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

DANU-ISG-2022-08

Advanced Reactor Content of Application Project

“Risk-Informed Technical Specifications”

Interim Staff Guidance

March 2024

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ADAMS Accession No.: Package – ML23277A105; ISG – ML23277A146; Enclosure – ML23277A155; FRN –ML23277A232; CRA Summary – ML23277A272

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INTERIM STAFF GUIDANCE

ADVANCED REACTOR CONTENT OF APPLICATION PROJECT

"RISK-INFORMED TECHNICAL SPECIFICATIONS"

DANU-ISG-2022-08

PURPOSE

The U.S. Nuclear Regulatory Commission (NRC or Commission) staff is providing this interim staff guidance (ISG) for two reasons. First, this ISG provides guidance on the contents of applications to an applicant submitting a risk-informed, performance-based application for a construction permit (CP) or operating license (OL) under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities" (Ref. 1), or for a combined license (COL), a manufacturing license (ML), or a design certification (DC) under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants" (Ref. 2), for a nonlight-water reactor (non-LWR). The application guidance found in this ISG supports the development of the portion of a non-LWR application associated with an applicant's technical specifications (TS).[1] Second, this ISG provides guidance to NRC staff on how to review such an application.

As of the date of this ISG, the NRC is developing a rule to amend 10 CFR Parts 50 and 52 (RIN 3150-AI66). The NRC staff notes this guidance 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 ISG, the NRC is developing an optional performance-based, technology-inclusive regulatory framework for licensing nuclear power plants designated as 10 CFR Part 53, "Licensing and Regulation of Advanced Nuclear Reactors," (RIN 3150-AK31). After promulgation of those regulations, the NRC staff anticipates that this guidance will be updated and incorporated into the NRC's Regulatory Guide (RG) series or a NUREG series document to address content of application considerations specific to the licensing processes in this document.

BACKGROUND

This ISG is based on the advanced reactor content of application project (ARCAP), whose purpose is to develop technology-inclusive, risk-informed, and performance-based application guidance. The ARCAP is broader than, and encompasses, the industry-led technology-inclusive content of application project (TICAP). The guidance in this ISG supplements the guidance found in Division of Advanced Reactors and Non-power Production and Utilization Facilities (DANU)-ISG-2022-01, "Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications – Roadmap," issued in March 2024 (Ref. 3), which provides a roadmap for developing all portions of an application. The guidance in this ISG is limited to the portion of

[1] The NRC is issuing this ISG to describe methods that are acceptable to the NRC staff for implementing specific parts of the agency's regulations, to explain techniques that the NRC staff uses in evaluating specific issues or postulated events, and to describe information that the NRC staff needs in its review of applications for permits and licenses. The guidance in this ISG that pertains to applicants is not NRC regulations and compliance with it is not required. Methods and solutions that differ from those set forth in this ISG are acceptable if supported by a basis for the issuance or continuance of a permit or license by the Commission.

non-LWR application associated with the development of technical specifications for the nuclear reactor plant applicant and the NRC staff review of that portion of the application.

RATIONALE

The current application guidance related to technical specifications is directly applicable only to light water reactors (LWRs) and may not fully identify the information to be included in a non-LWR application or efficiently provide a technology-inclusive, risk-informed, and performance-based review approach for non-LWR technologies. This ISG serves as the non-LWR application guidance for technical specifications. This ISG provides both applicant content of application and NRC staff review guidance.

APPLICABILITY

This ISG is applicable to applicants for non-LWR[2] permits and licenses that submit risk-informed, performance-based applications for CPs or OLs under 10 CFR Part 50 or for COLs, DCs, or MLs under 10 CFR Part 52. This ISG is also applicable to the NRC staff reviewers of these applications.

PAPERWORK REDUCTION ACT

This ISG provides voluntary guidance for implementing the mandatory information collections in 10 CFR Parts 50 and 52 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et. seq.). These information collections were approved by the Office of Management and Budget (OMB), approval numbers 3150-0011 and 3150-0151. Send comments regarding this information collection to the FOIA, Library, and Information Collections Branch (T6-A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555 0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150-0011 and 3150-0151), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street, NW Washington, DC 20503.

PUBLIC PROTECTION NOTIFICATION

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

GUIDANCE

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

[2] An applicant desiring to use this ISG for a light water reactor application should contact the NRC staff to hold pre-application discussions on its proposed approach.

> 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 10 CFR 50.36, "Technical specifications," the Commission established its regulatory requirements related to the content of TS. In doing this, the Commission emphasized matters related to the prevention of accidents and the mitigation of accident consequences; the Commission noted that applicants were expected to incorporate into their TS "those items that are directly related to maintaining the integrity of the physical barriers designed to contain radioactivity."[3]

According to 10 CFR 50.36, TS for operating nuclear power reactors are required to include items in the following categories: (1) safety limits and limiting safety system settings (LSSSs), (2) limiting conditions for operation (LCOs), (3) surveillance requirements, (4) design features, and (5) administrative controls.

In its "Final Policy Statement on Technical Specification Improvements for Nuclear Power Reactors," dated July 22, 1993 (Ref. 5), the Commission stated that it—

> [e]xpects that licensees, in preparing their Technical Specification related submittals, will utilize any plant-specific PSA [probabilistic safety assessment] or risk survey and any available literature on risk insights and PSAs…. Similarly, the NRC staff will also employ risk insights and PSAs in evaluating Technical Specifications related submittals. Further, as a part of the Commission's ongoing program of improving Technical Specifications, it will continue to consider methods to make better use of risk and reliability information for defining future generic Technical Specification requirements.

This ISG describes methods acceptable to the NRC staff for an applicant to prepare proposed TS using a risk-informed evaluation process, such as the process 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," issued June 2020 (Ref. 6). For risk-informed application that does not use the RG 1.233 methodology, an applicant should discuss with the NRC staff in preapplication interactions how their TS approach differs from that proposed in this ISG. This ISG also includes guidance for the NRC staff to review risk-informed TS.

Application Guidance

RG 1.233 provides the NRC staff's guidance on using a technology-inclusive, risk-informed, and performance-based methodology to inform the licensing basis and content of applications for non-LWRs, including, but not limited to, molten salt reactors, high-temperature gas-cooled reactors, and a variety of fast reactors at different thermal capacities. This RG may be used by non-LWR applicants applying for permits, licenses, certifications, and approvals under 10 CFR Part 50 and 10 CFR Part 52. RG 1.233 endorses Nuclear Energy Institute (NEI) 18-04,

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[3] The Commission adopted its current approach to § 50.36, ''Technical Specifications,'' which implements section 182a. of the Atomic Energy Act on December 17, 1968 (33 FR 18610). The Commission first promulgated § 50.36 in 1962 (27 FR 5492), but the rule took a different approach than the 1968 amendment and currently employed in the regulations.

"Risk-Informed Performance-Based Technology Inclusive Guidance for Non-Light Water Reactor Licensing Basis Development," Revision 1, issued August 2019 (Ref. 7), as one acceptable method for non-LWR designers to use when carrying out these activities and preparing their applications. The methodology in NEI 18-04 provides a process by which the content of applications will permit understanding of the system designs and their relationship to safety evaluations for a variety of non-LWR designs.[4] Figure 1 is taken from NEI 18-04, Revision 1, and illustrates the concepts used to classify safety-related structures, systems, and components (SSCs), risk-significant SSCs, and safety-significant SSCs.

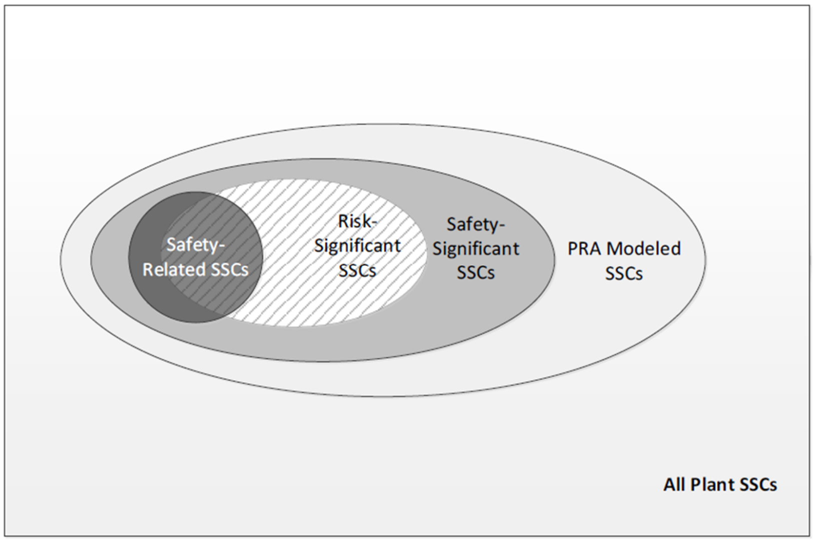

Figure 1 - Definition of Safety Related, Risk Significant, and Safety Significant Structures, Systems and Components from NEI 18-04, Revision 1

NEI 18-04 states that the safety classification for an SSC requires that an assessment be performed of the risk significance of SSCs and the licensing-basis events (LBEs). The assessment should describe the probabilistic risk assessment (PRA) safety functions (PSFs)[5] of the SSCs credited in the prevention and mitigation of events. Information from the PRA is used as input to the selection of reliability targets and performance requirements[6] for SSCs that set the stage for the selection of special treatment requirements. NEI 18-04, Task 16, "Specify Special Treatment Requirements for SR [Safety-Related] and NSRST [Non-Safety-Related with

[4] As noted in NEI 18-04, the plant on which the TSs are based includes the collection of site, buildings, radionuclide sources, and SSCs seeking a single design certification or one or more operating licenses under the LMP framework. The plant may include a single reactor unit or more than one reactor modules as well as non-reactor radionuclide sources

[5] According to NEI 18-04, PSFs are reactor design-specific SSC functions modeled in a PRA that serve to prevent or mitigate a release of radioactive material or to protect one or more barriers to release. They are a broader set of safety functions than those defined in NEI 18-04 by the term "required safety function (RSF)," which only applies to safety functions performed by safety-related SSCs.

[6] Performance "requirements," as referenced in NEI 18-04, should be understood as recommendations that the NRC staff considers adequate to satisfy portions of NRC regulatory requirements but that are not the only acceptable methods of compliance.

Special Treatment] SSCs," states the following:

> All safety-significant SSCs that are distributed between SR and NSRST are subject to special treatment requirements. These requirements always include specific performance requirements to provide adequate assurance that the SSCs will be capable of performing their PSFs with significant margins and with appropriate degrees of reliability. These include numerical targets for SSC reliability and availability, design margins for performance of the PSFs, and monitoring of performance against these targets with appropriate corrective actions when targets are not fully realized.

NEI 18-04 specifies special treatments, including TS, to address programmatic defense-in-depth (DID) attributes. Considerations specified in NEI 18-04 involving TS include the following:

- Are all risk-significant LBE LCOs reflected in TS?
- Are allowable outage (LCO action completion) times in TS consistent with assumed functional reliability levels for risk-significant LBEs?
- Are the TS for risk-significant SSCs consistent with achieving the necessary safety function outcomes for the risk-significant LBEs?

RG 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis" (Ref. 8), describes a general approach to developing risk-informed regulatory applications for licensing basis changes and discusses specific topics common to risk-informed regulatory applications. RG 1.177, "Plant-Specific, Risk-Informed Decision-making: Technical Specifications" (Ref. 9) also supports this ISG. While RG 1.177 focuses on methods acceptable to the NRC staff for assessing the use of risk analysis of proposed changes to TS, its guidance is also useful in evaluating certain aspects of initial TS development.

In 10 CFR 50.34(a)(5), the NRC requires an applicant for a CP under 10 CFR Part 50 to include, in the preliminary safety analysis report, "an identification and justification for the selection of those variables, conditions, or other items which are determined as the result of preliminary safety analysis and evaluation to be probable subjects of technical specifications for the facility, with special attention given to those items which may significantly influence the final design." As an option, a CP applicant may propose preliminary TS and include them in the preliminary safety analysis report or in a separate application document. Under 10 CFR 52.47(a)(11), a DC application must include proposed generic technical specifications,[7] as required by 10 CFR 50.36(a)(2), which should be derived from the analyses and evaluations included in the proposed DC FSAR.

At the CP, DC, or ML application stage, some numerical values, graphs, and other data are not as complete as necessary for plant operation because determination of specific numerical values is pending future decisions by the OL or COL applicant on selection and procurement of hardware after issuance of the CP, DC, or ML. A DC application may describe COL action items related to the generic technical specifications to be denoted by square brackets in the proposed

[7] For DCs, the TS required under 10 CFR 52.47(a)(11) that have been incorporated by reference in the DC rulemaking Appendices A, B, C, D, E, F, and G of 10 CFR Part 52 are referred to as "generic technical specifications."

generic technical specifications and associated bases with appropriate guidance to COL applicants for completing COL action items. At the OL or COL application stage, as-procured or site-specific information (denoted by brackets in the reference DC (i.e., generic design control document (DCD)) or ML TS) must be replaced with the final operational information, which must be in conformance with the final safety analysis report. For a COL application referencing a DC, this information is in the plant-specific DCD.

Content for a CP application is limited to whether the values reasonably agree with the anticipated operational capability of the plant. For preliminary safety analysis report (PSAR) technical specifications, information which may significantly influence the final design should be provided in preliminary LCOs, a preliminary list of the types of surveillance tests being considered, and a preliminary description of important “design features.” The PSAR technical specifications need not include surveillance requirement frequencies or administrative controls although inclusion of such information, if available, would assist the staff in understanding the design. Furthermore, the PSAR should include a preliminary Technical Specification Bases document to summarize the information in the PSAR on which the preliminary technical specifications are based.

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For a DC application, the applicant should provide generic TSs to confirm that they will preserve the validity of the plant design, as described in the DCD, by ensuring that the plant will be operated (1) within the required conditions bounded by the DCD and (2) with operable equipment that is essential to prevent postulated design-basis events or mitigate their consequences. For an ML application, the applicant should propose TSs in a similar manner to those provided in a DC application. For an OL or COL application, the applicant should propose TSs to ensure compliance with the applicable acceptance criteria below. For COL applications referencing a DC or ML, the applicant should also ensure that bracketed information is replaced with site specific information or final operational information, as applicable, in conformance with the final safety analysis report for the application.

Acceptance criteria are based on meeting the relevant requirements of the following Commission regulations:

- 10 CFR 50.34(a)(5)
- 10 CFR 50.34(b)(6)(vi)
- 10 CFR 50.36
- 10 CFR 50.36a, “Technical specifications on effluents from nuclear power reactors”
- 10 CFR 52.47(a)(11)
- 10 CFR 52.79(a)(30)
- 10 CFR 52.157(f)(18)

Contents of Technical Specifications

In 10 CFR 50.36, the NRC requires proposed TS for nuclear reactors to include the following:

(1) 10 CFR 50.36(c)(1)(i)(A) safety limits—Safety limits apply to important process variables necessary for an appropriate level of protection for the integrity of certain physical barriers that guard against the uncontrolled release of radioactive material.

(2) 10 CFR 50.36(c)(1)(ii)(A) Limiting safety system settings (LSSSs)—LSSSs are for automatic protective devices affecting variables with significant safety functions.

(3) 10 CFR 50.36(c)(2) Limiting conditions for operation (LCOs)—LCOs are the lowest functional capability or performance levels of equipment required for safe operation of the facility. When an LCO of a nuclear reactor is not met, the licensee must shut down the reactor or follow any remedial action permitted by the TS until the condition can be met. A TS LCO of a nuclear reactor must be established for each item meeting one or more of the following 10 CFR 50.36(c)(2)(ii) criteria:

a. Criterion 1. Installed instrumentation that is used to detect, and indicate in the control room, a significant abnormal degradation of the reactor coolant pressure boundary.

b. Criterion 2. A process variable, design feature, or operating restriction that is an initial condition of a design-basis accident (DBA) or transient analysis that either assumes the failure of or presents a challenge to the integrity of a fission product barrier.

c. Criterion 3. An SSC that is part of the primary success path and which functions or actuates to mitigate a DBA or transient that either assumes the failure of or presents a challenge to the integrity of a fission product barrier.

d. Criterion 4. An SSC that operating experience or PRA has shown to be significant to public health and safety.

(4) 10 CFR 50.36(c)(3) surveillance requirements—Surveillance requirements are requirements relating to test, calibration, or inspection to assure that the necessary quality of systems and components is maintained, that facility operation will be within safety limits, and that the LCOs will be met.

(5) 10 CFR 50.36(c)(4) design features—Design features include aspects of the facility (e.g., construction materials and geometric arrangements) not covered in the categories described above that, if altered or modified, would have a significant effect on safety.

(6) 10 CFR 50.36(c)(5) administrative controls—Administrative controls are provisions for organization and management, procedures, recordkeeping, review and audit, and reporting necessary to assure safe operation of the facility.

Also, 10 CFR 50.36 requires that a summary statement of the bases or reasons for the TS, other than those covering administrative controls, be included in the application but shall not become part of the TS. In addition, the TS should be consistent with the applicant's principal design criteria (PDC) in that all safety-related features specified in the PDC should be addressed in the TS.

To provide suitable guidance on risk-informed TS for advanced reactors, this ISG correlates the text in 10 CFR 50.36 with the analysis and outputs of the risk-informed approach described in NEI 18-04 and with the PDC applicable to the design (A risk-informed application not using NEI 18-04 may need to consider an approach that is modified in comparison to the corresponding guidance in NEI 18-04.). In some cases, this correlation may be inconsistent with the regulation text as applied to a particular design, in which case the applicant should include an exemption request as part of its application.

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<u>Safety Limits</u>

In the definition of safety limits in 10 CFR 50.36(c)(1)(i)(A), the text "important process variables" that are necessary to "reasonably protect the integrity of certain of the physical barriers that guard against the uncontrolled release of radioactivity" is compatible with NEI 18-04 analysis and outputs. The NEI 18-04 process provides insights on identification of barriers that guard against the release of radioactivity. Specifically, NEI 18-04 calls for the identification of reactor design-specific functional criteria that are necessary and sufficient to meet RSFs that maintain the consequences of one or more design-basis events (DBEs) or the frequency of one or more high-consequence beyond-design-basis events (BDBEs) inside the Frequency-Consequence (F-C) Target.[8] These RSFs include protecting barrier integrity to guard against release of radioactivity, therefore, the safety limit definition need not be changed.

Hence, for applications using the NEI 18-04 approach,[9] the TS should address safety limits as follows:

10 CFR 50.36(c)(1)(i)(A)	**TS Content Based on Corresponding NEI 18-04 Output**
Safety limits for nuclear reactors are limits upon important process variables that are found to be necessary to reasonably protect the integrity of certain of the physical barriers that guard against the uncontrolled release of radioactivity.	**Safety limits** for nuclear reactors are limits upon important process variables that are found to be necessary to reasonably protect the integrity of certain of the physical barriers that guard against the uncontrolled release of radioactivity.

Limiting Safety System Settings

In the definition of LSSSs in 10 CFR 50.36(c)(1)(ii)(A), the phrase "settings for automatic protective devices related to those variables having significant safety functions" can be correlated to NEI 18-04 outputs related to reactor design-specific functional criteria that are necessary and sufficient to meet RSFs.[10] RSFs prevent or mitigate a release of radioactive material or protect one or more barriers to maintain the consequences of one or more DBEs or the frequency of one or more high-consequence BDBEs inside the F-C Target. The discussion above on 10 CFR 50.36(c)(1)(i)(A) and safety limits contains more information.

An applicant may propose an administrative control TS to maintain a setpoint control program to satisfy 10 CFR 50.36(c)(1)(ii)(A) in lieu of specifying explicit values for the LSSSs in the TS.

[8] An applicant using a risk-informed process but not NEI 18-04 should discuss its alternative risk-informed process with the NRC staff in pre-application interactions.
[9] See footnote 8.
[10] Reactor design-specific functional criteria that are necessary and sufficient to meet the RSFs are defined as required functional design criteria in NEI 18-04.

Hence, for applications using the NEI 18-04 approach,[11] the TS should address LSSSs as follows:

10 CFR 50.36(c)(1)(ii)(A)	TS Content Based on Corresponding NEI 18-04 Output
Limiting safety system settings for nuclear reactors are settings for automatic protective devices related to those variables having significant safety functions. Where a limiting safety system setting is specified for a variable on which a safety limit has been placed, the setting must be so chosen that automatic protective action will correct the abnormal situation before a safety limit is exceeded.	**Limiting safety system settings** are settings for automatic protective devices related to those variables that prevent or mitigate a release of radioactive material or protect one or more barriers to maintain the consequences of one or more DBEs or the frequency of one or more high-consequence BDBEs inside the F-C Target. Where a limiting safety system setting is specified for a variable on which a safety limit has been placed, the setting must be so chosen that automatic protective action will correct the abnormal situation before a safety limit is exceeded.

<u>Limiting Conditions for Operation</u>

The NEI 18-04 process specifies that the TS for risk-significant SSCs be consistent with achieving the necessary safety function outcomes for the risk-significant LBEs. Additionally, the programmatic DID process should determine allowable outage (LCO action completion) times for applicable SSCs in TS such that they are consistent with assumed functional reliability levels for risk-significant LBEs. The NEI 18-04 process refines the fundamental safety functions applicable to all reactors (controlling heat generation, controlling heat removal, and retaining radionuclides) as necessary into reactor-technology-specific safety functions (i.e., RSFs). The RSFs provide the foundation for analyzing reactor-technology-specific SSCs selected to perform each function. LCOs should be specified for SSCs that (1) perform an RSF needed to mitigate the consequences of DBEs to within the F-C Target, (2) mitigate DBAs that only rely on the SR SSCs to meet the dose criteria of 10 CFR 50.34(a)(1)(ii)(D) or 52.79(a)(1)(vi), (3) maintain the frequency of one or more high-consequence BDBEs inside the F-C Target, or (4) perform risk-significant functions. Structures and physical barriers that are necessary to protect any SR SSCs in performing their RSFs in response to any design-basis external event are also classified as SR and should be addressed in an LCO. The discussion below on each specific 10 CFR 50.36(c)(2)(ii) LCO Criterion contains further information.

<u>Section 50.36(c)(2)(ii)(A)-(C) (LCO Criteria 1 through 3)</u>

LCO Criterion 1 applies to installed instrumentation that is used to detect a significant abnormal degradation of the reactor coolant pressure boundary. Criterion 2 applies to a process variable, design feature, or operating restriction that is an initial condition of a DBA or transient analysis that either assumes the failure of or presents a challenge to the integrity of a fission product barrier. Criterion 3 pertains to SSCs that are part of the primary success path and that function or actuate to mitigate a DBA or transient that either assumes the failure of or presents a

[11] See footnote 8.

challenge to the integrity of a fission product barrier.

The 10 CFR 50.36 text for these three criteria cannot be directly correlated to outputs for an advanced reactor using the NEI 18-04 process. Because each of these criteria involves challenges to the integrity of a fission product barrier, the RSFs are the NEI 18-04 process outputs that correlate to these criteria (as discussed above under Safety Limits). Since NEI 18-04 calls for SR SSCs to perform RSFs, LCO Criteria 1 through 3 should be defined for an advanced reactor in terms of SR SSCs. In accordance with NEI 18-04, SR SSCs are selected by the designer from the SSCs that are available to perform the RSFs to mitigate the consequences of DBEs to within the LBE F-C Target and to mitigate DBAs that only rely on the SR SSCs to meet the dose criteria of 10 CFR 50.34(a)(1)(ii)(D) or 52.79(a)(1)(vi) using conservative assumptions. Note that SR SSCs are also relied on to perform the RSFs to prevent the frequency of BDBEs with consequences greater than the 10 CFR 50.34 or 52.79 dose criteria from increasing into the DBE region and beyond the F-C Target. The discussion of LCO Criterion 4 below covers this latter function.

Hence, for applications using the NEI 18-04 approach,[12] the TS should address LCO Criteria 1 through 3 as follows:

10 CFR 50.36(c)(2)	TS Content Based on Corresponding NEI 18-04 Output
Limiting conditions for operation are the lowest functional capability or performance levels of equipment required for safe operation of the facility.	**Limiting conditions for operation** are the lowest functional capability or performance levels of equipment required for safe operation of the facility.
Criterion 1. Installed instrumentation that is used to detect, and indicate in the control room, a significant abnormal degradation of the reactor coolant pressure boundary.	**Criterion 1**. Installed instrumentation that is used to detect, and indicate where necessary, a significant abnormal degradation of barriers necessary to maintain the release of radioactive materials from the plant to within the DBE F-C Target or to mitigate DBAs that only rely on the SR SSCs to meet the dose criteria of 10 CFR 50.34 or identical criteria in 10 CFR Part 52 (i.e., 10 CFR 52.47(a)(11), 10 CFR 52.79(a)(30), and 10 CFR 52.158(f)(18).
Criterion 2. A process variable, design feature, or operating restriction that is an initial condition of a design basis accident or transient analysis that either assumes the failure of or presents a challenge to the integrity of a fission product barrier.	**Criterion 2**. A process variable, design feature, or operating restriction that is an initial condition of an anticipated operational occurrence (AOO) or DBE and is necessary to maintain consequences to within the F-C Target or is necessary for a SR SSC to mitigate a DBA to meet the dose criteria of 10 CFR 50.34 or identical criteria in 10 CFR Part 52.
Criterion 3. A structure, system, or component that is part of the primary success path and which functions or actuates to mitigate a design basis accident or transient	**Criterion 3**. An SSC that is part of the primary success path and that performs an RSF to mitigate the consequences of DBEs to within the F-C Target or to mitigate DBAs

[12] See footnote 8.

10 CFR 50.36(c)(2)	TS Content Based on Corresponding NEI 18-04 Output
that either assumes the failure of or presents a challenge to the integrity of a fission product barrier.	that only rely on the SR SSC to meet the dose criteria of 10 CFR 50.34 or identical criteria in 10 CFR Part 52.

LCO Criterion 4

Criterion 4 relates to SSCs that the PRA shows to be significant to public health and safety.[13] In correlating this text to the NEI 18-04 process, it is necessary to understand the term "significant to public health and safety." In the supplementary information provided in the NRC's 1995 revision to 10 CFR 50.36 (Volume 60 of the *Federal Register* (FR), page 36953 (60 FR 36953 (July 19, 1995))) (which codified the "Final Commission Policy Statement on Technical Specification Improvements for Nuclear Power Reactors," dated July 22, 1993), the Commission described Criterion 4 as follows:

> Criterion 4 is intended to capture those constraints that probabilistic risk assessment or operating experience show to be significant to public health and safety, consistent with the Commission's PRA Policies. The level of significance either would need to be such that it justified including the constraints in the technical specifications to ensure adequate protection of the public health and safety *or that the addition of such constraints provides substantial additional protection to the public health and safety*.

60 FR at 36955-56 (emphasis added). The Commission also discussed the application of Criterion 4 in the context of relocation of TS to licensee-controlled documents as follows:

> [With respect to relocating items from existing technical specifications which do not meet the first three criteria,] [i]f a technical specification provision does not meet any of the first three criteria, and if the current PRA knowledge or operating experience *does not identify the structure, system, or component as risk significant*, the NRC staff will not preclude relocating such technical specifications.

Id. (emphasis added). The NEI 18-04 process uses PRA as one input to identify RSFs that are tied to public health and safety through the F-C Target. The NEI 18-04 process identifies two groups of SSCs that are tied to public safety but are not addressed by Criteria 1 through 3 above:

(1) SR SSCs that perform RSFs to prevent the frequency of BDBEs with consequences greater than the 10 CFR 50.34 dose criteria (or the identical criteria in Part 52) from increasing into the DBE region and beyond the F-C Target.

(2) Non-SR SSCs that are relied on to perform risk-significant functions (i.e., NSRST SSCs). Risk-significant SSCs are those which perform functions that prevent or mitigate any LBE from exceeding the F-C Target or make significant contributions to the cumulative risk metrics selected for evaluating the total risk from all analyzed LBEs. The cumulative risk limit criteria address the situation in which an SSC may contribute to two or more

[13] In assessing Criterion 4, operating experience is not likely available for some aspects of non-LWRs.

LBEs that collectively may be risk significant even though each individual LBE may not be significant. All LBEs within the scope of the supporting PRA should be included when evaluating these cumulative risk limits. In such cases, the reliability and availability of such SSCs may need to be controlled to manage the total integrated risk over all the LBEs. Section 4.2.2 of NEI 18-04 further clarifies risk-significant SSCs.

Hence, for applications using the NEI 18-04 approach,[14] the TS should address LCO Criterion 4 as follows:

10 CFR 50.36(c)(2)	**TS Content Based on Corresponding NEI 18-04 Output**
Criterion 4. A structure, system, or component which operating experience or probabilistic risk assessment has shown to be significant to public health and safety.	**Criterion 4**. (a) An SR SSC relied on to perform a RSF to prevent the frequency of a BDBE with consequences greater than the 10 CFR 50.34 dose criteria or the identical criteria in Part 52 from increasing into the DBE region and beyond the F-C Target. (b) An NSRST SSC relied on to perform a risk-significant function. These risk-significant SSCs are those that perform functions that prevent or mitigate any LBE from exceeding the F-C Target or make significant contributions to the cumulative risk metrics selected for evaluating the total risk from all analyzed LBEs.

Note that Criterion 4 for the corresponding NEI 18-04 output does not include NSRST SSCs that only perform functions credited for DID.[15]

<u>Limiting Condition for Operation Format</u>

Applicants may determine the format for LCOs. However, in determining the format, the staff recommends that applicants use the format utilized in the Standard Technical Specifications (STS) [for example, NUREG-1431, Volume 1, Revision 5.0, “Standard Technical Specifications – Westinghouse Plants,” (Ref. 10)] since the STS format has been developed jointly by the NRC and the industry over the last 30 years to be logical, concise, and clear for nuclear power plant operators. In addition, applicants may also be informed by the format used for non-power utilization facilities (e.g., SHINE technical specifications at ADAMS No. ML19211C135). At a minimum, each LCO should include the following:

(1) Describe the operable condition.

[14] See Footnote 8.

[15] As noted in NEI 18-04, and in the “Technical Requirements Manual” section of DANU-ISG-2022-01, availability controls outside of TSs similar to those approved for some SSCs of passive light water reactors under the regulatory treatment of non-safety systems (RTNSS) approach could be appropriate for the NSRST SSCs that only perform functions credited for DID.

(2) Include the mode(s) of applicability (i.e., the operating modes during which the LCO must be met).

(3) Explain the actions that must be taken when the limiting condition is not met, including any required action and the associated completion time. For determining various LCO completion times, the risk impact should be evaluated using the PRA and DID analysis. RG 1.177, Regulatory Position 2.3.4, contains additional guidance in this area. RG 1.177, position 2.3.4, references the risk metrics of core damage frequency and large early release frequency based on LWRs as factors in determining completion times. Advanced reactor applicants should use other risk metrics, such as those described in NEI 18-04, for determining completion times. NEI 18-04, Section 3.3.5, *Selection of Risk Metrics for PRA Model Development,* describes several possible risk metrics (that are different from the core damage frequency (CDF) and Large Early Release Frequency (LERF) metrics developed for LWRs). These metrics could be used by an applicant to develop LCO completion times. Applicants should discuss their proposed risk metrics for developing LCO completion times with NRC staff during preapplication discussions.

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(4) Include a set of associated surveillance requirements.

<u>Surveillance Requirements</u>

In 10 CFR 50.36(c)(3), the NRC requires that TS include surveillance requirements. Surveillance requirements are requirements relating to test, calibration, or inspection to assure that the necessary quality of systems and components is maintained, that facility operation will be within safety limits, and that the LCOs will be met.

Surveillance requirements should be determined through the development of the “Special Treatments Considered for Programmatic DID” task in the NEI 18-04 process. The PRA, supplemented with additional data and analysis where necessary should provide a basis for determining the specified TS surveillance frequency. RG 1.177, Regulatory Position 2.3.4, offers additional guidance in this area.

Applicants may propose to locate time-based surveillance frequencies to a licensee-controlled program, called the surveillance frequency control program (SFCP), and add the SFCP to the administrative controls section of TS. In a letter dated September 19, 2007, (Ref. 11) NRC staff has accepted NEI 04-10, “Risk-Informed Method for Control of Surveillance Frequencies,” Revision 1 (Ref. 12) as an acceptable approach to developing the SFCP. As stated in NEI 04-10, the SFCP is not applicable to surveillance frequencies that are event driven, controlled by an existing program, or condition based.

<u>Design Features</u>

In 10 CFR 50.36(c)(4), the NRC requires that TS describe design features, specifically those features of the facility such as materials of construction and geometric arrangements that, if altered or modified, would have a significant effect on safety and are not covered in categories described in 10 CFR 50.36(c)(1), (2), and (3). Section 50.36(c)(4) covers design features such as the natural circulation configuration of a structure or the material composition of a graphite matrix. This requirement can be correlated to the design features that provide the RSFs determined via the NEI 18-04 process.

Administrative Controls

In 10 CFR 50.36(c)(5), the NRC requires that TS include administrative controls. Administrative controls are the provisions relating to organization and management, procedures, record keeping, review and audit, and reporting necessary to assure operation of the facility in a safe manner. Administrative controls can be derived, in part, from the development of special treatment and the “Application of Programmatic DID Guidelines” described in the NEI 18-04 process. In addition to controls identified for special treatment, the TS administrative controls should include requirements that address the following areas:[16]

(1) a description of important responsibilities within the operations organizational structure

(2) a description of onsite and offsite organizations, including lines of authority and facility staffing

(3) a description of facility staff qualifications

(4) a requirement that procedures be established, implemented, and maintained covering the following:

- a. applicable procedures recommended in RG 1.33, “Quality Assurance Program Requirements (Operation)” (Ref. 13)
- b. emergency operating activities
- c. quality assurance for effluent and environmental monitoring
- d. fire protection program implementation
- e. all programs specified below

(5) a requirement that programs and reports necessary to operate the plant in a safe manner be established, implemented, and maintained, including but not limited to the following:

- a. safety function determination program (SFDP)—This program ensures loss of safety function is detected and appropriate actions taken.[17] The SFDP description should specify that the program includes the following:
    - i. provisions for cross train checks to ensure a loss of the capability to perform the safety function credited or relied upon in the accident analysis does not go undetected

[16] NUREG-1431, Volume 1, Revision 5.0, “Standard Technical Specifications—Westinghouse Plants,” issued September 2021 (Ref. 10), Section 5.5, “Administrative Controls—Programs and Manuals,” provides a better understanding of these terms. Note that, depending on the specific reactor technology, additional programs may need to be included in the section of the TS on administrative controls.

[17] The SFDP identifies where a loss of safety function exists. If a loss of safety function is determined to exist by this program, the appropriate conditions and required actions of the LCO in which the loss of safety function exists are required to be entered.

ii. provisions for ensuring the plant is maintained in a safe condition if a loss of function condition exists

iii. provisions to ensure that an inoperable support system's completion time is not inappropriately extended as a result of multiple support system inoperabilities

iv. other appropriate limitations and remedial or compensatory actions

b. setpoint control program (if used)—This program should establish the requirements for ensuring that setpoints for automatic protective devices are initially within, and remain within, the bounds of the applicable safety analyses; provide a means for processing changes to instrumentation setpoints; and identify setpoint methodologies to ensure instrumentation will function as credited.

c. surveillance frequency control program (if used)—This program provides controls for surveillance frequencies and should ensure that surveillance requirements specified in the TS are performed at intervals sufficient to assure that the necessary quality of systems and components is maintained, that facility operation will be maintained within safety limits, and that the associated LCOs are met.

d. program that addresses high radiation area controls as provided in 10 CFR 20.1601(c) (Ref. 14)

e. Offsite Dose Calculation manual and radiological effluent control program

f. annual radiological environmental operating report and radioactive effluent release report covering the operation of the plant during the previous calendar year

g. core operating limits report (or similar report for reactor cores that do not have a traditional stationary reactor core) that defines core operating limits before each reload cycle or before any remaining portion of a reload cycle

h. TS bases control program that addresses provisions to ensure that the bases are maintained consistent with the final safety analysis report

i. Reactor Coolant System (RCS) Pressure and Temperature Limits Report that addresses RCS pressure and temperature limits for heat up, cooldown, low temperature operation, criticality, and hydrostatic testing, Low Temperature Overpressure Protection (LTOP) arming, and power operated relief valves (PORVs) lift settings, if applicable to the specific design, as well as heatup and cooldown rates

<u>Technical Specification Bases</u>

Applicants should provide a TS bases document that provides the technical basis for all safety limits, LCOs, surveillance requirements, and design feature TS. This document should provide a basis for the operability and availability controls, including allowable outage times and surveillance testing intervals that are included in the TS. The TS bases should conform to the applicable analysis described in the safety analysis report. This document will be licensee controlled and updated according to the requirements in 10 CFR 50.59, “Changes, tests and experiments,” or a similar change process under 10 CFR Part 52.

As an alternative, an applicant may provide the appropriate TS bases within the scope of the safety analysis report and alleviate the need to provide a separate TS bases document. If this approach is used, the safety analysis report bases should clearly address each TS, other than those covering administrative controls.

Technical Specification Use and Application Information

In addition to the information specified above, the TS should address the following:[18]

(1) A description of the Use and Application rules for the technical specifications, including as a minimum:

   a. Include a set of definitions for terms used in the TS.

   b. Define the plant modes used in determining LCO applicability.

   c. Describe logical connectors (if used). Logical connectors are used in TS to discriminate between, and yet connect, discrete conditions, required actions, completion times, surveillances, and frequencies. Logical connectors that have been generally used in TS include “AND” and “OR.” The physical arrangement of these connectors constitutes logical conventions with specific meanings.

   d. Describe the completion time conventions used in the TS and guidance for their use.

(2) A set of Surveillance Requirements that establish general requirements applicable to all specifications and apply at all times unless otherwise stated. For example, a general Surveillance Requirement includes one that states that failure to meet an individual surveillance requirement means that the associated LCO is not met.

(3) A set of LCOs that establish the general requirements applicable to all specifications and apply at all times, except when otherwise stated. For example, an LCO providing the requirements for what actions the licensee must take when an individual LCO is not met and the associated Required Actions are also not met.

Staff Review Guidance **- Acceptance Criteria**

The NRC reviewer should ensure that the application includes information sufficient to allow the NRC reviewer to understand the proposed technical specifications. The reviewer should be able to reach a safety finding and address the topic[s] in the NRC’s safety evaluation report if the application includes the following information:

[18] NUREG-1431, Volume 1, Revision 5.0, Section 1.0, “Use and Application,” and Section 3.0, “Limiting Condition for Operation Applicability,” and “Surveillance Requirement Applicability,” provide a better understanding of the items set forth below.

(1) For a CP application, in accordance with 10 CFR 50.34, those variables, conditions, or other items identified through preliminary safety analysis as probable subjects for plant-specific TS and justification for their selection, with special attention to items that could significantly influence the final design.

(2) Justification that the TS preserve the validity of the plant design, as described in the safety analysis, by ensuring that the plant will be operated (1) within the conditions bounded by the safety analysis, (2) with operable equipment that is essential to prevent accidents and to mitigate the consequences of accidents postulated in the safety analysis, and (3) with key design features consistent with those described in the safety analysis report.

(3) An LCO for each aspect of the design that meets the criteria in 10 CFR 50.36(c)(2)(ii) as correlated to the corresponding outputs of a risk-informed analysis.

(4) TS that reflect all risk-significant SSCs for preventing or mitigating LBEs.

(5) Completion times for LCO actions in TS that conform to functional reliability levels for risk-significant LBEs credited or relied upon in the FSAR.

(6) TS for risk-significant SSCs sufficient to assure achievement of the necessary safety function outcomes for the risk-significant LBEs.

(7) Surveillance requirements sufficient to assure that the necessary quality of systems and components is maintained, that facility operation will be within safety limits, and that the LCOs will be met. Specifically, the reviewer should confirm that the surveillance requirements include specific performance requirements and frequencies to provide adequate assurance that the TS SSCs will do the following:

a. Be capable of performing their RSFs with significant margins and with appropriate degrees of reliability.

b. Provide additional confidence that the risk-significant SSCs will perform as intended.

(8) TS that meet the regulations in 10 CFR 50.36 unless the departure is explicitly related to a requested exemption.

(9) TS consistent with the DID philosophy as described in NEI 18-04. (RG 1.177, Regulatory Position 2.2.1, contains additional guidance.)

(10) TS that maintain sufficient safety margins. (RG 1.177, Regulatory Position 2.2.2, contains additional guidance.)

(11) Administrative controls adequate to address organization and management, procedures, recordkeeping, review and audit, and reporting necessary to assure operation of the facility in a safe manner.

(12) TS bases consistent with the analysis described in the safety analysis report and justify the specified variables, conditions, or other limitations as those required by

10 CFR 50.36 (as modified above) to be LCO subjects.

(13) TS that address all of the safety-related features specified in the PDC.

(14) TS that meet the requirements of 10 CFR 50.36a in that the technical specifications include TS that require (a) operating procedures for the control of effluents and (b) annual reports of the quantity of principal radionuclides released to unrestricted areas in both gaseous and liquid effluents.

IMPLEMENTATION

The NRC staff will use the information discussed in this ISG to review non-LWR applications for CPs, OLs, COLs, DCs, and MLs under 10 CFR Part 50 and 10 CFR Part 52. The NRC staff intends to incorporate this guidance in updated form in the RG or NUREG series, as appropriate.

BACKFITTING AND ISSUE FINALITY DISCUSSION

The NRC staff may use DANU-ISG-2022-08 as a reference in its regulatory processes, such as licensing, inspection, or enforcement. However, the NRC staff does not intend to use the guidance in this ISG to support NRC staff actions in a manner that would constitute backfitting as that term is defined in 10 CFR 50.109, “Backfitting,” and as described in NRC Management Directive 8.4, “Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests” (Ref. 15), nor does the NRC staff intend to use the guidance to affect the issue finality of an approval under 10 CFR Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants.” The staff also does not intend to use the guidance to support NRC staff actions in a manner that constitutes forward fitting as that term is defined and described in Management Directive 8.4. If a licensee believes that the NRC is using this ISG in a manner inconsistent with the discussion in this paragraph, then the licensee may file a backfitting or forward fitting appeal with the NRC in accordance with the process in Management Directive 8.4.

CONGRESSIONAL REVIEW ACT

DANU-ISG-2022-08 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

The NRC staff will transition the information and guidance in this ISG into the RG or NUREG series, as appropriate. Following the transition of all pertinent information and guidance in this document into the RG or NUREG series, or other appropriate guidance, this ISG will be closed.

ACRONYMS

ARCAP	advanced reactor content of application project
BDBE	beyond-design-basis event
CDF	core damage frequency
CFR	*Code of Federal Regulations*
COL	combined license

CP	construction permit
DBA	design-basis accident
DBE	design-basis event
DC	design certification
DCD	design control document
DID	defense in depth
ISG	interim staff guidance
LBE	licensing-basis event
LCO	limiting condition for operation
LERF	large early release frequency
LSSS	limiting safety system setting
LWR	light-water reactor
ML	manufacturing license
NEI	Nuclear Energy Institute
NRC	U.S. Nuclear Regulatory Commission
NSRST	non-safety-related with special treatment
OL	operating license
PDC	principal design criterion/a
PRA	probabilistic risk assessment
PSA	probabilistic safety assessment
PSF	probabilistic risk assessment safety function
RG	regulatory guide
RSF	required safety function
SFCP	surveillance frequency control program
SFDP	safety function determination program
SR	safety related
SSC	structure, system, and component
TICAP	technology-inclusive content of application project
TS	technical specification/s

REFERENCES

1. Title 10 of the *Code of Federal Regulations* (10 CFR), Part 50, "Domestic Licensing of Production and Utilization Facilities."

2. 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants."

3. U.S. Nuclear Regulatory Commission, DANU-ISG-2022-01, "Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications - Roadmap," March 2024 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML23277A139).

4. U.S. Nuclear Regulatory Commission, NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," Chapter 16, "Technical Specifications."

5. U.S. Nuclear Regulatory Commission, “Final Policy Statement on Technical Specifications Improvements for Nuclear Power Reactors,” 58 FR 44071, July 22, 1993 (Available at https://www.nrc.gov/reading-rm/doc-collections/commission/policy/58fr39132.pdf).

6. U.S. Nuclear Regulatory Commission, Regulatory Guide 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,” Washington, DC

7. Nuclear Energy Institute (NEI) 18-04, “Risk-Informed Performance-Based Technology Inclusive Guidance for Non-Light Water Reactor Licensing Basis Development,” Revision 1, August 2019 (ADAMS Accession No. ML19241A472).

8. U.S. Nuclear Regulatory Commission, Regulatory Guide 1.174, “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis,” Washington, DC

9. U.S. Nuclear Regulatory Commission, Regulatory Guide 1.177, “Plant-Specific, Risk-Informed Decisionmaking: Technical Specifications,” Washington, DC

10. U.S. Nuclear Regulatory Commission, NUREG-1431, “Standard Technical Specifications—Westinghouse Plants,” Volume 1, “Specifications,” Revision 5.0, September 2021 (ADAMS Accession No. ML21259A155).

11. U.S. Nuclear Regulatory Commission, “Final Safety Evaluation for Nuclear Energy Institute (NEI) Topical Report (TR) 04-10, Revision 1, “Risk-Informed Technical Specification Initiative 5B, “Risk -Informed Method for Control of Surveillance Frequencies,” September 19, 2007 (ADAMS Accession No. ML072570267)

12. NEI 04-10, ““Risk-Informed Method for Control of Surveillance Frequencies,” Revision 1, April 2007 (ADAMS Accession No. ML071360456).

13. U.S. Nuclear Regulatory Commission, Regulatory Guide 1.33, “Quality Assurance Program Requirements (Operation),” Washington, DC

14. 10 CFR Part 20, “Standards for Protection against Radiation.”

15. U.S. Nuclear Regulatory Commission, Management Directive 8.4, “Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests.”