

Responses to NRC comments in ML20099C323

NRC staff comments on Nuclear Energy Institute (NEI) 17-06, “Guidance on Using IEC 61508 Safety Integrity Level (SIL) Certification to Support the Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Related Applications” Revision B Related to Quality Assurance (QA) Oversight of the SIL Certification Process

(1) NEI 17-06 Section 5 should be revised to provide more details of how the requirements of International Organization for Standardization (ISO) 17065, “Requirements for bodies certifying products, processes and services,” are verified and how that is comparable to controls verified during a commercial-grade survey.

Section 5 will be revised as described.

(2) NEI 17-06 Section 6 should be revised to better describe any periodic oversight activities envisioned for this process to assure consistent application of the certification methods and controls used by the certifying body (CB). This includes the accrediting body (AB), industry oversight, licensee, OEM, etc.

Section 6 will be revised as described.

(3) Objective evidence should be provided by NEI in consultation with ABs and CBs as to how the ISO 17065 accreditation was performed (initial accreditation, and reaccreditation) for the staff to understand how quality and technical requirements of ISO 17065 are being evaluated.

NEI is working to gather evidence on the initial and reaccreditation of certifiers. NEI is currently planning additional interactions with CBs and ABs.

As discussed in the public meeting, this may be able to be achieved by NEI facilitating a onetime observation of how a CB performs it’s SIL certification process, which includes detailed specific activities associated with the CBs implementation of a sub-set of technical requirements from International Electrotechnical Commission (IEC) 61508, “Functional safety of electrical/electronic/programmable electronic safety-related systems, to a broadly representative safety case.” The subset could be those criteria within IEC 61508 that address the product’s reliability and dependability characteristics.

(4) NEI 17-06 should be revised to describe how operating experience field data would be used to adjust the level of periodic oversight of a CB described in item (2) above.

The document will be revised as described.