

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

[NRC-2018-0056]

**Digital Instrumentation and Controls-Interim Staff Guidance-06,
Revision 2, “Licensing Process”**

AGENCY: Nuclear Regulatory Commission.

ACTION: Interim staff guidance; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing Interim Staff Guidance (ISG) Digital Instrumentation and Controls (DI&C)-ISG-06, Revision 2, “Licensing Process.” This ISG defines the licensing process used to support the review of license amendment requests (LARs) associated with safety-related D&IC equipment modifications in operating plants and in new plants once they become operational. This ISG provides guidance for activities performed before a LAR is submitted and for activities performed during LAR review. The NRC staff uses the process described in this ISG to evaluate compliance with NRC regulations.

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

ADDRESSES: Please refer to Docket ID **NRC-2018-0056** when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov> and search for Docket ID **NRC-2018-0056**. Address questions about Docket IDs in Regulations.gov to Krupskaya Castellon; telephone: 301-287-9221; e-mail: Krupskaya.Castellon@nrc.gov. For technical questions, contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.

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

(ADAMS): You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The Digital Instrumentation and Controls-Interim Staff Guidance-06, Rev. 2, is available in ADAMS under Accession No. ML18269A259.

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Joseph Golla, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001; telephone: 301-415-1002, e-mail: Joe.Golla@nrc.gov.

SUPPLEMENTARY INFORMATION

I. Background

The NRC published a notice of the availability of ISG-06, Rev. 2, in the *Federal Register* (83 FR 38731) on August 7, 2018, for a 30-day public comment period. The public comment period closed on September 6, 2018. Public comments on ISG-06, Rev. 2, and the staff responses to the public comments are available under ADAMS Accession No. ML18290A623.

This ISG provides guidance for the NRC staff's review of LARs supporting installation of Digital I&C equipment in accordance with licensing processes defined in the NRC's office instruction LIC-101, "License Amendment Review Procedures." This

ISG identifies information the NRC staff should review for Digital I&C equipment. This ISG provides guidance on when that information should be reviewed.

This ISG is designed to be used with the NRC's topical report review and approval process defined in the NRC's Office of Nuclear Reactor Regulation office instruction LIC-500, "Topical Report Process." Where a licensee references an NRC-approved topical report, the NRC staff should be able to, where appropriate, limit its review to assessing whether the application of the Digital I&C modification falls within the envelope of the topical report approval. This ISG was developed based upon, and is designed to work in concert with, established guidance. As a result, this ISG references other guidance documents for review criteria.

The NRC staff performs evaluations of proposed Digital I&C equipment to ensure equipment will perform required functions. These evaluations use the guidance in the Standard Review Plan, Chapter 7, and other associated guidance. When a licensee seeks to amend its license, the application for amendment must fully describe the changes desired. The application should describe the safety functions of identified in the Final Safety Analysis Report, as updated, and the Digital I&C equipment that performs each function. Additionally, licensees identify those parts of the licensing basis being updated as a result of the proposed change.

The Standard Review Plan, Appendix 7.0-A, and Branch Technical Position 7-14, guide the NRC staff in performing reviews of digital systems in support of safety evaluations. For reviews using the Alternate Process as defined in the ISG, the ISG provides additional guidance for performing early stage reviews of digital safety-related systems in support of safety evaluations. The NRC staff may review the system design and development process to support a determination that the design meets regulatory requirements and that in safety-related applications in nuclear power plants, the process

is of sufficiently high quality to produce systems and software suitable for use. The NRC staff review processes include activities for evaluating documentation of plans and processes that are used to support system development activities and their outcomes.

II. Backfitting and Issue Finality

The NRC is issuing a revision to interim guidance for the NRC staff regarding its review of requests from nuclear power plant licensees for license amendments involving installation of Digital I&C equipment. Issuance of the revised ISG does not constitute backfitting as defined in title 10 of the Code of Federal Regulations (10 CFR) section 50.109 (the Backfit Rule) and is not otherwise inconsistent with the issue finality provisions in 10 CFR part 52. The NRC's position is based upon the following considerations.

1. The ISG positions do not constitute backfitting, inasmuch as the ISG is guidance directed to the NRC staff with respect to its regulatory responsibilities.

The ISG provides interim guidance to the staff on how to review certain requests for license amendments. Changes in guidance intended for use by only the staff are not matters that constitute backfitting as that term is defined in 10 CFR 50.109 or involve the issue finality provisions of 10 CFR part 52.

2. Backfitting and issue finality—with certain exceptions discussed in this section—do not apply to current or future applicants.

Applicants and potential applicants are not, with certain exceptions, the subject of either the Backfit Rule or any issue finality provisions under 10 CFR part 52. This is because neither the Backfit Rule nor the issue finality provisions of 10 CFR part 52 were intended to apply to every NRC action that substantially changes the expectations of current and future applicants.

The exceptions to the general principle are applicable whenever a 10 CFR part 50 operating license applicant references a construction permit or a 10 CFR part 52 combined license applicant references a license (e.g., an early site permit) and/or an NRC regulatory approval (e.g., a design certification rule) for which specified issue finality provisions apply.

The NRC staff does not currently intend to impose the positions represented in this final SRP section in a manner that constitutes backfitting or is inconsistent with any issue finality provision of 10 CFR part 52. If in the future the NRC staff seeks to impose positions stated in this SRP section in a manner that would constitute backfitting or be inconsistent with these issue finality provisions, the NRC staff must make the showing as set forth in the Backfit Rule or address the regulatory criteria set forth in the applicable issue finality provision, as applicable, that would allow the staff to impose the position.

3. The NRC staff has no intention to impose the ISG positions on existing nuclear power plant licensees either now or in the future (absent a voluntary request for a change from the licensee).

The staff does not intend to impose or apply the positions described in the ISG to existing (already issued) licenses (e.g., operating licenses and combined licenses). Hence, the issuance of this ISG—even if considered guidance subject to the Backfit Rule or the issue finality provisions in 10 CFR part 52—would not need to be evaluated as if it were a backfit or as being inconsistent with issue finality provisions. If, in the future, the NRC staff seeks to impose a position in the ISG on holders of already issued licenses in a manner that would constitute backfitting or does not provide issue finality as described in the applicable issue finality provision, then the staff must make a showing as set forth in the Backfit Rule or address the criteria set forth in the applicable issue finality provision, as applicable, that would allow the staff to impose the position.

III. Congressional Review Act

This Interim Staff Guidance document 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.

Dated at Rockville, Maryland, this 2nd day of January, 2019.

For the Nuclear Regulatory Commission.

Eric J. Benner, Director,
Division of Engineering,
Office of Nuclear Reactor Regulation.

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