

From: Dale Thatcher
To: Theresa Sutter
Date: 2/25/04 1:27PM
Subject: Re: QA Question for Dale Thatcher
Place: OPA

The short answer is there are no specific regulatory definitions for those terms related to QA. However the following information may help:

Regulatory Guide 1.33, "Quality Assurance Program Requirements (Operation)," endorses, with some exceptions, ANSI N18.7-1976/ANS 3.2 as an acceptable method of complying with the quality assurance program requirements of Appendix B to 10 CFR 50. ANSI N18.7-1976/ANS 3.2, Section 4.5, "Audit Program," states that audits of selected aspects of operational phase activities shall be performed with a frequency commensurate with their safety significance and in such a manner as to assure that an audit of all safety-related functions is completed within a period of two years. Regulatory position C.4 of RG 1.33 provides additional amplification of ANSI N18.7-1976/ANS 3.2 audit frequencies for certain program activities such as corrective action and conformance with technical specifications. 10 CFR 50, Appendix B, Criteria XVIII, "Audits," requires that a comprehensive system of planned audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program.

It should be noted that the term "safety-related structures, systems, and components" is defined in 10 CFR 50.2. However, in the context of quality assurance audits as used above, the terms "all aspects" and "all safety-related functions" refer to all those planned and systematic actions (i.e. QA program elements) necessary to provide adequate confidence that safety-related structures, systems, and components will perform satisfactorily in service. Although not a regulatory requirement, NRC staff review guidance for quality assurance audits is contained NUREG-0800, "Standard Review Plan," Sections 17.1, "Quality Assurance During the Design and Construction Phases," and 17.2, "Quality Assurance During the Operations Phase." As described in the Standard Review Plan, audits should provide: (1) a comprehensive independent verification and evaluation of quality-related procedures and activities, and (2) verification and evaluation of the quality assurance programs, procedures, and activities of suppliers. Although the NRC staff recognizes that the audit program relies on review and evaluation of a sampling of quality-related activities, provisions should be established requiring that audits be performed in all areas where the requirements of Appendix B to 10 CFR 50 are applicable.

>>> Theresa Sutter <tsutter@scientech.com> 02/19/04 12:47PM >>>
Mr. Thatcher,

The following question has been posed by a utility we are assisting. In the context of QA audits, the ANSI standards contain the phrases "all aspects" and "all safety related functions." The utility we are assisting is currently reviewing their audit program and they have asked if the terms are defined, in QA space, in any regulatory document. Are you familiar with the location of regulatory definitions for those terms?

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