
**Recommended Guidelines for Conducting Quality and Safety Audits of
Electronic/Software Based Products Used in Vital Signal Applications**

Revised 2025 (4 Pages)

A. Purpose

This Manual Part contains guidelines for conducting quality and safety audits of electronic/software-based products and systems used in vital signal applications.

B. General

1. This Manual Part contains guidelines to consider when auditing products and systems used in vital signal applications. The basis for these guidelines is contained in Manual Parts within Section 17, but can be adapted for use in a similarly defined plan. The intent is to:
 - a. Assist a railroad or auditor in determining that the electronic/software based products developed for vital signal applications, after August 1997, have been designed and manufactured under a product development program having quality and safety assurance programs similar to the programs set forth in Manual Parts:
 - (1) 17.1.1 Recommended Definitions of Terms Used in Section 17.
 - (2) 17.2.1 Recommended Quality Assurance Program for Electronic/Software Based Products Used in Vital Signal Applications.
 - (3) 17.3.1 Recommended Safety Assurance Program for Electronic/Software Based Products Used in Vital Signal Applications.
 - (4) 17.4.1 Recommended Reliability, Availability and Maintainability Assurance Program for Electronic/Software Based Products Used in Vital Signal Applications.
 - (5) 17.5.1 Recommended Configuration Management Program for Electronic/Software Based Products Used in Vital Signal Applications.
 - (6) 17.7.1 Recommended Guidelines for Verification and Validation of New Application Software for Electronic and/or Software Based Products Used in Vital Signal Applications.
 - (7) 17.7.2 Recommended Guidelines for Verification and Validation Testing of Revised Application Software for

Electronic/Software Based Products Used in Vital Signal Applications.

- b. To verify compliance with the specified requirements for a particular type of product.

C. Evidence of Qualification

- 1. Upon request, the supplier should make available for the purposes of auditing, documents that show compliance with the requirements as set forth in Manual Parts, 17.2.1, 17.3.1, 17.4.1, 17.5.1, 17.7.1 and 17.7.2 This documentation may include:
 - a. The Quality Manual and applicable quality procedures. Refer to Manual Part 17.2.1.
 - b. Documentation specific to the product being audited that will show compliance to the Quality Manual, the overall Product Development Plan, the safety assurance program and the specified requirements of the product.
- 2. All documentation submitted for the audit remains the property of the supplier and shall be returned or, at the supplier's discretion, destroyed following the completion of the audit. Both the auditors and suppliers should arrange for non-disclosure agreements with regard to confidential documentation.

D. Development of the Audit Plan

An Audit Plan should be developed prior to conducting the audit of the product and/or system.

E. Conducting the Audit

- 1. The audit should consist of reviewing the Quality documentation of the following activities:
 - a. Reference to applicable quality procedures and quality documents;
 - b. Reference to applicable methodologies for:
 - (1) Design
 - (2) Development
 - (3) Reliability
 - (4) Availability

- (5) Maintainability
 - (6) Safety assurance
 - c. The quality and safety organization;
 - d. The methods of control and verification of product requirements;
 - e. The control documents related to requirements and standards;
 - f. Configuration management and version control procedures;
 - g. Purchased product conforms to requirements;
 - h. Control of customer supplied product;
 - i. Identification of product during production;
 - j. Inspection and testing of product to requirements;
 - k. Control and calibration of test equipment, including test software;
 - l. Control of non-conforming product;
 - m. Implementing corrective and preventive actions;
 - n. Handling and delivery of product;
 - o. Handling and use of quality records;
 - p. Training of personnel and training records; and
 - q. Internal audits.
2. The audit should review the Product Development Plan to determine compliance with the following general activities:
- a. Definition of the product;
 - b. Design requirements and implementation;
 - c. Design reviews;
 - d. Verification and validation; and
 - e. Problem reporting procedures.
3. The audit should review the documentation specific to the product being audited. This review may include the following documentation:

- a. Design specification, to determine if the product requirements are appropriate for the intended use of the product. These may include functional requirements, safety requirements, and requirements for reliability, availability and maintainability.
- b. Safety documentation, in particular, hazard analyses, safety requirement allocation, and safety verification and validation documentation to determine if the safety requirements have been adequately determined and the product meets its safety requirements.
- c. Design documentation, verification and validation documentation to determine if the verification and validation adequately demonstrates the design meets the specified requirements.

F. Audit Documentation

1. The audit should be documented in the form of a report. This report should include:
 - a. Purpose and scope of the audit;
 - b. A description of the equipment or system being audited;
 - c. A description of the audit procedures;
 - d. The dates and location of the audit;
 - e. A list of auditors;
 - f. A list of documents and equipment reviewed;
 - g. The reports of any independent reviews conducted; and
 - h. The observations and findings of the auditors.
2. A summary of the audit findings shall be provided to the supplier. The supplier should be given an opportunity to respond to the audit observations and findings.
3. The resolution of issues raised by the audit should be included in the final audit report.