

*Risk assessment* means the process of determining, either quantitatively or qualitatively, the measure of risk associated with use of the product under all intended operating conditions or the previous condition.

*Safety-critical*, as applied to a function, a system, or any portion thereof, means the correct performance of which is essential to safety of personnel or equipment, or both; or the incorrect performance of which could cause a hazardous condition, or allow a hazardous condition which was intended to be prevented by the function or system to exist.

*Subsystem* means a defined portion of a system.

*System* refers to a signal or train control system and includes all subsystems and components thereof, as the context requires.

*System Safety Precedence* means the order of precedence in which methods used to eliminate or control identified hazards within a system are implemented.

*Validation* means the process of determining whether a product's design requirements fulfill its intended design objectives during its development and life-cycle. The goal of the validation process is to determine "whether the correct product was built."

*Verification* means the process of determining whether the results of a given phase of the development cycle fulfill the validated requirements established at the start of that phase. The goal of the verification process is to determine "whether the product was built correctly."

**§ 236.905 Railroad Safety Program Plan (RSPP).**

(a) *What is the purpose of an RSPP?* A railroad subject to this subpart shall develop an RSPP, subject to FRA approval, that serves as its principal safety document for all safety-critical products. The RSPP must establish the minimum PSP requirements that will govern the development and implementation of all products subject to this subpart, consistent with the provisions contained in § 236.907.

(b) *What subject areas must the RSPP address?* The railroad's RSPP must ad-

dress, at a minimum, the following subject areas:

(1) *Requirements and concepts.* The RSPP must require a description of the preliminary safety analysis, including:

(i) A complete description of methods used to evaluate a system's behavioral characteristics;

(ii) A complete description of risk assessment procedures;

(iii) The system safety precedence followed; and

(iv) The identification of the safety assessment process.

(2) *Design for verification and validation.* The RSPP must require the identification of verification and validation methods for the preliminary safety analysis, initial development process, and future incremental changes, including standards to be used in the verification and validation process, consistent with appendix C to this part. The RSPP must require that references to any non-published standards be included in the PSP.

(3) *Design for human factors.* The RSPP must require a description of the process used during product development to identify human factors issues and develop design requirements which address those issues.

(4) *Configuration management control plan.* The RSPP must specify requirements for configuration management for all products to which this subpart applies.

(c) *How are RSPP's approved?* (1) Each railroad shall submit a petition for approval of an RSPP to the Associate Administrator for Safety, FRA, 1200 New Jersey Avenue, SE., Mail Stop 25, Washington, DC 20590. The petition must contain a copy of the proposed RSPP, and the name, title, address, and telephone number of the railroad's primary contact person for review of the petition.

(2) Normally within 180 days of receipt of a petition for approval of an RSPP, FRA:

(i) Grants the petition, if FRA finds that the petition complies with applicable requirements of this subpart, attaching any special conditions to the approval of the petition as necessary to carry out the requirements of this subpart;

(ii) Denies the petition, setting forth reasons for denial; or

(iii) Requests additional information.

(3) If no action is taken on the petition within 180 days, the petition remains pending for decision. The petitioner is encouraged to contact FRA for information concerning its status.

(4) FRA may reopen consideration of any previously-approved petition for cause, providing reasons for such action.

(d) *How are RSPP's modified?* (1) Railroads shall obtain FRA approval for any modification to their RSPP which affects a safety-critical requirement of a PSP. Other modifications do not require FRA approval.

(2) Petitions for FRA approval of RSPP modifications are subject to the same procedures as petitions for initial RSPP approval, as specified in paragraph (c) of this section. In addition, such petitions must identify the proposed modification(s) to be made, the reason for the modification(s), and the effect of the modification(s) on safety.

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#### § 236.907 Product Safety Plan (PSP).

(a) *What must a PSP contain?* The PSP must include the following:

(1) A complete description of the product, including a list of all product components and their physical relationship in the subsystem or system;

(2) A description of the railroad operation or categories of operations on which the product is designed to be used, including train movement density, gross tonnage, passenger train movement density, hazardous materials volume, railroad operating rules, and operating speeds;

(3) An operational concepts document, including a complete description of the product functionality and information flows;

(4) A safety requirements document, including a list with complete descriptions of all functions which the product performs to enhance or preserve safety;

(5) A document describing the manner in which product architecture satisfies safety requirements;

(6) A hazard log consisting of a comprehensive description of all safety-relevant hazards to be addressed during

the life cycle of the product, including maximum threshold limits for each hazard (for unidentified hazards, the threshold shall be exceeded at one occurrence);

(7) A risk assessment, as prescribed in § 236.909 and appendix B to this part;

(8) A hazard mitigation analysis, including a complete and comprehensive description of all hazards to be addressed in the system design and development, mitigation techniques used, and system safety precedence followed, as prescribed by the applicable RSPP;

(9) A complete description of the safety assessment and verification and validation processes applied to the product and the results of these processes, describing how subject areas covered in appendix C to this part are either: addressed directly, addressed using other safety criteria, or not applicable;

(10) A complete description of the safety assurance concepts used in the product design, including an explanation of the design principles and assumptions;

(11) A human factors analysis, including a complete description of all human-machine interfaces, a complete description of all functions performed by humans in connection with the product to enhance or preserve safety, and an analysis in accordance with appendix E to this part or in accordance with other criteria if demonstrated to the satisfaction of the Associate Administrator for Safety to be equally suitable;

(12) A complete description of the specific training of railroad and contractor employees and supervisors necessary to ensure the safe and proper installation, implementation, operation, maintenance, repair, inspection, testing, and modification of the product;

(13) A complete description of the specific procedures and test equipment necessary to ensure the safe and proper installation, implementation, operation, maintenance, repair, inspection, testing, and modification of the product. These procedures, including calibration requirements, shall be consistent with or explain deviations from the equipment manufacturer's recommendations;