



NUCLEAR REGULATORY COMMISSION

[NRC-2022-0078]

Interim Staff Guidance: Advanced Reactor Content of Application Project Chapter 11, Organization and Human-System Considerations

AGENCY: Nuclear Regulatory Commission.

ACTION: Final guidance; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing Interim Staff Guidance (ISG) DANU-ISG-2022-05, Chapter 11, "Organization and Human-System Considerations." The purpose of this ISG is to provide guidance for prospective applicants in preparing applications for non-light water reactor (non-LWR) designs that use the Licensing Modernization Project (LMP) process and to assist the NRC staff in determining whether such applications meet the minimum requirements for construction permits, operating licenses, combined licenses, manufacturing licenses, standard design approval, or design certifications.

DATES: This guidance is effective on **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Please refer to Docket ID **NRC-2022-0078** when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- **Federal rulemaking website:** Go to <https://www.regulations.gov> and search for Docket ID **NRC-2022-0078**. Address questions about Docket IDs in Regulations.gov to Stacy Schumann; telephone: 301-415-0624; email: Stacy.Schumann@nrc.gov. For technical questions, contact the individual listed in the "For Further Information Contact" section of this document.

- **NRC's Agencywide Documents Access and Management System**

(ADAMS): You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the

search, select “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1-800-397-4209, at 301-415-4737, or by email to PDR.Resource@nrc.gov. The ISG, DANU-ISG-2022-05, Chapter 11, “Organization and Human-System Considerations,” is available in ADAMS under Accession No. ML23277A143.

- **NRC’s PDR:** The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1-800-397-4209 or 301-415-4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: James O’Driscoll, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone: 301-415-1325; email: James.O’Driscoll@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The NRC staff anticipates the submission of advanced power-reactor applications within the next few years based on preapplication engagement initiated by several prospective applicants. Because many of these designs are non-LWRs, the NRC staff developed technology-inclusive, risk-informed, performance-based guidance to support the development and review of these non-LWR applications. The guidance will facilitate the development and review of non-LWR applications for construction permits or operating licenses under part 50 of title 10 of the *Code of Federal Regulations* (10 CFR), “Domestic Licensing of Production and Utilization Facilities,” or combined licenses, manufacturing licenses, standard design approval, or design certifications under 10 CFR part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants.” The NRC staff notes it is developing a rule to amend 10 CFR parts 50 and 52 to align reactor licensing processes and incorporate lessons learned from new reactor licensing into the regulations (RIN 3150-A166). This ISG may need to be updated to

conform to changes to 10 CFR parts 50 and 52, if any, adopted through that rulemaking. Further, as of the date of this final ISG, the NRC staff is developing an optional performance-based, technology-inclusive regulatory framework for licensing nuclear power plants designated as 10 CFR part 53 (RIN 3150-AK31). The NRC intends to revise this guidance as a part of the ongoing rulemaking for 10 CFR part 53.

To standardize the development of content of a non-LWR application, the NRC staff 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 non-LWR application for review under 10 CFR part 50 or 10 CFR part 52, and which the NRC staff would update, as appropriate, pending the issuance of the 10 CFR part 50 and 10 CFR part 52 rulemaking as previously mentioned in this notice, or if the Commission issues a final 10 CFR part 53 rule. As a result, the 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.

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 safety analysis report that describe the fundamental safety functions of the design and document the safety analysis of the facility using the LMP-based approach. The LMP-based approach is described in Regulatory Guide (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," (ADAMS Accession No. ML20091L698).

The ARCAP ISG titled "Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications – Roadmap" (ARCAP Roadmap ISG) was developed to provide a general overview of the information that should be included in a non-LWR application. The ARCAP Roadmap ISG also provides a review roadmap for the NRC

staff with the principal purpose of ensuring consistency, quality, and uniformity of NRC staff reviews. The ARCAP Roadmap ISG includes references to eight other ARCAP ISGs and a TICAP RG that are the subject of separate *Federal Register* notices (FRNs) notifying the public of the issuance of these guidance documents. Information regarding the eight other ARCAP ISGs and the TICAP RG can be found in the table at the end of the “Discussion” section.

II. Discussion

The ARCAP ISG titled, Chapter 11, “Organization and Human-System Considerations,” that is the subject of this FRN, was developed because the current application and review guidance related to organization and human-systems interface considerations is directly applicable only to light water reactors and may not fully (or efficiently) identify the information to be included in a technology-inclusive, risk-informed, and performance-based application or provide a review approach for such an application.

The table in this notice provides the document description, ADAMS accession number, and, if appropriate, the docket identification number.

| Document Description | ADAMS Accession No. | Regulations.gov Docket ID No. |
|--|----------------------------|--------------------------------------|
| Interim Staff Guidance DANU-ISG-2022-01. “Advanced Reactor Content of Application Project, ‘Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications – Roadmap.’” | ML23277A139 | NRC-2022-0074 |
| Interim Staff Guidance DANU-ISG-2022-02, “Advanced Reactor Content of Application Project Chapter 2, ‘Site Information.’” | ML23277A140 | NRC-2022-0075 |
| Interim Staff Guidance DANU-ISG-2022-03, “Advanced Reactor Content of Application Project Chapter 9, ‘Control of Routine Plant Radioactive Effluents, Plant Contamination and Solid Waste.’” | ML23277A141 | NRC-2022-0076 |
| Interim Staff Guidance DANU-ISG-2022-04, “Advanced Reactor Content of Application Project Chapter 10, ‘Control of Occupational Dose.’” | ML23277A142 | NRC-2022-0077 |
| Interim Staff Guidance DANU-ISG-2022-05, “Advanced Reactor Content of Application Project Chapter 11, ‘Organization and Human-System Considerations.’” | ML23277A143 | NRC-2022-0078 |

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| Interim Staff Guidance DANU-ISG-2022-06, “Advanced Reactor Content of Application Project Chapter 12, ‘Post-manufacturing and construction Inspection, Testing, and Analysis Program.’” | ML23277A144 | NRC-2022-0079 |
| Interim Staff Guidance DANU-ISG-2022-07, “Advanced Reactor Content of Application Project, ‘Risk-Informed Inservice Inspection/Inservice Testing Programs for Non-LWRs.’” | ML23277A145 | NRC-2022-0080 |
| Interim Staff Guidance DANU-ISG-2022-08, “Advanced Reactor Content of Application Project, ‘Risk-Informed Technical Specifications.’” | ML23277A146 | NRC-2022-0081 |
| Interim Staff Guidance DANU-ISG-2022-09, “Advanced Reactor Content of Application Project, ‘Risk-Informed Performance-Based Fire Protection Program (for Operations).’” | ML23277A147 | NRC-2022-0082 |
| RG 1.253, Revision 0, “Guidance for a Technology-Inclusive Content of Application Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors.” | ML23269A222 | NRC-2022-0073 |
| Regulatory Analysis for ARCAP ISGs | ML23093A099 | NRC-2022-0074 |
| Review of Advanced Reactor Content of Application Project/Technology-Inclusive Content of Application Project Guidance | ML23348A182 | NRC-2022-0074 |
| Response to the Advisory Committee on Reactor Safeguards Letter, “Review of Advanced Reactor Content of Application Project/Technology-Inclusive Content of Application Project Guidance” | ML24024A025 | NRC-2022-0074 |

III. Additional Information

During the 711th meeting of the Advisory Committee on Reactor Safeguards (ACRS), December 6-7, 2023, the ACRS, the NRC staff, and representatives of other stakeholders discussed guidance documents related to the ARCAP and the TICAP. On December 20, 2023, the ACRS issued a report documenting its review of these guidance documents (ADAMS Accession No. ML23348A182). The conclusions and recommendations in the ACRS report apply to all the ARCAP and TICAP guidance documents. In its December 2023 report, the ACRS recommended changes to DANU-ISG-2022-05. As set forth in its letter dated March 18, 2024 (ADAMS Accession No. ML24024A025) in which the NRC staff responded to the ACRS report, the NRC staff considered the ACRS recommendations and, for the reasons stated in the staff letter,

determined that changes to DANU-ISG-2022-05 were unnecessary.

Draft DANU-ISG-2022-05, Chapter 11, “Organization and Human-System Considerations,” was published in the *Federal Register* for public comment on May 25, 2023, (88 FR 33928) with a 45-day comment period. Subsequently, the comment period was extended by 30 days as noted in the *Federal Register* dated June 28, 2023 (88 FR 41992). The NRC staff received twelve public comments from stakeholders. The NRC staff’s evaluation and resolution of the public comments can be found in a document located in ADAMS under Accession No. ML23277A152.

IV. Congressional Review Act

DANU-ISG-2022-05, Chapter 11, “Organization and Human-System Considerations,” 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.

V. Backfitting, Forward Fitting, and Issue Finality

DANU-ISG-2022-05 does not constitute backfitting as defined in 10 CFR 50.109, “Backfitting,” and as described in Management Directive (MD) 8.4, “Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests”; does not constitute forward fitting as that term is defined and described in MD 8.4; and does not affect the issue finality of any approval issued under 10 CFR part 52. The guidance would not apply to any current licensees or applicants or existing or requested approvals under 10 CFR part 52, and therefore its issuance cannot be a backfit or forward fit or affect issue finality. Further, as explained in DANU-ISG-2022-05, applicants and licensees would not be required to comply with the positions set forth in DANU-ISG-2022-05.

Dated: March 28, 2024.

For the Nuclear Regulatory Commission.

Steven T. Lynch,

Chief,

Advanced Reactor Policy Branch,

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Office of Nuclear Reactor Regulation.

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