NUCLEAR UTILITY GROUP
ON EQUIPMENT QUALIFICATION

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December 14, 2001

Annette L. Vietti-Cook
Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

ATTENTION: Rulemakings and Adjudications Staff

SUBJECT: Nuclear Utility Group on Equipment Qualification - Comments Concerning Draft NRC Regulatory Guidance on "Guidelines for Environmental Qualification of Microprocessor-Based Equipment Important to Safety in Nuclear Power Plants" (66 Fed. Reg. 51,479 (2001))

Dear Ms. Vietti-Cook:

We appreciate the opportunity to comment on the subject draft regulatory guide concerning environmental qualification of microprocessor-based equipment. On behalf of the

Template = ADM-013

E-RIDS = ADM-03

Add = A. Berarek (AFB)
C. Antonescu (CEAI)

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Nuclear Utility Group on Equipment Qualification ("NUGEQ" or "Group"),[1] we submit the attached comments in response to the referenced request for comments. Our principal comment is that the draft regulatory guide is unnecessary and unwarranted because NRC regulations and regulatory guidance already adequately address environmental qualification of digital equipment. Further, the draft guide reflects many positions that are new and inconsistent with the current regulatory processes in this area (e.g., expanding the scope of 10 C.F.R. § 50.49 to apply to equipment in mild environments). Implementation of this guide would serve only to cause regulatory confusion. We recommend, therefore, that the NRC not issue, in final form, the draft regulatory guide.

In the event the NRC elects, nonetheless, to issue the final regulatory guide, we have made several suggestions concerning changes we believe would be necessary to more accurately reflect the regulatory requirements related to environmental qualification. In any event, in view of the numerous new staff positions – and inconsistencies with both existing regulations and NRC guidance for implementing the applicable regulations – we believe that, without substantial revisions to the draft, a final regulatory guide could not be issued absent rulemaking and, in any case, performance of a backfitting analysis of the new staff positions in accordance with 10 C.F.R. § 50.109.

Finally, we strongly disagree with the Staff's assertion that it may apply, without a backfitting analysis, the guidance to "operating reactor licensees who propose system modifications, voluntarily initiated by the licensee, if there is a clear connection between the proposed modifications and the guidance" (see DG-1077, Section D, "Implementation"). To the contrary, imposing the new staff positions included in the draft regulatory guide to currently operating reactors represents a backfit. Indeed, licensees may continue to meet a plant's current licensing and design basis, even when making system modifications, unless the NRC imposes the guidance with the appropriate supporting backfitting analysis. Thus, the NRC must perform a backfitting analysis should it choose to issue and apply the final regulatory guide as stated.

Again, we appreciate the opportunity to comment. Please contact us if you have any questions regarding our comments.

Sincerely,

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[1] The NUGEQ is comprised of member electric utilities in the United States and Canada, including NRC licensees authorized to operate over 90 nuclear power reactors in the United States. The NUGEQ was formed in 1981 to address and monitor topics and issues related to equipment qualification, particularly with respect to the environmental qualification of electrical equipment pursuant to 10 C.F.R. § 50.49.

Original signed by William A. Horin

William A. Horin

Patricia L. Campbell

Counsel to the Nuclear Utility Group on Equipment Qualification

Attachment

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General Comments

1. The draft guide as presently structured will create confusion and does not improve the overall review and approval process for digital devices. According to SECY-01-0155, the draft guide was developed as part of the NRC Research Plan for Digital Instrumentation and Control ("I&C"). That plan indicates that short-term efforts, such as the draft guide, were intended to focus on improving efficiency in the technical review process.[1] Our review of the draft guide indicates that it does not meet this objective. Instead, it creates confusion in what have become stable regulatory review processes for harsh environmental qualification (10 C.F.R. § 50.49) and digital systems (NUREG-0800, "Standard Review Plan," Section 7, including Appendices 7.1-B and 7.1-C[2]). Consequently, the guide should not be issued in its present form. For the reasons described below, the draft regulatory guide, if issued, must be revised based on a review that establishes consistency with existing regulations, guidance, and practices for digital systems and environmental qualification.

It appears that the guide is based solely on the results of several digital research projects, including academic reviews and comparisons of two environmental qualification standards, IEEE 323 (1983) and IEC 60780.[3] Neither the draft guide nor its referenced NUREG research reports examine the adequacy of current regulatory practices – let alone find them to be lacking – for environmental qualification or the review/acceptance of safety-related digital I&C equipment. Instead the limited regulatory analysis in the draft guide appears to assume some problem with the current regulatory scheme in this area. We consider this a significant oversight in the underlying regulatory analysis because practices in both areas appear to be stable, well defined, and technically appropriate.

The NRC's Office of Nuclear Reactor Regulation ("NRR") and the nuclear industry have expended significant efforts to design, qualify, review, and license digital safety-related equipment over the past several decades. In addition to several successful licensing efforts, the lessons learned from these efforts have been incorporated into SRP Section 7. More

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1 According to SECY-01-0155, "NRC Research Plan for Digital Instrumentation and Control (I&C)," August 15, 2001, development of the draft guide is Task 3.2.3, "Complete Environmental Qualification Guidelines."

2 Appendix 7.1-B, "Guidance for Evaluation of Conformance to ANSI/IEEE Std. 279," and Appendix 7.1-C, "Guidance for Evaluation of Conformance to IEEE Std. 603" (hereinafter "7.1-B" and "7.1-C").

3 Neither of these standards is currently part of the regulatory scheme for environmental qualification.

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recently, there have been significant and successful efforts on the part of EPRI and various digital system vendors to develop and implement methodologies, including environmental qualification, for acceptance of digital I&C safety systems.[1] In fact, NRR has recently expended significant resources reviewing submittals and issuing SERs for several of these digital systems. Our review of the draft regulatory guide suggests that neither these efforts nor existing guidance documents were adequately evaluated during development of the draft guide and, thus, there is no demonstrated need for additional guidance in this area.

Similarly, the NRC and the nuclear industry have considerable experience establishing compliance with the requirements of 10 C.F.R. § 50.49 for electrical equipment located in harsh environments. Several NRC guidance documents, including Regulatory Guide 1.89,[2] NUREG-0588,[3] and NUREG-0800, Section 3.11, "Environmental Design of Mechanical and Electrical Equipment," provide additional clarifying information regarding environmental qualification for both harsh and mild environments.[4] In addition to licensee specific efforts, the NRC has also issued SERs accepting the environmental qualification programs of several vendors (e.g., Westinghouse) for both existing plants and advanced reactors. Our review of the draft regulatory guide suggests that existing practice and guidance documents were not adequately considered during development of the draft guide.

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1 See, e.g., the following three EPRI reports for licensing of programmable logic controllers (PLC) safety systems and the associated NRC SERs – TR-114017 (TELEPERMXS), TR-110045 (COMMONQ), and 1000799 (TRICON).

2 RG-1.89, "Environmental Qualification of Certain Electrical Equipment Important to Safety for Nuclear Power Plants," Rev. 1 (March 1984).

3 NUREG-0588, "Interim Staff Position on Environmental Qualification of Safety-Related Electrical Equipment," Rev. 1 (July 1, 1981).

4 Practices acceptable to the NRC for establishing environmental qualification for equipment in mild environments are identified in NUREG-0800, Section 3.11, and in the statements of consideration accompanying 10 C.F.R. § 50.49. In summary, the application of other regulations, such as 10 C.F.R. Part 50, Appendix B, are sufficient to ensure adequate performance of electrical equipment important to safety located in mild environments and the provisions of 10 C.F.R. § 50.49 do not apply. Further, a design/purchase specification containing functional and normal/abnormal environmental descriptions, coupled with the application of quality controls (including the provisions of 10 C.F.R. Part 50, Appendix B, as appropriate), is sufficient documentation to demonstrate environmental qualification for mild environments.

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2. The draft guide should be withdrawn and appropriate insights from the digital research program issued as a Regulatory Information Summary ("RIS"). As enumerated in other specific comments, the draft guide often conflicts with existing regulatory practice and the basis for its conclusions appears limited to the results of several research projects. Absent a review of the adequacy of existing regulatory practices for either environmental qualification or digital system licensing, and a finding of some deficiency therein, the research results are more appropriately described in an RIS or similar communication vehicle "for licensee information" rather than in a regulatory guide. Based on the draft guide and NUREG/CR-6406, "Environmental Testing of an Experimental Digital Safety Channel" (Sept. 1, 1996), the research results that could be described in the RIS include:

- A conclusion that both the IEEE 323 (1983)[1] and IEC 60780[2] standards describe equivalent qualification concepts and processes and are an adequate basis for establishing environmental qualification of electrical equipment in conformance with existing NRC regulations and NRC guidance documents.[3]
- Design guidance regarding component selection, and circuit board, module, rack, and system design considerations that can be used to "build-in" tolerance to certain environmental stressors.
- Results of temperature/humidity tests on prototypical digital modules which suggest that the <u>combination</u> of high humidity and high temperature may generate digital system errors at conditions below the published equipment limits for some digital devices.
- Results of smoke exposure investigations, including the benefits of conformal coatings and chip packaging to minimize potential degradation and failure.

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1 IEEE 323, "Standard for Qualifying Class 1E Equipment for Nuclear Power Generating Stations," Institute of Electrical and Electronics Engineers, 1983.

2 IEC 60780, "Nuclear Power Plants – Electrical Equipment of the Safety System – Qualification," International Electrotechnical Commission, 1998.

3 NUREG/CR-6479, "Technical Basis for Environmental Qualification of Microprocessor-Based Safety-Related Equipment in Nuclear Power Plants," January 1998, compares IEEE 323-1974 and IEEE 323-1983 and concludes that the 1983 version is adequate for applicability. Similarly, NUREG/CR-6741, "Application of Microprocessor-Based Equipment in Nuclear Power Plants – Technical Basis for a Qualification Methodology" (Draft Report for Comment), August 2001, concludes that both IEEE 323-1983 and IEC 60780 are appropriate for establishing environmental qualification.

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- An observation that aging "does not appear to pose a significant design concern for digital systems in mild environments because the equipment is accessible for monitoring, calibration, and replacement" and can be "assumed to have like-new performance."[1]

The RIS, after an appropriate review of existing regulatory guidance documents and ongoing practices, could also affirm the adequacy of applying existing environmental qualification guidance to digital systems and equipment.

Specific Comments on "Discussion" Section of Draft Regulatory Guide

3. Discussion (4th paragraph) incorrectly suggests that EMI/RFI is a significant aging mechanism per 10 C.F.R. § 50.49(e)(5): EMI/RFI is not a significant aging mechanism and consequently need not be included in the environmental qualification testing sequence as part of preconditioning. The NRC does not provide references or a technical basis for this conclusion. In addition, we are unaware of information suggesting that EMI/RFI is a significant aging mechanism. According to IEEE 323 (1983) a significant aging mechanism is one that "causes degradation during the installed life of the equipment that progressively and appreciably renders the equipment vulnerable to failures to perform its safety function under DBE conditions." EMI/RFI can cause failures to inappropriately designed equipment, but such effects do not render the equipment, particularly equipment located in mild environments, vulnerable to failure during accidents. Consequently, while testing for EMI/RFI susceptibility is appropriate to demonstrate equipment capability and tolerance, it need not be performed as part of the environmental qualification testing sequence.

4. Discussion (4th paragraph) incorrectly suggests that "accumulation of deposits" is a significant aging mechanism per 10 C.F.R. § 50.49(e)(5): The draft guide does not provide references or a technical basis for this conclusion. It would appear that these "deposits" are in reference to fire and smoke effects. It is inappropriate to assume that any safety-related digital equipment exposed to such fire and smoke effects would then be placed back in service without repair or replacement. Consequently, it is unclear how such deposits are considered significant aging mechanisms, as that term is applied in the existing regulatory scheme. In addition, like existing analog designs, digital devices in harsh environments would have their circuitry protected from direct exposure to LOCA or HELB steam conditions. Such protection would similarly protect the circuitry from smoke/deposit effects.

5. Discussion beginning at the 5th paragraph inappropriately uses two "significant differences" between analog and digital systems as a basis for proposing a different

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[1] See NUREG/CR-6406, p. 7.

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environmental qualification approach for digital equipment. There is general agreement with the guide's observation that the use of computers in safety systems poses challenges different from those of analog systems. However, these differences are not relevant to the overall process of establishing environmental qualification of this equipment for harsh or mild environments. These differences are relevant to the digital design process and the methods used to qualify the design (e.g., software qualification and verification/validation). This perspective is consistent with the information in SRP Section 7, including referenced regulatory guides, IEEE standards, as well as ongoing industry/NRC efforts to license digital safety systems.

The draft guide identifies two "significant" differences between analog and digital systems that "suggest a different approach to qualification for digital instrumentation and control (I&C) safety systems".[1] We disagree with this assessment. Regarding metal oxide semiconductors ("MOS") radiation tolerance, several NRC documents, including Regulatory Guide 1.89 (Section B, "Discussion"), already caution that MOSs have experienced failures at doses below 10^4 rads.[2] Importantly, MOS technology is not unique to digital devices or systems. The vast majority of integrated circuits used in analog devices use MOS technology. Existing qualification guidance already cautions that devices exposed to low-level radiation doses should not be considered exempt from radiation qualification unless analysis supported by test data establishes operability at these levels.[3] There is broad industry recognition that commercial MOS technologies can have degradation thresholds as low as 10^3 rads.[4] Given these considerations, existing guidance and practices regarding radiation qualification appear to be adequate and a different approach is not warranted.

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1 The first difference is the low threshold radiation level for metal oxide semiconductor ("MOS") devices and the second is the rapid evolution of digital technology (increasing density and complexity).

2 Even the DOR Guidelines identifies radiation susceptibility for MOS technology at levels of 10^3 to 10^4 rads.

3 See, e.g., NUREG-0588, ¶ 1.4(12).

4 See, e.g., the EPRI EQ Reference Manual, "Effects of Radiation on Semiconductors" p. 3-11, and the referenced biblographical compilations: NUREG/CR-3156, "A Survey of the State-of-the-Art in Aging of Electronics With Application to Nuclear Power Plant Instrumentation" (Sandia National Laboratories, April 1983), and "Bibliography of Total Dose Radiation Effects on Electronics" (National Aeronautics and Space Administration Jet Propulsion Laboratory, California Institute of Technology, JPL D-2817, Vols. 1-3, October 15, 1985).

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Regarding the rapid evolution of digital technology, system/component reliability analyses and the associated digital design and component selection practices necessitate the conservative design, manufacture, and application of digital components within their published capabilities. Component manufacturers establish these capabilities based on extensive device testing in accordance with their quality assurance programs. Although the digital technologies have evolved more rapidly than other technologies, the manufacturing and quality practices, including stress-screening tests, demonstrate a level of device reliability and performance rarely achieved by other technologies. These activities are appropriately part of design verification and quality practices and should not be considered as elements of an environmental qualification program. Consequently, evolution of digital technology is not an appropriate basis suggesting a different environmental qualification approach for digital technology.

6. Discussion (9th paragraph): The NUREG/CR-6406 results are based on experimental apparatus that do not reflect derating and conservative design practices. We generally agree that it is inappropriate to assume that components will always accurately function at their maximum design conditions. However, conservative design practices for digital safety systems dictate that component selection and module/circuit board design should be conservative to ensure reliable performance at environmental extremes. When design practices are not sufficiently conservative, then testing at the environmental extremes plus margin should be used to demonstrate performance. The use of either conservative design practices or system environmental tests is consistent with existing guidance in SRP Section 7 (see ¶ 7.1-B 6 and ¶ 7.1-C 10). Finally, regarding the NUREG/CR-6406 test results, the report also observes that high relative humidity ("RH") conditions are not likely in a controlled environment such as a control room.[1]

7. Discussion (10th paragraph): The proposed three environmental categories are inconsistent with existing regulations and guidance, are unnecessary, and lack a cited technical basis. Based on several regulatory positions in draft guide Section C, equipment in the suggested "Category A" would be qualified in accordance with 10 C.F.R. § 50.49 and Regulatory Guide 1.89. This is an inappropriate expansion of the intended scope of 10 C.F.R. § 50.49 and does not meet its criteria for equipment in a harsh environment. As noted in Comment 11, Category A is inconsistent with the scope criteria in 10 C.F.R. § 50.49. Further, based on the limits of Category B, Category A would include all digital equipment satisfying any of the following:

- normal (including anticipated operational occurrence) operating temperatures in excess of 38°C,
- normal operating relative humidity in excess of 80%, or

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[1] NUREG/CR-6406, p. 100.

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- normal plus accident integrated radiation dose in excess of 10^4 rad.

Regarding temperature, there is no cited basis for the 38°C limit. While conservative component selection and design practices should be used to establish equipment temperature limits, dogmatic application of a 38°C limit is inappropriate. This is particularly true for safety-related equipment designed for substantially higher operating temperatures with supporting prototype or production test data. The 80% RH criterion is similarly inappropriate and without basis, particularly for safety-related equipment designed for substantially higher RH levels with supporting prototype or production test data.

Equipment exposed to radiation levels in excess of 10^4 rad during normal operation need not be included in the scope of 10 C.F.R. § 50.49. Adequate assurance of performance during normal operation for such equipment can be achieved by the conservative application of radiation-hardened MOS technologies combined with circuit analysis. The provisions of 10 C.F.R. § 50.49 apply only when accident conditions are significantly different than normal.[1] The basis for this distinction recognizes the capabilities of surveillance and operating testing to identify degradation during normal conditions to minimize common-mode failures for equipment appropriately designed for the specified service conditions. Since this capability is not available during accidents, qualification in accordance with 10 C.F.R. § 50.49 provides reasonable assurance of operability for accident conditions that are significantly different than normal conditions.[2]

Regarding Categories B and C, the 400 rad limit is without basis and substantially below the generally recognized damage threshold (1000 rad) for the least capable CMOS [complementary metal oxide semiconductor] devices.[3] Further, the 40-year time duration is unnecessary since semiconductor damage is related to integrated dose and not whether the dose occurs over 10, 40, or 60 years. The only other difference between these categories is

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1 10 C.F.R. § 50.49(c) states: "Requirements for ... (3) environmental qualification of electric equipment important to safety located in a mild environment are not included within the scope of this section. A mild environment is an environment that would at no time be significantly more severe than the environment that would occur during normal plant operation, including anticipated operational occurrences."

2 See EPRI EQ Reference Manual, Section 5.2, "Mild-Environment Qualification," and Section 5.7, "Distinguishing Mile and Harsh Environments," for additional information concerning the basis for qualification differences for equipment in mild and harsh environments.

3 See Comment 5.

the accident service temperature (38°C for Category C and 90% of maximum rated temperature for Category B). As noted above, this 38°C limit is inappropriate.

Specific Comments on "Regulatory Position" Section of Draft Regulatory Guide

8. We agree that either IEEE 323 (1983) or IEC 60780 is appropriate for satisfying the environmental qualification of safety-related equipment. The draft guide limits its endorsement of these two standards to microprocessor based equipment. The general concepts in these standards, however, were intended to apply to all types of electrical and electromechanical equipment. The NRC should consider endorsing the standards more broadly. The IEEE has twice reaffirmed the 1983 version and continues to state that the 1983 version was issued to clarify the requirements and it imposes no additional requirements for qualifying Class 1E equipment. Further, the provisions of the 1983 version appear fully consistent with current regulatory practice regarding compliance with 10 C.F.R. § 50.49 and extension of qualified life. Consequently, we suggest that the NRC recognize the acceptability of IEEE 323 (1983). Since the NRC-sponsored evaluation concludes that IEEE 323 (1983) and IEC 60780 are essentially equivalent, it would seem appropriate to also recognize the adequacy of the IEC standard for achieving compliance with 10 C.F.R. § 50.49.

9. Regulatory Position 1 is redundant to existing guidance and is unnecessary. SRP Section 7, specifically ¶ 7.1-B 6 and ¶ 7.1-C 10, specifies that tests on components, racks and panels "as a whole" demonstrate adequate performance over the range of transient and steady-state conditions for the environment and energy supply. Section 7 also permits the use of a confirmed conservative design for the range of conditions in lieu of testing (see ¶ 7.1-B 6 and ¶ 7.1-C 10). This regulatory position should be deleted.

10. Regulatory Position 2 is unnecessary and could cause confusion. Regulatory Guide 1.180[1] and SRP Section 7 currently identify the need to perform EMI/RFI testing and identify acceptable methods of qualifying equipment for these conditions. Such testing for digital systems is specified by Regulatory Guide 1.180, IEEE 7-4.3.2, and various EPRI

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[1] RG 1.180, "Guidelines for Evaluating Electromagnetic and Radio-Frequency Interference in Safety-Related Instrumentation and Control Systems," January 2000.

reports concerning qualifying digital safety systems.[1] No further guidance regarding the use of Regulatory Guide 1.180 is needed.

This draft guide creates confusion when it inappropriately specifies that EMI/RFI testing be performed as part of the environmental qualification test sequence. This is not common practice and is inappropriate and unnecessary. Further, when digital equipment is tested for EMI/RFI, the module/rack/system configuration appropriate to demonstrate EMI/RFI tolerance may not necessarily be the appropriate (i.e., limiting) configuration to demonstrate temperature/humidity or seismic capability. Requiring sequential tests forces unnecessary compromises when specifying the prototype system to be tested (see Comment 3 regarding EMI/RFI as an aging mechanism). Finally, this testing demonstrates tolerance of the design to EMI/RFI, which is not an environmental condition. The regulatory position should either be deleted or limited to a simple reference to Regulatory Guide 1.180.

11. Regulatory Position 3 is inconsistent with 10 C.F.R. § 50.49 based on the definition of Category A locations. 10 C.F.R. § 50.49 is the governing regulation for harsh environment qualification. According to 50.49(c), a harsh environment (i.e., non-mild) is an environment that is significantly more severe than the environment occurring during normal plant operation, including anticipated operational occurrences. Draft guide DG-1077 has established Category A conditions without regard to the "significantly more severe" criterion. Further, technical bases are not provided for the proposed Category A radiation, temperature, and humidity limits. For harsh environment equipment, 50.49(e)(5) contains criteria regarding qualified life (or "end-of-installed life") and preconditioning by natural or artificial aging. A qualified life is not required by regulations or existing staff guidance for equipment in a mild environment. For mild environments, equipment design, component selection, and controlled environmental conditions (e.g., HVAC) preclude significant environmental aging mechanisms. We suggested the following revision to Regulatory Position 3:

> **3.** 10 C.F.R. § 50.49 requires preconditioning to an end-of-life condition for harsh environment equipment, including microprocessor-based equipment, qualified by sequential type tests. Preconditioning (accelerated aging) may be applied in accordance with IEEE 323-1983 or IEC 60780-1998, depending on the standard being applied. In addition, the enumerated exceptions and clarifications in Regulatory Guide 1.89 apply.

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[1] See, e.g., previously referenced EPRI reports on specific PLCs (supra n. 4), as well as these other NRC-reviewed reports: TR-107330, "Generic Requirements Specification for Qualifying a Commercially Available PLC for Safety-Related Applications in Nuclear Power Plants," and TR-1001045, "Guideline on the Use of Pre-Qualified Digital Platforms for Safety and Non-Safety Applications in Nuclear Power Plants."

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12. Regulatory Positions 4 and 5 are inconsistent with existing regulations and guidance based on the draft Category B and C criteria. Generic practices acceptable to the NRC for establishing environmental qualification for electrical equipment in mild (i.e., non-harsh) environments are identified in NUREG-0800, Section 3.11, "Environmental Design of Mechanical and Electrical Equipment," and in the Statement of Considerations accompanying 10 C.F.R. § 50.49.[1] Additional guidance for digital systems is provided in NUREG-0800, Section 7, specifically ¶ 7.1-B and ¶ 7.1-C. The applicable sections for equipment qualification (¶ 7.1-B 5 and ¶ 7.1-C 9) and for channel/system integrity (¶ 7.1-B-6 and ¶ 7.1-C 10) are consistent with the generic practices for mild environment equipment. In summary:

- Current regulations, such as 10 C.F.R. Part 50, Appendix B, are sufficient to ensure adequate performance of electrical equipment important to safety located in mild environments and the provisions of 10 C.F.R. § 50.49 do not apply.
- A design/purchase specification containing functional and normal/abnormal environmental descriptions, along with certification to the specification, is sufficient documentation to demonstrate environmental qualification for mild environments.
- Mild environment qualification should conform to IEEE 323.[2]
- System/component tests should demonstrate that performance is adequate over the range of electrical and environmental conditions or other information should confirm that the system/components are conservatively designed to operate over the range of service conditions.

DG-1077 apparently establishes Category B and C conditions without regard to the existing regulatory guidance and industry practice. Further, technical bases are not provided for the proposed Category B and C radiation, temperature, and humidity limits. The draft guide should be revised to be consistent with existing regulatory practice.

Regulatory Positions 4 and 5 should be deleted or revised. If the positions are revised, the following text is suggested:

> **4.** For microprocessor-based equipment in a mild environment, qualification may be demonstrated by specifying equipment operation under normal, abnormal, and accident service environments that are conservatively

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1 48 Fed. Reg. 2,729 (1983). See NRC response to Comment 3, Scope – Equipment in a Mild Environment – Paragraph 50.49(b).

2 IEEE 323 (1983), Section 8.6, identifies documentation guidance for mild environment equipment and is consistent with the above regulatory guidance.

within the manufacturer's specified operating service environment. Applicable quality assurance programs require an adequate technical basis, including tests, for the specified service environment. Preconditioning is not required.

For equipment that is operated outside the manufacturer's specified operating service environment, qualification should be based on testing for the required range of environmental conditions plus margin. The need for preconditioning should be based on an assessment of environmental factors to identify aging mechanisms that may significantly contribute to common-mode failures at the tested conditions. Preconditioning is not required if accident conditions are not significantly different than normal operating conditions.

13. Regulatory Position 6 concerning margin is unnecessary and could cause confusion. Regulatory Guide 1.89, which endorses IEEE 323, contains adequate regulatory guidance in Position C.4 regarding margin for accident environmental testing. Further clarification regarding saturated/superheated temperature margin is unnecessary and may create unnecessary confusion.[1] Regarding mild environments, testing margin need not conform to the IEEE 323 "accident" margin recommendations, which were developed for LOCA and HELB accident conditions. This position should be deleted.

14. Regulatory Position 7 concerning life-limited components is unnecessary and could cause confusion. This guidance is unnecessary since no unique characteristics of digital devices/systems suggest component analysis and periodic maintenance/replacement evaluation methods should differ for analog and digital systems. Further, such activities are typically focused on operational duration (i.e., installed life) and not on "shelf life". Existing guidance regarding harsh environment devices requires the identification and scheduled replacement of life limiting components. For mild environment digital devices, the conservative design practices necessary to achieve high reliability, coupled with sophisticated self-diagnostic and self-test schemes and performance monitoring, maintain high availability and are not considered part of environmental qualification. This position should be deleted.

15. The environmental stress screening tests identified in Regulatory Position 8 are not part of environmental qualification. These stress-screening tests do not replicate operating conditions, but are intended to reveal failure modes and mechanisms under accelerated stress conditions. The regulatory position appropriately characterizes these tests as providing evidence of quality processes. They are not, however, environmental

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[1] The standards permit a smaller temperature margin under saturation LOCA/HELB steam conditions in order to prevent excessive test pressures.

qualification tests, since they do not represent operational conditions. Along with numerous other considerations, these tests provide useful information for system/module designers in selecting components and manufacturers with proven reliability and capability. Such tests are not unique to digital integrated circuits. Similar tests are employed for analog devices and other components (e.g., capacitors, connectors) in both digital and analog circuits. The "component" qualification suggested by this regulatory position is inconsistent with the "equipment/system" environmental qualification practices for other types of equipment. This position should be deleted.

16. The multi-tiered "protection" approach identified in Regulatory Position 9 is not part of environmental qualification. This draft regulatory position provides design recommendations that, while reflecting elements of good design practice, are not elements of environmental qualification. Except for the referenced Regulatory Position 8 and stress screening tests discussed in ¶ 9.1, none of this guidance establishes measurable characteristics or criteria. Such guidance is open to broad interpretation and, thus, is inappropriate as a regulatory position. Furthermore, rigidly implementing portions of this guidance, in lieu of other methods to achieve equivalent or enhanced capabilities, may be counterproductive to the overall design process. Such micromanagement of the design process is inappropriate and not an efficient utilization of either NRC or industry resources. This position and the associated Figure 1 should be deleted.

17. The guidance in Regulatory Position 10 does not relate to environmental qualification. In addition to being inappropriate in an equipment qualification regulatory guide, this guidance is redundant to the more detailed information contained in SRP Section 7. In particular Branch Technical Position [NRR Instrumentation and Controls Branch] HICB-17, "Guidance on Self-Test and Surveillance Test Provisions," contains more appropriate and detailed guidance and criteria including specific information on topics such as failure detection, self-test features, periodic testing, and actions on failure detection. This position should be deleted.

Specific Comments on "Regulatory Analysis" Section of Draft Regulatory Guide

18. The regulatory analysis fails to identify the problems requiring issuance of this regulatory guide. The "Problem" discussion incorrectly states that "existing guidance does not specifically address the so-call mild environment" and "there is a recognized need to address the full scope of 10 CFR § 50.49." Both statements reflect a misunderstanding of existing regulatory guidance regarding digital equipment in mild environments and the regulatory basis for 10 C.F.R. § 50.49. A reasoned review of existing regulatory guidance, licensee submittals, and NRR review practices for the licensing of digital system would indicate that the overall process is adequate to ensure environmental qualification of these digital systems.

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19. The "Take No Action" alternative incorrectly presumes important deficiencies in the existing review process for digital systems and an absence of adequate guidance (see prior Comments 1, 2, and 18). The alternative also incorrectly assumes that without additional guidance NRR review efforts will increase and there could be less consistency among reviewers. As noted in prior comments, there currently is a stable regulatory environment with respect to the licensing of digital systems. The draft guide introduces concepts and guidance, such as the three environmental categories, and EMI/RFI as an aging mechanism, that will produce instability and confusion rather than enhance the licensing process. A reasoned review of existing regulatory guidance, licensee submittals, and NRR review practices for the licensing of digital system will find that the overall process is adequate to ensure environmental qualification of these digital systems.

20. The "Enhance Current Qualification Approaches" option, based on three environmental categories (A, B, and C) is inconsistent with current regulatory guidance for harsh and mild environment qualification and is unnecessary. See Comments 7, 11, and 12.