# REGULATORY ANALYSIS

## DRAFT REGULATORY GUIDE DG-1402
## DEDICATION OF COMMERCIAL-GRADE DIGITAL INSTRUMENTATION AND CONTROL ITEMS FOR USE IN NUCLEAR POWER PLANTS

(Proposed New Regulatory Guide)

## 1. Statement of the Problem

The U.S. Nuclear Regulatory Commission (NRC) staff is considering issuing a new regulatory guide (RG) to provide dedicating entities pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance," with guidance for use of an accredited third-party certification within a commercial-grade dedication process for digital equipment. Dedication may be applied to nuclear facilities. Dedication is an acceptance process to provide reasonable assurance that a commercial-grade item will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under a quality assurance program in accordance with Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities." This guidance would provide an acceptable method to use an accredited certification of compliance to an International Electrotechnical Commission (IEC) 61508, "Functional Safety of Electrical/Electronic/Programmable Safety-related Systems," Edition 2.0, issued April 2010, safety integrity level (SIL) of a digital instrumentation and control (I&C) item for verification of its critical characteristic of dependability within the dedication process.

RG 1.164, "Dedication of Commercial-Grade Items for Use in Nuclear Power Plants," Revision 0, issued June 2017 (Agencywide Document Access and Management System (ADAMS) Accession No. ML17041A206), describes methods that the NRC staff considers acceptable in meeting regulatory requirements for the dedication of commercial-grade items and services used in nuclear power plants. RG 1.164 endorses, with exceptions or clarification, Electrical Power Research Institute (EPRI) 3002002982, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications," Revision 1 to EPRI NP-5652 and TR-102260, issued September 2014 (ADAMS Accession No. ML18199A161). In part, EPRI 3002002982 provides guidance for two methods: Method 2—Commercial-Grade Survey, and Method 4—Item/Supplier Performance Record. The use of an accredited SIL certification of compliance to IEC 61508 could provide an acceptable approach when addressing these two methods in dedication of digital equipment.

EPRI 3002002982 references EPRI TR-106439, "Guideline on Evaluation and Acceptance of Commercial-Grade Digital Equipment for Nuclear Safety Applications," issued October 1996. The NRC staff evaluated TR-106439 as documented in its safety evaluation report (ADAMS Accession No. ML12205A284). Where RG 1.164 and EPRI 3002002982 consider the broad scope of dedication of commercial-grade items, TR-106439 provides guidance specific to digital equipment.

In part, TR-106439 provides acceptance criteria and methods of verification for the critical characteristic of dependability. TR-106439 states that verification of dependability characteristics typically involves a commercial-grade survey of the vendor's processes (Method 2) and a review of the vendor performance record and product operating history (Method 4). The NRC staff's safety evaluation report highlights that TR-106439 proposes a

combination of methods, including Methods 2 and 4, for digital I&C items. As documented in the NRC staff's safety evaluation report for TR-106439, the NRC staff determined TR-106439 contains an acceptable method for dedicating commercial-grade digital equipment for use in nuclear power plant safety applications and meets the requirements of 10 CFR Part 21. The NRC staff further concluded that when digital equipment is dedicated using the methods described in TR-106439, it may be considered equivalent to digital equipment designed and manufactured under a 10 CFR Part 50, Appendix B, quality assurance program. The NRC staff noted that licensees referencing TR-106439 would need to document application-specific details about the dedication process and specific critical characteristics. Neither TR-106439 nor the NRC staff's safety evaluation report address the use of SIL certification to IEC 61508.

Presently, no guidance exists for the use of SIL certification in verification that critical characteristics are acceptable. The nuclear power industry is seeking guidance that would allow such a method to verify a digital I&C item's dependability critical characteristics to leverage a well-established commercial infrastructure built around the IEC 61508 SIL certification process. Industry representatives engaged the NRC staff on this topic as part of activities to modernize the NRC regulatory infrastructure for digital I&C. From this engagement, the Nuclear Energy Institute (NEI) produced NEI 17-06, "Guidance on Using IEC 61508 SIL Certification to Support the Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Related Applications," Revision 1, issued December 2021 (ADAMS Accession No. ML21337A380). NEI 17-06 provides guidance for the use of an accredited third-party SIL certification to the IEC 61508 standard within a digital I&C item's dedication process for its critical characteristic of dependability. An endorsement of NEI 17-06 by this RG would establish guidance for an acceptable method to use an accredited SIL certification to IEC 61508 of a digital I&C item when verifying dependability critical characteristic within the commercial grade dedication process.

## 2. Objective

The objective of this regulatory action is to create new NRC staff guidance that provides an acceptable method for compliance with a portion of dedication as defined by 10 CFR Part 21 for nuclear power plants licensed pursuant to 10 CFR Part 50 and 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants." This objective is limited to the use of an accredited SIL certification to IEC 61508 for the verification of a digital I&C item's critical characteristic of dependability during its dedication in accordance with NEI 17-06. As such, this RG will endorse NEI 17-06 with any necessary exceptions or clarifications.

## 3. Alternative Approaches

The NRC staff considered the following alternative approaches for addressing guidance on accepting an accredited SIL certification to IEC 61508 for the verification of a digital I&C item's critical characteristic of dependability during its dedication:

(1) Do not create a new draft regulatory guide (DG), DG-1402, or revise RG 1.164.
(2) Revise RG 1.164 to expand its scope.
(3) Create a new DG, DG-1402, specific to the desired guidance.

Alternative 1: Do Not Create a New Draft Regulatory Guide, DG-1402, or Revise RG 1.164

Under this alternative, the NRC staff would not issue additional new guidance, and current acceptable methods would be retained (i.e., RG 1.164's endorsement of

EPRI 3002002982 in further consideration of the NRC staff's safety evaluation report when applying TR-106439). If the NRC staff does not take action, then (1) no reduction in anticipated licensee costs associated with commercial-grade dedication of SIL-certified digital items would occur, and (2) the public, licensees, and the NRC would not benefit from greater expanded safe use of digital I&C items that had been suitably SIL certified to an internationally recognized IEC 61508 standard. This alternative is considered the "no-action" alternative and provides a baseline condition from which any other alternatives will be assessed. The no-action alternative does not address the concerns that the nuclear power industry has identified with currently available methods that do not leverage SIL certifications to IEC 61508 for digital item dependability, and instead it would continue to include licensee surveys at commercial vendor facilities in the absence of new guidance. The NRC would continue to inspect commercial-grade dedication activities for the critical characteristic of dependability based on current acceptable methods.

Under this alternative, the NRC staff could wait for an applicant to propose using NEI 17-06 as a change to its quality assurance program, then perform a safety evaluation that other licensees could reference later. However, waiting for an applicant is a less-transparent process in comparison to a new RG, because it does not include a formal opportunity for public comment or potential Advisory Committee for Reactor Safeguards interactions. This alternative is also dependent upon a first-of-a-kind application, which bears some regulatory uncertainty. In addition, a first-of-a-kind applicant could request a fee exemption; if one were granted, the NRC would be impacted by the costs associated with the review. If a fee exemption were not granted, the first-of-a-kind applicant would be impacted by the costs associated with the review, and this in turn could delay the issuance of related guidance.

Alternative 2: Revise RG 1.164 to Expand Its Scope

Under this alternative, the NRC staff would not create a new RG but would instead revise RG 1.164 to expand its scope to include an endorsement of NEI 17-06. This alternative would alter the character of RG 1.164 from addressing commercial-grade dedication at a high level that is technology neutral. This method would provide greater public involvement and transparency than Alternative 1 as well as an opportunity for Advisory Committee for Reactor Safeguards interactions. This alternative is anticipated to increase the number of public comments and the time to resolve them, because it would alter the character of RG 1.164, as the proposed additional guidance is very low level and specific to digital equipment.

The impact to the NRC would be the costs associated with preparing and issuing the RG revision. The impact to the public would be the voluntary costs associated with reviewing the draft and providing comments to the NRC during the public comment period.

Alternative 3: Create a New DG, DG-1402, Specific to the Requested Guidance

Under this alternative, the NRC staff would create a new draft RG, DG-1402. The new RG would endorse NEI 17-06 with any necessary exceptions or clarifications. The NRC staff anticipates that any exceptions or clarifications will be minimal, based on prior engagements with industry and initial reviews of NEI 17-06. This alternative enables the generation of clear and limited guidance that directly addresses use of an accredited SIL certification to IEC 61508 for the verification of a digital I&C item's dependability critical characteristics for dedication. Unlike Alternative 1, this alternative provides clear process points for public involvement without any dependency on a first-of-a-kind application. Unlike Alternative 2, this alternative is considered more efficient, because it is considered less likely to incur a large number of public

comments. Unlike Alternative 2, this alternative can remain limited to addressing technology-dependent guidance on a specific topic. This alternative is considered likely to be completed in a shorter time than Alternative 2.

The impact to the NRC would be the costs associated with preparing and issuing the new guide. The impact to the public would be the voluntary costs associated with reviewing the draft and providing comments to the NRC during the public comment period. The value to the NRC and applicants would be the benefits associated with enhanced efficiency and effectiveness in using the new guidance for license applications and other interactions between the NRC and its regulated entities.

## Conclusion

Based on this regulatory analysis, the NRC staff concludes that issuance of a new RG is warranted. The action will enhance licensing efficiency and inspection oversight by establishing an acceptable method to admit an accredited SIL certification to IEC 61508 for the verification of a digital I&C item's critical characteristic of dependability during its dedication. Use of the new guidance could lead to cost savings for industry for any commercial-grade dedication of digital equipment by leveraging a well-established commercial infrastructure built around the internationally recognized IEC 61508 standard. The NRC staff anticipates that industry costs for the commercial-grade dedication of digital equipment will be reduced as a result of new guidance to accept an accredited SIL certification to IEC 61508 that extends beyond established methods for identifying and verifying the critical characteristic of dependability.