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Rules and Directives Branch
Office of Administration
U.S. Nuclear Regulatory Commission
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Comments on Draft Regulatory Guide Concerning Equipment Qualification

- Ref.: 1. Draft Regulatory Guide DG-1077, "Guidelines for Environmental Qualification of Microprocessor-Based Equipment Important to Safety in Nuclear Power Plants."
- Ref.: 2. EPRI TR-107330, "Generic Requirements Specification for Qualifying a Commercially Available PLC for Safety-Related Applications in Nuclear Power Plants."

Framatome ANP has reviewed the draft regulatory guide on the environmental qualification (EQ) of digital control systems (Reference 1) and offers several comments. Framatome does not believe this document should be incorporated into the NRC's formal regulatory guidance. Our overall comments, which are summarized below, are supported by a more detailed discussion contained in the attachment.

First, a new regulatory guide of this nature is not needed. The differences between analog and digital systems from the standpoint of EQ do not justify separate guidance. Adequate guidance is already available and has been successfully used by the NRC in regulatory reviews. For example, the EPRI report (Reference 2) sets forth detailed guidance on EQ.

Second, as written, the draft regulatory guide adds unnecessary regulatory burden and would significantly complicate the EQ process. In addition, some of the guidance provided in this draft applies to the design process and is not applicable to EQ.

Third, this draft document is confusing in many respects and is inconsistent with existing guidance and regulatory practice. As already demonstrated in the NRC's review and approval of specific digital control system designs, a stable and adequate body of guidance is in place and can be confidently relied on to evaluate the adequacy of EQ activities on digital control systems.

Finally, we urge the NRC not to proceed with the development of this regulatory guide. We believe the argument given in the Regulatory Analysis Section of the draft to disregard the "take no action" option is flawed and should be reconsidered.

Template = ADM-013

E-RIDS = ADM-03
Add = A. Beranek (AIFB)
A. Antonesco (EA1)

Framatome ANP appreciates this opportunity to provide comments on the draft regulatory guide. We would be pleased to discuss our comments further with the NRC staff, as appropriate.

Very truly yours,

A handwritten signature in black ink, appearing to read "J. Mallay". The signature is fluid and cursive, with a long horizontal stroke at the end.

James F. Mallay, Director
Regulatory Affairs

/lmk

Attachment

cc: Project 693

ATTACHMENT

Comments on Draft Regulatory Guide DG-1077, "Guidelines for Environmental Qualification of Microprocessor-Based Equipment Important to Safety in Nuclear Power Plants," by Framatome ANP, December 2001.

General Comments

The guidance presented in DG-1077 creates confusion and is not consistent with previous EQ guidance. The current regulatory approach offers a stable review and licensing process for digital systems and has been demonstrated to be adequate. This draft document is not needed as part of the regulatory process and should not be issued.

If this draft regulatory guide is believed necessary, it should be revised based on a review that establishes consistency with existing regulations, guidance, and practices for digital systems and environmental qualification. There are other guidance documents that contain EQ guidance for digital systems and have been endorsed by the NRC. The EQ guidance contained in EPRI Report TR-107330 is one example. Environmental requirements are discussed in Section 4.3.6 of this EPRI report. EMI/RFI, ESD, and seismic requirements are given in Sections 4.3.7, 4.3.8, and 4.3.9. In addition, the Standard Review Plan gives environmental qualification guidance for digital systems and references pertinent guides and standards. In addition to licensee specific efforts, the NRC has also issued SERs accepting the environmental qualification programs of several vendors (e.g., Framatome ANP) for plant specific applications. Our review of the draft regulatory guide suggests that existing practice and guidance documents were not adequately considered during development of the draft regulatory guide. A regulatory guide on EQ should be issued only when consistency with other guidance currently used in the regulatory review process has been assured.

Comments on the Regulatory Positions

Regulatory Position 1 is not necessary. As discussed earlier, this information can be found in several other guidance documents, including the SRP.

Regulatory Position 3 is not consistent with 10CFR 50.49 based on the definition of Category A locations as given in DG-1077. Technical bases are not provided for the proposed Category A radiation, temperature, and humidity limits. DG-1077 should be revised to reflect positions taken in existing regulations and practice.

Regulatory Positions 4 and 5 are not consistent with existing regulations and guidance based on the Category B and C criteria presented in DG-1077. Technical bases are not provided for the proposed Category B and C radiation, temperature, and humidity limits. Existing regulatory guidance is in direct conflict with the criteria assumed for B and C. The draft regulatory guide should be revised to be consistent with existing regulatory practice.

Regulatory position 6 on margin needs to be redeveloped and justified or deleted. Applying a margin on aging parameters is not required by Regulatory Guide 1.89 or by ANSI/IEEE-323 (IEEE Standard for Qualifying Class 1E Equipment for Nuclear Power Generating Stations). Margins are not quantifiable relative to accelerated aging parameters, and they should not be

part of DG-1077. Regulatory Guide 1.89, which endorses IEEE-323, contains adequate guidance on margins.

Regulatory Position 7 is unnecessary and should be deleted. A qualified life is not required by RG 1.89 or IEEE Std 323 for equipment located in a mild environment, which is the location for most digital systems. Component life is designed into the process using specified quality techniques. This design process, along with required testing, ensures that components will not exceed their operational life-span.

Regulatory Position 8 lists six tests that the IC manufacturer should perform. No criteria are given for these tests. An applicant cannot be expected to apply the criteria given in the discussion section of this draft. These tests place an unnecessary burden on an applicant to ensure that the IC component is stressed to a certain level before insertion into the system. The present practice of qualifying the PLC with the IC components mounted on the boards demonstrates an acceptable level of qualification.

Regulatory Position 8 specifies environmental stress screening tests that are not part of environmental qualification. These stress-screening tests do not replicate any operational conditions but are intended to reveal failure modes and mechanisms under accelerated stress conditions. These tests are quality processes and are used to aid designers in the selection of the optimum components with proven reliability and capability. The process suggested in this position deviates from the processes used for analog components and as such burdens and complicates the EQ process while adding no value. This position should be deleted.

Regulatory Position 10 is also not part of environmental qualification. Digital system testing is covered in detail in the SRP and other associated guidance documents. This position should be deleted.

Additional Technical Comments

The differences noted in DG-1077 between digital and analog systems do not appear to be so significant that a new digital EQ guide is required. There are, however, significant design process differences so that new digital licensing criteria for safety systems needed to be established; this is not the case for EQ. The only two differences noted in the draft document are in radiation tolerance and the speed of development. IC technology is not unique to digital devices or systems. Existing qualification guidance discusses component exposure and recommends a qualification process through testing and analysis. The rapid development of digital technology is not a valid reason for suggesting that unique EQ guidance is necessary. The IC manufacturers and the system manufacturers have ensured that their quality procedures achieve the highest reliability and qualification levels necessary.

EMI/RFI should not be categorized as a significant aging factor. EMI/RFI has the potential to create failures when equipment is not designed to operate in the correct environment. These failures do not cause the digital equipment to be more vulnerable to failure during accidents due to any aging degradation.

Likewise, deposits are not an aging mechanism. For this to occur, there would have to be a smoke or fire incident. After which, in a realistic application, the equipment would not be placed back into service unless it was demonstrated that the equipment was operational.

The protection hierarchy levels specified in DG-1077 produce a much more complicated qualification program than is necessary. These levels impose an unnecessary EQ burden. Besides, this subject is a design issue. This regulatory position provides design recommendations that, while reflecting good practice, are not valid for EQ. This position should not be a part of any EQ standard.

Using the manufacture's maximum temperature range to establish the qualification level for the system seems to be inappropriate and confusing. Furthermore, it is difficult to establish whether this is based on the IC manufacturer's test range or the system manufacturer's test range. The manufacturer's stress test has no bearing on the qualification level for a PLC system or any other type of digital system.

Comment on the Need for a New Regulatory Guide

In the Regulatory Analysis Section, the "take no action" approach is clearly the only valid choice. The reasons set forth for disregarding this approach are incorrect. First, there is no lack of appropriate guidance for digital EQ. Second, NRC review efforts will not increase in the absence of new guidance. In fact, the adoption of the proposed approach will increase NRC review time because of the introduced inconsistencies. The current review and approval process is well established and stable. Existing regulatory guidance, licensee submittals, and NRR review practices for the licensing of digital system proves that the overall process is adequate to ensure proper environmental qualification of digital systems. The draft regulatory guide contains new guidance that we believe will complicate the approval process and cause new instabilities.