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[75 FR 2718, Jan. 15, 2010]

APPENDIX D TO PART 236—INDEPENDENT
REVIEW OF VERIFICATION AND VALI-
DATION

(a) This appendix provides minimum requirements for independent third-party assessment of product safety verification and validation pursuant to subpart H or subpart I of this part. The goal of this assessment is to provide an independent evaluation of the product manufacturer's utilization of safety design practices during the product's development and testing phases, as required by any mutually agreed upon controlling documents and standards and the applicable railroad's:

(1) Railroad Safety Program Plan (RSPP) and Product Safety Plan (PSP) for processor based systems developed under subpart H or,

(2) PTC Product Development Plan (PTCDP) and PTC Safety Plan (PTCSP) for PTC systems developed under subpart I.

(b) The supplier may request advice and assistance of the reviewer concerning the actions identified in paragraphs (c) through (g) of this appendix. However, the reviewer shall not engage in any design efforts associated with the product, the products subsystems, or the products components, in order to preserve the reviewer's independence and maintain the supplier's proprietary right to the product.

(c) The supplier shall provide the reviewer access to any and all documentation that the reviewer requests and attendance at any design review or walkthrough that the reviewer determines as necessary to complete and accomplish the third party assessment. The reviewer may be accompanied by representatives of FRA as necessary, in FRA's judgment, for FRA to monitor the assessment.

(d) The reviewer shall evaluate the product with respect to safety and comment on the adequacy of the processes which the supplier applies to the design and development of the product. At a minimum, the reviewer shall compare the supplier processes with acceptable validation and verification methodology and employ any other such tests or comparisons if they have been agreed to previously with FRA. Based on these analyses, the reviewer shall identify and document any significant safety vulnerabilities which are not adequately mitigated by the supplier's (or user's) processes. Finally, the reviewer shall evaluate and document the adequacy of the railroad's

(1) RSPP, the PSP, and any other documents pertinent to a product being developed under subpart H of this part; or

(2) PTCDP and PTCSP for systems being developed under subpart I of this part.

(e) The reviewer shall analyze the Hazard Log and/or any other hazard analysis documents for comprehensiveness and compliance with applicable railroad, vendor, supplier, industry, national, and international standards.

(f) The reviewer shall analyze all Fault Tree Analyses (FTA), Failure Mode and Effects Criticality Analysis (FMECA), and other hazard analyses for completeness, correctness, and compliance with applicable railroad, vendor, supplier, industry, national and international standards.

(g) The reviewer shall randomly select various safety-critical software, and hardware modules, if directed by FRA, for audit to verify whether the requirements of the applicable railroad, vendor, supplier, industry, national, and international standards were followed. The number of modules audited must be determined as a representative number sufficient to provide confidence that all unaudited modules were developed in compliance with the applicable railroad, vendor, supplier, industry, national, and international standards.

(h) The reviewer shall evaluate and comment on the plan for installation and test procedures of the product for revenue service.

(i) The reviewer shall prepare a final report of the assessment. The report shall be submitted to the railroad prior to the commencement of installation testing and contain at least the following information:

(1) Reviewer's evaluation of the adequacy of the PSP in the case of products developed under subpart H, or PTCSP for products developed under subpart I of this part, including the supplier's MTTHE and risk estimates for the product, and the supplier's confidence interval in these estimates;

(2) Product vulnerabilities, potentially hazardous failure modes, or potentially hazardous operating circumstances which the reviewer felt were not adequately identified, tracked, mitigated, and corrected by either the vendor or supplier or the railroad;

(3) A clear statement of position for all parties involved for each product vulnerability cited by the reviewer;

(4) Identification of any documentation or information sought by the reviewer that was denied, incomplete, or inadequate;

(5) A listing of each applicable vendor, supplier, industry, national, or international standard, procedure or process which was not properly followed;

(6) Identification of the software verification and validation procedures, as well as the hardware verification validation procedures if deemed appropriate by FRA, for the product's safety-critical applications, and the reviewer's evaluation of the adequacy of these procedures;

(7) Methods employed by the product manufacturer to develop safety-critical software;

(8) If deemed applicable by FRA, the methods employed by the product manufacturer to develop safety-critical hardware by generally acceptable techniques;

(9) Method by which the supplier or railroad addresses comprehensiveness of the product design which considers the safety elements listed in paragraph (b) of appendix C to this part.

[75 FR 2720, Jan. 15, 2010]

APPENDIX E TO PART 236—HUMAN-MACHINE INTERFACE (HMI) DESIGN

(a) This appendix provides human factors design criteria applicable to both subpart H and subpart I of this part. HMI design criteria will minimize negative safety effects by causing designers to consider human factors in the development of HMIs. The product design should sufficiently incorporate human factors engineering that is appropriate to the complexity of the product; the gender, educational, mental, and physical capabilities of the intended operators and maintainers; the degree of required human interaction with the component; and the environment in which the product will be used.

(b) As used in this section, “designer” means anyone who specifies requirements for—or designs a system or subsystem, or both, for—a product subject to subpart H or subpart I of this part, and “operator” means any human who is intended to receive information from, provide information to, or perform repairs or maintenance on a safety-critical product subject to subpart H or I of this part.

(c) Human factors issues the designers must consider with regard to the general function of a system include:

(1) *Reduced situational awareness and over-reliance.* HMI design must give an operator active functions to perform, feedback on the results of the operator’s actions, and information on the automatic functions of the system as well as its performance. The operator must be “in-the-loop.” Designers must consider at a minimum the following methods of maintaining an active role for human operators:

(i) The system must require an operator to initiate action to operate the train and require an operator to remain “in-the-loop” for at least 30 minutes at a time;

(ii) The system must provide timely feedback to an operator regarding the system’s automated actions, the reasons for such actions, and the effects of the operator’s manual actions on the system;

(iii) The system must warn operators in advance when it requires an operator to take action;

(iv) HMI design must equalize an operator’s workload; and

(v) HMI design must not distract from the operator’s safety related duties.

(2) *Expectation of predictability and consistency in product behavior and communications.* HMI design must accommodate an operator’s expectation of logical and consistent relationships between actions and results. Similar objects must behave consistently when an operator performs the same action upon them.

(3) *End user limited ability to process information.* HMI design must therefore minimize an operator’s information processing load. To minimize information processing load, the designer must:

(i) Present integrated information that directly supports the variety and types of decisions that an operator makes;

(ii) Provide information in a format or representation that minimizes the time required to understand and act; and

(iii) Conduct utility tests of decision aids to establish clear benefits such as processing time saved or improved quality of decisions.

(4) *End user limited memory.* HMI design must therefore minimize an operator’s information processing load.

(i) To minimize short-term memory load, the designer shall integrate data or information from multiple sources into a single format or representation (“chunking”) and design so that three or fewer “chunks” of information need to be remembered at any one time.

(ii) To minimize long-term memory load, the designer shall design to support recognition memory, design memory aids to minimize the amount of information that must be recalled from unaided memory when making critical decisions, and promote active processing of the information.

(d) Design systems that anticipate possible user errors and include capabilities to catch errors before they propagate through the system;

(1) Conduct cognitive task analyses prior to designing the system to better understand the information processing requirements of operators when making critical decisions; and

(2) Present information that accurately represents or predicts system states.

(e) When creating displays and controls, the designer must consider user ergonomics and shall:

(1) Locate displays as close as possible to the controls that affect them;

(2) Locate displays and controls based on an operator’s position;

(3) Arrange controls to minimize the need for the operator to change position;

(4) Arrange controls according to their expected order of use;

(5) Group similar controls together;