commensurate with their risk significance. The RAP during the operations phase can be implemented through regulatory requirements for SSCs, including the areas of (1) the MR program established through 10 CFR 50.65, (2) the QA program for safety-related SSCs established through Appendix B to 10 CFR Part 50, (3) QA controls for non-safety-related RAP SSCs established in accordance with QA requirements other than 10 CFR Part 50, Appendix B, such as GDC 1 or an equivalent principal design criterion, and (4) the ISI, IST, surveillance testing, and maintenance programs.

SRP Section 17.4, Revision 1, "Reliability Assurance Program," issued May 2014 (ML13296A435), provides staff guidance to review the RAP. SECY-18-0093, "Recommended Change to Verification of the Design Reliability Assurance Program," dated September 20, 2018 (ML18192B471), further discussed the D-RAP and discontinuation of the use of ITAAC for that operational program. The Commission approved the staff's recommendation in SRM-SECY-18-0093, dated August 7, 2019 (ML19219A944). Although the RAP guidance does not prohibit review and approval of the program for a CP/OL, the guidance is currently geared toward a COL applicant. A DC or ML application needs to adequately describe the first stage of the RAP program for SSCs within the scope of the design that are subject to the RAP.

Program Standardization Considerations and NOAK Strategy

Standardization of the QA program, MR program, and RAP would depend on considerations such as the standardization of design, deployment, and organization and the application's level of detail and quality of information. Because these programs would not typically rely on site-specific factors, generic standard programs could likely be developed at the design stage and could be implemented for any deployment site.

The NRC's regulations require a QA program description to be submitted for each application. For example, the NRC staff reviews a DC applicant's QA program description for design. The COL applicant also has responsibilities related to the review of the design for all portions of the design outside the scope of the certified design, i.e., including site-specific elements, in addition to the QA information required for construction and operation. An applicant that is the same entity for both the DC and CP/OL or COL could potentially generate standardized QA programs more easily. For example, Appendix B to 10 CFR Part 50 requires that the "authority and duties of persons and organizations performing activities affecting the safety-related functions of structures, systems, and components shall be clearly established and delineated in writing." This information and clear delineation of duties for the operational QA program may not be known at the DC or ML design phase but would more likely be known if the same entity owns all QA program descriptions (i.e., is the applicant for both the DC and COL or CP/OL). Additionally, the NRC staff notes that the clear delineation of program authorities and responsibilities is important to ensure that the QA requirements across all phases of the facility's life are understood. An applicant for a design certification proposing a standardized program could also consider how the design QA requirements for a DC or ML are incorporated into the CP/OL or COL QA programs, and which additional operational QA measures are required for a CP/OL or COL. A standardized operational QA program should take into account early consideration of program implementation.

The scope of these programs may also be driven by the life cycle, design, and safety categorization of the plant SSCs. For example, if few structures meet the requirements for inclusion in the MR and very little maintenance is expected for the plant (e.g., a microreactor with a shortened deployment cycle), the applicant could potentially justify a more limited program scope.

Process and Effluent Monitoring and Sampling Program

Current Framework

The purpose of the process and effluent monitoring and sampling program is for a licensee to control, monitor, and evaluate all radiological releases and to document and report all radiological effluents discharged into the environment. Multiple regulations contain the principal regulatory basis for requiring the effluent and environmental monitoring at nuclear power plants, including GDC 60, "Control of releases of radioactive materials to the environment"; GDC 61, "Fuel storage and handling and radioactivity control"; GDC 64, "Monitoring radioactivity releases"; 10 CFR 50.34a, "Design objectives for equipment to control releases of radioactive material in effluents—nuclear power reactors"; and 10 CFR 50.36a, "Technical specifications on effluents from nuclear power reactors." The regulations in 10 CFR Part 20, "Standards for Protection Against Radiation," also provide dose limits and further require licensees to comply with the U.S. Environmental Protection Agency's generally applicable environmental radiation standards of 40 CFR Part 190, "Environmental Radiation Protection Standards for Nuclear Power Operations," for facilities that are part of the fuel cycle. Appendix I, "Numerical Guides for Design Objectives and Limiting Conditions for Operation to Meet the Criterion 'As Low as is Reasonably Achievable' [ALARA] for Radioactive Material in Light-Water-Cooled Nuclear Power Reactor Effluents," to 10 CFR Part 50 also includes guidance on design objectives that applicants use to meet provisions in 10 CFR 50.34a.

This program consists of five component programs: the radiological effluent TS, the standard radiological effluent controls, the offsite dose calculation manual, the radiological environmental monitoring program, and the process control program, all of which must be implemented before initial fuel load.

The generic template in NEI 07-09A, Revision 0, "Generic FSAR Template Guidance for Offsite Dose Calculation Manual (ODCM) Program Description," was approved by the NRC for use by COL applicants and issued March 2009 (ML091050234). NEI 07-09A fully describes, at the functional level, elements of the process and effluent monitoring and sampling programs required by 10 CFR Part 50, Appendix I, and 10 CFR 52.79(a)(16). NEI 07-10A, Revision 0, "Generic FSAR Template Guidance for Process Control Program (PCP)," issued March 2009 (ML091460627), also states one acceptable element of the process and effluent monitoring and sampling program. The NRC staff has approved each template through a safety evaluation, which is similar to treatment of an approved topical report.

SRP Section 11.4, Revision 4, "Solid Waste Management System," issued January 2016 (ML15029A174), and Section 11.5, Revision 6, "Process and Effluent Radiological Monitoring Instrumentation and Sampling Systems," issued January 2016 (ML15029A182), provide NRC staff review guidance. The ARCAP roadmap and DANU-ISG-2022-03, "Advanced Reactor Content of Application Project, Chapter 9, 'Control of Routine Plant Radioactive Effluents, Plant Contamination and Solid Waste,'" issued March 2024 (ML23277A141), also discuss process and effluent monitoring and sampling programs for non-LWRs.

Program Standardization Considerations and NOAK Strategy

For DC and ML applications, 10 CFR 52.47, "Contents of applications; technical information," and 10 CFR 52.157, "Contents of applications; technical information in final safety analysis report," respectively, require that information be provided with respect to the design of equipment to maintain control over radioactive materials in gaseous and liquid effluents during normal operations described in 10 CFR 50.34a(e), the kinds and quantities of radioactive materials expected to be produced during operations, and the means for controlling and limiting radioactive effluents and radiation exposures within the limits set forth in 10 CFR Part 20. However, these regulations require description of the design of SSCs for accomplishing these functions, not the associated operational program.

An applicant could submit information during the design stage to describe this operational program. Such information could include, if applicable, specific instruments or monitoring equipment, the location of the monitoring equipment, and operational procedures for sampling and minimizing the generation of radioactive waste. The NRC staff notes that site-specific information, such as sampling or monitoring locations, if not fixed by the standard design, could be conditioned in the license and verified by the NRC staff upon implementation.

Radiation Protection Program (Including Minimization of Contamination)

Current Framework

The purpose of the radiation protection (RP) program is to protect people and the environment from exposure to radiation as a result of civilian uses of nuclear materials. An ALARA program is included as part of the RP program. The base requirements for the RP and ALARA programs are found in 10 CFR 20.1101, "Radiation protection programs," which requires, in 10 CFR 20.1101(a), that licensees develop, document, and implement an RP program commensurate with the scope and extent of licensed activities and sufficient to comply with 10 CFR Part 20, and in 10 CFR 20.1101(b) that licensees use, to the extent practical, procedures and engineering controls based upon sound RP principles to achieve occupational doses and doses to members of the public that are ALARA.

To ensure that the requirements in 10 CFR Part 19, “Notices, Instructions and Reports to Workers: Inspection and Investigations,” and 10 CFR Part 20 are met with respect to RP, a design application typically presents a variety of information. This information includes,

- how RP practices are incorporated into operational programs and plans and design decisions,
- a general description of the radiation source terms,
- RP design features, including a description of plant shielding, ventilation systems, and area radiation and airborne radioactivity monitoring instrumentation,
- designation of radiation areas,
- a dose assessment for operating and construction personnel, and
- the design of the health physics facilities.

The application must also include proposed principal design criteria that address the design, fabrication, construction, testing, and quality of the SSCs necessary to control occupational exposures to within regulatory limits. Appendix A to 10 CFR Part 50 sets forth the minimum requirements for principal design criteria for water-cooled reactors regarding occupational and public exposure in GDC 19, “Control room”; GDC 61; GDC 63, “Monitoring fuel and waste storage”; and GDC 64. These GDC form guidance for the principal design criteria on this topic for non-LWR designs. For COL reviews, the description of the operational program and the proposed implementation milestones for the RP programs are reviewed in accordance with 10 CFR 20.1101 and, to the extent that it is not described in other sections, the leakage control program required by 10 CFR 50.34(f)(2)(xxvi).

NEI 07-03A, Revision 0, “Generic FSAR Template Guidance for Radiation Protection Program Description,” issued May 2009 (ML091490684), is a complete generic RP program description for use with COL applications. While the NRC staff has not endorsed NEI 07-03A, it has approved the NEI 07-03A RP program template through a safety evaluation, and NEI 07-03A is similar to an approved topical report. An applicant may also refer to NEI 07-08A, Revision 0, “Generic FSAR Template Guidance for Ensuring that Occupational Radiation Exposures are as Low as is Reasonably Achievable (ALARA),” issued October 2009 (ML093220178), which provides a complete generic ALARA program description for use in developing COL applications. While the NRC staff has not endorsed NEI 07-08A, it has approved the NEI 07-08A generic program description template through a safety evaluation and NEI 07-08A is similar to an approved topical report.

SRP Section 12.1, Revision 4, “Assuring that Occupational Radiation Exposures Are as Low as Is Reasonably Achievable,” issued September 2013 (ML13151A061); SRP Section 12.5, Revision 5, “Operational Radiation Protection Program,” issued September 2013 (ML13155A232); and DANU-ISG-2022-04, “Advanced Reactor Content of Application Project, Chapter 10, ‘Control of Occupational Dose,’” issued March 2024 (ML23277A142), provide current staff guidance for RP programs.

In addition to the RP program requirements in 10 CFR 20.1101, 10 CFR 20.1406, “Minimization of contamination,” requires that facility design and procedures be in place to minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste. The regulations in 10 CFR 20.1406 also require that licensees, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface, in accordance with the existing RP requirements in Subpart B, “Radiation Protection Programs,” of 10 CFR Part 20 and the radiological criteria for license termination in Subpart E, “Radiological Criteria for License Termination,” of 10 CFR Part 20.

An application for a DC and an ML must describe the design features associated with minimizing contamination of the facility and the environment, facilitating eventual decommissioning, and minimizing the generation of radioactive waste in accordance with 10 CFR 20.1406(b). The description of the programmatic and procedural aspects of 10 CFR 20.1406 is not required until the COL or OL application is filed. The minimization of contamination program or procedures, or both, are usually included as part of the RP program.

RG 4.21, Revision 0, “Minimization of Contamination and Radioactive Waste Generation: Life-Cycle Planning,” issued June 2008 (ML080500187), provides guidance for meeting the requirements of 10 CFR 20.1406. NEI 08-08A, Revision 0, “Generic FSAR Template Guidance for Life Cycle Minimization of Contamination,” issued October 2009 (ML093220530), provides a complete generic program description for use in developing a 10 CFR 20.1406 program for a COL application. While the NRC has not endorsed NEI 08-08A, it has approved the template through a safety evaluation and NEI 08-08A is similar to an approved topical report.

While NEI 07-03A, NEI 07-08A, and NEI 08-08A do not apply by their terms to the issuance of CPs and OLs under 10 CFR Part 50, these documents may be useful as templates to develop programs for these applications.

Program Standardization Considerations and NOAK Strategy

Although a detailed RP program is required for an OL or COL application, the DC and ML regulations only require some discussion of RP information, such as the kinds and quantities of radioactive materials expected to be produced during operation and the means for controlling and limiting radioactive effluents and radiation exposures within the limits set forth in 10 CFR Part 20. The regulations and the AEA do not preclude an applicant from providing additional RP program information (including 10 CFR 20.1406 program or procedural information) at the design stage for a DC or ML application. Staff review and approval would depend heavily on the level of detail and specificity of the applicant’s information.

The NRC staff notes that site-specific information could be subject to conditions in the DCR or ML and be verified upon implementation. For example, under the current guidance in section C.I.12 of RG 1.206, before initial fuel receipt, the RP program should detail the RP organization and the facilities available to support receipt, storage, and control of nonexempt radioactive sources. This information may be specific to a site or COL applicant and may, therefore, not be known during the review of the DC or ML application. However, the DC or ML applicant could provide a recommended organization or facilities that a COL applicant could reference, and the COL applicant could justify any site- or owner-specific differences.

While most of the RP program may not require site-specific information, some aspects of the programs and procedures to minimize contamination are more likely to require that information, such as the appropriate ground water monitoring provisions or potential leakage paths to the environment at a specific site.

The NRC anticipates that the size of the RP program and amount of RP work required for microreactors would be smaller than that of the current operating power reactor fleet. Specific details of the RP program for a particular microreactor application, including the necessary size and scope of the program, would depend on the specific application.

Non-licensed Plant Staff Training, Reactor Operator Training, and Requalification Programs

Current Framework for Non-licensed Plant Staff

The purpose of the non-licensed plant staff training program is to provide qualified personnel to operate and maintain the facility in a safe manner, as well as to keep the facility in compliance with its license, TS, and applicable regulations. The regulations in 10 CFR 50.120, "Training and qualification of nuclear power plant personnel," require, in part, that the program be derived from a systems approach to training and provide for the training and qualification of the following categories of nuclear power plant personnel: non-licensed operator, shift supervisor, shift technical advisor, instrument and control technician, electrical maintenance personnel, mechanical maintenance personnel, radiological protection technician, chemistry technician, and engineering support personnel. Those regulations also require this training program to be in effect 18 months before fuel load. At present, all U.S. commercial nuclear plants have obtained training program accreditation through the National Academy for Nuclear Training as a means of complying with this requirement.

An application for a DC or ML is not required to describe the non-licensed plant staff training program. However, for an OL or COL application, the staff review focuses on the applicant's detailed program, which should include the initial training, periodic retraining, and qualifications that are required for non-licensed plant staff. Power reactor facility licensees can commit to meeting RG 1.8, Revision 4, "Qualification and Training of Personnel for Nuclear Power Plants," issued June 2019 (ML19101A395), which endorses American National Standards Institute (ANSI)/American Nuclear Society (ANS)-3.1-2014, "Selection, Qualification, and Training of Personnel for Nuclear Power Plants," as a means of complying with the personnel qualification requirements. Applicants can also commit to meeting the guidelines of NEI 06-13A, Revision 2, "Template for an Industry Training Program Description," issued March 2009 (ML090910554), as a means of addressing training requirements. While the NRC staff has not endorsed NEI 06-13A, it has approved the generic training program description in it through a safety evaluation and NEI 06-13A is similar to an approved topical report.

SRP Section 13.2.2, Revision 4, "Non-Licensed Plant Staff Training," issued August 2016 (ML15006A129), and DANU-ISG-2022-05, "Advanced Reactor Content of Application Project, Chapter 11, 'Organization and Human-System Considerations,'" issued March 2024 (ML23277A143), provide staff review guidance for these programs.

Current Framework for Reactor Operator Training and Requalification Programs

Similar to the non-licensed plant staff training program, the purpose of the reactor operator training and requalification programs is to enable licensed operators and senior operators to operate the facility in a safe manner, as well as to keep the facility in compliance with its license, TS, and applicable regulations. The requirements in 10 CFR Part 55, "Operators' Licenses," set the criteria for the issuance of licenses to operators and senior operators of utilization facilities.

The regulations in 10 CFR Part 52 do not require a DC or ML applicant to describe the training programs in the application. However, as described below, NRC regulations require an OL or COL application to describe format, attributes, and level of detail of these training programs in sufficient detail to demonstrate that the requirements of 10 CFR Part 55 will be met. In particular, 10 CFR 55.31(a) requires, among other things, that an applicant must provide evidence that the applicant has completed the facility licensee's requirements to be licensed as an operator or senior operator. Section 55.31(a) further requires that an authorized representative of the facility licensee certify the details of the applicant's qualifications, details on courses of instruction to be administered by the facility, the nature of training to be provided by the facility, and startup and shutdown experience provided. Section 55.31 provides that, in lieu of these details, the Commission may accept certification that the applicant has successfully completed a Commission-approved training program that is based on a systems approach to training and that uses a simulation facility acceptable to the Commission under 10 CFR 55.45. A training program accredited by the National Academy of Nuclear Training is acceptable as a means of meeting the training-related requirements of 10 CFR Part 55. As an option to addressing the licensed operator training criterion, the applicant may provide a commitment to meet the guidelines of NEI 06-13A for its licensed operator training program. An OL or COL applicant must also describe the licensed operator requalification program, as required in 10 CFR 50.54(i-1) and 10 CFR 55.59, "Requalification," including the first anticipated requalification period set in 10 CFR 55.59(a)(1). The requalification program is required to be in effect within 3 months after issuance of an OL or the date the Commission makes the finding under 10 CFR 52.103(g).

SRP Section 13.2.1, Revision 4, "Reactor Operator Requalification Program; Reactor Operator Training," issued August 2016 (ML15006A035), and DANU-ISG-2022-05 provide guidance for reactor operator training requirements for staff review of LWR and non-LWR applications.

Program Standardization Considerations and NOAK Strategy

For a NOAK application, it is presumed that a design-specific knowledge and abilities list, which is necessary to develop licensing examinations, has already been developed in conjunction with the FOAK licensing process or has been developed during the DC or ML stage. Similarly, staff presumes the approval of any modifications to the operator licensing and examination process (including establishing the technical justification for any related exemption requests), has also already occurred. Site-specific information may include crew complement (which may change, for example, due to the number of units on site), response activities and training (such as for fire protection), and site-specific systems. While the NRC staff has not endorsed NEI 06-13A, it has approved the generic training program description in it via a safety evaluation and NEI 06-13A is similar to an approved topical report. As such, a similar process could be used for the NOAK framework.

<u>Technical Specifications</u>

Current Framework

The TS establish requirements for items such as safety limits, limiting safety system settings, limiting conditions for operation (LCOs), surveillance requirements, design features, and administrative controls. Section 182a. of the AEA requires applicants for nuclear power plant operating licenses to provide TS. The regulations in 10 CFR 50.36, "Technical specifications," and 10 CFR 50.36a require that each applicant for a license authorizing operation of a production or utilization facility include proposed TS in its application. The regulations in

10 CFR 50.36 require the TS to include LCOs and define LCOs as the lowest functional capability or performance levels of equipment required for safe operation of the facility. This regulation requires that, when an LCO of a nuclear reactor is not met, the licensee must shut down the reactor or follow any remedial actions permitted by the TS until the condition can be met.

Standard TS are issued as NUREG-series publications. The Standard TS are modified through the NRC staff approval of "travelers" typically submitted by the nuclear power industry's Technical Specifications Task Force. The purpose of the traveler program is to minimize industry and NRC time and effort by providing a streamlined review and approval of Standard TS changes. The NRC encourages licensees to upgrade their TS consistent with the criteria in the Final Commission Policy Statement on Technical Specification Improvements for Nuclear Power Reactors, dated July 22, 1993 (58 FR 39132), and conform, to the extent practical, to the latest revision with incorporated travelers of the improved Standard TS. Following the NRC staff's approval of a traveler, licensees may submit a license amendment request to adopt the traveler.

DANU-ISG-2022-08, "Advanced Reactor Content of Application Project, 'Risk-Informed Technical Specifications,'" issued March 2024 (ML23277A146), describes methods acceptable to the NRC staff for an applicant to prepare proposed TS using a risk-informed evaluation process. At the CP, DC, or ML application stage, some numerical values, graphs, and other data are not as complete as necessary for plant operation because the determination of specific numerical values is pending future decisions by the OL or COL applicant on selection and procurement of hardware after issuance of the CP, DCR, or ML. A DC application may describe COL action items related to the generic TS to be denoted by square brackets in the proposed generic TS and associated bases with appropriate guidance for completing COL action items. At the OL or COL application stage, as-procured or site-specific information (denoted by brackets in the reference DCR (i.e., generic DCD) or ML TS) must be replaced with the final operational information, which must be in conformance with the FSAR. For a COL application referencing a DCR, this information is in the plant-specific DCD.[4]

Under 10 CFR 52.47(a)(11), a DC applicant must propose generic TS to confirm that it will preserve the validity of the plant design, as described in the DCD, by ensuring that the plant will be operated (1) within the conditions bounded by the analysis in the DCD and (2) with operable equipment that the FSAR analysis credits to prevent postulated design-basis events or mitigate their consequences. For the same reasons, an ML applicant must propose TS under 10 CFR 52.157(f)(18).

Program Standardization Considerations and NOAK Strategy

The DC and ML regulations require that an applicant provide proposed TS prepared in accordance with 10 CFR 50.36 and 10 CFR 50.36a. Some provisions may not be known at the time of a DC or ML application, such as information on operating organization and management and site location. A DC or ML applicant could provide a proposed program with site-specific gaps that a future COL applicant could adopt if it pursued standardized TS. For the site location,

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4 For an ML, as-procured information will be available upon completion of the first or first few reactors manufactured under the ML. Amendment of the ML to specify the portions of the TS that depend on the as-procured information would resolve the adequacy of the TS in regard to that information in proceedings on referencing applications, rather than leaving such matters for resolution in the individual proceedings on the referencing applications.

the staff could verify that the TS provide the information during the CP/OL or COL review. There are also optional programs in the Standard TS for which a DC or ML applicant could provide a proposed program that a CP/OL or COL applicant may or may not want to pursue (e.g., risk-informed completion time program and setpoint control program). Lastly, the NRC staff notes that there have been years of operating experience with TS and that modeling TS on the operating fleet Standard TS (e.g., format and content), as appropriate, could make the staff's review more efficient for the NOAK framework.

Security

Current Framework for Physical Security

The licensee security programs deal with threats, thefts, and sabotage relating to special nuclear material (SNM), high-level radioactive wastes, nuclear facilities, and other radioactive materials and activities that the NRC regulates. The security programs that apply to nuclear power plant applicants and licensees are specified in 10 CFR 73.55, "Requirements for physical protection of licensed activities in nuclear power reactors against radiological sabotage."

Current staff review guidance associated with physical security is provided in SRP Section 13.6, Revision 4, "Physical Security," issued February 2019 (ML18344A041), which establishes criteria that the NRC staff uses in evaluating whether an applicant or licensee meets NRC regulations to construct and operate nuclear power plants. A DC application contains certain security elements as outlined in SRP Section 13.6.2, Revision 2, "Physical Security—Review of Physical Security System Designs—Standard Design Certification and Operating Reactor Licensing Applications," issued June 2015 (ML14140A210). Although SRP Section 13.6.2 does not mention ML applications, the rationale stated there for DC applications would appear to apply equally to ML applications. An application might not need these security elements if one or more of the following criteria apply: (1) physical security systems or functions will not be located within the nuclear island or structures, or (2) physical security systems will not be integral to the construction of the nuclear island and structures (e.g., the systems are independent of building structure). A nuclear island may not exist for microreactors due to the reactor design. The physical security program is required before fuel receipt. The ARCAP roadmap, DANU-ISG-2022-01, also discusses security plans.

Current Framework for Cybersecurity

The cybersecurity program is an integral part of each current nuclear power plant licensee's physical protection program. These programs must comply with the performance objectives and requirements set forth in 10 CFR 73.55, and 10 CFR 73.55(b)(8) requires licensees to establish, maintain, and implement a cybersecurity program in accordance with 10 CFR 73.54, "Protection of digital computer and communication systems and networks." The regulations in 10 CFR 50.34(c)(2) and 10 CFR 52.79(a)(36)(iii) require applications for an OL or COL, respectively, to include a cybersecurity plan. The current power reactor cybersecurity requirements in 10 CFR 73.54 require applicants for an OL under the provisions of 10 CFR Part 50 and applicants for a COL under the provisions of 10 CFR Part 52 to address the security of digital computer and communication systems and networks in their cybersecurity plans. The regulation in 10 CFR 73.55(a)(4) requires that this program must be implemented before receipt of fuel on site.

Under the existing cybersecurity framework, a licensee's cybersecurity program must provide reasonable assurance that digital computer and communication systems and networks associated with safety-related functions, functions important to safety, security functions, and emergency preparedness (EP) functions are adequately protected against cyberattacks, up to and including the design-basis threat, as described in 10 CFR 73.1, “Purpose and scope.” While the cybersecurity requirements in the existing regulation were developed for the current fleet of large LWRs and do not specifically address standardization of advanced reactors such as microreactors, the performance-based nature of the regulation allows for standardization of the cybersecurity program. While FOAK microreactors may incorporate the concept of security by design, a cybersecurity program is not required to be submitted with a DC or ML application. Licensees and applicants are encouraged to use existing RG 5.71, Revision 1, “Cyber Security Programs for Nuclear Power Reactors,” issued February 2023 (ML22258A204), or NEI 08-09, Revision 6, Addendum 1, “Cyber Security Plan for Nuclear Power Reactors”[5] guidance documents, which contain templates for developing a cybersecurity plan to comply with the licensing requirements of 10 CFR 73.54. SRP Section 13.6.6, Revision 0, “Cyber Security Plan,” issued November 2010 (ML102630477), and the ARCAP roadmap (DANU-ISG-2022-01) also discuss cybersecurity plans.

Current Framework for Access Authorization

The existing access authorization requirements in 10 CFR 73.55; 10 CFR 73.56, “Personnel access authorization requirements for nuclear power plants”; and 10 CFR 73.57, “Requirements for criminal history records checks of individuals granted unescorted access to a nuclear power facility, a non-power reactor, or access to Safeguards Information,” provide reasonable assurance that individuals subject to access authorization programs are trustworthy and reliable, so as not to constitute an unreasonable risk to the public health and safety or the common defense and security, including the potential to commit radiological sabotage, regardless of the reactor technology.

SRP Section 13.6.4, Revision 0, “Access Authorization—Operational Program,” issued October 2016 (ML15226A009), provides guidance to the NRC staff for reviewing a COL or CP applicant’s plans for determining access authorization measures before fuel enters the protected area. These licensing documents for the access authorization program should provide reasonable assurance, until nuclear fuel is in the protected area and the requirements under 10 CFR 73.56 are applicable, that the individuals subject to this section are trustworthy and reliable, such that they do not constitute an unreasonable risk to public health and safety or the common defense and security, including the potential to commit radiological sabotage.

Current Framework for Fitness for Duty

The performance objectives of 10 CFR Part 26, “Fitness for Duty Programs,” require licensees’ fitness-for-duty programs to, in part, (1) provide reasonable assurance that individuals are trustworthy and reliable as demonstrated by the avoidance of substance abuse, (2) provide reasonable assurance that individuals are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform their duties, (3) provide reasonable measures for the early detection of individuals who are not fit to perform their duties, (4) provide reasonable assurance that the workplaces subject to the requirements of 10 CFR Part 26 are free from the presence and effects of illegal drugs and alcohol, and (5) provide reasonable assurance that the

[5] The NRC approved NEI 08-09, Revision 6, Addendum 1 via a letter dated April 25, 2017 (ML17086A408).

effects of fatigue and degraded alertness on individuals' abilities to safety and competently perform their duties are managed.

SRP Section 13.7, Revision 0, "Fitness for Duty—Introduction," issued October 2016 (ML15111A091), provides guidance to the NRC staff for reviewing proposed fitness-for-duty programs submitted in an application for a COL or early site permit (ESP) under 10 CFR Part 52, or a CP/OL under 10 CFR Part 50 to ensure compliance with programmatic requirements. Additional fitness-for-duty programmatic requirements apply as a reactor under construction progresses to completion and fueling. The staff notes that a fitness-for-duty program is not related to the design of the reactor and is not required by regulation to be submitted with a DC or ML application. The type of reactor licensed under 10 CFR Part 50 or 10 CFR Part 52 would not impact the fitness-for-duty program requirements applicable during construction or reactor operations. The ARCAP roadmap guidance also discusses the fitness-for-duty program.

Program Standardization Considerations and NOAK Strategy

In order to standardize its security program through a DC or ML application, the DC or ML applicant would need to submit more information than is currently required in 10 CFR Part 52, Subpart B and Subpart F. Currently, a DC applicant may submit security information as part of the application according to the guidance provided in SRP section 13.6.2. Although this SRP is specific to DCs, the guidance could also be applied to an ML review; there is no specific guidance for an ML applicant. Additionally, the NRC does not require security plans (i.e., physical security plan, training and qualification plan, safeguards contingency plan, cybersecurity plan) to be submitted for review until the OL or COL phase of the licensing process. The NRC also does not require a DC or ML applicant to submit information on access authorization or fitness for duty, but a DC or ML applicant could provide, at their option, that information for NRC review and approval. The staff notes that the access authorization and fitness for duty programs are not related to the design of the plant. For NOAK microreactors, the staff anticipates that site-specific requirements for these programs will be minimal (e.g., a specimen collection site), and that an applicant for a DC or ML could provide a standardized program for review with its application.

The level of approval that can be achieved in a DC or ML is entirely dependent on what the applicant seeks for the DC or ML and the completeness and quality of information that it is able to provide when requesting NRC approval. The staff notes that currently, the format and content of the security plans may conform to the most recent revision of the NRC-accepted NEI 03-12, "Template for the Security Plan, Training and Qualification Plan, Safeguards Contingency Plan, [and Independent Spent Fuel Storage Installation Security Program]." As stated in SRP Section 13.6.1, Revision 2, "Physical Security—Combined License and Operating Reactors," issued August 2018 (ML17291B265), bracketed text identified in NEI 03-12 is intended to act as a placeholder for each applicant to address and provide additional details of specific proposed physical protection measures, to account for site-specific conditions and ensure an understanding of how the licensee intends to meet certain Commission requirements. Applicants could use this template to inform types of site-specific information that might be needed and provide that up front in the DC or ML application. Such information could be in the form of a site-specific security parameter. That is, if site characteristics fall within certain values, the design will achieve specified security functions. Additionally, when referencing a FOAK CP/OL or COL microreactor application, the more information that is provided, reviewed, and approved, the greater the potential for streamlining subsequent NOAK microreactor application reviews.

The staff notes that several geographic factors may impact the security posture of a facility and thus the standardization of the program. For example, a single microreactor versus multiple microreactors in the same localized area may change the risk profile of the identified site. If security is initially designed at a specific site for a single microreactor, adding microreactors may alter the radiological consequences and ultimately the risk profile. Pending an analysis from the CP/OL or COL applicant, the results could require additional security measures at the determined location.

A microreactor geographically located in a remote location may have a low population zone over a substantial distance, while a microreactor located in a more densely populated location may not have this option. The size of the low population zone could impact the security measures required to maintain adequate protection. Additionally, the geographic location could impact the response capability of local law enforcement or other offsite armed responders, based upon the number of responders available and the time it would take them to react to a security event. As proposed in "Alternative Physical Security Requirements for Advanced Reactors; Proposed Rule," issued August 9, 2024 (89 FR 65226), and "Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors; Proposed Rule," issued October 31, 2024 (89 FR 86918), if the applicant states in its security plans that it commits to relying on local law enforcement or other offsite armed responders, the response capability may depend on the location of the site.

Developing standardized security plan templates as part of a DC or ML application could allow applicants that meet certain geographic bounding conditions to use security plans based on these templates. In that case, the NRC review and approval of security plan templates for a given geographical location could be accomplished to the maximum extent practicable during consideration of a DC or ML application, which would minimize the need for site-specific information in a NOAK application. For example, a microreactor applicant could submit for NRC review a security plan template for a standard design that would specify the bounding conditions of the geographic location (e.g., considering the radiological consequences and ability to depend on local law enforcement in a remote location versus a densely populated location). Once the NRC has approved the template and any associated guidance, the application for a deployment site meeting those bounding conditions could use a security plan based on the template and finalized with site-specific information.

Regarding cybersecurity, the staff notes that plants historically have had distinct network topologies. If a NOAK microreactor applicant's defensive computer security architecture (DCSA) deviates from the previously NRC-approved DCSA through a DCR, an ML, or a FOAK COL or CP/OL proceeding, it may decrease the efficiency of the NOAK licensing by requiring additional NRC staff review. For example, a FOAK DCSA has a boundary data communication device that separates and protects critical digital assets of a higher security level from a lower security level; changing the same boundary data communication device in the DCSA of a NOAK may warrant an analysis to assess the impact of the change to the overall effectiveness of the defense-in-depth protective strategy. The staff notes that preapplication engagement activities would facilitate early discussions between the staff and developers to gain a better understanding of any site-specific conditions that could influence changes in the DCSA.

The staff is aware that evolving technology and emerging threats may also present a challenge to efficient NOAK licensing that may require additional analysis and NRC review. For example, if a COL applicant chooses to deviate from previously approved technology, it should provide sufficient information and analyses to demonstrate that the implementation is safe and does not decrease the overall effectiveness of the defense-in-depth protective strategy. The staff expects concepts such as security by design applied to FOAK microreactors to facilitate more efficient licensing of NOAK microreactors, especially in the cybersecurity program. As mentioned, applicants may also use cybersecurity plan templates to comply with the regulations. It is likely that the standardization and protection against the disruption or malicious control of microreactors will rely heavily on the DCSA, as described in RG 5.71, and fully understanding the architecture of a FOAK microreactor will be essential in providing insights for standardizing the cybersecurity plan template for a NOAK microreactor.

Material Control and Accounting

Current Framework

The NRC's regulations require the licensee to maintain a nuclear material control and accounting (MC&A) program that tracks and verifies the SNM on site. The MC&A regulations ensure that the information collected by the licensee about SNM is accurate, authentic, and sufficiently detailed to enable a licensee to (1) maintain current knowledge of its SNM, and (2) manage its program for securing and protecting SNM. The MC&A program, together with physical protection of facilities and information security requirements, make up the primary elements of the NRC's SNM safeguards program. The MC&A component of the larger safeguards program helps ensure that SNM within a licensed facility is not stolen or otherwise diverted from the facility. A licensee's MC&A program should provide accurate, complete, up-to-date, and reliable information about quantities and precise locations of the facility's SNM; maintain control over the SNM to ensure continuity of knowledge, thus enhancing the ability to detect unauthorized removal; detect loss or attempted or actual theft of SNM; investigate and resolve any indications of loss or attempted theft of SNM; and maintain sufficient information to aid in recovery of missing SNM if loss or theft has actually occurred.

All licensees authorized to possess SNM in quantities greater than 1 gram must meet the applicable regulations of 10 CFR Part 74, "Material Control and Accounting of Special Nuclear Material." Subpart B, "General Reporting and Recordkeeping Requirements," of 10 CFR Part 74 contains general reporting and recordkeeping requirements for licensees authorized to possess 1 gram or more of SNM. Specific control and accounting requirements are provided in Subparts C, D, and E[6] of 10 CFR Part 74 for certain licensees based on the category of the SNM.

Facilities licensed under 10 CFR Part 50 or 10 CFR Part 52 are required to account for and control their SNM as part of a condition for obtaining a license. In general, for both 10 CFR Part 50 and 10 CFR Part 52 applicants and licensees, 10 CFR Part 74, Subpart B (excluding 10 CFR 74.17, "Special nuclear material physical inventory summary report") contains the applicable MC&A requirements. RG 5.29, Revision 2, "Special Nuclear Material Control and Accounting Systems for Nuclear Power Plants," issued June 2013 (ML13051A421), provides ANSI N15.8-2009, "Material Control Systems—Special Nuclear Material Control and Accounting Systems for Nuclear Power Plants," as an acceptable approach for complying with the NRC's regulations regarding MC&A requirements in Subpart B of 10 CFR Part 74. However, ANSI N15.8-2009 is intended for LWRs that use low-enriched uranium oxide fuel. Applicants for

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6 Subpart C, "Special Nuclear Material of Low Strategic Significance," also known as Category III material; Subpart D, "Special Nuclear Material of Moderate Strategic Significance," also known as Category II material; and Subpart E, "Formula Quantities of Strategic Special Nuclear Material," also known as Category I material.

other types of reactors using designs and fuels that may differ from those described in ANSI N15.8-2009 may need to implement additional MC&A measures.

Program Standardization Considerations and NOAK Strategy

Preliminarily, if a microreactor maintains SNM at Category II levels or below in discrete items, either in fuel assemblies or a packaged core, then it would be subject to the same regulatory framework as nuclear power plants. MC&A requirements are applicable for these reactors at the fixed site in which they are operated and include documenting the transfer of SNM during shipment. No detailed fundamental nuclear material accounting plan would need to be submitted; however, a plan to implement the 10 CFR Part 74, Subpart B, requirements should be described in the license application and would need to be in place before receipt of the material. If the microreactor design can account for SNM through item counting, then item count and identification check may be sufficient for physical inventory if continuity of knowledge of the manufacturers or shippers' values for SNM is maintained, in accordance with the guidance in ANSI N15.8-2009.

MC&A plans are not necessarily site specific. For nuclear power plants (and microreactors), a description of how the facility will meet the requirements of 10 CFR Part 74, Subpart B, is generally submitted in the application for an OL or COL. This can, in principle, be standardized across any specific design of microreactors and submitted as part of the design approval in either a DC or ML application. Of note, a plant at which microreactors are fabricated under an ML is subject to the requirements of 10 CFR Part 70 and 10 CFR Part 74 only if the licensee also holds a 10 CFR Part 70 license authorizing possession of SNM in the requisite quantity. The staff does not currently anticipate the need to include special or additional considerations in the requirements in 10 CFR Part 74, Subpart B, for ML and DC applicants.

Emergency Preparedness

Current Framework

The purpose of EP is to ensure adequate protective measures can and will be taken in the event of a radiological emergency. EP is not a design feature of a particular technology or reactor design; it is an operational program that provides defense in depth through effective planning to reduce radiation dose to the public in the event of a significant radiological release. The NRC's EP regulations are not design specific; they are intentionally design inclusive. Applicant and licensee emergency plans must demonstrate compliance with required planning standards. These planning standards are similar across NRC-licensed facilities, as the operational aspects of EP are well established in regulation and in practice across all hazards. The broad language of planning standards offers flexibility to address plant-specific and site-specific planning considerations.

The requirements in 10 CFR 50.47, "Emergency plans," and 10 CFR Part 50, Appendix E, "Emergency Planning and Preparedness for Production and Utilization Facilities," provide planning standards that were originally developed for the hazards and emergency planning needs of large LWRs. As one alternative, applicants may comply with 10 CFR 50.47(b) and Appendix E to 10 CFR Part 50 or could seek exemptions from certain requirements based on differences in design characteristics that significantly reduce radiological risks compared to large LWRs. Further, the provisions in 10 CFR 50.33(g)(1) provide for scaling of the emergency planning zone (EPZ) on a case-by-case basis for reactors with authorized power levels of less than 250 megawatts thermal. As an alternative, the requirements in 10 CFR 50.160, "Emergency preparedness for small modular reactors, non-light-water reactors, and non-power production or utilization facilities," provide risk-informed, performance-based planning standards for small modular reactor, non-LWR, and non-power production or utilization facility applicants without the need for exemptions. Microreactor applicants may choose to use 10 CFR 50.160 and the provisions in 10 CFR 50.33(g)(2) for a scalable EPZ. The regulations in 10 CFR 50.47(a) describe the findings that the NRC must make before issuing an OL under 10 CFR Part 50, or a COL or ESP under 10 CFR Part 52. The regulations in 10 CFR 50.47(a) apply to an ESP application submitted under 10 CFR Part 52 in which an applicant proposes complete and integrated emergency plans or major portions of emergency plans for review.

Program Standardization Considerations and NOAK Strategy

Many aspects of a microreactor EP program could be reviewed and approved in connection with a DC or ML application. The review would consist of evaluating whether the proposed emergency planning functions provide the resources or capabilities necessary to demonstrate compliance with the required planning standards. The ability to review and approve standard emergency plans (or specific EP elements) in a DC or ML application is subject to the quality and completeness of information submitted by the applicant. Approval of a standard emergency plan, or specific EP elements, through the DC or ML application does not make EP a design feature or a system, structure, or component of design and subject to design standards. Standard emergency plans, or specific EP elements, remain part of the EP operational program regardless of when and how they were approved.

The staff has identified three primary considerations in addressing the standardization of EP for NOAK reactors.

<u>Site-Specific Considerations to Standardize Emergency Preparedness Approaches</u>

Commensurate with the radiological risks and hazards of the facility, many of the emergency planning functions for the emergency plan could be standardized and reviewed through the DC or ML application. In this context, "standardized" refers to the standardization of methods and means used to accomplish a planning function or required element of the emergency plan. To the extent practicable, approval could be granted to standardized planning functions that are not site specific. Examples could include onsite emergency response organization staffing, emergency action levels, accident assessment capabilities, and emergency response facilities and equipment that would be standard for the design and operation of the facility at any site. Some planning functions require site-specific planning elements that cannot be either standardized or established until a specific site is identified, such as site-specific memoranda or agreements with State, local, and Tribal governments and evacuation time estimates (if needed).

If a microreactor EPZ extends beyond the site boundary and additional offsite planning elements are required, the plans to meet those requirements would be site specific and would involve Federal Emergency Management Agency (FEMA) findings and determinations that the plans are adequate and capable of being implemented. These FEMA findings and determinations cannot be addressed as part of the DC or ML application and would need to be included in the ESP, COL, or OL application. If the applicant demonstrates that the plume exposure pathway EPZ does not extend beyond the site boundary, then further consideration of some site-specific requirements would not be necessary.

Some elements of an emergency plan could be approved as part of a DC or ML with placeholders for site-specific information. For example, identification of principal response organizations and assistance resources could be included as ITAAC or license conditions and subject to verification. The ITAAC closure verification confirmation process for 10 CFR Part 52 license applications or use of license conditions for 10 CFR Part 50 applications as part of an OL could be used as regulatory tools to confirm implementation of a standard emergency plan from the DC or ML.

Efficiently Addressing Emergency Planning Zone Sizing Determinations

The established planning basis for EP is an evaluation of the consequences from a spectrum of accidents to scope the planning efforts for the distance, time, and materials released. The planning distance, or EPZ, establishes the physical bounds for which emergency planning is in place to ensure predetermined, prompt protective measures can be taken. In addition, the detailed planning within the EPZ provides a basis for expanding the response efforts beyond the EPZ, should it become necessary during an actual emergency.

The staff anticipates that many NOAK microreactor facilities will be designed with the programmatic goal of having a site-boundary EPZ or no EPZ. A standard site-boundary EPZ, or no EPZ, could be approved in the DC or ML application review if sufficient and complete information is provided for the analysis used in the EPZ determination. Such an analysis would likely make use of bounding assumptions for site-specific factors like meteorology and consequences of event scenarios like seismic and security events. Efficiency would be gained by using information developed for other parts of the licensing basis to inform the spectrum of accidents and provide source terms and consequence analyses; this includes considerations of licensing-basis events, acts of sabotage, and credit for mitigation capabilities. A subsequent COL application would need to demonstrate that the NOAK facility remains within the bounding analysis and assumptions approved for the DC or ML. An applicant may also seek approval of a methodology to determine EPZ sizing, such as through a topical report that could be used in a site-specific application.

Deployment of Multiple NOAK Reactors at the Same Site

There are additional considerations for multiple NOAK reactors being deployed at the same site in a phased manner. A designer or manufacturer could address in the standard emergency plan in a DC or ML application the deployment of multiple reactors at a common site. The safety analysis and hazard analysis would need to account for the radiological risks and hazards associated with a specified number of reactors. In addition, existing emergency planning functions could be used, in part, to meet the planning standards for a NOAK reactor at a multi-reactor site. Common resources and capabilities like emergency response facilities and equipment can be shared, similar to the approach taken by many large LWRs operating on the same site.

The DC or ML application would need to specifically consider and analyze relevant multiple reactor scenarios. A COL application that requests additional reactors beyond what has been considered in the facility emergency plans, or other significant differences in deployment, operation, and site characteristics than those assessed in the standardized emergency plan approved in a DC or ML could be considered a departure from the approved standard emergency plan.