

Enclosure 3
Staff Responses to Public Comments on Draft Regulatory Guide DG-1142
(Proposed Revision 0 of Regulatory Guide 1.209)

Comments			NRC Comment Resolution
Originator	DG-1142 Section	Specific Comments	
John J. Disosway, Institute of Electrical and Electronics Engineers (IEEE) 12/13/2006, Letter (ML0635201 07)	Regulatory Position 1 (C-1)	<p>Since it was noted in the public meeting on December 5, 2006, that the test data are the manufacturer's test data and not a separate EQ test, the following wording is suggested:</p> <p>"For environmental qualification of safety-related computer-based I&C systems in a mild environment, the design specification should require and the Certificate of Conformance (CoC) should include the manufacturer's test data supporting the CoC. Manufacturer's test data should document performance to the applicable service conditions in Section 6.1.5.1 of IEEE Std. 323-2003."</p>	The staff agrees with the comment. The staff will revise Regulatory Position 1 to reflect the IEEE comment by adding the sentence: "The type tests may be manufacturer's tests that document performance to the applicable service conditions with due consideration for synergistic effects, if applicable."
IEEE	Regulatory Position 4 (C-4)	<p>Since it was noted in the public meeting on December 5, 2006, that the test data are the manufacturer's or supplemental test data and not necessarily a separate EQ test, that the documentation requirements for harsh environments will be not applicable, and that it is desired that the manufacturer's and any supplemental data be available and maintained at the plant, the following wording is suggested:</p> <p>"For safety-related computer-based I&C systems intended for implementation in a mild environment, the design specification and manufacturer's test data supporting the CoC and any supplemental information for the safety-related application should include the applicable elements consistent with the guidance in Section 7.2 of IEEE Std. 323-2003 and should be maintained at the nuclear plant in an auditable form."</p>	The staff agrees with the comment. However, Regulatory Position 1 already conveys the same idea. Therefore, the regulatory guide (RG) requires no change.

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James H. Riley, Nuclear Energy Institute (NEI) Letter 12/15/2006 (ML0635600 29)	Cover Letter	It is our understanding that the main focus of DG-1142 is on the retention of documents related to qualification of computer-based instrumentation and control (I&C) systems. Specifically, Regulatory Position 4 (C-4) states that the evidence of qualification in a mild environment should be consistent with guidance for harsh environment qualification selectively based on actual environment conditions and should be retained at the plant site. 10 CFR Part 50, Appendix B, Requirement XVII, "Quality Assurance Records," has been adequate and sufficient for current operating plants. Therefore, the regulatory guide as drafted is not necessary since requirements of Appendix B will apply to safety-related computer-based I&C systems.	The staff disagrees. The main focus of DG-1142 is not just the retention of documents related to qualification of computer-based I&C systems. The purpose of DG-1142 is to describe a method that the NRC staff considers acceptable for determining the environmental qualification guidance for safety-related computer-based I&C systems for service within nuclear power plants. For Position C-4, measures taken to maintain records cited in Criterion XVII, "Quality Assurance Records," under Appendix B are not adequate. Because the expected documentation is a collection of hardware and software design and test information specific to safety-related I&C computer systems, position C-4 is necessary for proper I&C system operation and for future system modifications. Thus, the staff revised the retention of documents in RG C-4 position to read "The records should be retained at a facility in an auditable and readily accessible form for review and use as necessary."
NEI	Cover Letter	Additionally, there are other separate existing regulatory guides (RGs) that endorse IEEE Std. 323 and the EPRI document referenced in the draft regulatory guide.	The staff agrees that there are other RGs that endorse IEEE Std. 323 (e.g., RG 1.89, "Environmental Qualification of Certain Electric Equipment Important to Safety for Nuclear Power Plants") and the Electric Power Research Institute (EPRI) document (TR-107330). However, the intent of this RG is to specifically address environmental qualification of safety-related computer-based I&C systems to satisfy General Design Criterion 4, "Environmental and Dynamic Effects Design Bases," and 10 CFR 50.55(a)(h)(2). No change to the RG is required.

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NEI	Discussion Section of Draft Regulatory Guide Page 6	<p>This section states, "In the absence of acceptable methods and practices for smoke-tolerant design and installation, the most effective approach for addressing smoke susceptibility is to minimize the likelihood of smoke exposure by rigorously adhering to the fire protection guidance in Appendix R, 'Fire Protection Program for Nuclear Power Facilities Operating Prior to January 1, 1979,' to 10 CFR Part 50."</p> <p>Replace reference to Appendix R with a more generic applicable statement such as "approved fire protection program" or "individual plant license commitment."</p>	The staff agrees and will revise the RG to read, "The most effective approach for addressing smoke susceptibility is to minimize the likelihood of smoke exposure by rigorously adhering to the fire protection requirements in 10 CFR 50.48, 'Fire Protection,' or other individual plant license commitments."
NEI	Regulatory Position 1 (C-1)	In response to type testing as the preferred method for environmental qualification of safety-related computer-based I&C systems, NEI proposed to replace the first sentence with "All methods described in Section 6.3 of IEEE Std. 323 should be acceptable to demonstrate qualification for equipment located in mild environments."	The staff disagrees. In qualifying equipment located in a certain environment, testing is necessary to demonstrate that the software items or system meets its specified requirements operating over the range of environmental service conditions. Applicants can use a combination of type testing, operating experience, and analysis to qualify, but type testing should remain as the preferred method. No change to the RG is required.
NEI	Regulatory Position 2 (C-2)	<p>The paragraph discusses environmental qualification and dynamic testing in Regulatory Position 2 (C-2). NEI proposed to change the last sentence to read:</p> <p>"In those cases, confirmation of the functional response for a computer-based I&C system under the required environmental conditions is based on type testing of the individual modules and analysis of the cumulative effects of environmental and normal operational stress on the entire system."</p>	The staff agrees in part with the NEI comment on dynamic testing. The staff will clarify the last sentence of Regulatory Position 2 (C-2) to read, "In those cases, confirmation of the dynamic response to the most limiting environmental and operational conditions for a computer-based I&C system is based on type testing of the individual modules...."

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NEI	Regulatory Position 3 (C-3)	<p>This position provides guidelines for conducting electromagnetic susceptibility testing of safety-related I&C systems. NEI proposed the change—</p> <p>“Guidelines for conducting electromagnetic susceptibility testing of safety-related I&C systems appear in Revision 2 of RG 1.180, ‘Guidelines for Evaluating Electromagnetic and Radio-Frequency Interference in Safety-Related Instrumentation and Control Systems,’ issued (revise) and in ‘Guidelines for Electromagnetic Interference Testing of Power Plant Equipment,’ Revision 3 to TR-102323, EPRI 1003697 Final Report, November 2004.”</p>	<p>The staff agrees. The staff has not yet completed Revision 2 of RG 1.180. Once the staff issues Revision 2, the applicants or licensees will have the option to use the later version. No change to the RG is required.</p>
NEI	Regulatory Position 4 (C-4)	<p>For equipment located in mild environments, this section should be revised to state that the guidance of Section 7.1 of IEEE Std. 323-2003 should be followed.</p>	<p>The staff disagrees. Applicants/licensees must document all the information necessary to confirm that the safety-related computer-based I&C system is designed to meet the functional performance requirements over the range of environmental conditions. The documentation consists of functional descriptions, schematics, the software and hardware configuration used for qualification, and various test reports. It also includes equipment specifications, system drawings, hardware and software designs, test specifications, test reports, design evaluations, verification and validation (V&V) test reports, and parts list. It is necessary for the licensee or applicant to retain the required information at a facility in an auditable and readily accessible form for review and use as necessary. For equipment located in mild environments, the guidance of Section 7.2 of IEEE Std. 323-2003 should remain.</p>

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William A Horin, Nuclear Utilities Group on Equipment Qualification (NUGEQ) 12/15/2006 E-Mail (ML0635600 26)	Regulatory Position 4 (C-4)	Regulatory Position 4 (C-4) should be revised to specify environmental qualification documentation guidance that is consistent with the guidance for other design verification activities associated with acceptance and use of digital computers (i.e., V&V processes). The NUGEQ recommends that the last sentence in C-4 be revised to read, "The evidence used to demonstrate environmental qualification of safety-related computer-based systems located in a mild environment shall be pertinent to the application and shall be organized in a readily understandable and traceable manner that permits independent auditing of the conclusions presented."	<p>The staff disagrees. The applicant/licensee needs to confirm that the equipment is qualified to meet the functional performance requirements over the range of environmental conditions for the area in which it is located. IEEE Std. 7-4.3.2 addresses functional requirements, while IEEE Std. 323 addresses environmental conditions where the equipment will be located. By specifying "Section 7.2 selectively based on actual environmental conditions," Regulatory Position C-4 clarifies the meaning of "pertinent to the application."</p> <p>As for the retention of documents, the staff will revise the last sentence of Regulatory Position C-4 to read "The records should be retained at a facility in an auditable and readily accessible form for review and use as necessary."</p>
NUGEQ	Discussion of Testing Sequence in Regulatory Position 2 (C-2)	The NUGEQ recommends the addition of a new regulatory position with the following suggested text: "IEEE Std. 323, Section 6.3.1.7, <i>Test sequence</i> , provides guidance regarding test sequence and the use of the same test specimen. For safety-related computer-based I&C systems intended for implementation in a mild environment, it is not necessary to subject the same test specimens to all the relevant environmental simulations. IEEE Std. 323-2003 permits EMI/RFI susceptibility testing on a separate test specimen; it also recognizes that a seismic event is not assumed to occur in conjunction with a design-basis event (loss-of-coolant accident). The NRC also recognizes that different limiting device configurations may be preferred for each of these environmental simulations. Consequently, the same test specimen need not be used for all the environmental simulations. The same test specimen should be used for aging and event simulations if aging conditioning is required prior to simulating those design-basis event conditions."	<p>The staff disagrees. The use of the same test specimen is required to demonstrate the capability of components for all operational and environmental conditions. The simulation of test conditions should reflect the most practical approach to anticipated plant conditions with due consideration for synergistic effects, if applicable.</p> <p>Therefore, the staff will clarify the last sentence of Regulatory Position 2 (C-2) to read, "In those cases, confirmation of the dynamic response to the most limiting environmental and operational conditions for a computer-based I&C system is based on type testing of the individual modules...."</p>

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NUGEQ	Pages 4 and 10 of Draft Regulatory Guide	<p>Characterization of IEEE Std. 7.4.3.2, Section 5.4.1</p> <p>The NUGEQ suggests the following revision to the last paragraph on page 4: "Use of computers in safety systems poses challenges that differ from those associated with analog systems, prompting the development of IEEE Std. 7.4.3.2, issued in 1993 and revised in 2003. The NRC has issued RG 1.152, Revision 2, that accepts, with certain exceptions, clarifications, and additions, the use of IEEE Std. 7.4.3.2-2003, including detailed V&V guidance, as an acceptable method for satisfying the NRC's regulations with respect to high functional reliability and design requirements for computers used in safety systems of nuclear power plants. Addressing environmental qualification requirements for safety-related computer-based I&C systems is one method of ensuring that the probability of common-cause failure attributable to environmental stressors is reduced to an acceptable level. Specifically, Section 5.4.1 of IEEE Std. 7.4.3.2 provides criteria for the equipment qualification of computer-based safety systems. Environmental qualification is one element of equipment qualification."</p>	<p>The staff agrees in part that the paragraph's characterization of IEEE Std. 7.4.3.2, Section 5.4.1 "Computer System Testing," may be misinterpreted. This is because paragraphs in Section 5.4.1, under 5.4, "Equipment Qualification," do not specifically mention environmental stress or environmental compatibility, other than in relation to performance testing of the equipment.</p> <p>However, "Equipment Qualification" in Sections 4.4 (Appendix 7.1-B) and 5.4 (Appendix 7.1-C) of the Standard Review Plan states that "the applicant/licensee should confirm that the protection system equipment is designed to meet the functional performance requirements over the range of environmental conditions for the area in which it is located."</p> <p>Therefore, equipment qualification of I&C systems means both functional and environmental qualification. The staff does not explicitly distinguish between the two qualifications. No changes to the RG are required.</p>
NUGEQ	Pages 5 and 6 on Smoke as an Environmental Stressor	<p>NUGEQ recommends (1) deleting the last sentence in the last paragraph on page 5 (i.e., delete "However, as no practical, repeatable testing methodology is available, it is not feasible to assess smoke susceptibility as part of qualification"), and (2) deleting the words "In the absence of acceptable methods and practices for smoke-tolerant design and installation," in the last sentence of the first paragraph on page 6. The NUGEQ also notes that the title of Appendix R, "Fire Protection Program for Nuclear Power Facilities Operating Prior to January 1, 1979," suggests that its provisions may not apply to new plants. Accordingly, the NRC should consider substituting "rigorously adhering to the plant's fire protection licensing basis" on page 6, first paragraph, last sentence, for "rigorously adhering to the fire protection guidance in Appendix R, 'Fire Protection Program for Nuclear Power Facilities Operating Prior to January 1, 1979,' to 10 CFR Part 50."</p>	<p>The staff agrees.</p> <p>(1) The staff will delete the last sentence of the last paragraph on page 5 ("However, as no practical, repeatable testing methodology is available, it is not feasible to assess smoke susceptibility as part of qualification").</p> <p>(2) For a similar reason, the staff agrees to delete the words "In the absence of acceptable methods and practices for smoke-tolerant design and installation," in the last sentence of the first paragraph on page 6. To be more general, the staff will revise the last sentence of the first paragraph on page 6 ("adhering to the fire protection guidance in 10 CFR 50.48, 'Fire Protection'"") by deleting "Appendix R, 'Fire Protection Program for Nuclear Power Facilities Operating Prior to January 1, 1979,' to 10 CFR Part 50."</p>

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Mark Burzynski, AREVA NP 12/15/2006 E-Mail (ML0701104 33)	Regulatory Position 1 (C-1)	Regulatory Position 1 states that for environmental qualification of safety-related computer-based I&C systems, type testing is the preferred method. The option to use other methods described in Section 6.3 of IEEE Std. 323-2003, with the appropriate technical justification, should be retained as acceptable methods to demonstrate qualification for equipment located in mild environments.	The staff disagrees. In qualifying equipment located in a certain environment, testing is necessary to demonstrate that the software items or system meets its specified requirements operating over the range of environmental service conditions. Applicants can use a combination of type testing, operating experience, and analysis to qualify, but type testing should remain as the preferred method. No change to the RG is required.
AREVA NP	Regulatory Position 4 (C-4)	Regulatory Position 4 takes exception to the requirements of clause 7.1 of IEEE Std. 323-2003 and requires that the same level of documentation be provided for digital equipment located in a mild environment as is provided for equipment located in a harsh environment. There is no regulatory basis for this exception. 10 CFR 50.49 does not require such a rigorous level of documentation for equipment located in a mild environment. The NRC staff has not required any documentation beyond that specified in clause 7.1 for any other electrical equipment located in a mild environment. There is no technical basis for applying clause 7.2 to digital equipment located in a mild environment. There is marginal benefit from requiring the additional documentation that does not justify the substantial cost associated with complying with this additional documentation requirement. It is recommended that Position C-4 be deleted.	<p>The staff disagrees. The C-4 position qualifies “selectively based on actual environmental conditions” for components in a mild environment. Thus, the C-4 position does not require that the same level of documentation be provided for digital equipment located in a mild environment as in a harsh environment.</p> <p>Applicants/licensees must document all the information necessary to confirm that the safety-related computer-based I&C system is designed to meet the functional performance requirements over the range of environmental conditions. The documentation consists of functional descriptions, schematics, the software and hardware configuration used for qualification, and various test reports. It also includes equipment specifications, system drawings, hardware and software designs, test specifications, test reports, design evaluations, V&V test reports, and a parts list. Further, it is necessary for the licensee or applicant to retain the necessary information available at a facility in an auditable and readily accessible form. This level of documentation is considered essential for promptly addressing potential nuclear safety issues. Thus, RG position C-4 is not deleted.</p>