

GENERAL ELECTRIC

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March 27, 1979

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M/C 682

Subject: Comments on Proposed Reg. Guide 1.144

Reference: My Quick Letter to you dated March 12, 1979

As noted in the above referenced quick letter, the following comments are the coordinated comments from the various QA organizations in NEBG. It is my understanding that these comments should be transmitted to the secretary of the NRC by the end of this month.

1. The last sentence of the last paragraph under Section B. Discussion should be included under Section C. Regulatory Position as a Section C5 which should read as follows:

"5. Where more than one purchaser buys from a single supplier, and it is deemed advantageous to the purchasers and suppliers to perform a single audit of the supplier on behalf of the purchasers, such an audit is acceptable to the NRC staff in meeting the requirements of this Regulatory Guide provided all other requirements of the Regulatory Guide are met."
2. The overriding of the exclusion statement regarding applicability of ASME/ANSI N45.2.12 to ASME Code Section III, Divisions 1 & 2, and Section XI, as presented in Section C2, may cause purchaser confusion and nonconformance with respect to activities involving ASME Code products or services. It takes detailed study and analysis to recognize that the Regulatory Guide requires that the purchaser must conduct audits of suppliers of ASME Code products and services in the same manner as is required for any safety-related product or service since the ASME audit requirements do not cover all subjects required by 10CFR50, Appendix B, and they are not required to be conducted in accordance with the requirements of ASME/ANSI N45.2.12. The NRC is, in effect, not accepting the ASME audit program of their authorized code stamp holders and thus will increase the audits of such suppliers.

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Based on the history of ASME control of authorized stamp holders, and the quality of products produced by them, we consider this to be an unnecessary escalation of the audit process.

3. The second paragraph of Section C3b(2)(b) has been misinterpreted by some persons as being applicable to Sections C3b(1) and C3b(2)(a). It is requested that it be made clear that the annual evaluation is necessary only when triennial audits are conducted of suppliers.
4. We agree with and recommend incorporation of the comments supplied by ALF. If their comment regarding Section C3a(2) is found to be unacceptable to the NRC, we recommend revising as follows:

C3a(2) Design and Construction Phase Activities - Applicable elements of an organization's quality assurance program should be evaluated at least annually to establish the need for audits. The evaluation should include some or all of the following: prior quality program audits, results of audits from other sources (ASME, NRC, or customer, etc.), nature and frequency of identified discrepancies, significant changes in the organization or quality assurance program and the corrective actions taken to correct discrepancies. The evaluation should show that the activities affecting quality are controlled, or an audit should be conducted.

5. It is not clear how a purchaser will have other purchaser audits or ASME audits available to him to use in the annual evaluation of a supplier. (He might obtain NRC audits from the public document room if they had been performed). It is therefore recommended that item (4) in the last paragraph of Section C3b(2)(b) be revised to read: (4) results of audits from other sources, if available.
6. Since Section 4a converts the "should" of ASME/ANSI N45.2.12, paragraph 3.5.3 to "shall," it has in effect made it mandatory to conduct audits "when necessary to verify implementation of required corrective action." It is therefore unnecessary to convert the "should" of paragraph 4.3.2.7 of ASME/ANSI N45.2.12 to "shall" as done by Section 4b. It is recommended that Section 4b be deleted, thus accepting the recommendation as presented by paragraph 4.3.2.7 of ASME/ANSI N45.2.12.

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