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Sent: Thursday, December 2, 2021 1:14 PM
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Subject: Transmittal of Draft White Paper Interim Staff Guidance titled, "Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications—Roadmap"
Attachments: ARCAP ISG - Roadmap dec 2021 version.docx

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Mr. Afzali, Mr. Holtzman, and Mr. Draffin,

The purpose of this email is to provide you with the attached draft white paper interim staff guidance titled, "Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications—Roadmap." The purpose of providing you this document is to support ongoing stakeholder interactions to develop advanced reactor content of application project (ARCAP) guidance. The attached document is expected to be referenced in future public meetings on the topic.

This email will be captured in ADAMS and the email will be made publicly available so that interested stakeholders will have access to the information.

If you have questions regarding the attached documents please contact me or Eric Oesterle.

Sincerely,

Joe Sebrosky
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Advanced Reactor Policy Branch
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This draft staff white paper has been prepared and is being released to support ongoing public discussions. This draft white paper uses an interim staff guidance (ISG) format because the staff is considering using this format to provide staff guidance in the near future to support the review of advanced reactor applications. This draft white paper is being issued in parallel with the NRC staff's review of draft industry guidance. The main purpose of this document at this early stage of advanced reactor guidance development is to engage stakeholders on the staff's initial high-level considerations on issues to be considered in such guidance.

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

U.S.NRC
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

DANU [XX]-ISG-[YYYY-##]

Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications—Roadmap

Interim Staff Guidance

December 2021

DANU [XX]-ISG-[YYYY-##]

Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications—Roadmap

Interim Staff Guidance

ADAMS Accession No.: MLxxxxxxxxx

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REVIEW OF RISK-INFORMED, TECHNOLOGY-INCLUSIVE ADVANCED REACTOR APPLICATIONS—ROADMAP

INTERIM STAFF GUIDANCE

DANU-ISG-YYYY-##

PURPOSE

The U.S. Nuclear Regulatory Commission (NRC) staff is providing this interim staff guidance (ISG) to facilitate the review of advanced reactor applications for an advanced reactor construction permits (CPs), operating licenses (OLs), combined licenses (COLs), manufacturing licenses (MLs), standard design approval (SDAs), or design certifications (DCs) under Title 10 of the Code of Federal Regulations (10 CFR) Part 50, “Domestic Licensing of Production and Utilization Facilities” (Ref. X), and 10 CFR Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants” (Ref. X). The staff intends to incorporate this guidance in updated form in the NRC’s Regulatory Guide (RG) series as a part of the ongoing rulemaking for 10 CFR Part 53, “Licensing and Regulation of Advanced Nuclear Reactors.”

This guidance found in this ISG provides a general overview of the information that should be included in an advanced reactor application, a review roadmap for NRC staff with the principal purpose of ensuring consistency, quality and uniformity of staff reviews, and a well-defined base from which the staff can evaluate proposed changes in the scope and requirements of reviews. While specific sections of the information described in this ISG are primarily aligned with the Licensing Modernization Project (LMP) methodology as one acceptable process for applicants to use when developing portions of an application, the concepts and general information may be used to inform the review of an application submitted using other methodologies (as applicable) such as a maximum hypothetical accident, or deterministic approaches. Other sections of the information described in this ISG are generally applicable and independent of the methodology used to develop an advanced reactor application.

This ISG is being made publicly available to make information about regulatory matters widely available and to improve communication and understanding of the staff review process by interested members of the public. The staff anticipates that consultation of this ISG by applicants could improve the efficiency of development of their applications and navigation of the review process by providing a roadmap of items that staff will cover in it.

BACKGROUND

This ISG uses the term “advanced reactor” or “advanced nuclear reactor” interchangeably as defined in the Nuclear Energy Innovation and Modernization Act (NEIMA) and further refined by the Energy Act of 2020. That definition is provided below:

> (1) ADVANCED NUCLEAR REACTOR. —The term ‘advanced nuclear reactor’ means—
> (A) a nuclear fission reactor, including a prototype plant (as defined in sections 50.2 and 52.1 of title 10, *Code of Federal Regulations* (or successor regulations)),

with significant improvements compared to reactors operating on the date of enactment of the Energy Act of 2020, including improvements such as—

(i) additional inherent safety features;
(ii) lower waste yields;
(iii) improved fuel and material performance;
(iv) increased tolerance to loss of fuel cooling;
(v) enhanced reliability or improved resilience;
(vi) increased proliferation resistance;
(vii) increased thermal efficiency;
(viii) reduced consumption of cooling water and other environmental impacts;
(ix) the ability to integrate into electric applications and nonelectric applications;
(x) modular sizes to allow for deployment that corresponds with the demand for electricity or process heat; and
(xi) operational flexibility to respond to changes in demand for electricity or process heat and to complement integration with intermittent renewable energy or energy storage; and

(B) a fusion reactor.

In SECY 20-0032, "Rulemaking Plan On 'Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN-3150-AK31; NRC-2019-0062)' (Ref. x), the staff further clarified its interpretation of the advanced reactors described in NEIMA to include light-water small modular reactors (SMRs), non-light-water reactors (non-LWRs), and fusion reactors.

The NRC described efforts to prepare for possible licensing of non-LWR technologies in "NRC Vision and Strategy: Safely Achieving Effective and Efficient Non-Light Water Reactor Mission Readiness," (Ref. x). The staff then developed "NRC Non-Light Water Reactor Near Term Implementation Action Plans" (Ref. x), and "NRC Non-Light Water Reactor Mid-Term and Long-Term Implementation Action Plans" (Ref. x), to identify specific activities that the NRC will conduct in the near-term, mid-term, and long-term timeframes. Similarly, the Commission encouraged the use of a performance-based technology-inclusive licensing framework for SMRs in SRM-COMGBJ-10-0004/COMGEA-10-0001, "Use of Risk Insights to Enhance Safety Focus of Small Modular Reactor Reviews," and SRM-SECY-11-0024, "Use of Risk Insights to Enhance the Safety Focus of Small Modular Reactor Reviews."

To ensure review readiness to regulate a new generation of advanced reactors, a key element of this new and flexible regulatory framework is to standardize the process for the development of content within an advanced reactor application to promote uniformity among applicants. A standardized process for the development of the content of application for advanced reactors also ensures review consistency and predictability from NRC staff, and presents a well-defined base from which to evaluate proposed changes in the scope and requirements of reviews. The development of applications for NRC licenses, certifications, and approvals is a major undertaking, in that an applicant must provide sufficient information to support the agency's safety findings. The needed information and level of detail will vary according to the design and whether an application is for a construction permit, design approval, design certification, operating license, combined license, or other action.

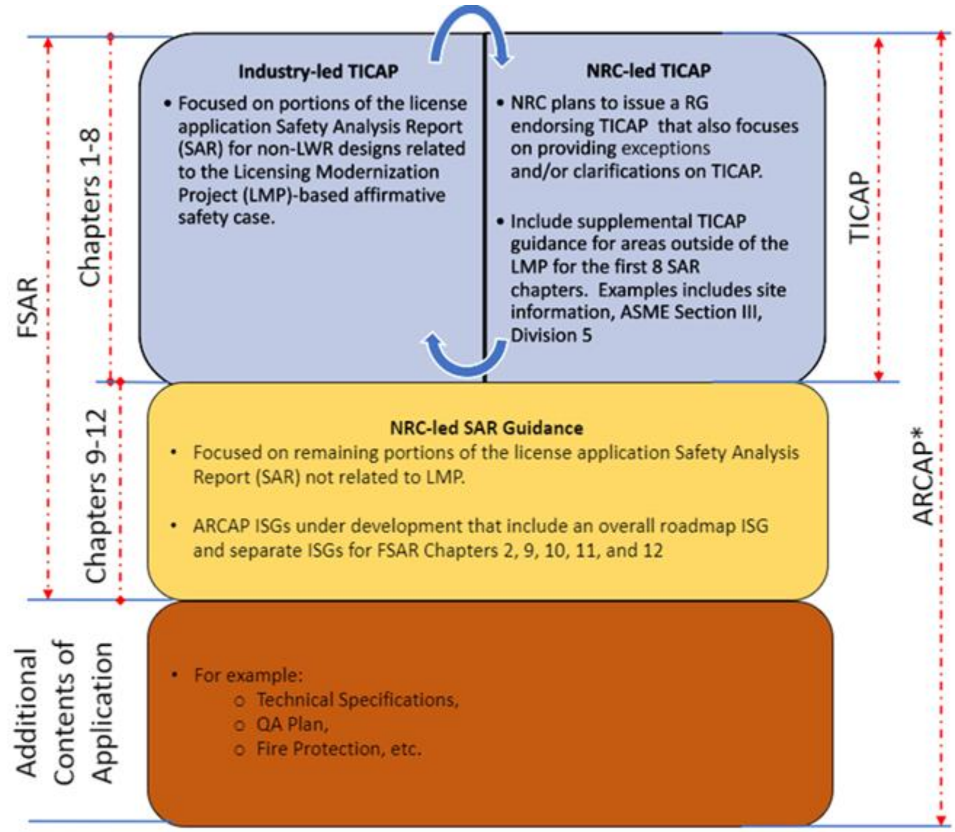
The NRC staff has had success with a standard content of application methodology for large-LWRs. The NRC's efforts to standardize the format and content of applications for LWRs are reflected in RG 1.70, “Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants, LWR Edition,” issued in the 1970s, and RG 1.206, “Applications for Nuclear Power Plants,” issued in 2007 and revised in 2018. Guidance documents, such as NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition,” (NUREG-0800 or LWR SRP) and numerous other documents on specific technical areas, address the suggested scope and level of detail for applications. While it is not the intent of this document to re-create a NUREG-0800 type broad spectrum of review guidance for advanced reactors, it is the staff’s intention to leverage the previous experience and insights gained from having the benefit of standard application content principles in this document.

To standardize the development of content within an advanced reactor application, the staff has focused on two activities: the Advanced Reactor Content of Application Project (ARCAP), and the Technology-Inclusive Content of Application Project (TICAP).

The ARCAP is an NRC-led activity that is intended to result in guidance for a complete advanced reactor application for review under 10 CFR Part 50 or 10 CFR Part 52, and that would be applicable to the ongoing 10 CFR Part 53 rulemaking effort. As a result, ARCAP is broad and encompasses several industry-led, and NRC-led guidance document development activities aimed at facilitating a consistent approach to the development of application documents. A complete advanced reactor application is required to include a safety analysis report SAR, a Quality Assurance plan, a Fire Protection program, Emergency and Physical Security plans, etc. The information described in this ISG summarizes the results of the NRC-led ARCAP efforts.

The TICAP is an industry-led activity that is focused on providing guidance on the appropriate scope and depth of information related to the specific portions of the SAR that describe the fundamental safety functions of the design and details the safety case for items covered in the LMP approach. The specific portions of the SAR addressed by TICAP are described below in more detail. Because of the limited scope of the TICAP guidance, it is encompassed by and supplemented by the ARCAP guidance, which will cover the areas of the SAR that are outside the scope of the LMP process and TICAP, such as site information, and information consistent with use of the American Society of Mechanical Engineers (ASME) Section III, Division 5 construction codes.

Figure 1 below illustrates the relationship between guidance produced under ARCAP and TICAP and other guidance to the review of advanced reactor applications.



*Staff plans to issue an ARCAP Roadmap ISG that would provide pointers to various guidance documents developed/issued.

Figure 1: Relationship between ARCAP, TICAP, and the content of an application.

The LMP process is described in Nuclear Energy Institute (NEI) document NEI–18–04, Revision 1, "Risk-Informed Performance-Based Guidance for Non-Light Water Reactor Licensing Basis Development," as endorsed by the NRC in RG 1.233, "Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors." The LMP methodology outlines an approach for use by reactor developers to identify and select licensing basis events (LBEs) applicable to the site under consideration, classify structures, systems, and components (SSCs), determine special treatments and programmatic controls, and assess the adequacy of a design in terms of providing layers of defense –in depth (DID). In addition, the LMP methodology and RG 1.233 also describe a general approach for identifying an appropriate scope and depth of information that applications for licenses, certifications, and approvals should provide. The content formulation should optimize the type and level of detail of information provided, based on the complexity of the design's safety case and the nexus between elements of the design and public health and safety.

In its "Policy Statement on the Regulation of Advanced Reactors," the Commission "encourages the earliest possible interaction of applicants, vendors, other government agencies, and the

NRC to provide for early identification of regulatory requirements for advanced reactors and to provide all interested parties, including the public, with a timely, independent assessment of the safety and security characteristics of advanced reactor designs." (73 FR 60612, 60616; October 14, 2008). These interactions with prospective applicants may be initiated once a prospective applicant has indicated sufficient commercial intent, organizational capacity, design maturity, and expectation of an application submittal to support commencement of meaningful regulatory discussions with NRC staff. Appendix C to this document provides preapplication engagement guidance.

In addition to using a well-defined standard content of application methodology, the scope of information and level of detail should be commensurate with the type of application submitted (CP, ESP, COLA, etc.), the advanced reactor design and technology described in the application, and the safety and risk significance of the SSCs described in the facility design. The appropriate scope and level of detail of technical and programmatic information described above is a key component of any advanced reactor application using a risk-informed and performance-based approach. That scope and level of detail should be supplemented with the safety justifications prepared by the developer and consideration all regulatory requirements the NRC and other agencies have established. To inform the review of the licensing basis information of a non-LWR application independent of the specific design or methodology used, the staff should use Appendix D of this document, which describes the regulations that are generally applicable to non-LWR applications for construction permits and operating licenses under 10 CFR Part 50 and standard design certifications, combined licenses, and standard design approvals under 10 CFR Part 52.

For applicants using the 10 CFR Part 50 process, application requirements include those in 10 CFR 50.34 "Contents of applications; technical information." For applicants using the 10 CFR Part 52 process, application requirements for early site permits (ESPs) include those in 10 CFR 52.17 "Contents of applications; technical information," and for combined operating licenses (COLs) the application requirements include those in 10 CFR 52.79 "Contents of applications; technical information in final safety analysis report" . Additionally, the Part 52 process application requirements for standard design certifications, standard design approvals, and manufacturing licenses include those in Sections 52.47, 52.137, and 52.157, respectively.

The guidance in this document will be updated to support the ongoing rulemaking for 10 CFR Part 53 to reflect any differences in requirements between Part 50/52 and Part 53. The goal of the 10 CFR Part 53 rulemaking effort is to develop an additional optional regulatory framework for the licensing of advanced nuclear reactors.

The guidance resulting from TICAP and ARCAP cover the following elements of an advanced reactor application:[1]

- Safety Analysis Report (SAR)
- Technical Specifications
- Technical Requirements Manual

[1] The need for submittal of certain information in this list will depend on the regulatory path of an application. Additional items to support an application required under the content of applications, general information regulations (e.g., § 50.33) is not covered by TICAP/ARCAP guidance.

- Quality Assurance (QA) Plan
- Fire Protection Program (design)
- Probabilistic Risk Assessment
- Emergency Plan
- Physical Security Plan
- Special Nuclear Material (SNM) Control and Accountability
- Fire Protection program (Operational)
- Radiation Protection Program
- Offsite Dose Calculation Manual
- Inservice Inspection (ISI) and Inservice Testing (IST)
- Environmental Report and Site Redress Plan
- Financial Qualification and Insurance and Liability
- Cyber Security Plan
- Facility Safety Program (Under Consideration for Part 53 Applications)
- Inspections, Tests, Analysis and Acceptance Criteria (ITAAC)

This ISG provides information and references for the application components identified above. The guidance in this ISG leverages:

- Industry-led guidance (as endorsed),
- NRC-developed guidance for advanced reactors,
- Existing guidance the NRC staff has found generally applicable, and
- Future guidance currently under development.

Subsequent revisions to this ISG will incorporate additional guidance as it is identified and developed.

RATIONALE

The current review guidance in NUREG-0800 is directly applicable only to LWRs and may not fully (or efficiently) provide a technology-inclusive, risk-informed and performance-based review approach for advanced reactor technologies or identify the information to be included in an application. The development of a new standard content of application is warranted to support staff readiness to perform consistent and predictable licensing reviews of advanced reactor technologies. This ISG will serve as the advanced reactor application roadmap.

APPLICABILITY

This ISG applies to the review of advanced reactor applications for permits, licenses, certifications, and approvals for nuclear reactors[2] using non-LWR and modular designs under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities" (Ref. x), and 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants" (Ref. x).

[2] Certain elements of this RG may be applicable to fusion reactors. The options for regulatory treatment of fusion reactors are currently being considered by the NRC staff and may result in the development of separate fusion-specific guidance.

GUIDANCE

- **<u>Safety Analysis Report (SAR)</u>**

Under § 50.34(a), an applicant for a CP shall include a preliminary SAR as part of its application. Under §§ 50.34(b) and 52.79, applicants for an OL or a COL shall include a final SAR in their applications. Similarly, under §§ 52.47(a), 52.137(a), and 52.157 respectively, an application for a DC, SDA, or an ML must include a final SAR. The SAR includes information that describes the facility, presents the design bases and the limits on facility operation, and presents a safety analysis of the SSCs and of the facility as a whole. In general, the SAR must be sufficiently detailed to permit the staff to determine whether the plant can be built and operated without undue risk to the health and safety of the public. Prior to submission of an SAR, an applicant should have designed and analyzed the plant in sufficient detail to conclude that it can be built and operated safely. The SAR is the principal document in which the applicant provides the information needed to understand the basis upon which this conclusion has been reached and will be maintained and updated by the applicant and later as a licensee.

A 12-chapter structure for developing the SAR was discussed with stakeholders in a series of public interactions as one acceptable approach for an advanced reactor application. The 12-chapter approach is largely aligned with the LMP methodology, which revolves around describing the safety case for the facility. Pre-application engagement with applicants is encouraged to optimize resources and review schedule. The 12 chapter structure for the SAR follows:

- Chapter 1 – General Plant Information, Site Description, and Overview of the Safety Case
- Chapter 2 – Methodologies and Analyses
- Chapter 3 – Licensing Basis Events
- Chapter 4 – Integrated Evaluations
- Chapter 5 – Safety Functions, Design Criteria, and SSC Categorization
- Chapter 6 – Safety-Related SSC Criteria and Capabilities
- Chapter 7 – Non-Safety-Related with Special Treatment (NSRST) SSC Criteria and Capabilities
- Chapter 8 – Plant Programs
- Chapter 9 – Routine Plant Radioactive Effluents, Plant Contamination, and Solid Waste
- Chapter 10 – Control of Occupational Dose
- Chapter 11 – Organization and Human-Systems Considerations
- Chapter 12 – Post Construction Inspection, Testing, and Analysis Program.

The format and content above is one approach to develop the contents of the SAR, but applicants have the discretion to identify alternate approaches to accommodate a variety of site conditions and plant designs. In a scenario where a particular developer uses an alternate SAR approach, particular focus should be given by the staff reviewers to any deviations from and exceptions to the review guidance on requested information and the organization of the information in order to ensure the required information is available to permit the staff to determine whether there is reasonable assurance that the plant can be built and operated without undue risk to the health and safety of the public.

SAR Chapters 1-8

The SAR chapters 1-8 are largely focused on describing the fundamental safety functions of the design and the safety case for each application consistent with the LMP approach. The industry-led TICAP effort resulting in guidance for these chapters is documented in NEI 21-07. NEI 21-07 describes the scope and level of detail in specific portions of the first 8 chapters of the SAR that are associated with the LMP-based safety case.

The NRC staff reviewed NEI 21-07 and endorsed the guidance as one acceptable approach to develop portions of the first 8 chapters of the SAR in RG 1.2XX. RG 1.2xx includes additional clarifications, exceptions, points of emphasis, and further details relevant to the specific sections discussed in NEI 21-07. In addition, RG 1.2xx describes additional information outside the scope of LMP and NEI 21-07 that NRC staff has determined is also relevant and should be included in the first 8 chapters of the SAR or otherwise provided in the application.

Construction Permit Guidance

The TICAP guidance document, NEI 21-07includes guidance for developing portions of a CP application under 10 CFR Part 50. However, for advanced reactor applicants pursuing a CP under Part 50 using an alternate risk-informed performance-based approach, additional information unrelated to an LMP-based safety case should be provided. Specifically, the additional information must meet the minimum information required for the staff to issue a CP under 10 CFR 50.35(a) when the applicant has not supplied all of the technical information required to complete the application (i.e., 50.34(a)) and support the issuance of a CP that approves all proposed design features. Regulatory Guide 1.2xx provides additional CP information necessary to supplement the first 8 Chapters of the SAR. As previously stated, the SAR chapters 1-8 are largely focused on describing the fundamental safety functions of the design and the safety case for an application consistent with the LMP approach.

The guidance in Appendix E of this ISG covers the review of one acceptable approach in scope and level of detail for applicants to provide additional CP information for advanced reactor applications. That guidance is for Chapters 9 through 12 of the SAR and other relevant portions of an advanced reactor application outside of the SAR.

Chapter 9 - Control of Routine Plant Radioactive Effluents, Plant Contamination, and Solid Waste

Overview

Nuclear power plants generate liquid, gaseous and solid waste during normal operations and must have processes to contain, store, and release these wastes under NRC regulations. In general, the information in this chapter should provide details associated with the waste management systems that ensure the requirements of 10 CFR 20, 50, 52, and 61 are met, or propose alternative requirements consistent with the technology of the proposed advanced reactor design.

Each waste management system included in the design should be described in Chapter 9 of the SAR. That description should include discussion of the specific functions performed by the system, the sources of normal radioactive liquid and gaseous waste including the general quantities and composition of liquid and gaseous radioactive waste anticipated to be contained in the system, any performance monitoring of the system, and a risk-informed approach to demonstrate compliance with the applicable regulations.

Staff Guidance
The guidance for the content and review, including acceptance criteria and any exceptions and clarifications are described in DANU-ISG-2021-XX, "Control of Routine Plant Radioactive Effluents, Plant Contamination and Solid Waste," (ADAMS Accession No ML21DDDANNN).

Additional References described in the ISG
- NUREG-0800, "Standard Review Plan (SRP) for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition" Sections 11.2, 11.3, and 11.4.
- Regulatory Guide (RG) 1.109 "Calculation of Annual Doses to Man from Routine Releases of Reactor Effluents for the Purpose of Evaluating Compliance with 10 CFR Part 50, Appendix I"
- RG 1.111 "Methods for Estimating Atmospheric Transport and Dispersion of Gaseous Effluents in Routine Releases from Light-Water-Cooled Reactors"
- RG 4.21 "Minimization of Contamination and Radioactive Waste Generation: Life-Cycle Planning"
- NEI 07-10A "Generic FSAR Template Guidance for Process Control Program (PCP)"

Chapter 10 - Control of Occupational Dose

Overview
The information in this chapter should provide information on facility and equipment design, radiation sources, and operational programs that are necessary to ensure that the occupational radiation protection standards set forth in 10 CFR Part 20 are met. The information should also include any commitments made by the applicant to develop the management policy and organizational structure necessary to ensure occupational radiation exposures are as low as is reasonably achievable (ALARA).

Staff Guidance
The guidance for the content and review, including acceptance criteria and any exceptions and clarifications are described in DANU-ISG-2021-XX, "Control of Occupational Dose," (ADAMS Accession No. ML21DDDANNN).

Additional References described in the ISG
- RG 8.8 "Information Relevant to Ensuring that Occupational Radiation Exposures at Nuclear Power Stations Will Be as Low as Is Reasonably Achievable"
- RG 8.10 "Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as Is Reasonably Achievable"
- ANSI/ANS 18.1-1999 "Radioactive Source Term for Normal Operation of Light Water Reactors"

- NEI 07-08A "Generic FSAR Template Guidance for Ensuring that Occupational Radiation Exposures Are as Low as Is Reasonably Achievable (ALARA)"

Chapter 11 – Organization and Human-Systems Considerations

Overview
The information in this chapter should provide descriptions of the organizational structure and key management positions within the design, construction and operating organizations that are responsible for facility design, design review, design approval, construction management, testing, and operation of the plant. In addition, the information in this chapter should provide descriptions of the most important human factors engineering (HFE) issues for a particular applicant and demonstration of how the applicant's HFE program incorporates HFE practices and guidelines that satisfy the current requirements. The HFE review covers the HFE design process, the HFE final design, its implementation, and ongoing performance monitoring, including the ongoing confirmation of human reliability and capability targets (where applicable).

Staff Guidance
The guidance for the content and review, including acceptance criteria and any exceptions and clarifications are described in DANU-ISG-2021-XX, "Organization and Human-Systems Considerations," (ADAMS Accession No. ML21DDDANNN).

Additional References described in the ISG
- NUREG-0800, Standard Review Plan, Chapter 18, Human Factors Engineering
- NUREG-0711, Human Factors Engineering Program Review Model
- NUREG-1791, Guidance for Assessing Exemption Requests from the Nuclear Power Plant Licensed Operator Staffing Requirements Specified in 10 CFR 50.54(m)
- Final Report: Development of HFE Review Guidance for Advanced Reactors (ADAMS Accession No. ML21287A088)
- RG 1.8, "Qualification and Training of Personnel for Nuclear Power Plants."
- NUREG-1021, Operator Licensing Examination Standards for Power Reactors
- RG 1.149, "Nuclear Power Plant Simulation Facilities for Use in Operator Training and License Examinations"
- Nuclear Energy Institute (NEI) 06-13A, "Template for an Industry Training Program Description,"
- NuScale Design Certification Application, Part 7, Section 6, "10 CFR 50.54(m), Control Room Staffing" (ADAMS Accession No. ML20224A521)
- NRC Final Safety Evaluation Report of the NuScale Design Certification Application, Chapter 18, "Human Factors Engineering," Section 18.5.4.2, "Evaluation of the Applicant's Technical Basis (Criterion 6.4(2))," (ADAMS Accession No. ML20023B605).
- RG 1.33, "Quality Assurance Program Requirements (Operation)"

Chapter 12 – Post Construction Inspection, Testing, and Analysis Program

Overview
The information in this chapter should provide a description of the post-construction inspection, testing, and analysis program (PITAP) in the application. The ISG consists of guidance related to post-construction inspection, preoperational testing (i.e., tests conducted following

construction and construction-related testing, but prior to initial fuel load), analysis verification and initial startup testing (i.e., tests conducted during and after initial fuel load, up to and including initial power ascension). The primary objective of the PITAP is to is to demonstrate, to the extent possible, that the safety-related (SR), safety-significant (SS) and radiation monitoring SSCs operate in accordance with the design and as assumed in the safety analysis.

Staff Guidance
The guidance for the content and review, including acceptance criteria and any exceptions and clarifications are described in DANU-ISG-2021-XX, "Post Construction Inspection, Testing, and Analysis Program," (ADAMS Accession No. ML21DDDANNN).

Additional References described in the ISG

- NUREG-0800 (SRP), Section 14.2, Initial Plant Test Program - Design Certification and New License Applicants
- NUREG-0800 (SRP) Sec. 14.3, Inspections, Tests, Analyses, and Acceptance Criteria
- RG 1.68, Initial Test Programs for Water-Cooled Nuclear Power Plants

- **Technical Specifications**

Overview
In general, Technical Specifications (TS) are part of an NRC license authorizing the operation of a nuclear production or utilization facility. A technical specification establishes requirements for items such as safety limits, limiting safety system settings, limiting control settings, limiting conditions for operation, surveillance requirements, design features, and administrative controls.

Section 182a of the Atomic Energy Act of 1954, as amended, requires applicants for nuclear power plant operating licenses to state the following:

> *[S]uch technical specifications, including information of the amount, kind, and source of special nuclear material required, the place of the use, the specific characteristics of the facility, and such other information as the Commission may, by rule or regulation, deem necessary in order to enable it to find that the utilization...of special nuclear material will be in accord with the common defense and security and will provide adequate protection to the health and safety of the public. Such technical specifications shall be a part of any license issued.*

In Title 10 of the Code of Federal Regulations (10 CFR) Section 50.36, "Technical Specifications," the Commission established its regulatory requirements related to the content of TS. For an advanced reactor application, the NRC staff review may involve proposed TS developed by applicants using a risk-informed design process

Staff Guidance
The guidance for the content and review, including acceptance criteria and any exceptions and clarifications are described in DANU-ISG-2021-XX, "Risk-Informed Technical Specifications." (Note preliminary thoughts on potential guidance for this chapter that has not been subject to legal or management reviews are available in ADAMS at Accession No. ML21133A490).

Additional References described in the ISG

- **Technical Requirements Manual**

Technical Requirements Manuals (TRMs) are not required under Parts 50 and 52 but have been used to address (i) requirements that previously been addressed in Technical Specifications (TS), but later removed, and for documenting (ii) controls associated with the Regulatory Treatment of Nonsafety Systems (RTNSS).

TRMs were developed as a result of the Improved Technical Specifications (ITS) and Standard Technical Specifications efforts (STS). As the ITS and STS were implemented, licensees removed items from their TS that did not meet the updated criteria in the 10 CFR 50.36 requirements promulgated in a final rule published in 1995(Technical Specifications, 60 FR 36953; July 19, 1995) and relocated those items to licensee-controlled documents that were typically incorporated by reference into FSARs and subject to the 10 CFR 50.59 change process. Discussions contained in the statements of consideration for the 1995 final technical specification rule update provide the following background:

> Technical specifications cannot be changed by licensees without prior NRC approval. However, since 1969, there has been a trend toward including in technical specifications not only those requirements derived from the analyses and evaluation in the safety analysis report but also essentially all other Commission requirements governing the operation of nuclear power reactors. This extensive use of technical specifications was due in part to a lack of well-defined criteria (in either the body of the rule or in some other regulatory document) for what should be included in technical specifications. Since 1969, this use has contributed to the volume of technical specifications and to the several-fold increase in the number of license amendment applications to effect changes to the technical specifications. It has diverted both NRC staff and licensee attention from the more important requirements in these documents to the extent that it has resulted in an adverse but unquantifiable impact on safety.

Since promulgation of the updated requirements for technical specifications, the NRC has approved standardized technical specifications (STS) for various LWR designs:

- NUREG-1430, “Standard Technical Specifications Babcock and Wilcox Plants”
- NUREG-1431, “Standard Technical Specifications Westinghouse Plants”
- NUREG-1432, “Standard Technical Specifications Combustion Engineering Plants”
- NUREG-1433, “Standard Technical Specifications General Electric Plants, BWR/4”
- NUREG-1434, “Standard Technical Specifications General Electric Plants, BWR/6”

Guidance provided in RG 1.206 for new LWRs indicates that the format and content of the TS and bases for a COL application not referencing a certified design should be based on the most recent version of the STS appropriate to the NSSS design. Applicants for advanced reactors should refer to ARCAP ISG DANU [XX]-ISG [YYYY-##] “Risk-Informed Technical Specifications” for guidance in developing appropriate TS for their design.

Advanced reactor applicants may include both passive systems and non-safety systems that are designated with special treatments as part of their design. Staff review of these advanced reactor designs may be informed by SRP 19.3, "Regulatory Treatment of Nonsafety Systems for Passive Advanced Light Water Reactors," which describes the underlying requirement for controls of certain non-safety-related systems in advanced light-water reactors (i.e., RTNSS) as 10 CFR 50.36(c)(2)(ii)(D). This regulation requires that a limiting condition for operation of a nuclear reactor must be established for a system, structure or component which operating experience or PRA has shown to be significant to public health and safety. These Commission papers and their associated SRMs describe the implementation of controls for RTNSS:

- SECY-94-084, "Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems in Passive Plant Designs," dated March 28, 1994 (ADAMS Accession No. ML003708068), and its associated SRM dated June 30, 1994 (ADAMS Accession No. ML003708098).
- SECY-95-132, "Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems (RTNSS) in Passive Plant Designs," dated May 22, 1995 (ADAMS Accession No. ML003708005), and its associated SRM dated June 28, 1995 (ADAMS Accession No. ML003708019).

Previous design certifications (e.g., ESBWR and AP1000) ultimately included these RTNSS controls in their SARs rather than in TS). COL applicants and holders have incorporated this information in their TRMs or similar applicant- or licensee-controlled documents such as Availability Control Documents.

- **<u>Quality Assurance Plan</u>**

Overview
Applicants for advanced reactor licenses, permits, or certifications are required to provide a description of their quality assurance plan as part of their application. Depending on whether the application is for a CP, OL, COL, DC, SDA, or ML, the quality assurance plan will describe varying scopes of applicability. For example, a quality assurance plan description for a CP application should cover the design, fabrication, construction, post-construction and pre-operational testing activities. A quality assurance plan description for an OL should describe the operational activities and a quality assurance plan description for a COL should cover the scope of both CP and OL plans. The quality assurance plan description (QAPD) is expected to be a standalone document and may be submitted by applicants as a topical report that may be incorporated by reference in the SAR.

Staff guidance
The staff's review will be consistent with the guidance provided in SRP 17.5, "Quality Assurance Program Description – Design Certification, Early Site Permits, and New License Applicants," since quality assurance plans for advanced reactor applications are primarily programmatic and technology specific. Although there may be some guidance in SRP 17.5 that specifically addresses LWR related requirements, the staff should consider these requirements and associated acceptance criteria within the context of applicability to the applicant's specific reactor technology. For example, reference to specific General Design Criteria in 10 CFR 50, Appendix A, may not be applicable to advanced reactor applicants since they are required to provide proposed design criteria in their applications. For quality assurance associated with non-safety related SSCs that are risk significant (i.e., NSRST classification using the LMP

process), additional staff review guidance contained in SRP 17.4, “Reliability Assurance Program (RAP)” may be appropriate.

Additional insights and precedent regarding the implementation of quality assurance guidance is available for users considering the incorporation of legacy fuel data to perform fuel qualification. Specifically, the NRC reviewed and approved a quality assurance program plan (QAPP) developed by Argonne National Laboratory (ANL) to provide adequate quality assurance (QA) controls to validate key legacy nuclear fuel developmental information and plant data for use by potential developers of advanced reactor design applications (ML20054A297). The information was generated, characterized, and summarized at historic DOE research and development facilities. The ANL legacy metallic fuel data qualification program collected, maintained, and qualified metallic fuel data generated through the Sodium Cooled Fast Reactor (SFR) program. The QAPP establishes a general process to determine the use of the historical information and legacy metallic fuel data for a future end user’s licensing activities using the standards and QA requirements of the American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA)-1-2008/2009 Standard, which the NRC staff has found as an acceptable method of meeting Appendix B, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,” to Title 10 of the Code of Federal Regulations (10 CFR) Part 50.

Additional References

- RG 1.28 “Quality Assurance Program Criteria (Design and Construction)”
- RG 1.30 “Quality Assurance Requirements for the Installation, Inspection, and Testing of Instrumentation and Electric Equipment (Safety Guide 30)”
- RG 1.33 “Quality Assurance Program Requirements (Operation)”
- RG 1.164 “Dedication of Commercial-Grade Items for Use in Nuclear Power Plants”
- ANL/NE-16/17, Revision 2, “Quality Assurance Program Plan for SFR Metallic Fuel Data Qualification.” (ML20054A297)

- **<u>Fire Protection Program (design)</u>**

Overview

Advanced reactor applicants must describe the features included in the design for prevention, detection and suppression of fire hazards for their proposed facility, as well as the design of the fire protection features that are determined appropriate for their proposed facility. The analysis of the risk from for both internal and external fire hazards is addressed in the guidance for advanced reactor applicants using the LMP process contained in the TICAP DRG which endorses NEI 21-07, “Technology Inclusive Guidance for Non-Light-Water Reactors, Safety Analysis Report Content for Applicants Using the NEI 18-04 Methodology”. In addition, the application must describe the results of the fire hazard analysis, including designation of fire zones, fire areas, design of fire barriers, penetration seals, and fire doors, as well as the fire protection detection, suppression, and mitigation systems.

The fire protection design features will be dependent upon the coolant used in the design. For example, in general, designs that utilize water or inert gas for the reactor coolant will be expected to comply with the fire protection requirements contained in an appropriate PDC related to GDC 3 in 10 CFR 50, Appendix A, and 10 CFR 50.48, “Fire Protection.” In addition, for designs that utilize coolants other than water or inert gas, such as liquid metal or molten salt, those portions of the design not containing liquid metal or molten salt should also comply with the requirements in an appropriate PDC related to GDC 3 and 10 CFR 50.48. However, for designs that do not utilize water or inert gas as the coolant, design specific fire protection features will be required to address the unique fire hazards posed by these coolants. The hazards can include adverse impacts on surrounding SSCs from leakage of the coolants, fires initiated by the leaking coolant and chemical reactions with surrounding materials, including the generation of flammable gas. The applicant will need to describe and justify the fire protection design features proposed for use when coolants other than water or inert gas are used.

Staff guidance
The staff's review may be informed by guidance provided in SRP 9.5.1.1, "Fire Protection Program." The review guidance addresses fire protection programs associated with fire protection features included in water or inert gas cooled advanced reactor facilities. and those portions of other facilities that contain only water or inert gas. For additional information see RG 1.189, "Fire Protection for Nuclear Power Plants".

For reactor designs that do not use water or inert gas as a coolant, the reviewer needs to review the proposed fire protection features and determine whether the features adequately address the unique hazards presented by the coolants. For example, does the design include features (1) to preclude the coolant from coming in contact with water and concrete in the event of a leak (to avoid possible chemical reactions and the production of flammable gas), (2) to suppress any fire initiated by a leak (e.g., to avoid the generation of toxic combustion products and the spread of radiation), (3) to detect fires initiated by coolant leaks and (4) to contain the volume of coolant available to leak (to keep the coolant from spreading and initiating fires or damage in other areas).

Typical features used in designs containing liquid metal or molten salt coolants include:

- Steel liners in compartments containing liquid metal or molten salt
- Inert atmospheres in areas containing radioactive liquid metal or molten salt
- Features (e.g., steel lined compartments, steel catch pans) that can hold the entire inventory of liquid metal or molten salt available to leak
- Fire suppression decks to cover the catch pans to limit air ingress
- Fire suppression systems in areas containing non-radioactive liquid metal or molten salt
- Fire detection systems capable of detecting and annunciating the presence of liquid metal or molten salt aerosols and combustion products
- Ventilation systems to remove smoke and combustion products

Additional References for the review of fire protection features for designs not using water or inert gas as the coolant include

-
- NUREG-0968, "SER Related to the Construction of the Clinch River Breeder Reactor Plant," March 1983
- NUREG-1368, "Preapplication SER for the Power Reactor Innovative Small Module (PRISM) Liquid-Metal Reactor," February 1994
- ANS Standard 54.8, "Liquid Metal Fire Protection in LMR Plants," November 1988

- **Probabilistic Risk Assessment**

Overview
Applicants for advanced reactor licenses, permits, or certifications may be using risk-informed, performance-based methodologies to develop their safety analysis reports. These methodologies rely on probabilistic risk assessments (PRA) used to develop risk significance insights during the design process. NRC regulations in 10 CFR Part 52 require the use of PRAs however the standards for PRA development and for peer reviews were developed for use on light-water reactor designs only. To support the development of an advanced reactor regulatory framework under proposed Part 53, standards for PRA development and for peer reviews have been proposed for use on non-light-water reactor designs. In addition, although not required in 10 CFR Part 50, these proposed non-light-water PRA standards may be used by applicants for Part 50 CPs and OLs for non-light-water reactor designs. The staff has developed a draft regulatory guide as discussed below that endorses an ASME non-light-water reactor PRA standard.

Staff Guidance
During staff reviews of advanced reactor applications using risk-informed, performance-based methodologies that include the use of PRAs, staff should ensure that the non-LWR PRAs conform with the guidance contained in RG 1.247, "XXXXXX" issued for trial use on Month, Day 2022. Trial Use RG 1.247 endorses with exceptions and clarifications ASME/ANS RA-S-1.4-2021, "Probabilistic Risk Assessment Standard for Advanced Non-Light Water Reactor Nuclear Power Plants".

Additional References
- NEI 20-09, Revision 1, "Performance of PRA Peer Reviews Using the ASME/ANS Advanced Non-LWR PRA Standard" (ML20302A115)

- **Emergency Preparedness Plan**

Overview
The ongoing "Emergency Preparedness Requirements for Small Modular Reactors and Other New Technologies" rulemaking would amend the NRC's regulations to add new emergency preparedness requirements for small modular reactors and other new technologies such as non-light-water reactors and non-power production or utilization facilities. The rule would adopt a scalable plume exposure pathway emergency planning zone approach that is performance-based, consequence-oriented, and technology-inclusive. This rulemaking would affect applicants for new NRC licenses and reduce regulatory burden related to the exemption process.

Staff Guidance
Current staff review guidance for emergency planning is provided in SRP 13.3, "Emergency Planning" Rev. 3 (March 2007) and, although LWR-based, may provide some useful insights for reviewing advanced reactor applications. However, additional guidance is described in DG-1357, "Emergency Response Planning and Preparedness for Nuclear Power Reactors." Guidance for emergency planning will be updated based upon finalization of DG-1357 and issuance as an RG.

Additional References

- NUREG-0396 "Planning Basis for the Development of State and Local Government Radiological Emergency Response Plans in Support of Light Water Nuclear Power Plants"
- NUREG-0654 "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants (FEMA-REP-1)"
- RG 1.101 "Emergency Planning and Preparedness for Nuclear Power Reactors"
- SRM-SECY-16-0069
- SECY-18-0103 related to EP for SMRs and other technologies

- **Physical Security Plan**

Overview

Current staff review guidance associated with physical security is provided in SRP 13.6, "Physical Security" draft Rev. 4 (Sept. 2018) and, although LWR-based, may provide useful insights for reviewing advanced reactor applications. Additional guidance in this area will be developed in conjunction with the current Physical security rulemaking and the guidance in this area will be updated as appropriate.

Additional References

- SECY-18-0076 "Options and Recommendation for Physical Security for Advanced Reactors"
- DG-5071 – in development
- DG-1365 – in development
- NEI 21-05 – in development

- **Special Nuclear Material (SNM) Control and Accountability**

Staff is still considering whether guidance in this area is necessary. Further discussion is warranted.

Additional References for discussion

- Check NUREG-2159 for applicability
- Check Advanced Reactors integrated schedule list of reports

- **Fire Protection program (Operational)**

Overview

The fire protection program description required to be provided in an application for an advanced reactor will include operational aspects. Review of the operational program information by the staff will focus on program elements such as fire protection staff training and qualification, monitoring, fire-fighting strategies, etc. The full scope of the staff's review of fire protection operational programs for advanced reactors is described in the ISG referenced below.

Staff Guidance
The staff has developed application review guidance for the operational aspects of the fire protection program proposed by applicants for advanced reactors. This review guidance is contained in Interim Staff Guidance document DANU [XX]-ISG-[YYYY-##] Advanced Reactor Content of Application "Risk-informed, Performance-Based Fire Protection Program (for Operations)".

Additional references described in the ISG

- National Fire Protection Association (NFPA) 804, "Standard for Fire Protection for Advanced Light Water Reactor Electric Generating Plants."
- NFPA Standard 805, "Performance-Based Standard for Fire Protection for Light Water Reactor Electric Generating Plants, 2001 Edition"
- NFPA 806, "Performance-Based Standard for Fire Protection for Advanced Nuclear Reactor Electric Generating Plants Change Process,"
- RG 1.205, Revision 2, "Risk-Informed, Performance-Based Fire Protection for Existing Light-Water Nuclear Power Plants,"
- RG 1.189, Revision 4, "Fire Protection for Nuclear Power Plants,"

- **Radiation Protection program**

Overview
The information that is typically presented in an application includes a discussion of how radiation practices are incorporated into plant policy and design decisions; a general description of the radiation source terms; radiation protection design features, including a description of plant shielding, ventilation systems, and area radiation and airborne radioactivity monitoring instrumentation; a dose assessment for operating and construction personnel; and a discussion of the design of the health physics facilities. Specifically, applicants should provide information on facility and equipment design, planning and procedures programs, and techniques and practices employed by the applicant to meet the radiation protection standards set forth in 10 CFR Part 20, and to be consistent with the guidance given in the appropriate regulatory guides, where the practices set forth in such guides are used to implement NRC regulations. The NRC previously endorsed guidance in NEI 07-03A, "Generic FSAR Template Guidance for Radiation Program Description." Staff may glean insights from NEI 07-03SA for their reviews for radiation protection programs for advanced reactor applications. The guidance for advanced reactor applicants using the LMP process is contained in the TICAP DRG which endorses NEI 21-07, "Technology Inclusive Guidance for Non-Light-Water Reactors, Safety Analysis Report Content for Applicants Using the NEI 18-04 Methodology," however, the LMP process focuses on radiation exposure to the public as a result of AOOs, DBEs, DBAs, and BDBEs, and must be supplemented with guidance for maintaining occupational radiation exposures for facility personnel during construction activities, normal plant operations and in response to AOOs within regulatory limits.

Staff guidance
The staff's review may be informed by the guidance provided in NEI 07-03A, "Generic FSAR Template Guidance for Radiation Protection Program Description." The review will focus on the

radiation protection program associated with the design of the proposed advanced reactor facility to ensure occupational radiation exposures are maintained within regulatory limits.

Additional References

- NEI 07-03A, "Generic FSAR Template Guidance for Radiation Protection Program Description."
- RG 1.206, "Combined License Applications for Nuclear Power Plants," Part I, Standard Format and Content for Combined License Applications, Section C.I.12, Radiation Protection (June 2007)

- **Offsite Dose Calculation Manual**

Overview

The offsite dose calculation manual (ODCM) is an example of one of the documents that may be identified in the administrative controls section of the technical specifications that is used to develop reports required to be submitted to the NRC but is not required to be submitted as part of an application. Other examples from LWR based technical specifications include the core operating limits report and reactor coolant system pressure and temperature limits report. These documents are also referred to in the ARCAP Technical Specifications guidance document DANU-ISG-YYYY-##, "Risk-Informed Technical Specifications," however, there is no prescribed guidance provided in that ARCAP guidance on the format and content for an ODCM. For COL applicants, guidance developed in RG 1.206 considered the ODCM as part of the Process and Effluent Sampling and Monitoring Program. SECY 95-087 included requirements for applicants to fully describe their operational programs in the FSAR. A template for the ODCM was developed in NEI 07-09A "Generic FSAR Template Guidance for Offsite Dose Calculation Manual Program Description," (ML091050234) and approved for use by the NRC for COL applicants. As the guidance provided in NEI 07-09A on ODCM format and content was LWR-based the final ODCM format and content for specific non-LWR reactor technologies may differ. The adequacy of these final ODCMs will be determined through NRC inspection and oversight activities.

Staff guidance

The guidance for the ODCM provided in NEI 07-09A, "Generic FSAR Template Guidance for Offsite Dose Calculation Manual Program Description," (ML091050234) may provide insights for the staff in the review of advanced reactor OL and COL applications. A description of this program is not required for a CP, DC, or ML application.

Additional References

- NUREG-1301, "Offsite Dose Calculation Manual Guidance: Standard Radiological Effluent Controls for Pressurized Water Reactors," Generic Letter 89-01, Supplement No. 1 (ML091050061)
- RG 1.206, "Combined License Applications for Nuclear Power Plants," Part I, Standard Format and Content for Combined License Applications, Section C.I.16, Technical Specifications (June 2007)

- **ISI/IST**

Overview
Currently, the requirements for ISI and IST programs are described in 10 CFR 50.55a. These requirements apply only to LWRs and are based upon requirements developed by the American Society of Mechanical Engineers (ASME). With the increased use of probabilistic risk information in the design and regulation of nuclear power plants, it is expected that applications for future nuclear power plants will include risk-informed ISI and IST programs. The staff has developed guidance in the ISG referenced below that describes the methods acceptable to the NRC staff for reviewing applications for risk-informed ISI and IST programs described by advanced reactor applicants as part of a licensing application.

Staff Guidance
The staff has developed application review guidance for risk-informed inservice inspection and inservice testing (ISI/IST) programs proposed by applicants for advanced reactors. This review guidance is contained in Interim Staff Guidance document DANU [XX]-ISG-[YYYY-##] Advanced Reactor Content of Application "Risk-informed ISI/IST Programs".

Additional references described in the ISG
- DG-1383, "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" (ADAMS package accession no. ML21120A180).
- ASME RA-Sb-2005, "Standard for Probabilistic Risk Assessment for Nuclear Power Plant Applications", December 30, 2005
- US NRC Regulatory Guide (RG) 1.200, "Acceptability of Probabilistic Risk Assessment Results for Risk-Informed Activities", Rev. 3, December 2020.
- ASME/ANS RA-S-1.4-2021, "Probabilistic Risk Assessment Standard for Advanced Non-Light Water Reactor Nuclear Power Plants"
- NRC Regulatory Issue Summary (RIS) 2012-08 (Revision 1), "Developing Inservice Testing and Inservice Inspection Programs Under 10 CFR Part 52," dated July 17, 2013.
- RG 1.147, "Inservice Inspection Code Case Acceptability, ASME, Section XI, Division 1, Rev. 19, October 2019.
- RG 1.178, "An Approach for Plant-Specific Risk-Informed Decision-making for Inservice Inspection of Piping," Rev. 1, September 2003.
- RG 1.192, "Operation and Maintenance Code Case Acceptability, ASME OM Code," Revision 3, October 2019.
- NUREG-1482, "Guidelines for Inservice Testing at Nuclear Power Plants," Revision 3, July 2020

- **Environmental Report and Site Redress Plan**

The staff has determined that no additional guidance for advanced reactor applications in this area is necessary.

References
- RG 4.2 "Preparation of Environmental Reports for Nuclear Power Stations"

- NUREG-1555 “Standard Review Plans for Environmental Reviews for Nuclear Power Plants: Environmental Standard Review Plan (with Supplement 1 for Operating Reactor License Renewal)”
- COL/ESP-ISG-026
- COL/ESP-ISG-027
- Environmental ISG for Micro Reactors
- Draft GEIS for Adv. Rxs

- **Financial Qualification and Insurance and Liability**

Additional References

1. Price-Anderson Report under development to address issues. Expected to be completed by end of 2021. Additional details in the Advanced Reactor Integrated Schedule.

- **Cyber Security Plan**

Staff is still considering whether additional guidance in this area is necessary. Further discussion is warranted.

Additional References

2. RG 5.71 “Cyber Security Programs for Nuclear Facilities”

- **Facility Safety Program**

Overview
This section is specific to 10 CFR 53 and does not apply to 10 CFR 50 or 10 CFR 52 applicants. The need to develop guidance in this area is dependent on the outcome of Commission direction on the proposed rulemaking.

Staff guidance

- TBD

Additional References

- TBD

- **Inspections, Tests, Analysis, and Acceptance Criteria (ITAAC)**

Overview
Advanced reactor applicants for COLs, DCs, and MLs in accordance with 10 CFR Part 52 are required to provide the proposed inspections, tests, and analysis that must be performed, and the acceptance criteria that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria are met, the facility has been constructed and will operate in conformity with the license, the provisions of the Atomic Energy Act, and the NRC regulations. Advanced reactor applicants for CPs and OLs in accordance with 10 CFR Part 50 are not required to provide ITAAC. Instead, guidance for the post-construction inspection testing and analysis program for CP and OL applicants is provided in DANU-ISG-2021-XX, “Post Construction Inspection, Testing,and Analysis Program.

Staff guidance
Guidance is currently under development that will address proposed ITAAC to be provided by an applicant using the LMP process contained in the TICAP DRG which endorses NEI 21-07, "Technology Inclusive Guidance for Non-Light-Water Reactors, Safety Analysis Report Content for Applicants Using the NEI 18-04 Methodology." Availability of this proposed guidance is TBD.

Additional References

- TBD

IMPLEMENTATION

The staff will use the information discussed in this ISG to determine the following:

[Identify how the information will facilitate staff review of license amendments, license renewal applications, etc.]

BACKFITTING AND ISSUE FINALITY DISCUSSION

[OGC provides this discussion, but the staff can propose text for OGC consideration].

Example: The NRC staff issuance of this ISG is not considered backfitting as defined in 10 CFR 50.109(a)(1), nor is it deemed to be in conflict with any of the issue finality provisions in 10 CFR Part 52.

CONGRESSIONAL REVIEW ACT

[OGC provides this discussion to support issuance of the final ISG. However, the staff can propose text for OGC consideration].

Example: This ISG is a rule as defined in the Congressional Review Act (5 U.S.C. §§ 801-808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

FINAL RESOLUTION

By [insert date], this information will be transitioned into [identify the appropriate regulatory process (Standard Review Plan (SRP), Regulatory Guide (RG))]. Following the transition of this guidance to the [SRP, RG], this ISG will be closed.

APPENDIXES

I. Resolution of Public Comments
II. References
III. Pre-Application Engagement Guidance
IV. Applicability of NRC Regulations to Non-Light-Water Power Reactors
V. Construction Permit Guidance

APPENDIX A

Resolution of Public Comments

A notice of opportunity for public comment on this Interim Staff Guidance (ISG) was published in the *Federal Register* (*insert FR Citation #)* on [date] for a 30-60 day comment period. [Insert number of commenters] provided comments which were considered before issuance of this ISG in final form.

Comments on this ISG are available electronically at the NRC's electronic Reading Room at http://www.nrc.gov/reading-rm/adams.html. From this page, the public can gain entry into ADAMS, which provides text and image files of NRC's public documents. Comments were received from the following individuals or groups:

Letter No.	ADAMS No.	Commenter Affiliation	Commenter Name	Abbreviation
1				
2				
3				
4				
5				

The comments and the staff responses are provided below.

Comment 1: [Each comment summary must clearly identify the entity that submitted the comment and the comment itself].

NRC Response: Comment responses should begin with a direct statement of the NRC staff's position on a comment, e.g., "the NRC staff agrees with the comment" or the "NRC staff disagrees with the comment".

- If the NRC staff agrees, explain why and provide a clear statement as to how the relevant language was revised or supplemented to address the comment. Include the following language at the end of the comment response: "The final ISG was changed by <*describe the change; if necessary, by quoting the newly revised language*>."
- If the NRC disagrees with a comment and no change was made to the generic communication, then explain why and provide the following language at the end of the comment response: "No change was made to the final ISG as a result of this comment."

APPENDIX B

References

APPENDIX C

Pre-Application Engagement Guidance

Purpose: The purpose of this Appendix is to provide guidance on the benefits of robust pre-application engagement with advanced reactor developers in order to optimize both safety and environmental application reviews.

Background: In its Policy Statement on the Regulation of Advanced Reactors,[1] the Commission encourages early interactions with advanced reactor developers and prospective applicants as follows:

> To provide for more timely and effective regulation of advanced reactors, the Commission encourages the earliest possible interaction of applicants, vendors, other government agencies, and the NRC to provide for early identification of regulatory requirements for advanced reactors and to provide all interested parties, including the public, with a timely, independent assessment of the safety and security characteristics of advanced reactor designs. Such licensing interaction and guidance early in the design process will contribute towards minimizing complexity and adding stability and predictability in the licensing and regulation of advanced reactors.

Further, Section 103 of the Nuclear Energy Innovation and Modernization Act (NEIMA) required the NRC to develop licensing strategies that (1) include the use of topical reports, standard design approval, and other appropriate mechanisms as tools to introduce stages into the commercial advanced nuclear reactor licensing process; (2) evaluate options for improving the efficiency, timeliness, and cost-effectiveness of licensing reviews of commercial advanced nuclear reactors, including opportunities to minimize the delays that may result from any necessary amendment or supplement to an application; and (3) options for improving the predictability of the commercial advanced nuclear reactor licensing process, including the evaluation of opportunities to improve the process by which application review milestones are established and met.

While pre-application interactions are not unique to advanced reactors, the agency recognizes that such interactions may be particularly beneficial with advanced reactor developers because they allow early identification and resolution of technical and policy issues that could affect licensing. Therefore, the NRC staff has identified a set of pre-application activities that, if accomplished, would enable the staff to offer more predictable and shorter schedules during the review of an advanced reactor license application. These pre-application activities are equivalent to a staged licensing approach, where some key elements of an advanced reactor design are reviewed, and the evaluation documented, before the license application is submitted. A staged licensing approach can provide the following advantages:

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[1] 73 FR 60612; October 14, 2008

Advantages for Applicants	Advantages for NRC
Enhanced regulatory predictability, reducing project risk	Greater review efficiency because NRC staff becomes familiar with the design and develops topical report safety evaluations that can be referenced by the application safety evaluation report
Greater review efficiency because NRC staff becomes familiar with design. Efficiency translates to lower costs and shorter review schedules	Early public engagement on the attributes of a design, increasing transparency and enhancing public awareness
Early interactions between the NRC, the applicant, and other agencies that have a role in the environmental review could shorten the licensing review schedule.	NRC staff becomes familiar with new approaches an applicant is considering and unique environmental aspects of a site
Early engagement with the Advisory Committee on Reactor Safeguards (ACRS) through the review of safety evaluations on topical reports. This early ACRS involvement will improve regulatory reliability and shorten application review times.	Early engagement with the ACRS through the review of safety evaluations on topical reports. This early ACRS involvement will reduce the number of issues addressed during the application review and lessen the effort of application review.

Program for Robust Pre-application engagement: In response to NEIMA, the NRC staff established generic milestone schedules for licensing reviews.[2] When the generic milestone schedules were established, the NRC staff noted that it will work with each licensee or applicant to establish a specific schedule for each request, which may be shorter or longer than the generic milestone schedule based on the specific needs of the licensee or applicant and the staff's resources. Completion of the applicable items[3] described in the following sections prior to application submittal would allow the NRC staff to establish a review schedule at least 6 months shorter than the generic schedules depending on the complexity of the design.[4] The NRC staff would complete the issuance of the final safety evaluation within that application-specific review schedule as long as the following conditions are met:

- Applicants submit responses to requests for additional information (RAIs) and other necessary information within agreed upon timeframes.
- The applicant makes no substantive changes to the application after submittal.

[2] https://www.nrc.gov/about-nrc/generic-schedules.html

[3] For a design certification, only the safety review items would be applicable. For a combined license application referencing a certified design, the environmental review items would be applicable in addition to safety topics associated with site specific features and any departures to the certified design. For a combined license not referencing a certified design, all the review topics listed would be applicable.

[4] Substantive pre-application engagement of a lesser extent than that described in this paper may result in a shorter review schedule than the NEIMA generic schedules, which would be determined on a case-by-case basis.

- For an applicant that participates in pre-application activities, the design does not change significantly between the pre-application activities and the time the application is submitted so that matters resolved in pre-application are not adversely impacted.

In addition to a substantially shorter overall application review, the acceptance review could be shorter if the activities described below are completed before submission of an application. The staff could complete the acceptance review in as little as two weeks[5] if only administrative aspects, such as making the application publicly available and issuing a notice of availability, need to be addressed at that time.

A. Topical reports

To support robust preapplication interactions, the applicant should submit topical reports on key topics for review during the pre-application phase. The NRC staff will review these topical reports during the pre-application phase and prepare safety evaluations with findings that can be relied on for the application review. These topical reports would be beneficial to the review schedule if received early enough to support staff issuance of final staff safety evaluations prior to submittal of an application. Any substantive changes to the design between submission of a topical report and submission of the application, however, could require additional staff review and result in significant changes to the review schedule. The key topics described below are those that should be addressed. At the construction permit stage, the level of design completeness would not typically support reaching conclusive staff findings on some safety and security topics during the preapplication or permit application review,[6] however, most of the topics below address methods or design fundamentals, and pre-application engagement in these areas is encouraged and would be beneficial for prospective construction permit applicants to manage project risk as well as produce schedule efficiencies.

- **Principal design criteria**

  Under Title 10 of the *Code of Federal Regulations* (10 CFR) 50.34(a)(3)(i), 10 CFR 52.47(a)(3)(i), and 10 CFR 52.79(a)(4)(i), proposed PDCs must be included in an application for a construction permit (CP), design certification (DC), or combined license (COL). The PDCs establish the necessary design, fabrication, construction, testing, and performance of safety significant structures, systems, and components (SSCs). The General Design Criteria (GDC) in 10 CFR 50 Appendix A establish minimum requirements for the principal design criteria for water-cooled nuclear power plants similar in design and location to plants for which construction permits have been issued by the Commission and provide guidance to applicants for CPs in establishing PDCs for other types of nuclear power units. The NRC staff expects non-LWR applicants will review the GDC and the guidance in Regulatory Guide (RG) 1.232, “Guidance for Developing Principal Design Criteria for Non-Light-Water

[5] Assuming that the applicant submittal meets NRC's requirements for electronic submittal and protection of sensitive information to facilitate release of a public version of the application.
[6] Under 10 CFR 50.35(b) a construction permit constitutes authorization for an applicant to proceed with construction but does not constitute Commission approval of the safety of any design feature or specification unless the applicant specifically requests such approval and such approval is incorporated in the permit.

Reactors," to develop their PDC and ensure that necessary safety functions and SSCs are covered under the selected PDC. For the applications that follow the risk-informed and performance-based (RIPB) approach in Nuclear Energy Institute (NEI) 18-04, Revision 1, "Risk-Informed Performance-Based Technology Inclusive Guidance for Non-Light Water Reactor Licensing Basis Development," the design-specific criteria identified by the RIPB approach may be used to supplement or modify the applicable GDC or Advanced Reactor Design Criteria in RG 1.232 in the formulation of PDC. The NRC staff will review the applicant's proposed PDCs to determine if they are acceptable. LWR applicants should discuss how the General Design Criteria (GDC) in Appendix A to 10 CFR Part 50 will be applied to their design and discuss any proposed exemptions to the GDC.

- **Selection of licensing basis events and classification and treatment of structures, systems, and components**

  a) The applicant should submit their proposed process for selection of licensing basis events and classification and treatment of SSCs, or indicate that they plan to use an approved process such as the process described in NEI 18-04 and RG 1.233, "Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors."

  b) The applicant should submit, for NRC information, the anticipated list of licensing basis events and the associated list of safety-related and risk-significant SSCs to improve understanding of the design, to support discussions on the preliminary SSC classifications, and to prepare for an efficient and effective application review.

- **Fuel qualification and testing**

  Preapplication engagement on fuel qualification should include the following steps: staff approval of the fuel qualification plan and associated methodologies, potential staff observation of execution of the testing, and verification of the results of the testing to support qualification of the fuel for the associated reactor design. Applicants need to demonstrate that the fuel is qualified for use in their reactor design (i.e., demonstrate that fuel manufactured in accordance with a specification will perform as described in the licensing safety case). Sufficient information should be provided to conclude that:

  - The role of the fuel in the safety case is adequately described. This can be addressed by providing fuel performance requirements during (1) normal operation, including the effects of anticipated operational occurrences, and (2) accident conditions. Sufficient information should be provided to describe the safety limits of the fuel and the fuel contribution in the accident source term. Understanding of the safety limits and source term should address uncertainty associated with any limitations on data available during the pre-application stage.

- The fuel qualification plan is adequate. Information should be provided in the fuel qualification plan that describes proposed analysis methodologies (e.g., fuel performance codes), the use of existing data, and any ongoing testing or plans to utilize lead test specimens. Where legacy data is used, a justification for the applicability of the data to the current application (e.g., data was collected for a fuel fabricated consistent with the proposed fuel design and irradiated in an applicable environment) and justification that the data was collected under an appropriate quality assurance program commensurate with the safety significance and in conformance with NRC quality assurance requirements should be provided.

- **Mechanistic or accident source term development**[7]

  The applicant should submit their source term methodology to the NRC staff for review and approval during preapplication. The source term methodology needs to include radiological source terms for effluents, radwaste system design, shielding design, and equipment qualification and should include validation and verification of associated engineering computer programs.

- **Quality assurance program**

  Applicants should submit a quality assurance program description (QAPD) for NRC review and approval during the pre-application phase to ensure that the design and the application have been developed in accordance with 10 CFR Part 50, Appendix B. The QAPD should cover the scope of the planned type of license application (e.g., 10 CFR 52.47(a)(19) discusses the quality assurance program (QAP) requirements for DC applications and 10 CFR 52.79(a)(25) discusses the QAP requirements for COL applications) as applied to the fabrication, construction, and testing, of the SSCs of the facility. The QAPD should include a discussion of how the applicable requirements of Appendix B to 10 CFR part 50 have been and will be satisfied, including a discussion of how the QAP will be implemented.

- **Safeguards Information Plan**

  The review and approval of an applicant's plan for the protection of safeguards information (SGI) by NRC staff during the pre-application period will enable the staff to provide the applicant with SGI information, as necessary, for the applicant to consider safeguards and security in the design of the facility and development of the physical security program in order for the applicant to address the requirements of 10 CFR Part 73, "Physical Protection of Plants and Materials," and 10 CFR 50.150, "Aircraft impact assessment," in their application.

[7] Developers of light-water small modular reactors may use the accident source term in NUREG-1465, "Accident Source Terms for Light-Water Nuclear Power Plants," or propose a design-specific accident source term.

- **Safety and accident analysis methodologies and associated validation**

  Applicants should develop and execute plans to perform safety and accident analyses that include testing of applicable SSCs and validation and verification of associated engineering computer programs. The analysis plans need to include development of associated methodologies and applications of those methods, which include but are not limited to event specific analysis methodologies, scaling methodology, setpoint methodology, reactor coolant analysis methodology, core design methodology, and reactivity control methods. The analysis plans need to include a test plan and test program as well as equipment qualification methodology to ensure appropriate verification and validation of the engineering computer programs. The test program should satisfy 10 CFR 50.43(e), which requires applicants to demonstrate that sufficient data exist on the safety features of the design to assess the analytical tools used for safety analyses over a sufficient range of normal operating conditions, transient conditions, and specified accident sequences, including equilibrium core conditions. The applicant should submit the safety analysis methodologies and application of those methods to the NRC staff for review and approval.

B. Meetings, audits and white papers:

In addition to the topical reports discussed above, applicants should engage in pre-application interactions on the key topics below. The NRC staff will review the information submitted or discussed and will provide feedback to the applicant which will be useful in preparation of the application.

- **Probabilistic risk assessment (PRA)**

  The PRA provides important insights in the selection of licensing basis events, safety classification of SSCs and associated risk-informed special treatments, and determination of defense-in-depth (DID) adequacy. As such, early regulatory engagement on the PRA can make the review of an application more effective and efficient.

  The applicant should facilitate the NRC staff's audit of the PRA peer review during the pre-application phase. The applicant should explain how the PRA will be used to support their application (e.g., risk-informed licensing, licensing basis event selection, siting, emergency preparedness, use of maintenance rule, etc.) to determine acceptability of the PRA for its planned use. The applicant should describe the development of its PRA, highlighting the use of any approaches that differ significantly from endorsed consensus codes and standards and NRC staff-approved guidance. The NRC staff will audit the resolution of the peer review findings and observations if a peer review has been completed. The NRC staff will provide feedback on these topics during the pre-application interactions. The applicant should address any issues identified before submittal of the application. Pre-application interactions on the PRA and its results should also assist the NRC staff in gaining valuable risk insights on the plant design. These risk insights will help the NRC staff conduct the application review by enabling the use of such risk insights in determining the depth and scope of the review, as well as by facilitating the use of risk-informed decision-making.

For applications submitted under 10 CFR Part 50, the degree of realism and the level of detail represented in the PRA at the CP stage will be less than that available at the operating license stage. Similarly, for applications submitted under 10 CFR Part 52, the scope represented in the PRA at the design certification stage will likely be less than that available at the COL stage. The NRC staff will adjust the depth and scope of its review, including consideration of the PRA acceptability appropriate to the maturity of the design. If an applicant considers seeking finality on safety matters at the CP stage, such as risk-informed licensing basis event selection or SSC classification, the PRA would need to be at a state of development that would support NRC staff's decisions in these areas. Early pre-application discussion with the NRC staff is important in this area to receive timely feedback.

- **Regulatory gap analysis**

The applicant should submit a regulatory gap analysis report listing those 10 CFR Part 50 or Part 52 requirements for which the applicant plans to request an exemption or seek a case-specific order or rule of particular applicability.[8] This would allow the NRC staff and the applicant to establish an efficient approach for reviewing proposed exemption requests or developing a case-specific order or rule of particular applicability for the Commission's consideration. Case-specific orders have been used to license new facilities and technologies (e.g., Louisiana Energy Services, L.P., enrichment facility application). Examples of potential exemption requests may include emergency planning zone size and number of armed responders for physical security in advance of completion of ongoing rulemakings.

For non-LWR applications submitted under 10 CFR Part 50 or 52, the regulatory gap analysis and decision to seek a case-specific order, rule of particular applicability, and/or exemptions should be informed by the information found in Appendix D of this document associated with the "Analysis of Applicability of NRC Regulations to Non-Light-Water Power Reactors."

- **Policy issues**

The wide range of designs and/or design features being contemplated by advanced reactor designers may present unique regulatory issues. The NRC staff will consider these issues, as presented in white papers or at meetings, as early as possible so that they can be properly addressed before the application is submitted. Early engagement will allow time to pursue a Commission decision for those issues that rise to the level of policy matters. If additional policy issues arise during the application review, the schedule may be affected.

[8] In lieu of exemptions, applicants may request alternate licensing approaches such as case-specific orders and rules of particular applicability. These are discussed further in Enclosure 2 to SECY 20-0093, Policy and Licensing Considerations Related to Micro-Reactors (ADAMS Accession No. ML20254A366).

- **Novel design features or approaches**

  The applicant should identify any novel design features, through white papers or meetings, during the pre-application review to allow staff familiarization so staff can develop a review strategy and review guidance, if needed. If the applicant intends to use novel design features (such as passive systems, inherent safety features, or simplified control features), early identification of these features or approaches to the NRC staff will facilitate timely identification and resolution of any unique regulatory topics. Topics to be considered beyond the reactor system include unique features such as seismic isolators, novel digital instrumentation and control systems, physical and cyber security features, safeguards features, or novel approaches to operational programs. Under 10 CFR 50.43(e), the performance of each safety feature must be demonstrated, and it must be demonstrated that the interdependent effects among the safety features of the design is acceptable. The applicant should inform the NRC how this demonstration will be made in their application.

- **Consensus codes and standards and code cases**

  During the pre-application stage the applicant should use a white paper to identify any consensus codes and standards or code cases they intend to use and specifically identify any standards or code cases that have not been endorsed or previously accepted by the staff. For any such standards or code cases, the applicant should engage in pre-application discussions to identify any areas where additional information may be needed in the application to support the proposed approach.

C. Environmental activities

The NRC conducts its environmental review in accordance with the National Environmental Policy Act's requirement that Federal agencies assess the environmental effects of proposed actions prior to making decisions. Environmental review is an integral but distinct part of the NRC's licensing review.

Early and frequent pre-application interactions is a key component of federal directives outlined in Title 41 of the Fixing America's Surface Transportation Act (FAST-41) to streamline the NRC's environmental review process. As part of these pre-application interactions, the NRC staff expects that applicants would conduct meetings, support audits, and provide white papers beginning approximately 2 years in advance of the application submittal. An applicant seeking greater confidence in a predictable review schedule should engage in substantive pre-application interactions with the NRC staff as early as possible in the planning process in accordance with 10 CFR 51.40, "Consultation with NRC staff," and as discussed in RG 1.206, "Applications for Nuclear Power Plants." In addition, an applicant is expected to address the environmental issues described in RG 4.2, "Preparation of Environmental Reports for Nuclear Power Stations," which provides guidance to applicants for the format and content of environmental reports that are submitted as part of an application for a permit, license, or other authorization to site, construct, and/or operate a new nuclear power plant, or provide a justification for any issues that do not need to be analyzed. In addition, an applicant should also consider following the guidance:

- NEI 10-07, “Industry Guideline for Effective Pre-Application Interactions with Agencies Other Than NRC During the Early Site Permit Process”
- COL/ESP-ISG-026 Combined License and Early Site Permit Environmental Issues Associated with New Reactors
- COL/ESP-ISG-027 Combined License and Early Site Permit Specific Environmental Guidance for Light Water Small Modular Reactor Reviews
- Interim Staff Guidance (ISG)-29, “Environmental Considerations Associated with Micro-reactors.”

Early engagement is important for assuring that sufficient data is available in the application and that appropriate engagement with other Federal and State agencies has begun. For example, a project may affect a threatened or endangered species, necessitating consultation with the U.S. Fish and Wildlife Service. If the service or the NRC need data on the species, seasonal lifecycles could affect the ability to collect the data, which in turn could delay a project.

White Papers

The applicant should submit white papers on the following key areas and on any novel approaches to environmental topics. The NRC staff will assess the approaches, document a position, and provide feedback to the applicant during the pre-application phase.

1. Unique or Novel Methodologies and Issues

The applicant should identify any novel environmental methodology or issue to allow staff familiarization so it can develop a review strategy and review guidance, if needed. An example of a unique issue would be a purpose and need statement for the project that specifies uses other than electricity production. The purpose and need for the project is the foundation on which the environmental review is based. The purpose and need statement informs analyses of the need for the project and of alternatives, including alternative sites and alternative sources of energy.

2. Alternatives to the Proposed Project

A recurring issue on many of the previous COLs and ESPs was the alternative site selection process. The applicant should support meetings to discuss the site selection process. In addition, energy alternatives could be a unique issue for an advanced reactor application, depending on the purpose and need statement for the project. A purpose other than generating baseload electricity could change the alternative energy analysis, relative to what was previously considered for large LWRs.

3. Cooling Water Availability

The NRC staff understands that advanced reactors may use less cooling water than the operating reactor fleet; however, access to cooling water and approvals by the relevant permitting authorities have proved to be a challenge for many previous projects. Therefore, the staff expects an applicant to provide information on the proposed facility's water consumption so the staff can gain an understanding of the facility's water needs and assess the appropriateness of the permits being sought. The staff also recommends that the applicant, the NRC staff, and the water permitting agencies meet at least once during the pre-application activities.

4. Status of Permits and Authorizations for the Proposed Project

The NRC staff recommends that the applicant interact with other permitting agencies as discussed in NEI 10-07, "Industry Guideline for Effective Pre-Application Interactions With Agencies Other Than NRC During the Early Site Permit Process," and provide a list of the needed authorizations, permits, licenses, and approvals for the project. This documentation should also contain a timeline for obtaining the necessary permits and the current status. The applicant should also provide copies of available correspondence between the applicant and State Historic Preservation Office (SHPO), Tribes, U.S. Fish and Wildlife Service, U.S. Army Corps of Engineers, National Marine Fisheries Service (NMFS), and state and local officials. The NRC staff will review the information and identify for the applicant any additional items that should be pursued, such as a consistency determination under the Coastal Zone Management Act.

Meetings

Based on recent experience, the following topics are critical components of environmental reviews that have caused schedule challenges during past reviews. Both the prospective applicant and the NRC staff would benefit from early discussion of any special aspects of these topics and a description of the applicant activities in these areas.

- Socioeconomic characteristics of the community
- Aquatic or terrestrial ecology studies that have been performed (if any).
- Federally listed species and critical habitats present, and potential impacts on those species and habitats
- Potential impacts on Essential Fish Habitat, including prey of Federally managed species.
- Historic properties and other cultural resources within the direct and indirect areas of potential effect (APE). Summarize cultural resource investigations conducted in the APE (all past and current historic and

cultural resource investigations), and outreach conducted with the SHPO, Tribal Historic Preservation Officer, American Indian Tribes, and interested parties.

- The fuel cycle and its impacts as related to the reactor design including the management of spent nuclear fuel.
- The environmental impacts from the transportation of fuels and wastes.
- Design-specific information needed for the environmental review including:
- radiological health impacts (10 CFR Part 20 exposure analysis, annual population dose, non-human biota dose),
- radiological waste management including effluent releases and solid wastes, as applicable,
- non-radiological waste management, and
- postulated accidents and severe accident mitigation design alternatives, as applicable.

D. Pre-application Readiness Assessment

In addition to the above pre-application activities, the applicant should allow the staff to conduct a pre-application readiness assessment (see Office instruction LIC-116, "Pre-application Readiness Assessment," ADAMS Accession No. ML20104B698) of both safety and environmental topics. In accordance with the Office Instruction, the readiness assessment may focus on either the whole application or selected parts identified in early interactions between the staff and prospective applicant. Depending upon the type of application to be submitted and the extent of pre-application activities leading up to this point, the staff will propose a right-sized scope for the readiness assessment.

The readiness assessment would allow the NRC staff to: (1) identify information gaps between the draft application and the technical content expected to be included in the final application submitted to the NRC, (2) identify major technical and/or policy issues not previously identified that may adversely impact the docketing or technical review of the application, and (3) become familiar with the application, particularly in areas where prospective applicants are proposing new concepts or novel design features not previously identified. The results of the readiness assessment will inform prospective applicants in finalizing their application and assist the NRC staff in planning its resources for the review once the application is formally submitted. The staff plans to engage prospective applicants to schedule a pre-application readiness assessment at least 6 months prior to the expected date of submittal. The readiness assessment is not part of the NRCs official acceptance review process and does not predetermine whether the application will be docketed. An applicant should provide the most current draft of the safety analysis report and environmental report, referenced documentation, and applicant staff and contractors to assist the NRC staff during its readiness assessment.

APPENDIX D

Analysis of Applicability of NRC Regulations to Non-Light-Water Power Reactors

Note: This appendix will be provided in a future update to this document. A draft version of the content of this appendix can be found in ADAMS at Accession No. ML21175A287

Appendix E
Construction Permit Guidance

PURPOSE

The U.S. Nuclear Regulatory Commission (NRC, or Commission) staff is providing this guidance to facilitate discussion of the safety review of non-light water reactor (non-LWR) construction permit (CP) applications for power reactors. Note that this Construction Permit Guidance Section is a follow-on to a white paper on the topic. The draft white paper "Safety Review of Power Reactor Construction Permit Applications" be found in ADAMS Accession No. ML21043A339. The white paper included CP guidance for both LWRs and non-LWRs. The NRC staff has determined that going forward it is best to split the CP guidance into separate guidance for LWRs and non-LWRs. However, the staff recognizes that there is a portion of the guidance that is applicable to both types of designs. Portions of the guidance that is applicable to both LWRs and non-LWRs is shown in italics below. The information in italics will be updated as the LWR and non-LWRs guidance is further refined.

BACKGROUND

The NRC anticipates the submission of power reactor CP applications within the next few years. The review of these applications falls within the two-step licensing process under 10 CFR Part 50 and involves the issuance of a CP before an operating license (OL). The NRC last reviewed a power reactor CP in the 1970s. Most recently, the NRC issued combined construction and operating licenses (combined licenses) for power reactors through the one-step licensing process under 10 CFR Part 52 utilizing guidance in the Standard Review Plan (SRP, NUREG-0800) (Ref. 8) and Regulatory Guide (RG) 1.206 (Ref. 17, 18).

The licensing process under 10 CFR Part 50 allows an applicant to begin construction with preliminary design information as compared with the final design required for a combined license (COL) under 10 CFR Part 52. Although the two-step licensing process provides flexibility and a more limited safety review prior to construction, there is less finality on the design before the applicant commits to construction of the facility.

The SRP contains the staff review guidance for LWR applications submitted under 10 CFR Part 50 or 10 CFR Part 52. In addition, some insights on the level of detail that is required for the preliminary safety analysis report (PSAR) in support of the CP application may be obtained from RG 1.70, Revision 3, 1978, (Ref. 13) but these insights may be limited to the degree that the guidance does not account for subsequent requirements and NRC technical positions, or advances in technical knowledge. RG 1.206 provides guidance for COL applications and includes insights on the level of detail needed for final design information if the CP applicant chooses to provide such information.

The NRC is developing guidance for the safety review of non-LWR designs. The Advanced Reactor Content of Applications Project (ARCAP) document will reference existing guidance that may be applicable to non-LWR designs and recently developed non-LWR guidance for specific areas of review. The ARCAP is broader and encompasses the industry-led Technology-Inclusive Content of Application Project (TICAP). These projects build on the outcome of the Licensing Modernization Project (LMP), which provides guidance that focuses on identifying licensing basis events; categorizing and establishing performance criteria for structures, systems, and components; and evaluating defense in depth for advanced reactor designs.

ARCAP guidance is being developed independently of the SRP for light water reactors. Because ARCAP guidance is envisioned to use an application structure different than the SRP, Appendix C, “Advanced Reactor Construction Permit Guidance,” has been developed for applications that choose to follow this approach.

The NRC recently issued CPs for two non-power production and utilization facilities, SHINE Medical Isotopes (Ref. 9) and Northwest Medical Isotopes (Ref. 10). Some of the lessons learned from these reviews are applicable to the review of power reactor CP applications and are summarized below.

RATIONALE

During the June 12, 2020, public meeting on the Advanced Reactor Content of Application Project for non-LWR designs, the Nuclear Energy Institute (NEI) and U. S. Nuclear Industry Council (USNIC) requested guidance for CP applicants within the next 1-2 years.

In a subsequent public meeting on July 31, 2020, the staff presented options to address industry’s request to support the timeline of potential applications and received feedback that the interim staff guidance (ISG) option appears to address industry’s needs for near-term CP guidance.

This draft white paper focuses on the safety review of power reactor CP applications and may be further developed into an ISG applicable to any LWR design, including designs similar to those recently reviewed under 10 CFR Part 52, and may refer to the applicable guidance for the review of non-LWR designs. It has been approximately 40 years since the staff reviewed a CP application for a power reactor. Although the LWR CP application guidance in RG 1.70 dates from the 1970s and the more recent LWR application guidance in RG 1.206 was developed for a COL application, these documents provide some insights on the level of detail to support an LWR CP application review as discussed above. For a non-LWR CP application, the ARCAP guidance provides information on the level of detail to meet the applicable requirements for a CP.

This draft white paper also includes a discussion of how the staff’s safety review would address LWR applications that reference an approved design or other NRC approvals, specific CP safety review areas needing clarity, and applicability of ARCAP guidance.

GUIDANCE

<u>Requirements for a Power Reactor Construction Permit Application</u>

A number of regulations apply to a power reactor CP application, including:

- 10 CFR 50.30, “Filing of application; oath or affirmation”

- *10 CFR 50.33, "Contents of applications; general information"*[11]
- *10 CFR 50.34, "Contents of applications; technical information," particularly paragraph (a), "Preliminary safety analysis report,"*
- *10 CFR 50.34a, "Design objectives for equipment to control releases of radioactive material in effluents – nuclear power reactors"*
- *10 CFR 50.35, "Issuance of construction permits"*
- *10 CFR 50.40, "Common standards"*
- *10 CFR 50.55, "Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses"*
- *10 CFR 50.55a, "Codes and standards"*
- *10 CFR Part 20, "Standards of Protection Against Radiation"*
- *10 CFR Part 100, "Reactor Site Criteria"*

The regulations in 10 CFR 50.34(a) specify the minimum technical information in the preliminary safety analysis report (PSAR) accompanying a CP application, including a description and safety assessment of the site on which the facility is to be located. The site safety assessment is expected to include an analysis and evaluation of the major structures, systems and components (SSCs) of the facility that bear significantly on the acceptability of the site under the site evaluation factors identified in 10 CFR Part 100.

The regulations in 10 CFR 50.35, "Issuance of construction permits," provide for the issuance of a CP in cases where the application does not provide sufficient information for the staff to approve all proposed design features and when certain criteria are met. In its early practices, the predecessor to the NRC, the Atomic Energy Commission (AEC), had issued a "provisional" CP when the applicant had not submitted all the technical information to complete the application and to approve all proposed design features. However, almost all issued "provisional" CPs were never converted to a "final" CP but instead merged into an operating license. Therefore, the AEC proposed to codify the Commission's practice for issuing a CP (34 FR 6540, April 16, 1969). The final amendment to the regulations in 10 CFR 50.35 eliminated the term "provisional" construction permit but retained the "provisional" criteria for issuing a CP (35 FR 5317, March 31, 1970). By issuing a CP, the Commission authorizes the construction of the facility described in the application, including the principal architectural and engineering criteria and identification of major features or components for the protection of the health and safety of the public.

The current regulations for issuing a CP in 10 CFR 50.35(a) have not been modified since 1970:

> *(a) When an applicant has not supplied initially all of the technical information required to complete the application and support the issuance of a construction permit which approves all proposed design features, the Commission may issue a construction permit if the Commission finds that (1) the applicant has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public; (2) such further technical or design*

[11] Although referenced herein, guidance on compliance with the applicable requirements in 10 CFR 50.30 and 50.33 is outside the scope of this document.

> *information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the final safety analysis report; (3) safety features or components, if any, which require research and development have been described by the applicant and the applicant has identified, and there will be conducted, a research and development program reasonably designed to resolve any safety questions associated with such features or components; and that (4) on the basis of the foregoing, there is reasonable assurance that, (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in part 100 of this chapter, the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.*

In cases where a novel design has not sufficiently progressed and certain information is not available at the submission of the CP application, the PSAR should provide the criteria and bases used to develop the required information, the concepts and alternatives under consideration, and the schedule for completion of the design and submission of the missing information. In general, the PSAR should describe the preliminary design of the facility in sufficient detail to enable the staff to evaluate whether the facility can be constructed and operated without undue risk to the health and safety of the public.

The criteria in 10 CFR 50.35(a) focus on the safety aspects of the design, including the principal architectural and engineering criteria and the safety design features, as well as siting information to support construction of the facility. Given the advances in technology since the most recent amendment of the regulation, it may be easier for an applicant to provide more complete technical information in its CP application and thereby reduce the regulatory review in the subsequent licensing phase. As noted in 10 CFR 50.35(a), the findings above will be modified, if specifically requested by the applicant, for a complete CP application that includes all technical information, including the final design of the facility.

Under 10 CFR 50.35(b), a CP applicant may also request approval of any design features or specifications in its CP application. This request for approval would need more than preliminary information to support the staff's review to approve such design features or specifications. In such a case it would be expected that the level of design information available to support the approval of a proposed design feature in the application would be the same level of design information available for a 10 CFR Part 52 COL application. Guidance for the expected level of design information that is available to support a COL application can be found in RG 1.206. It should be noted that any approval, if granted, would apply only to the extent that the item has been fully addressed or treated in the application and would not extend beyond items or details not fully covered in the application. The regulation at 10 CFR 50.35(b) clarifies that a CP authorizes the applicant to proceed with construction but is not an approval of the safety of any design features or specifications unless the applicant requests for such approval and the approval is incorporated into the permit.

As described in 10 CFR 50.35(c), a license authorizing operation of the facility will not be issued until (1) the applicant submits, as part of an OL application, its final safety analysis report (FSAR) and (2) the Commission finds that the final design provides reasonable assurance that the health and safety of the public will not be endangered by operation of the facility. The FSAR *submitted with the OL should describe in detail the final design of the facility as constructed, identify the changes from the criteria, design, and bases in the PSAR, and discuss the bases and safety significance of the changes from the PSAR. Prior to the issuance of an operating license, the staff will review the applicant's final design in the FSAR to determine whether all the Commission's safety requirements have been met. Based on this determination, the Commission would issue an OL and the applicant may then operate the facility in accordance with the terms of the OL and the Commission's regulations under the continued oversight by the NRC staff.*

<u>Lessons Learned from Recently Issued CPs</u>

Recently, the NRC issued permits for the construction of medical radioisotope facilities as non-power production and utilization facilities (NPUFs) licensed under 10 CFR Part 50. The Commission issued CPs to SHINE Medical Technologies, LLC in February 2016, and Northwest Medical Isotopes, LLC in May 2018. Lessons learned from the review of these NPUF CP applications include the following:

- *Pre-application engagement is key to providing near-term guidance to the applicant.*
- *Early interactions supported common understanding of what information is needed in the PSAR and what information could be reasonably left for the FSAR accompanying the OL application, e.g., operational program descriptions.*
- *If the PSAR includes preliminary or limited descriptions of the facility's programs, structures, systems, or components, the staff may accept and approve the application with regulatory commitments from the applicant to provide complete information in its OL application.*
- *The staff's construction permit safety review is focused on ensuring appropriate use of analysis methodologies to meet the requirements in the regulations.*

In safety evaluations related to the CPs issued, the NRC staff noted applicant regulatory commitments regarding the resolution of items that were not necessary for the issuance of a construction permit, but that the applicant should address in the FSAR submitted with an operating license application. The CPs included conditions to ensure that the permit holder informed the NRC of safety significant areas of construction prior to the submission of an OL application. CP conditions of a confirmatory nature focused on additional information needed to address certain matters related to the safety of a final design and required the applicant to submit, prior to the completion of construction, periodic reports on such information to the NRC.

The NPUF lessons learned noted above may be applied for an effective and efficient safety review of the PSAR to determine whether the application meets the 10 CFR 50.35 requirements for issuing a CP. However, in drawing lessons from recent NPUF reviews, consideration should be given to the different technologies involved and the much more limited set of safety requirements that apply to an NPUF as opposed to a power reactor.

Consistent with past practice and experience, including the recent NPUF reviews discussed above, pre-application activities have proven effective in gaining early understanding of the applicant's plans and its proposed facility design, supporting early resolution of unique design aspects of the facility, and preparing resources for the review of the application. Also, a recent *staff draft white paper (Ref. 5) on preapplication engagement to optimize application reviews provides information to advanced reactor developers on the benefits of robust preapplication engagement in order to optimize application reviews. Although directed to the advanced reactor community, the draft white paper describes a set of pre-application activities that may be applicable to LWR license applicants and, if fully executed, will enable the staff to offer more predictable and shorter schedules and other benefits during the review of a reactor license application.*

<u>Special Topics</u>

The previous section provides guidance on the overall approach for the safety review of a CP application recognizing that if an application does not provide the information to support the issuance of a construction permit that approves all proposed design features, it may still meet the criteria in 10 CFR 50.35(a) for the Commission to issue a CP.

This section provides additional guidance on potential CP application submissions and the effect of ongoing regulatory activities on the review of future CP applications.

Concurrent Applications

A CP application may be accompanied by an application for a limited work authorization (LWA). For the LWA review, the staff should refer to the guidance in COL/ESP-ISG-4 (Ref. 7) related to the definition of construction and limited work authorization.

Questions have been raised regarding the possibility of submitting the OL application before the CP is issued. The staff is still considering the legal and policy implications of this possibility. For an OL application submitted before the construction permit is issued, a process would need to be developed to address the CP mandatory hearing (if not completed before the OL application is submitted) and the logistics associated with the OL hearing opportunity.

The staff notes that there are inherent complications associated with a concurrent CP and OL review. For example, as a result of the OL review, a need to reclassify SSCs (i.e., from non-safety-related to safety-related) could arise based on updated design information that was not available at the time of the CP. In such a case, extensive rework of both the CP and OL applications could be needed to address this reclassification.

CP Application Incorporating Prior NRC Approvals

A CP application may incorporate prior NRC approvals by reference, including a standard design approval (SDA), a certified design (DC), or an early site permit (ESP). Each of these approvals is supported by a staff safety evaluation concluding that the applicant has met the specific regulatory requirements for approval and may be subject to conditions and additional requirements and restrictions. These prior NRC approvals have finality when referenced in a CP application as defined by the issue finality provisions for the particular Part 52 approval.

If the staff determines that the CP application demonstrates the applicability of the prior NRC approval including compliance with any associated conditions and additional requirements and restrictions, the staff's CP review regarding the referenced material would generally be limited to *an evaluation of (1) how the referenced approval conditions and additional requirements and restrictions are addressed in the CP application, and (2) any deviations from the referenced material that are subject to prior NRC review. Portions of the application not receiving prior NRC approval will be the focus of the NRC staff's CP review.*

For a CP application referencing an ESP, the staff's review and evaluation may be more extensive in that the staff would conduct a safety review and evaluation of the proposed design of the facility, any requested variances from the ESP, the satisfaction of any relevant permit conditions, and the updating of emergency preparedness information in accordance with 10 CFR 52.39(b). As provided by 10 CFR 52.24(b), any ESP terms or conditions that cannot be met by CP issuance must be set forth as terms or conditions of the CP.

For a CP application referencing an SDA or DC, the staff's review and evaluation may be focused on the suitability of the selected site for the referenced design, the satisfaction of any additional requirements or restrictions for the approved design, and any design matters outside the scope of the referenced design. Under 10 CFR Part 52, a DC must be based on essentially complete design, while an SDA may approve only major features of the design; this difference may affect the level of design information that might be needed in the CP application. Also, Section IV.B in all issued design certification rules provides that "[t]he Commission reserves the right to determine in what manner this appendix may be referenced by an applicant for a construction permit or operating license under 10 CFR part 50."

For a CP application referencing an ESP and an SDA or DC, the staff's review and evaluation would generally be focused on whether the referenced design fits within the characteristics of the approved site; whether the other applicable conditions, requirements, and restrictions in the referenced approvals are satisfied; whether deviations from the referenced approvals that require prior NRC approval comply with NRC regulations; and whether requirements for matters outside the scope of the referenced approvals are met.

Ongoing Regulatory Activities

The NRC is currently pursuing the alignment of requirements in 10 CFR Parts 50 and 52 through rulemaking. The rulemaking is in its initial phases and may include additional licensing requirements for applications submitted under 10 CFR Part 50 (e.g., risk information). Until the final rule is issued, a CP application will be reviewed and evaluated in accordance with the existing regulations. The staff should continue to monitor the progress of the 10 CFR Parts 50 and 52 rulemaking since a CP applicant must comply with the applicable regulations that are in effect at the time the NRC issues the construction permit. A CP applicant may choose to provide risk information in its application and the staff should consider this information to enhance its review focus on the proposed safety design features of the facility.

The NRC is working on the advanced reactor content of application project (ARCAP) to develop technology-inclusive, risk-informed, and performance-based application guidance. The ARCAP guidance is intended for use by an advanced reactor applicant for a combined license, construction permit, operating license, design certification, standard design approval, or manufacturing license. Many of the topics covered in the ARCAP guidance may also be applicable to LWR designs, including updated siting guidance. The staff should consider the *updated guidance in the ARCAP, when finalized, for applicability to a CP application review as described in Appendix C of this document.*

Receipt, Possession, and Use of Source, Byproduct and Special Nuclear Material

This document does not provide guidance on the licensing requirements for byproduct, source, or special nuclear material under 10 CFR Parts 30, 40, and 70. The CP applicant may address the applicable materials licensing requirements with its CP application (in accordance with 10 CFR 50.31) or separately from the CP application.

Detailed Advanced Reactor Construction Permit Guidance

This portion of the construction permit (CP) content guidance is intended for CP applications involving advanced non-light-water reactors (LWRs). The guidance is based on an application using a risk-informed performance-based approach. Applicants are not required to utilize the TICAP/LMP approach and may instead use another methodology (e.g., traditional deterministic approach, maximum hypothetical accident[12]) to analyze non-LWR performance and develop a licensing basis. The TICAP/LMP process forms the basis for this guidance although in some areas the guidance provides additional considerations for acceptably addressing a specific topic when a TICAP/LMP approach is not used. As noted above applicants are encouraged to use the preapplication process to optimize reviews, which is especially important if an applicant intends to use a process other than the LMP to develop their licensing basis. Regardless, the review guidance in this document is limited in scope. NRC staff should continue to consult other established guidance documents, as applicable, to complete reviews of non-LWR applications.

This guidance addresses the minimum information necessary in a CP application for the staff to issue a CP under 10 CFR 50.35(a) when the applicant has not supplied all of the technical information required to complete the application (i.e., 50.34(a)) and support the issuance of a CP which approves all proposed design features (i.e., obtains finality for the design). When making its safety finding regarding the issuance of a CP under 50.35(a), the staff should make the determination that the application:

- Describes the proposed design of the facility, including, but not limited to,
  - the principal architectural and engineering criteria for the design, and
  - the major features or components incorporated therein for the protection of the health and safety of the public.
- Describes safety features or components, if any, which require research and development program necessary to resolve any safety questions associated with such features or components.
- Provides commitments that such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and

[12] In this context, “maximum hypothetical accident” refers to a conservatively assessed, deterministic accident with consequences that bound the full spectrum of accident conditions for the plant and is not necessarily a credible event.

- Describes the site criteria contained in 10 CFR Part 100 and the site characteristics and, based on those criteria, concludes that the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

Where an applicant desires design finality regarding a specific topic, the NRC staff should review that the application has provided sufficient information about the topic at a level of detail that is expected at the operating license (OL) stage.
<u>Specific Topic Guidance</u>

Chapters 1-8

NEI 21-07, Section xxx provides an acceptable method for developing portions of a construction permit application in accordance with 10 CFR Part 50 requirements. However, for advanced reactor applicants pursuing a construction permit (CP) application under 10 CFR Part 50 and using an alternative risk-informed performance-based approach, additional information not related to the LMP-based affirmative safety case should be provided. Specifically, the additional information is related to the minimum information necessary in a CP application for the staff to issue a CP under 10 CFR 50.35(a) when the applicant has not supplied all of the technical information required to complete the application (i.e., 50.34(a)) and support the issuance of a CP which approves all proposed design features (i.e., obtains finality for the design). The staff notes that the additional CP information described in RG 1.2xx provides the additional CP information necessary to supplement the first 8 Chapters of the SAR. As previously stated, the SAR chapters 1-8 are largely focused on describing the fundamental safety functions of the design and the affirmative safety case for each applicant consistent with the LMP approach.

- Control of Routine Plant Radioactive Effluents, Plant Contamination and Solid Waste

  For guidance regarding specific information content refer to *draft ARCAP ISG, "Control of Routine Plant Radioactive Effluents, Plant Contamination and Solid Waste."* (Note preliminary thoughts on potential guidance for this chapter that has not been subject to legal or management reviews are available in ADAMS at Accession No. ML20260H366).

- Control of Occupational Dose

  For guidance regarding specific information content refer to *draft ARCAP ISG, "Control of Occupational Dose."* (Note preliminary thoughts on potential guidance for this chapter that has not been subject to legal or management reviews are available in ADAMS at Accession No. ML20260H366).

- Organization

  For guidance regarding specific information content refer to *draft ARCAP ISG, "Organization and Human-System Considerations."* (Note preliminary thoughts on potential guidance for this chapter that has not been subject to legal or management reviews are available in ADAMS at Accession No. ML21309A020).

- Post-construction Inspection, Testing and Analysis Program

  For guidance regarding specific information content refer to *draft ARCAP ISG, "Post-construction Inspection, Testing and Analysis Program"* (Note preliminary thoughts on potential guidance for this chapter that has not been subject to legal or management reviews are available in ADAMS at Accession No. ML21294A266).

- Quality Assurance
  The staff should review the applicant's quality assurance program description (QAPD) applied to activities for design, fabrication, construction, and testing of the safety-related and safety-significant SSCs of a facility or facilities that may be constructed on the site. The staff should approve the QADP prior to the start of included activities.

  The staff's review should ensure that the applicant (and its principal contractors such as the reactor vendor, Architect Engineer, constructor and construction manager) has established a QA program for the design and construction phases in accordance with Appendix B to 10 CFR Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." The QA program should also address the collection of site information. The applicant's QA program (including its principal contractors) must describe in the CP application how each criterion of Appendix B will be met or propose an alternate or limited set of criteria with appropriate justifications. The staff should expect to review applicant submitted exemption requests where alternate requirements are being proposed to the Appendix B regulations.

  The staff should refer to the guidance in RG 1.28, "Quality Assurance Program Criteria (Design and Construction)," as an acceptable approach to establishing and implementing a QA program for the design and construction of nuclear power plants. This RG endorses, with certain exceptions and clarifications, the Part I and Part II requirements included in the NQA-1b-2011 Addenda to ASME NQA-1-2008, NQA-1-2012, and NQA-1-2015, "Quality Assurance Requirements for Nuclear Facility Applications," for the implementation of a QA program during the design and construction phases of nuclear power plants that provides an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50.

  NRC SECY-03-0117, "Approaches for Adopting More Widely Accepted International Quality Standards," documents the staff's effort to review international quality assurance standards against the existing 10 CFR Part 50 Appendix B framework and assess approaches for adopting international quality standards for safety-related components in nuclear power plants into the existing regulatory framework. The staff should refer to this document when reviewing an application that uses international QA standards to meet 10 CFR Part 50 Appendix B requirements.

- Security
  The staff should review the application to verify that it contains the following information:
  - Information demonstrating that site characteristics are such that adequate security plans and measures can be developed consistent with the guidance in *draft ARCAP ISG, section 2.1, "Site Characteristics and Site Parameters (Overview),"* (note that no

Physical Security Plan, Security Training and Qualifications Plan, or Safeguards Contingency Plan information is required at the CP stage).
  - Information Security Plan – the application should include a plan for the protection of safeguards information (SGI). This plan should be reviewed and approved by NRC during the preapplication period to enable the NRC staff to provide the applicant with SGI documents, as necessary, for the applicant to consider safeguards and security in the design of the facility, development of the physical security program to meet the requirements of 10 CFR Part 73, "Physical Protection of Plants and Materials," and address safety concerns associated with 10 CFR 50.150, "Aircraft impact assessment," in their application.

- Emergency Planning
  The NRC staff should review the application to verify that it contains the following information:
  - Describe any physical characteristics of the proposed site, such as egress limitations from the area surrounding the site, that could pose a significant impediment to the development of emergency plans (EPs) (note that no EP is required at the CP stage). If physical characteristics are identified that could pose a significant impediment to the development of EPs, the application should identify measures that would, when implemented, mitigate or eliminate the significant impediment.

  - Describe the major features of the EP which are aspects of the plan necessary to:
    - Address in whole or part either one or more of the 16 standards in 10 CFR 50.47(b) or the proposed requirements of 10 CFR 50.160(b)[13], as applicable; or
    - Describe the emergency planning zones as required in 10 CFR 50.33(g).

  Refer to *draft Regulatory Guide (DG), DG–1350, ''Performance-Based Emergency Preparedness for Small Modular Reactors, Non-Light-Water Reactors, and Non-power Production or Utilization Facilities*,'' May 2020, for additional guidance. Note that this DG is associated with the proposed requirements of 10 CFR 50.160(b) which may affect EP requirements for non-LWRs. [14]

- Aircraft Impact
  Construction permit applicants for new nuclear power reactors are required to address the impact of a large commercial aircraft as part of the design. Specifically, 10 CFR 50.150 requires the following:

    - 10 CFR 50.150(a)(1): that each applicant performs a design-specific assessment of the effects on the facility of the impact of a large commercial aircraft. Using realistic analysis, the applicant shall identify

[13] Proposed 10 CFR 50.160, "Emergency preparedness for small modular reactors, non-light water reactors, and non-power production or utilization facilities" can be found at 85 FR 28436.
[14] Ibid

and incorporate into the design those design features and functional capabilities to show that, with reduced use of operator actions: (1) the reactor core remains cooled, or the containment remains intact; and (2) spent fuel cooling or spent fuel pool integrity is maintained.

- 10 CFR 50.150(b): that the applicant must include a description of (1) the design features and functional capabilities identified in 10 CFR 50.150 (a)(1), and (2) how the design features and functional capabilities identified in 10 CFR 50.150 (a)(1) meet the assessment requirements in 10 CFR 50.150 (a)(1).

The staff should review the information contained in the CP application and reach conclusions as to whether the applicant has: (1) adequately described design features and functional capabilities in accordance with 10 CFR 50.150(b); and (2) conducted an assessment reasonably formulated to identify design features and functional capabilities to show, with reduced use of operator action, that the facility can withstand the effects of a large commercial aircraft impact.[15] The NRC staff should recognize that the information in the CP application may be based on preliminary design information. Therefore, 10 CFR 50.150 requires applicants to perform the aircraft impact assessment at both licensing stages and include the required information in both applications based on the level of design information available at the time of each application.

The staff should consider the review guidance in SRP Section 19.5, "Adequacy of Design Features and Functional Capabilities Identified and Described for Withstanding Aircraft Impacts," and RG 1.217, Revision 0, "Guidance for the Assessment of Beyond-Design-Basis Aircraft Impacts," which endorses the guidance in NEI 07-13, Revision 8, "Methodology for Performing Aircraft Impact Assessments for New Plant Designs," as an acceptable method for use in satisfying the NRC requirements in 10 CFR 50.150(a) regarding the assessment of aircraft impacts for new nuclear power reactors. When considering the review guidance, the staff should note that the guidance is based on traditional LWR technologies. For non-LWRs, a preapplication discussion with the applicant could aid in addressing the following issues:

- SECY-11-0112, "Staff Assessment of Selected Small Modular Reactor Issues Identified in SECY-10-0034," Enclosure 5, "Aircraft Impact Assessments for Small Modular Reactors," provides considerations for aircraft impact assessments for non-LWRs. This enclosure notes that the four functions identified in 10 CFR 50.150(a)(1) are applicable to LWRs, and may not be applicable to non-LWR reactor designs, or may have to be supplemented by other key functions. When reviewing non-LWR designs, the staff will evaluate the applicability of the acceptance criteria set forth in the aircraft impact rule and the possible need for other criteria. As noted in the statement of considerations for 10 CFR 50.150, if necessary, the staff will issue exemptions and impose supplemental

[15] Consideration of Aircraft Impacts for New Nuclear Power Reactors, 74 FR 28120 (June 12, 2009).

criteria to be used in the aircraft impact assessment for such non-LWR designs.

SECY-11-0112 also describes areas for additional staff consideration should an application include that ability to produce process heat for industrial use. In such cases the staff should include the impacts resulting from events at the industrial facility associated with the reactor, including aircraft impacts, as part of the external hazards analysis and the siting evaluation.

- SECY-20-0093, "Policy and Licensing Considerations Related to Micro-Reactors," Enclosure 1 includes a discussion of aircraft impact assessments. This enclosure includes the following considerations:

From a consequence perspective, the staff expects micro-reactors to more closely resemble nonpower reactors than large LWRs. Further, the site footprint of micro-reactors is likely to be substantially smaller than that of the existing power reactor fleet and the new reactors envisioned when the NRC promulgated the aircraft impact rule. Some micro-reactors might also be located underground, which could prevent a large commercial aircraft from striking safety-significant portions of a facility. A holistic risk-informed consideration of design-specific features, including the potential consequences of an aircraft impact, could provide a basis for meeting the underlying purpose of the rule and would be consistent with the Statements of Consideration, which stated that the NRC may need to issue exemptions and impose supplemental criteria for aircraft impact assessments of non-LWRs. Provided a micro-reactor applicant can make a case for demonstrating compliance with the rule, the staff expects that existing regulatory processes are sufficient to address micro-reactor applications in the near term.

The staff should note that the aircraft impact rule does not require that the actual aircraft assessment be submitted to the NRC. Therefore, the NRC will address the adequacy of the aircraft impact assessment through an inspection of that assessment that is independent of the licensing review of the application. The licensee is however expected to use the results of the aircraft impact assessment to provide the information identified in SRP 19.5 in its application.

- Research and Development
  The staff should review any identified research and development (R&D) program plans that are designed to resolve any safety questions associated with safety features or components. This review should consider the applicant's plan for research activities including testing of new safety or security features that differ from existing designs for operating reactors, or that use simplified, inherent, passive means to accomplish their safety or security function. The testing should ensure that these new features will perform as predicted, will provide for the collection of sufficient data to validate computer codes, and will show that the effects of system interactions are acceptable.

  The staff should ensure that the applicant's commitments to develop sufficient information (through testing or R&D) to support the reliability, availability and performance of safety-related and safety-significant SSCs and human actions modelled in the final PRA (e.g., commitments for items such as fuel testing and analytical code verification and validation) are completed on a schedule to support the staff's review of the final design.

The staff should ensure that the applicant has provided a summary description of preoperational and/or startup testing that is planned for each unique or first-of-a-kind principal design feature that may be included in the facility design or provide information, as applicable, that is sufficient to credit previously performed testing for identical unique or first-of-a-kind design features at other NRC-licensed production facilities.

The staff should conclude that the R&D plans will permit the staff to make the findings required by 10 CFR 50.43(e) (for applications which differ significantly from light-water reactor designs that were licensed before 1997 or use simplified, inherent, passive, or other innovative means to accomplish their safety functions).

- Fuel qualification
  The reactor core and its fuel are generally identified as safety-related due to the direct involvement in performing fundamental safety functions. The information requirements associated with safety-related SSCs are discussed in Section 6, "Safety-Related SSC Criteria and Capabilities." However, there are regulatory requirements, such as fuel design limits, that are attributed-to or identified with fuel performance and its qualification. One of the characteristics of fuel qualification is the need for irradiation data that corresponds to the transient and normal operating conditions expected over the life of the plant. Accordingly, it is anticipated that advanced reactor designs will use existing data (e.g., Advanced Gas Reactor (AGR) program data, legacy metal fuel data) to support regulatory licensing to some degree. Staff review of fuel qualification at the CP stage should focus on (1) understanding the role of the fuel in the safety case, and (2) determining the adequacy of the plan to provide the evidentiary basis for fuel performance as assumed in the safety case. Sufficient information should be available to support reasonable assurance findings that:

    - The role of the fuel of the safety case is adequately described. This can be addressed by providing fuel performance requirements during (1) normal operation, including the effects of anticipated operational occurrences, and (2) off-normal conditions, including DBEs, DBAs and BDBEs. In support of these findings, the staff should seek to understand the safety limits of the fuel and the fuel contribution to source terms associated with AOOs, DBEs, BDBEs and the siting determination. Understanding of the safety limits and source term should address uncertainty associated with any limitations on data available at the CP stage and reflected in the analyses discussed in Section 2c "Safety and Accident Analysis Methodologies and Associated Validation" and Section 3b "Discussion of accident source terms" of this paper.

    - The fuel qualification plan is adequate. Staff evaluation of the fuel qualification plan should consider the proposed analysis methodologies (e.g., fuel performance codes), the use of existing data, and any ongoing testing or plans to utilize lead test specimens. Where legacy data is used, a justification for the applicability of the data to the current application should be provided (e.g., data was collected for a fuel fabricated consistent with the proposed fuel design and irradiated in an applicable environment).

Two NRC documents provide additional guidance in the area of non-LWR FQ:

- NUREG-2246, Fuel Qualification for Advanced Reactors, Draft Report for Comment (ML21168A063)
- NRC staff report “Assessment of White Paper Submittals on Fuel Qualification and Mechanistic Source Terms: Next Generation Nuclear Plant”, Revision 1, July 2014 (ML14174A845).

- Regulatory Exemptions
  The staff should review the requested exemptions from NRC requirements. The applicant should refer to Appendix D of this document for guidance regarding the applicability of NRC regulations to their facility.

- Environmental Report
  The staff should review an applicant’s environmental report (ER) as part of the CP application in accordance with 10 CFR 51.50(a). The ER is expected to address the environmental issues described in RG 4.2, “Preparation of Environmental Reports for Nuclear Power Stations,” which provides guidance to applicants for the format and content of ERs that are submitted as part of an application for a permit, license, or other authorization to site, construct, and/or operate a new nuclear power plant, or provide a justification for any issues that do not need to be analyzed. Guidance on the review of environmental issues is given in NUREG-1555, “Standard Review Plans for Environmental Reviews for Nuclear Power Plants”