

Response to Public Comments on Draft Regulatory Guide (DG)-1402
“Dedication of Commercial-Grade Digital Instrumentation and Control Items
for Use in Nuclear Power Plants”
Proposed New Regulatory Guide (RG) 1.250

On March 18th, 2022, the U.S Nuclear Regulatory Commission (NRC) published a notice in the *Federal Register* (87 FR 15456) that Draft Regulatory Guide, DG-1402, (Proposed New Regulatory Guide (RG) 1.250), was available for public comment. The Public Comment period ended on April 18th, 2022. The NRC received comments from the organization listed below. The NRC has combined the comments and NRC staff responses in the following table.

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Commenter	Section of DG-1388	Specific Comments (These are the full comments as provided in each submission)	NRC Resolution
Alan Campbell, NEI	Section C, Staff Regulatory Guidance Section 1.b	<p>Comment 1: 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.</p> <p>Recommendation: 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</p>	<p>The NRC generally agrees with the comment but normal Appendix B procurement processes should be used in acquiring information to be used in the dedication of certifying bodies. The NRC will add the following text to clarify Staff position 1.b:</p> <p>"...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. If more than one licensee or dedicating entity intends to use SIL certification from a single certifying body, a licensee or dedicating entity may either perform commercial grade dedication of the certifying body or arrange for commercial grade dedication of the certifying body on behalf of itself and other licensees or dedicating entities to reduce the number of commercial grade dedications of the certifying body. The scope of this commercial grade dedication should satisfy the needs of all the purchasers, and all the purchasers for whom the commercial grade dedication was conducted should receive the relevant records. Nevertheless, each of the licensees or dedicating entities relying on the results of a commercial grade dedication performed on behalf of licensees or dedicating entities remains individually</p>

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		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.	responsible for the adequacy of the commercial grade dedication." The changes identified above were made to DG-1402 as a result of this comment.
Alan Campbell, NEI	Section B. Discussion for Issuance	<p>Comment 2: "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.</p> <p>Recommendation: 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)."</p>	<p>NRC partially agrees with the comment. NEI 17-06, in addition to criteria in IEC 61508, relies on a certification process, therefore the NRC revised Section B of DG-1402 as follows:</p> <p>“NEI 17-06 leverages an internationally recognized safety integrity level (SIL) certification process that relies on International Electrotechnical Commission (IEC) 61508,”</p> <p>The changes identified above were made to DG-1402 as a result of this comment.</p>
Alan Campbell, NEI	Section B. Discussion Background	<p>Comment 3: 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.</p> <p>Recommendation: 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."</p>	<p>NRC agrees with the comment. The recommended edit clarifies that the NRC’s purpose for DG-1402 was the suitability of 17-06 to meet Part 21 requirements for the dedication process.</p> <p>The recommended edit has been incorporated into DG-1402 as a result of this comment.</p>

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Alan Campbell, NEI	Section C. Staff Regulatory Guidance Section 2.a	<p>Comment 4: 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.</p> <p>Recommendation: 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.</p>	<p>NRC agrees with the comment, but not the recommended edit entirely. NRC staff made the following edits to clearly indicate that NEI 17-06 is leveraging an existing process as follows:</p> <p>“The NRC staff is aware that unaccredited certifying bodies exist that claim to provide SIL certification under IEC 61508. However, NEI 17-06 reiterates 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 the mutual recognition arrangement as described in NEI 17-06.”</p> <p>The changes identified above were made to DG-1402 as a result of this comment.</p>
Alan Campbell, NEI	Section C. Staff Regulatory Guidance Section 1.c	<p>Comment 5: 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.</p> <p>Recommendation:</p>	<p>NRC disagrees with the recommendation. This issue is beyond the scope of DG-1402 as discussed below:</p> <p>RG 1.28, revision 5, endorses various versions of ASME NQA-1 standard, with 2015 being the most recent version endorsed. Part I, Requirement 18, Section 202 (external audits), of the 2015 NQA-1 version states that “External audits (e.g.,</p>

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		<p>NRC should allow for re-evaluation of the frequency based on actual results from the initial observations and not rely on current practices.</p>	<p>Supplier audits) shall be performed on a triennial basis and supplemented by annual evaluations of the Supplier's performance to determine if the regular schedule audit frequency shall be maintained or decreased or if other corrective action is required. A continuous or ongoing evaluation of the Supplier's performance may be conducted in lieu of the annual evaluations, provided that the results are reviewed in order to determine if corrective action is required." This position reflects industry standard practice and the position the NRC staff has long taken on this topic.</p> <p>Therefore, no changes were made to DG-1402 as a result of this comment.</p>