

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 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.



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

Advanced Reactor Content of Application

“Risk-Informed Technical Specifications”

Interim Staff Guidance

May X, 2021

**DANU [XX]-ISG-[YYYY-##]
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Application
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Specifications”
Interim Staff Guidance**

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INTERIM STAFF GUIDANCE
ADVANCED REACTOR CONTENT OF APPLICATION
“RISK-INFORMED TECHNICAL SPECIFICATIONS”

DANU-ISG-YYYY-##

PURPOSE

The U.S. Nuclear Regulatory Commission (NRC, or Commission) staff is providing this interim staff guidance (ISG) to facilitate the review of advanced reactor content of application guidance that is used to support reviews of non-light water reactors (non-LWRs), stationary micro reactors, and small modular LWRs submitting risk-informed applications 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”; or for a combined license (COL), manufacturing license (ML), or design certification (DC) under 10 CFR Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants”; . The guidance found in this ISG supports the development of the portion of an advanced reactor application associated with an applicant’s “Risk-informed Technical Specifications.”

It is anticipated that this guidance will be updated to use for reviews of advanced nuclear reactor license and permit applications submitted under 10 CFR Part 53, “Licensing and Regulation of Advanced Nuclear Reactors,” once the content of that regulation is developed.

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 found in this ISG supplements the guidance found in DANU-ISG-YYYY-##, “Advanced Reactor Content of Application Guidance,” which provides a roadmap for developing all portions of an application. The guidance in this ISG is limited to the portion of an advanced reactor application associated with the development of risk-informed technical specifications for the nuclear reactor plant applicant.

The Part 53 regulation is under development, and as such, the guidance found in this document is subject to change based on the outcome of this rulemaking. As the 10 CFR Part 53 requirements are developed, this ISG guidance will be supplemented, as necessary, to provide guidance for developing technical specifications 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 the regulatory infrastructure to support the licensing of advanced nuclear reactors. The term “advanced nuclear reactor,” for purposes of this rulemaking, means “a nuclear fission or fusion reactor with significant improvements compared to commercial nuclear reactors operating on the date of enactment of the Energy Act of 2020” or under construction as of January 2019. This rulemaking would revise the NRC's regulations by adding a risk-informed, technology-inclusive regulatory framework for advanced nuclear reactors, in response to a growing interest in possible licensing and deployment of advanced nuclear reactors and the related requirements

of the Nuclear Energy Innovation and Modernization Act (NEIMA; Public Law 115-439), as amended by the Energy Act of 2020. Key documents related to the Part 53 rulemaking, including preliminary proposed rule language and stakeholder comments, can be found at Regulations.gov under Docket ID NRC-2019-0062.

RATIONALE

Note – this section will be updated with additional stakeholder interactions – expected during the monthly ARCAP meetings.

APPLICABILITY

This ISG is applicable to applicants for non-LWRs, stationary micro reactors, and small modular LWRs submitting risk-informed applications for a CP or OL under 10 CFR Part 50 or for a COL, DC, or ML under 10 CFR Part 52. Once the content of Part 53 is developed and this ISG is updated where necessary, this guidance will also apply to applicants for a power reactor CP, OL, DC, and ML under 10 CFR Part 53.

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 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 technical specifications (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.”

Pursuant 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, (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, the Commission stated that it:

...expects that licensees, in preparing their Technical Specification related submittals, will utilize any plant-specific PSA 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 assessing proposed TS by applicants 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." For risk-informed applications that do not use the RG 1.233 methodology, applicants should discuss with the NRC staff in pre-application interactions how their TS approach differs from that proposed in this ISG.

RG 1.233 provides the 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. This RG endorses Nuclear Energy Institute (NEI) 18-04, Revision 1, "Risk-Informed Performance-Based Technology Inclusive Guidance for Non-Light Water Reactor Licensing Basis Development," 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.

NEI 18-04 states that structure, system, and component (SSC) safety classification requires an assessment of the risk significance of SSCs and the licensing-basis events (LBEs) that describes the probabilistic risk assessment (PRA) safety functions (PSFs)¹ of the SSCs in the prevention and mitigation of events. Information from the probabilistic risk assessment (PRA) is used as input to the selection of reliability targets and performance requirements for SSCs that set the stage for the selection of special treatment requirements. NEI 18-04, Task 16, "Specify Special Treatment Requirements for SR and NSRST SSCs," states the following:

All safety-significant SSCs that are distributed between SR [safety-related] and NSRST [nonsafety-related with special treatment] 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:

- Are all risk-significant LBE LCOs reflected in TS?

¹ Per NEI 18-04, PSFs are reactor design specific SSC functions modeled in a PRA that serve to prevent and/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 by the term "required safety function (RSF)," which only applies to safety functions performed by safety-related SSCs.

- 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," describes a general approach to risk-informed regulatory decision-making and discusses specific topics common to all risk-informed regulatory applications. Additional guidance that supports this ISG can be found in RG 1.177, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Technical Specifications." While RG 1.177 is focused on methods acceptable to the NRC staff for assessing the use of risk analysis of proposed changes to TS, its guidance is useful in evaluating certain aspects of initial TS development.

An applicant for a CP under 10 CFR Part 50 is required by 10 CFR 50.34(a)(5) to include in the preliminary safety analysis report (PSAR) "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 PSAR or in a separate application document.

At the DC or ML application stage, numerical values, graphs, and other data are not as complete as necessary for plant operation because of the preliminary nature of the plant design or 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 DC or ML. The review of information provided in this area is limited to whether the values reasonably agree with the expected operational capability of the plant, as stated in the generic design control document (DCD) or ML. At the OL or COL application stage, site-specific information (denoted by brackets in a DC or ML) in the reference (i.e., generic DCD) TS must be replaced with the final operational information, which must be in conformance with the final safety analysis report (also referred to as the plant-specific DCD in COL applications).

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

- 10 CFR 50.34(b)(6)(vi),
- 10 CFR 50.36,
- 10 CFR 50.36a,
- 10 CFR 52.47(a)(11),
- 10 CFR 52.79(a)(30), and
- 10 CFR 52.157(f)(18)

Contents of Technical Specifications

10 CFR 50.36 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) 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 which 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 affect 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 significant effects on safety.
6. 10 CFR 50.36(c)(5) Administrative Controls - Administrative controls are provisions for organization and management, procedures, record-keeping, review and audit, and reporting necessary to assure safe operation of the facility.

10 CFR 50.36 also 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.

To evaluate the acceptability of risk-informed TS for advanced reactors, this ISG correlates the text in the 10 CFR 50.36 regulation with the analysis and outputs of the risk-informed approach described in NEI 18-04. (This corresponding NEI 18-04 text may need to be modified to be applicable to risk-informed approaches not using NEI 18-04.) Note the staff is looking for stakeholder interaction on the following italicized sentence: *In some cases, this correlation can be interpreted as a significant departure from the regulation text, and the staff will need to consider whether exemptions are necessary.*

Safety Limits

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 comparable to NEI 18-04 outputs that address performance of required safety functions (RSFs). The NEI 18-04 process requires the identification of reactor design-specific functional criteria that are necessary and sufficient to meet RSFs that are required to be fulfilled to maintain the consequence of one or more design-basis events (DBEs) or the frequency of one or more high-consequence beyond-design-basis events (BDBEs) inside the F-C Target.² The reference to RSFs in the advanced reactor TS safety limits definition is an appropriate correlation to the 10 CFR 50.36 rule text.

Hence, for applications using the NEI-18-04 approach³, 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 are limits upon important process variables that are found to be necessary for required safety functions that are necessary to prevent and/or mitigate a release of radioactive material or protect one or more 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. RSFs are required to be fulfilled to prevent and/or mitigate a release of radioactive material or to 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. Also see discussion under 10 CFR 50.36(c)(1)(i)(A) regarding safety limits.

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.

² The F-C Target is a target line on a frequency-consequence chart, defined in NEI 18-04, that is used to evaluate the risk significance of LBEs and to evaluate risk margins that contribute to evidence of adequate DID. For applications using a risk-informed process but not using the NEI 18-04 F-C Target as the risk criteria, applicants should discuss their risk criteria with NRC staff in pre-application interactions. Once there is general agreement on the values, those criteria could then be substituted for the references to the NEI 18-04 F-C Target in this ISG.

³ This corresponding NEI 18-04 text may need to be modified to be applicable to risk-informed approaches not using NEI 18-04.

Hence, for applications using the NEI 18-04 approach⁴, the TS should address LSSs as follows:

| 10 CFR 50.36(c)(1)(ii)(A) | TS Content Based on Corresponding NEI 18-04 Output |
|--|--|
| <p>Limiting safety system settings for nuclear reactors are settings for automatic protective devices related to those variables having significant safety functions.</p> | <p>Limiting safety system settings are settings for automatic protective devices related to those variables that prevent and/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.</p> |

Limiting Conditions for Operation

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 identifies RSFs that refine the fundamental safety functions applicable to all reactors (controlling reactivity, removing heat from the reactor and waste stores, and limiting the release of radioactive materials) as necessary into reactor-technology-specific safety functions. The RSFs provide the foundation for 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 LBE F-C Target, (2) mitigate DBAs that only rely on the SR SSCs to meet the dose limits of 10 CFR 50.34, (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. See discussion below regarding the specific 10 CFR 50.36(c)(2)(ii) Criteria 1 through 4.

LCO Criteria 1 through 3

LCO Criterion 1 applies to 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 the primary success path and which function or actuate to mitigate a DBA or transient that either assumes the failure of or presents a 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 involve challenges to the integrity of a fission product barrier, the appropriate correlation of these criteria to the NEI 18-04 process outputs is the RSF (as discussed above under Safety Limits). Since

⁴ See Footnote 3.

SR SSCs are required to perform RSFs, Criteria 1 through 3 should be defined for an advanced reactor in terms of SR SSCs. Per 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 limits of 10 CFR 50.34 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 dose limits from increasing into the DBE region and beyond the F-C Target. This latter function is addressed in Criterion 4, below.

Hence, for applications using the NEI 18-04 approach⁵, 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 limits of 10 CFR 50.34. |
| 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 necessary to maintain consequences to within the F-C Target or to mitigate DBAs that only rely on the SR SSCs to meet the dose limits of 10 CFR 50.34. |
| 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 that either assumes the failure of or presents a challenge to the integrity of a fission product barrier. | Criterion 3. A structure, system, or component that is part of the primary success path and which performs a RSF to mitigate the consequences of DBEs to within the F-C Target or to mitigate DBAs that only rely on the SR SSCs to meet the dose limits of 10 CFR 50.34. |

⁵ See Footnote 3.

LCO Criterion 4

Criterion 4 relates to SSCs that were shown in the PRA to be significant to public health and safety. 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 the 10 CFR 50.36 TS regulation [60 FR 36953] (which codified the “Final Commission Policy Statement on Technical Specification Improvements for Nuclear Power Reactors”), the Commission describes 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 [emphasis added] ...

[With respect to relocating items from existing technical specifications which do not meet the first three criteria]... If 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 [emphasis added], the NRC staff will not preclude relocating such technical specifications.”

The NEI 18-04 process uses PRA as one input to identify RSFs which 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 limits from increasing into the DBE region and beyond the F-C Target.
2. Non-safety-related SSCs relied on to perform risk-significant functions (i.e., NSRST SSCs). 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. The cumulative risk limit criteria are provided to address the situation in which an SSC may contribute to two or more LBEs that collectively may be risk-significant even though the individual LBEs 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 risks over all the LBEs. Refer to Section 4.2.2 of NEI 18-04 for a further clarification of risk-significant SSCs.

Hence, for applications using the NEI-18-04 approach⁶, the TS should address LCO Criterion 4, as follows:

⁶ See Footnote 3.

| 10 CFR 50.36(c)(2) | TS Content Based on Corresponding NEI 18-04 Output |
|---|--|
| <p>Criterion 4. A structure, system, or component which operating experience or probabilistic risk assessment has shown to be significant to public health and safety.</p> | <p>Criterion 4. (a) The group of SR SSCs relied on to perform RSFs to prevent the frequency of BDBEs with consequences greater than the 10 CFR 50.34 dose limits from increasing into the DBE region and beyond the F-C Target.</p> <p>(b) The group of NSRST SSCs relied on to perform risk-significant functions. 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.</p> |

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

LCO Format

Applicants may determine the format for LCOs. However, at a minimum, each LCO should include the following information:

1. A description of the operable condition,
2. The mode applicability,
3. The actions that must be taken when the operable condition is not met including any required action and the associated completion time. For determining various LCO completion times (CTs) the risk impact should be evaluated using the PRA and DID analysis. Refer to RG 1.177, Regulatory Position 2.3.4 for additional guidance in this area. It is noted that this RG position references the risk metrics of core damage frequency (CDF) and large early release frequency (LERF) based on LWRs as factors in determining CTs. Advanced reactor applicants should use other risk metrics, such as those described in NEI 18-04 for determining CTs.
4. A set of associated surveillance requirements.

Surveillance Requirements

10 CFR 50.36(c)(3) 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 LMP process. The PRA and DID

adequacy evaluations should provide a basis for determining the specified TS surveillance frequency. Refer to RG 1.177, Regulatory Position 2.3.4 for 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. The SFCP should not include surveillance frequencies that are event-driven, controlled by an existing program, or condition-based.

Design Features

10 CFR 50.36(c)(4) requires that TS include a description of design features. Design features to be included are those features of the facility such as materials of construction and geometric arrangements, which, if altered or modified, would have a significant effect on safety and are not covered in categories described in paragraphs 50.36(c)(1), (2), and (3) (e.g., the natural circulation configuration of a structure or the material composition of a graphite matrix). This requirement can again be correlated to the NEI 18-04 outputs for RSFs.

Administrative Controls

10 CFR 50.36(c)(5) 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 treatments 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:⁷

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 are established, implemented, and maintained covering:
 - a. applicable procedures recommended in Regulatory Guide 1.33, “Quality Assurance Program Requirements (Operation),”
 - b. emergency operating activities,
 - c. quality assurance for effluent and environmental monitoring,
 - d. fire protection program implementation, and
 - e. all programs specified below.
5. A requirement that the following programs/reports be established, implemented, and maintained:

⁷ To better understand these items, refer to NUREG-1431, Volume 1, Revision 4.0, “Standard Technical Specifications – Westinghouse Plants,” Section 5.5, “Administrative Controls – Programs and Manuals.” Note that depending on the specific reactor technology, additional programs may need to be included in the Administrative Controls section of the TS.

- a. A Safety Function Determination Program (SFDP) - This program ensures loss of safety function is detected and appropriate actions taken.⁸ The SFDP description should specify that the program addresses the following:
 - i. Provisions for cross train checks to ensure a loss of the capability to perform the safety function assumed in the accident analysis does not go undetected,
 - 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 supported system's Completion Time is not inappropriately extended as a result of multiple support system inoperabilities, and
 - iv. Other appropriate limitations and remedial or compensatory actions.
- b. A Setpoint Control Program - This program should establish the requirements for ensuring that setpoints for automatic protective devices are initially within and remain within the assumptions of the applicable safety analyses, provides a means for processing changes to instrumentation setpoints, and identifies setpoint methodologies to ensure instrumentation will function as required.
- c. A Surveillance Frequency Control Program (if used) - This program provides controls for Surveillance Frequencies. The program should ensure that surveillance requirements specified in the TS are performed at intervals sufficient to assure the associated LCO is met.
- d. A program that addresses high radiation area controls as provided in paragraph 20.1601(c) of 10 CFR Part 20.
- e. An Offsite Dose Calculation Manual (ODCM) and Radiological Effluent Control Program.
- f. An Annual Radiological Environmental Operating Report and Radioactive Effluent Release Report covering the operation of the plant during the previous calendar year.
- g. A Core Operating Limits Report (or similar report for reactor cores that do not have a traditional reactor core) that defines core operating limits prior to each reload cycle, or prior to any remaining portion of a reload cycle.
- h. A TS Bases Control Program that addresses provisions to ensure that the Bases are maintained consistent with the final safety analysis report.

TS Bases

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/availability controls, including allowable outage times and surveillance testing intervals that are included in the TS. The TS Bases should be consistent with the

⁸ 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.

applicable analysis described in the safety analysis report. This document will be licensee-controlled and updated pursuant to the requirements in 10 CFR 50.59, or similar change process under 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.

Other Miscellaneous Information

In addition to the information specified above, the TS should also include information that addresses the following:⁹

1. A set of definitions for terms used in the TS.
2. A definition of plant modes used in determining LCO applicability.
3. A description of 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.
4. A description of the Completion Time conventions used in the TS and guidance for their use.
5. A description of the proper use and application of surveillance requirement frequency requirements. An understanding of the correct application of the specified frequency is necessary for compliance with the surveillance requirements.
6. An explanation of LCO applicability and what actions are necessary when an LCO is not met and associated Required Actions are not met.

Acceptance Criteria

1. 10 CFR 50.34 requires applicants at the CP stage to justify the selection of those variables, conditions, or other items identified through preliminary safety analysis as probable subjects for plant-specific TS. Special attention should be given to items that could influence the final design significantly.
2. The TS preserve the validity of the plant design, as described in the safety analysis, by ensuring that the plant will be operated (a) within the required conditions bounded by the safety analysis, and (b) with operable equipment that is essential to prevent accidents and to mitigate the consequences of accidents postulated in the safety analysis.
3. An LCO is established for each aspect of the design that met the criteria in 10 CFR 50.36(c)(2)(ii) as correlated to the corresponding outputs of a risk-informed analysis.
4. All risk-significant LBE LCOs are reflected in plant operating TS.

⁹ To better understand these items, refer to NUREG-1431, Volume 1, Revision 4.0, “Standard Technical Specifications – Westinghouse Plants,” Section 1.0, “Use and Application.”

5. Allowable Outage (LCO Action Completion) Times in TS are consistent with assumed functional reliability levels for risk-significant LBEs.
6. The TS for risk-significant SSCs are consistent with achieving the necessary safety function outcomes for the risk-significant LBEs.
7. The surveillance requirements include specific performance requirements and frequencies to provide adequate assurance that the TS SSCs:
 - a. will be capable of performing their RSFs with significant margins and with appropriate degrees of reliability, and
 - b. will provide additional confidence that the risk-significant SSCs will perform as intended.
8. The TS meet 10 CFR 50.36 regulations unless the deviation is explicitly related to a requested exemption.
9. The TS are consistent with the DID philosophy as described in NEI 18-04. Refer to RG 1.177, Regulatory Position 2.2.1 for additional guidance.
10. The TS maintain sufficient safety margins. Refer to RG 1.177, Regulatory Position 2.2.2 for additional guidance.
11. Administrative controls are 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 are consistent with analysis described in the safety analysis report.

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.

APPENDIX

- A. Resolution of Public Comments

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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

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