

U.S. NUCLEAR REGULATORY COMMISSION

DRAFT REGULATORY GUIDE DG-1351



Proposed New Regulatory Guide

{This draft is provided for discussion at the October 17, 2019, Public Meeting with the Nuclear Energy Institute.}

DISPOSITIONING OF TECHNICAL SPECIFICATIONS THAT ARE INSUFFICIENT TO ENSURE PLANT SAFETY

A. INTRODUCTION

Purpose

This regulatory guide (RG) describes methods and procedures that are acceptable to the U.S. Nuclear Regulatory Commission (NRC) staff for the dispositioning of technical specifications (TS) that are insufficient to ensure power plant safety. This RG endorses, with exceptions and clarifications, the Nuclear Energy Institute (NEI) guidance in NEI 15-03, Revision 2, "Licensee Actions to Address Nonconservative Technical Specifications," issued September 2017 (Ref. 1).

Applicability

This RG applies to all holders of operating licenses for nuclear power reactors issued under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities" (Ref. 2), and all holders of power reactor combined licenses issued under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants" (Ref. 3).

Applicable Regulations

- 10 CFR Part 50 provides regulations for licensing production and utilization facilities.
 - 10 CFR 50.36, "Technical Specifications," establishes the requirements for power reactor TS.
 - 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," establishes quality assurance program requirements.
 - Criterion XVI, "Corrective Action," establishes corrective action requirements for conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances.

This RG is being issued in draft form to involve the public in the development of regulatory guidance in this area. It has not received final staff review or approval and does not represent an NRC final staff position. Public comments are being solicited on this DG and its associated regulatory analysis. Comments should be accompanied by appropriate supporting data. Comments may be submitted through the Federal rulemaking Web site, <http://www.regulations.gov>, by searching for draft regulatory guide DG-1351. Alternatively, comments may be submitted to the Office of Administration, Mailstop TWFN 7A-06M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Program Management, Announcements and Editing Staff. Comments must be submitted by the date indicated in the *Federal Register* notice.

Electronic copies of this DG, previous versions of DGs, and other recently issued guides are available through the NRC's public Web site under the Regulatory Guides document collection of the NRC Library at <http://www.nrc.gov/reading-rm/doc-collections/reg-guides/>. The DG is also available through the NRC's Agencywide Documents Access and Management System (ADAMS) at <http://www.nrc.gov/reading-rm/adams.html>, under Accession No. ML18086A690. The regulatory analysis may be found in ADAMS under Accession No. ML18086A685.

- 10 CFR 50.59, “Changes, Tests and Experiments,” contains requirements for the process by which licensees, under certain conditions, may make changes to their facilities and procedures as described in the final safety analysis report (as updated) without prior NRC approval.
- 10 CFR 50.72, “Immediate Notification Requirements for Operating Nuclear Power Reactors,” and 10 CFR 50.73, “Licensee Event Report System,” establish requirements for the notification of the NRC related to emergencies, ongoing events, licensing bases, potentially generic safety problems, assessing trends and patterns of operational experience, monitoring performance, identifying precursors of more significant events, and providing operational experience to the industry.

Related Guidance

- Administrative Letter (AL) 98-10, “Dispositioning of Technical Specifications That Are Insufficient to Assure Plant Safety,” dated December 29, 1998 (Ref. 4).

Purpose of Regulatory Guides

The NRC issues RGs to describe to the public methods that the staff considers acceptable for use in implementing specific parts of the agency’s regulations, to explain techniques that the staff uses in evaluating specific problems or postulated events, and to provide guidance to applicants. Regulatory guides are not substitutes for regulations and compliance with them is not required. Methods and solutions that differ from those set forth in RGs will be deemed acceptable if they provide a basis for the findings required for the issuance or continuance of a permit or license by the Commission.

Paperwork Reduction Act

This RG provides 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 Information Services 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; e-mail: oir_submission@omb.eop.gov.

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.

B. DISCUSSION

Reason for Issuance

This RG will aid in licensee compliance with the TS requirements in 10 CFR 50.36, the reporting requirements in 10 CFR 50.72 and 10 CFR 50.73, and the quality assurance requirements in Criterion XVI of 10 CFR Part 50, Appendix B. This RG endorses NEI 15-03, Revision 2, with exceptions and clarifications.

Background

10 CFR 50.36 specifies the requirements for power reactor TS:

- 10 CFR 50.36(a) requires applicants for utilization facilities to include a summary statement of the bases or reasons for proposed TS, other than those covering administrative controls, but the bases shall not become part of the TS.
- 10 CFR 50.36(b) requires each license authorizing operation of a utilization facility to include TS, which are to be derived from the analyses and evaluation included in the safety analysis report, and amendments thereto, submitted pursuant to 10 CFR 50.34, “Contents of Applications; Technical Information.”
- The Commission may include such additional TS as the Commission finds appropriate. TS are required to include items in the categories listed in 10 CFR 50.36(c). For this RG, the most relevant categories are the following:
 - *Safety limits, limiting safety system settings, and limiting control settings.*
 - Safety limits for nuclear reactors are limits on important process variables that are found to be necessary to reasonably protect the integrity of certain physical barriers that guard against the uncontrolled release of radioactivity. If any safety limit is exceeded, the reactor must be shut down.
 - Limiting safety system settings for nuclear reactors are settings for automatic protective devices related to those variables that have significant safety functions. When 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. If, during operation, it is determined that the automatic safety system does not function as required, the licensee shall take appropriate action, which may include shutting down the reactor.
 - *Limiting conditions for operation.* Limiting conditions for operation are the lowest functional capability or performance levels of equipment required for the safe operation of the facility. When a limiting condition for operation of a nuclear reactor is not met, the licensee shall shut down the reactor or follow any remedial action the TS permits until the condition can be met.

- *Surveillance requirements.* Surveillance requirements are related to test, calibration, or inspection to assure that the necessary quality of systems and components is maintained, the facility operates within safety limits, and the limiting conditions for operation are met.
- *Design features.* Design features of the facility include materials of construction and geometric arrangements that, if altered or modified, would have a significant effect on safety and are not covered in the categories listed above.
- *Administrative controls.* Administrative controls are the provisions related to organization and management, procedures, recordkeeping, review and audit, and reporting necessary to assure operation of the facility in a safe manner.

Operating licenses for nuclear power reactors are required to include TS. In its final policy statement on TS improvements for nuclear power reactors (Ref. 5), the Commission stated, in part, the following:

The purpose of Technical Specifications is to impose those conditions or limitations upon reactor operation necessary to obviate the possibility of an abnormal situation or event giving rise to an immediate threat to the public health and safety...and establishing on them certain conditions of operation which cannot be changed without prior Commission approval.

Occasionally, licensees have determined that the TS may be insufficient to ensure plant safety. Examples include, but are not limited to, an improper or inadequate TS value, required action, or allowed outage time. When this occurs, in the interim, licensees typically enter the degraded or nonconforming condition into their corrective action program, conduct an evaluation, and, if necessary, institute administrative controls that instruct the operators to maintain a more restrictive value for a particular parameter or to take a more conservative action.

Following the implementation of such administrative controls, most licensees have properly considered reporting under 10 CFR 50.72, 10 CFR 50.73, or both and have promptly submitted a license amendment request to correct the TS. However, some licensees have failed to comply with NRC reporting requirements, significantly delayed submitting a license amendment request to correct the TS, or improperly concluded that a license amendment request was unnecessary if administrative controls are implemented.

On December 29, 1998, the NRC issued AL 98-10 to reiterate the NRC's expectations about the correction of nuclear power reactor TS when they are found to contain nonconservative values or specify incorrect actions. Since the issuance of AL 98-10, both the NRC and industry have identified the need for additional guidance. Based on a suggestion at the 2014 NRC Regulatory Information Conference, NEI developed NEI 15-03 to provide additional guidance on dispositioning TS that are insufficient to ensure plant safety.

Discussion on NEI 16-07 as a Secondary Reference

As noted below in "Documents Discussed in Staff Regulatory Guidance," the NRC does not approve secondary references unless the secondary reference has itself been incorporated by reference into NRC regulations or endorsed by the NRC elsewhere as an acceptable approach for meeting an NRC requirement, subject to any applicable clarifications and/or exceptions. NEI 15-03, Revision 2,

specifically references NEI 16-07, “Improving the Effectiveness of Issue Resolution to Enhance Safety and Efficiency” (Ref. 6).

The NRC staff has not endorsed NEI 16-07 and does not endorse the concept of “condition adverse to regulatory compliance” (CARC). The NRC staff position is that a provision in the TS that is insufficient to ensure plant safety is a degraded or nonconforming condition. Whenever degraded or nonconforming conditions are discovered, Appendix B to 10 CFR Part 50 requires prompt corrective action to correct or resolve the condition. Therefore, corrective action must be taken to address a nonconservative TS (NCTS) in accordance with Criterion XVI of 10 CFR Part 50, Appendix B.

Discussion on Timeliness of Corrective Actions

The NRC introduced guidance on the resolution of degraded and nonconforming conditions in Generic Letter 91-18, Revision 1, “Information to Licensees Regarding NRC Inspection Manual Section on Resolution of Degraded and Nonconforming Conditions,” dated October 8, 1997 (Ref. 7), which stated the following:

In this proposed guidance, the staff stated that implementation of compensatory measures required a 10 CFR 50.59 evaluation with respect to the condition described in the final safety analysis report (FSAR) and that the staff would consider delay to have occurred when a licensee has not implemented corrective action at the first available opportunity (considering need for analysis or parts, or the need to be in cold shutdown to complete the action), in any event not to exceed the next refueling outage.

The NRC also clarified this concept of timeliness in Regulatory Issue Summary (RIS) 2005-20, “Revision to NRC Inspection Manual Part 9900 Technical Guidance, ‘Operability Determinations & Functionality Assessments for Resolution of Degraded or Nonconforming Conditions Adverse to Quality or Safety’” (Ref. 8), and additional revisions to this RIS.

Harmonization with International Standards

The NRC staff did not identify any relevant international standards that provided useful guidance to NRC staff, applicants, or licensees.

Documents Discussed in Staff Regulatory Guidance

This RG endorses the use of one or more codes or standards developed by external organizations, and other third-party guidance documents. These codes, standards and third-party guidance documents may contain references to other codes, standards or third-party guidance documents (“secondary references”). If a secondary reference has itself been incorporated by reference into NRC regulations as a requirement, then licensees and applicants must comply with that standard as set forth in the regulation. If the secondary reference has been endorsed in a RG as an acceptable approach for meeting an NRC requirement, then the standard constitutes a method acceptable to the NRC staff for meeting that regulatory requirement as described in the specific RG. If the secondary reference has neither been incorporated by reference into NRC regulations nor endorsed in a RG, then the secondary reference is neither a legally-binding requirement nor a “generic” NRC approved acceptable approach for meeting an NRC requirement. However, licensees and applicants may consider and use the information in the secondary reference, if appropriately justified, consistent with current regulatory practice, and consistent with applicable NRC requirements.

C. STAFF REGULATORY GUIDANCE

This RG describes methods and procedures that are acceptable to the NRC staff for the dispositioning of TS that are insufficient to ensure plant safety. This RG endorses the guidance in NEI 15-03, Revision 2, subject to the exceptions and clarifications identified in this section.

1. The NRC staff position is that if the TS are insufficient to ensure plant safety, this condition should be dispositioned as an NCTS in accordance with this guidance. Examples include, but are not limited to, improper or inadequate TS value, required action, or allowed outage time. Methods acceptable to the NRC staff for demonstrating that the TS comply with 10 CFR 50.36 are outside the scope of this guidance.
2. NEI 15-03, Section 2, "Purpose"

- a. The NRC staff takes exception to the following statement in Section 2:

This document provides guidance to licensees in addressing an existing technical specification requirement that does not protect the assumptions or conclusions in either Updated Final Safety Analysis Report (UFSAR) or the Technical Specification Bases, referred to herein as a nonconservative technical specification (NCTS).

This statement is not consistent with the Commission's policy on the purpose of TS, because not every assumption or conclusion in the UFSAR or TS bases needs to be protected by a TS requirement. In addition, nonconservative assumptions and incorrect conclusions in the UFSAR or TS bases can result in an NCTS.

- b. Section 2 of NEI 15-03, Revision 2, states, in part, "The reference to 'an existing technical specification requirement' clarifies that the simple absence of a TS requirement is not by itself an NCTS." The NRC staff agrees that the simple absence of a TS requirement is not by itself an NCTS. However, the final resolution of a TS that is insufficient to ensure plant safety may include the addition of TS requirements through the license amendment process.
3. NEI 15-03, Section 3.3, "NCTS Entry into the Corrective Action Process"

NEI 15-03, Section 3.3, references NEI 16-07, which is a secondary reference.

The NRC staff reminds licensees that in accordance with the subsection titled, "Documents Discussed in Staff Regulatory Guidance," in Section B of this RG and as specifically discussed in the subsection in Section B titled, "Discussion on NEI 16-07 as a Secondary Reference," the NRC staff has not endorsed NEI 16-07 and specifically does not endorse the concept of CARC. Therefore, NEI 16-07 does not constitute an NRC-approved acceptable approach for meeting NRC requirements.

4. NEI 15-03, Section 3.6, "Implementation of Final Corrective Action"
- a. The NRC staff provides clarification to the following statement in Section 3.6:

In addressing an NCTS, a licensee must take timely corrective action consistent with its quality assurance program. There is no definition of “timely” in the regulations or other binding requirements. 10 CFR 50, Appendix B, Criterion XVI, “Corrective Action,” refers to prompt identification and correction of conditions adverse to quality, but does not further define “prompt.” Because these terms are undefined, an appropriate timeline for correction must be commensurate with the safety significance of the issue. In determining priority, consideration should be given to the fact that compliance with the operating license would not necessarily assure plant safety. Based on evaluation of licensee efforts to resolve such issues, the NRC has issued non-cited violations to licensees for failure to promptly correct an NCTS.

The NRC staff disagrees with the statement that there are no binding requirements for timely corrective actions. The regulations in Criterion XVI of 10 CFR Part 50, Appendix B, clearly establish a requirement for “prompt” identification and correction of conditions adverse to quality.

The NRC staff clarifies that the concept of timeliness is broader than a risk-informed approach to corrective actions (i.e., “safety significance”). The NRC staff’s review and approval of TS changes through the license amendment process is an important part of its regulatory oversight function. As such, the implementation of the final corrective action for an NCTS should be completed as soon as practicable. Final corrective actions for a TS that is insufficient to ensure plant safety should be resolved at the first available opportunity, typically no later than the end of the next refueling outage. This timeframe is generally sufficient to complete the license amendment process and for the licensee to implement the amendment. However, final corrective actions for some NCTS may require complex analysis or plant modifications that justify a longer timeframe for completion.

D. IMPLEMENTATION

The purpose of this section is to provide information on how applicants and licensees¹ may use this guide and information regarding the NRC's plans for using this RG. In addition, it describes how the NRC staff complies with 10 CFR 50.109, "Backfitting" and any applicable finality provisions in 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants."

Use by Applicants and Licensees

Applicants and licensees may voluntarily² use the guidance in this document to demonstrate compliance with the underlying NRC regulations. Methods or solutions that differ from those described in this RG may be acceptable if they provide sufficient basis and information for the NRC staff to verify that the proposed alternative demonstrates compliance with the appropriate NRC regulations. Current licensees may continue to use guidance the NRC found acceptable for complying with the identified regulations as long as their current licensing basis remains unchanged.

Licensees may use the information in this RG for actions that do not require NRC review and approval such as changes to a facility design under 10 CFR 50.59, "Changes, Tests, and Experiments," provided those changes are not in conflict with the current requirements in the applicable technical specifications. Licensees may use the information in this RG or applicable parts to resolve regulatory or inspection issues.

Use by NRC Staff

The NRC staff does not intend or approve any imposition or backfitting of the guidance in this RG. The NRC staff does not expect any existing licensee to use or commit to using the guidance in this RG, unless the licensee makes a change to its licensing basis. The NRC staff does not expect or plan to request licensees to voluntarily adopt this RG to resolve a generic regulatory issue. The NRC staff does not expect or plan to initiate NRC regulatory action that would require the use of this RG. Examples of such unplanned NRC regulatory actions include issuance of an order requiring the use of the RG, requests for information under 10 CFR 50.54(f) as to whether a licensee intends to commit to use of this RG, generic communication or promulgation of a rule requiring the use of this RG without further backfit consideration.

During regulatory discussions on plant specific operational issues, the staff may discuss with licensees various actions consistent with staff positions in this RG, as one acceptable means of meeting the underlying NRC regulatory requirement. Such discussions would not ordinarily be considered backfitting even if prior versions of this RG are part of the licensing basis of the facility. However, unless this RG is part of the licensing basis for a facility, the staff may not represent to the licensee that the licensee's failure to comply with the positions in this RG constitutes a violation.

If an existing licensee voluntarily seeks a license amendment or change and (1) the NRC staff's consideration of the request involves a regulatory issue directly relevant to this new or revised RG and

¹ In this section, "licensees" refers to licensees of nuclear power plants under 10 CFR Parts 50 and 52; and the term "applicants," refers to applicants for licenses and permits for (or relating to) nuclear power plants under 10 CFR Parts 50 and 52, and applicants for standard design approvals and standard design certifications under 10 CFR Part 52.

² In this section, "voluntary" and "voluntarily" means that the licensee is seeking the action of its own accord, without the force of a legally binding requirement or an NRC representation of further licensing or enforcement action.

(2) the specific subject matter of this RG is an essential consideration in the staff's determination of the acceptability of the licensee's request, then the staff may request that the licensee either follow the guidance in this RG or provide an equivalent alternative process that demonstrates compliance with the underlying NRC regulatory requirements. This is not considered backfitting as defined in 10 CFR 50.109(a)(1) or a violation of any of the issue finality provisions in 10 CFR Part 52.

Additionally, an existing applicant may be required to comply with new rules, orders, or guidance if 10 CFR 50.109(a)(3) applies.

If a licensee believes that the NRC is either using this RG or requesting or requiring the licensee to implement the methods or processes in this RG in a manner inconsistent with the discussion in this Implementation section, then the licensee may file a backfit appeal with the NRC in accordance with the guidance in NRC Management Directive 8.4, "Management of Facility-Specific Backfitting and Information Collection" (Ref. 9), and in NUREG-1409, "Backfitting Guidelines," (Ref. 10).

REFERENCES³

1. Nuclear Energy Institute (NEI), NEI 15-03, Revision 2, "Licensee Actions to Address Nonconservative Technical Specifications," Washington, DC, September 2017 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML17276A642).
2. *U.S. Code of Federal Regulations* (CFR), "Domestic Licensing of Production and Utilization Facilities," Part 50, Chapter 1, Title 10, "Energy."
3. CFR, "Licenses, Certifications and Approvals for Nuclear Power Plants," Part 52, Chapter 1, Title 10, "Energy."
4. U.S. Nuclear Regulatory Commission (NRC), Administrative Letter 98-10, "Dispositioning of Technical Specifications That Are Insufficient to Assure Plant Safety," Washington, DC, December 29, 1998.
5. NRC, "Final Policy Statement on Technical Specifications Improvements for Nuclear Power Reactors," *Federal Register*, 58 FR 39132, July 22, 1993.
6. Nuclear Energy Institute (NEI), NEI 16-07, "Improving the Effectiveness of Issue Resolution to Enhance Safety and Efficiency."⁴
7. NRC, Generic Letter 91-18, Revision 1, "Information to Licensees Regarding NRC Inspection Manual Section on Resolution of Degraded and Nonconforming Conditions," Washington, DC, October 8, 1997.
8. NRC, Regulatory Issue Summary 2005-20, "Revision to NRC Inspection Manual Part 9900 Technical Guidance, 'Operability Determinations & Functionality Assessments for Resolution of Degraded or Nonconforming Conditions Adverse to Quality or Safety,'" Washington, DC.
9. NRC, Management Directive 8.4, "Management of Facility-Specific Backfitting and Information Collection," Washington, DC, October 9, 2013 (ADAMS Accession No. ML12059A460).
10. NRC, NUREG-1409, "Backfitting Guidelines," Washington, DC, July 1990 (ADAMS Accession No. ML032230247).

³ Publicly available NRC published documents are available electronically through the NRC Library on the NRC's public Web site at <http://www.nrc.gov/reading-rm/doc-collections/> and through the NRC's Agencywide Documents Access and Management System (ADAMS) at <http://www.nrc.gov/reading-rm/adams.html>. The documents can also be viewed online or printed for a fee in the NRC's Public Document Room (PDR) at 11555 Rockville Pike, Rockville, MD. For problems with ADAMS, contact the PDR staff at 301-415-4737 or (800) 397-4209; fax (301) 415-3548; or e-mail pdr.resource@nrc.gov.

⁴ Publications from NEI are available at its Web site: <http://www.nei.org/> or by contacting the headquarters at Nuclear Energy Institute, 1776 I Street NW, Washington, DC 20006-3708, Phone: 202-739-800, Fax 202-785-4019.