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General Comment

See attached file(s)

Attachments

04-18-22 NRC_Industry Comments on DG-1402 Comments

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U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
ATTN: Program Management, Announcements and Editing Staff

Subject: NEI Comments on Draft Regulatory Guide DG-1402, "Dedication of Commercial-Grade Digital Instrumentation and Control Items for Use in Nuclear Power Plants," Docket ID NRC-2022-0039

Project Number: 689

Submitted via regulations.gov

Dear Program Management, Announcements and Editing Staff,

The Nuclear Energy Institute's (NEI)[1], on behalf of our members, appreciates the opportunity to provide comments on the subject Draft Regulatory Guide DG-1402, "Dedication of Commercial-Grade Digital Instrumentation and Control Items for Use in Nuclear Power Plants." The purpose of this letter is to provide the attached comments which recommend several changes to improve the clarity of the guidance.

The draft guide endorses NEI 17-06, Rev. 1, "Guidance on Using IEC 61508 SIL Certification to Support the Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Related Applications," with clarifications. One clarification stated in DG-1402 Section C.1.b states the following: "To be clear, each dedicating entity should dedicate the services of each certifying body whose certificates the dedicating entity wishes to rely on, and should not rely on dedication by, e.g., another NRC licensee." This clarification appears to be inconsistent with the intent of NEI 17-06 and may impose implementation barriers to using this guidance. As noted in DG-1402, NEI 17-06 demonstrates the dependability critical characteristics described in EPRI TR-106439 can be met if equipment is manufactured to an appropriate safety integrity level (SIL) in conformance with IEC 61508. The dedication process described within NEI 17-06 verifies the Accreditation Body and Certification Body knowledge, skills, and adherence to standards and processes. The

[1] The Nuclear Energy Institute (NEI) is responsible for establishing unified policy on behalf of its members relating to matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include entities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect and engineering firms, fuel cycle facilities, nuclear materials licensees, and other organizations involved in the nuclear energy industry.

observation process does not vary based on the project or technology being procured, allowing for transference of the dedication results with no impact to their acceptability. Limiting the acceptability of each dedication activity to only the dedicating entity that performed the dedication process limits the use of this guidance and imposes undue burden on implementors, Accreditation Bodies, and Certification Bodies by increasing the demand to perform redundant observations of the accreditation process.

Additionally, NEI acknowledges the clarification provided in Section C.1.c stating: "To be consistent with NRC staff-accepted practices, the certifying bodies' IEC 61508 SIL certification process should be observed every 3 years." The processes being observed are mature, stable processes that support safety applications in numerous non-nuclear industries. Consistency with current NRC practices may be appropriate during the initial applications; however, the NRC should allow for reevaluation of this frequency based on the actual results from the initial observations.

We trust that you will find these comments useful and informative as you finalize the regulatory guidance document. Please contact me at adc@nei.org or (202)439-3698 with any questions or comments about the content of this letter or the attached comments.

Sincerely,

Alan Campbell

Attachment

c: Eric Benner (NRR/DEX)
Jeanne Johnston (NRR/DEX/ELTB)
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Note: Blue text in the following table indicates additions or changes to the existing text in DG-1402.

#	Section	Comment	Recommendation
1	Section C. Staff Regulatory Guidance Section 1.b	This section requires each dedicating entity to perform a unique dedication of certifying body's services. The intent of NEI 17-06, Rev. 1 is to allow for the certification bodies' dedications, performed in accordance with NEI 17-06 Rev. 1 Section 5.3, to be utilized by other licensees, designees, or dedicating entities. As noted in DG-1402, NEI 17-06 demonstrates the dependability critical characteristics described in EPRI TR-106439 can be met if equipment is manufactured to an appropriate safety integrity level (SIL) in conformance with IEC 61508. The dedication process described within NEI 17-06 verifies the Accreditation Body and Certification Body knowledge, skills, and adherence to standards. This process does not vary based on the project or technology being procured, allowing for transference of the dedication results with no impact to their acceptability. Limiting the acceptability of each dedication activity to only the dedicating entity that performed the dedication process limits the use of this guidance and imposes undue burden on implementors, Accreditation Bodies and Certification Bodies by increasing the demand to perform observations of the accreditation process.	Recommend the following: NEI 17-06 states, among other things, that the certifying body's services should be dedicated by "[a] U.S. NRC licensee, their designee, or the dedicating entity." To be clear, each dedicating entity should dedicate the services of each certifying body whose certificates the dedicating entity wishes to rely on, and should not rely on dedication by, e.g., another NRC licensee. Accreditation activity observations performed in accordance with NEI 17-06 Section 5.3 may be performed by a U.S. NRC licensee, their designee, or the dedicating entity and, once accepted, used as input to other licensees, designees, or dedicating entities in support of their own commercial grade dedication process.
2	Section B. Discussion Reason for Issuance	"NEI 17-06 leverages the internationally recognized safety integrity level (SIL) certification process in International Electrotechnical Commission (IEC) 61508, "Functional Safety of Electrical/Electronic/Programmable Electronic Safety-related Systems," Edition 2.0, issued April 2010 (Ref. 8)." The certification process is not described in IEC 61508. The certification process is based on the criteria in IEC 61508.	Recommend the following: NEI 17-06 leverages internationally recognized safety integrity level (SIL) criteria in International Electrotechnical Commission (IEC) 61508, "Functional Safety of Electrical/Electronic/Programmable Electronic Safety-related Systems," Edition 2.0, issued April 2010 (Ref. 8)."

3	Section B. Discussion Background	In the statement beginning with "Verification of acceptability of the certifying body's commercial grade surveys…," the certifying body does not have or perform a survey. The certifying body performs a commercial grade service.	Include text consistent with Public Meeting slide 7, 1st bullet point to define equivalent terms prior to this statement to provide appropriate context. "The NRC staff considers SIL certification to be a commercial grade survey for the purposes of Part 21."
4	Section C. Staff Regulatory Guidance Section 2.a	References to IEC 61508 in the 2nd and 3rd sentences should be replaced with references to NEI 17-06. IEC 61508 does not address requirements for certifying bodies.	Recommend the following: The NRC staff is aware that unaccredited certifying bodies exist that claim to provide SIL certification under IEC 61508. However, NEI 17-06 stipulates that certifying bodies be accredited by signatories to the International Accreditation Forum Multilateral Recognition Arrangement. The NRC staff has not reviewed and is not endorsing the use of SIL certification by certifying bodies that have not been accredited in conformance with NEI 17-06. Therefore, dedicating entities should verify the certifying body's accreditation consistent with the guidance in section 6.3 of NEI 17-06.
5	Section C. Staff Regulatory Guidance Section 1.c	Section 7.3 of NEI 17-06 states, "[t]he U.S. nuclear industry observations will be performed initially on a three (3) year frequency with the possibility of re-evaluating the frequency based on the results of the observations." To be consistent with NRC staff-accepted practices, the certifying bodies' IEC 61508 SIL certification process should be observed every 3 years.	NRC should allow for re-evaluation of the frequency based on actual results from the initial observations and not rely on current practices.