

the territory following the discontinuance or modification. NOTE: This is an instance in which the base case is posited as greater risk than the actual (unadjusted) previous condition because the railroad would have obtained relief from the requirement to maintain the existing signal or train control system even if no new product had been proffered.

(ii) If FRA determines that discontinuance or modification of the system should be denied without regard to whether the product is installed on the territory, then the base case shall remain the previous condition (unadjusted).

(iii) If, after consideration of the application and review of the PSP, FRA determines that neither paragraph (e)(4)(i) nor paragraph (e)(4)(ii) of this section should apply, FRA will establish a base case that is consistent with safety and in the public interest.

§ 236.911 Exclusions.

(a) *Does this subpart apply to existing systems?* The requirements of this subpart do not apply to products in service as of June 6, 2005. Railroads may continue to implement and use these products and components from these existing products.

(b) *How will transition cases be handled?* Products designed in accordance with subparts A through G of this part which are not in service but are developed or are in the developmental stage prior to March 7, 2005, may be excluded upon notification to FRA by June 6, 2005, if placed in service by March 7, 2008. Railroads may continue to implement and use these products and components from these existing products. A railroad may at any time elect to have products that are excluded made subject to this subpart by submitting a PSP as prescribed in § 236.913 and otherwise complying with this subpart.

(c) *How are office systems handled?* The requirements of this subpart do not apply to existing office systems and future deployments of existing office system technology. However, a subsystem or component of an office system must comply with the requirements of this subpart if it performs safety-critical functions within, or affects the safety performance of, a new or next-genera-

tion train control system. For purposes of this section, "office system" means a centralized computer-aided train-dispatching system or centralized traffic control board.

(d) *How are modifications to excluded products handled?* Changes or modifications to products otherwise excluded from the requirements of this subpart by this section are not excluded from the requirements of this subpart if they result in a degradation of safety or a material increase in safety-critical functionality.

(e) *What other rules apply to excluded products?* Products excluded by this section from the requirements of this subpart remain subject to subparts A through G of this part as applicable.

§ 236.913 Filing and approval of PSPs.

(a) *Under what circumstances must a PSP be prepared?* A PSP must be prepared for each product covered by this subpart. A joint PSP must be prepared when:

(1) The territory on which a product covered by this subpart is normally subject to joint operations, or is operated upon by more than one railroad; and

(2) The PSP involves a change in method of operation.

(b) *Under what circumstances must a railroad submit a petition for approval for a PSP or PSP amendment, and when may a railroad submit an informational filing?* Depending on the nature of the proposed product or change, the railroad shall submit either an informational filing or a petition for approval. Submission of a petition for approval is required for PSPs or PSP amendments concerning installation of new or next-generation train control systems. All other actions that result in the creation of a PSP or PSP amendment require an informational filing and are handled according to the procedures outlined in paragraph (c) of this section. Applications for discontinuance and material modification of signal and train control systems remain governed by parts 235 and 211 of this chapter; and petitions subject to this section may be consolidated with any relevant application for administrative handling.

(c) *What are the procedures for informational filings?* The following procedures apply to PSPs and PSP amendments which do not require submission of a petition for approval, but rather require an informational filing:

(1) Not less than 180 days prior to planned use of the product in revenue service as described in the PSP or PSP amendment, the railroad shall submit an informational filing to the Associate Administrator for Safety, FRA, 1120 Vermont Avenue, NW., Mail Stop 25, Washington, DC 20590. The informational filing must provide a summary description of the PSP or PSP amendment, including the intended use of the product, and specify the location where the documentation as described in §236.917(a)(1) is maintained.

(2) Within 60 days of receipt of the informational filing, FRA:

(i) Acknowledges receipt of the filing;

(ii) Acknowledges receipt of the informational filing and requests further information; or

(iii) Acknowledges receipt of the filing and notifies the railroad, for good cause, that the filing will be considered as a petition for approval as set forth in paragraph (d) of this section, and requests such further information as may be required to initiate action on the petition for approval. Examples of good cause, any one of which is sufficient, include: the PSP describes a product with unique architectural concepts; the PSP describes a product that uses design or safety assurance concepts considered outside existing accepted practices (see Appendix C); and the PSP describes a locomotive-borne product that commingles safety-critical train control processing functions with locomotive operational functions. In addition, good cause includes any instance where the PSP or PSP amendment does not appear to support its safety claim of satisfaction of the performance standard, after FRA has requested further information as provided in paragraph (c)(2)(i) of this section.

(d) *What procedures apply to petitions for approval?* The following procedures apply to PSPs and PSP amendments which require submission of a petition for approval:

(1) *Petitions for approval involving prior FRA consultation.* (i) The railroad

may file a Notice of Product Development with the Associate Administrator for Safety not less than 30 days prior to the end of the system design review phase of product development and 180 days prior to planned implementation, inviting FRA to participate in the design review process and receive periodic briefings and updates as needed to follow the course of product development. At a minimum, the Notice of Product Development must contain a summary description of the product to be developed and a brief description of goals for improved safety.

(ii) Within 15 days of receipt of the Notice of Product Development, the Associate Administrator for Safety either acknowledges receipt or acknowledges receipt and requests more information.

(iii) If FRA concludes that the Notice of Product Development contains sufficient information, the Associate Administrator for Safety determines the extent and nature of the assessment and review necessary for final product approval. FRA may convene a technical consultation as necessary to discuss issues related to the design and planned development of the product.

(iv) Within 60 days of receiving the Notice of Product Development, the Associate Administrator for Safety provides a letter of preliminary review with detailed findings, including whether the design concepts of the proposed product comply with the requirements of this subpart, whether design modifications are necessary to meet the requirements of this subpart, and the extent and nature of the safety analysis necessary to comply with this subpart.

(v) Not less than 60 days prior to use of the product in revenue service, the railroad shall file with the Associate Administrator for Safety a petition for final approval.

(vi) Within 30 days of receipt of the petition for final approval, the Associate Administrator for Safety either acknowledges receipt or acknowledges receipt and requests more information. Whenever possible, FRA acts on the petition for final approval within 60 days of its filing by either granting it or denying it. If FRA neither grants nor denies the petition for approval within 60

days, FRA advises the petitioner of the projected time for decision and conducts any further consultations or inquiries necessary to decide the matter.

(2) *Other petitions for approval.* The following procedures apply to petitions for approval of PSPs which do not involve prior FRA consultation as described in paragraph (d)(1) of this section.

(i) Not less than 180 days prior to use of a product in revenue service, the railroad shall file with the Associate Administrator for Safety a petition for approval.

(ii) Within 60 days of receipt of the petition for approval, FRA either acknowledges receipt, or acknowledges receipt and requests more information.

(iii) Whenever possible, considering the scope, complexity, and novelty of the product or change, FRA acts on the petition for approval within 180 days of its filing by either granting it or denying it. If FRA neither grants nor denies the petition for approval within 180 days, it remains pending, and FRA provides the petitioner with a statement of reasons why the petition has not yet been approved.

(e) *What role do product users play in the process of safety review?* (1) FRA will publish in the FEDERAL REGISTER periodically a topic list including docket numbers for informational filings and a petition summary including docket numbers for petitions for approval.

(2) Interested parties may submit to FRA information and views pertinent to FRA's consideration of an informational filing or petition for approval. FRA considers comments to the extent practicable within the periods set forth in this section. In a proceeding consolidated with a proceeding under part 235 of this chapter, FRA considers all comments received.

(f) *Is it necessary to complete field testing prior to filing the petition for approval?* A railroad may file a petition for approval prior to completion of field testing of the product. The petition for approval should additionally include information sufficient for FRA to arrange monitoring of the tests. The Associate Administrator for Safety may approve a petition for approval contingent upon successful completion of the test program contained in the

PSP or hold the petition for approval pending completion of the tests.

(g) *How are PSPs approved?* (1) The Associate Administrator for Safety grants approval of a PSP when:

(i) The petition for approval has been properly filed and contains the information required in § 236.907;

(ii) FRA has determined that the PSP complies with the railroad's approved RSP and applicable requirements of this subpart; and

(iii) The risk assessment supporting the PSP demonstrates that the proposed product satisfies the minimum performance standard stated in § 236.909.

(2) The Associate Administrator for Safety considers the following applicable factors when evaluating the risk assessment:

(i) The extent to which recognized standards have been utilized in product design and in the relevant safety analysis;

(ii) The availability of quantitative data, including calculations of statistical confidence levels using accepted methods, associated with risk estimates;

(iii) The complexity of the product and the extent to which it will incorporate or deviate from design practices associated with previously established histories of safe operation;

(iv) The degree of rigor and precision associated with the safety analyses, including the comprehensiveness of the qualitative analyses, and the extent to which any quantitative results realistically reflect appropriate sensitivity cases;

(v) The extent to which validation of the product has included experiments and tests to identify uncovered faults in the operation of the product;

(vi) The extent to which identified faults are effectively addressed;

(vii) Whether the risk assessment for the previous condition was conducted using the same methodology as that for operation under the proposed condition; and

(viii) If an independent third-party assessment is required or is performed at the election of the supplier or railroad, the extent to which the results of the assessment are favorable.

(3) The Associate Administrator for Safety also considers when assessing PSPs the safety requirements for the product within the context of the proposed method of operations, including:

(i) The degree to which the product is relied upon as the primary safety system for train operations; and

(ii) The degree to which the product is overlaid upon and its operation is demonstrated to be independent of safety-relevant rules, practices and systems that will remain in place following the change under review.

(4) As necessary to ensure compliance with this subpart and with the RSPP, FRA may attach special conditions to the approval of the petition.

(5) Following the approval of a petition, FRA may reopen consideration of the petition for cause. Cause for reopening a petition includes such circumstances as a credible allegation of error or fraud, assumptions determined to be invalid as a result of in-service experience, or one or more unsafe events calling into question the safety analysis underlying the approval.

(h) *Under what circumstances may a third-party assessment be required, and by whom may it be conducted?* (1) The PSP must be supported by an independent third party assessment of the product when FRA concludes it is necessary based upon consideration of the following factors:

(i) Those factors listed in paragraphs (g)(2)(i) through (g)(2)(vii) of this section;

(ii) The sufficiency of the assessment or audit previously conducted at the election of a supplier or railroad; and

(iii) Whether applicable requirements of subparts A through G of this part are satisfied.

(2) As used in this section, “independent third party” means a technically competent entity responsible to and compensated by the railroad (or an association on behalf of one or more railroads) that is independent of the supplier of the product. An entity that is owned or controlled by the supplier, that is under common ownership or control with the supplier, or that is otherwise involved in the development of the product is not considered “independent” within the meaning of this section. FRA may maintain a roster of

recognized technically competent entities as a service to railroads selecting reviewers under this section; however, a railroad is not limited to entities currently listed on any such roster.

(3) The third-party assessment must, at a minimum, consist of the activities and result in production of documentation meeting the requirements of Appendix D to this part. However, when requiring an assessment pursuant to this section, FRA specifies any requirements in Appendix D to this part which the agency has determined are not relevant to its concerns and, therefore, need not be included in the assessment. The railroad shall make the final assessment report available to FRA upon request.

(i) *How may a PSP be amended?* A railroad may submit an amendment to a PSP at any time in the same manner as the initial PSP. Notwithstanding the otherwise applicable requirements found in this section and § 236.915, changes affecting the safety-critical functionality of a product may be made prior to the submission and approval of the PSP amendment as necessary in order to mitigate risk.

(j) *How may field testing be conducted prior to PSP approval?* (1) Field testing of a product may be conducted prior to the approval of a PSP by the submission of an informational filing by a railroad. The FRA will arrange to monitor the tests based on the information provided in the filing, which must include:

(i) A complete description of the product;

(ii) An operational concepts document;

(iii) A complete description of the specific test procedures, including the measures that will be taken to protect trains and on-track equipment;

(iv) An analysis of the applicability of the requirements of subparts A through G of this part to the product that will not apply during testing;

(v) The date testing will begin;

(vi) The location of the testing; and

(vii) A description of any effect the testing will have on the current method of operation.

(2) FRA may impose such additional conditions on this testing as may be

necessary for the safety of train operations. Exemptions from regulations other than those contained in this part must be requested through waiver procedures in part 211 of this chapter.

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§ 236.915 Implementation and operation.

(a) *When may a product be placed or retained in service?* (1) Except as stated in paragraphs (a)(2) and (a)(3) of this section, a railroad may operate in revenue service any product 180 days after filing with FRA the informational filing for that product. The FRA filing date can be found in FRA's acknowledgment letter referred to in § 236.913(c)(2).

(2) Except as stated in paragraph (a)(3) of this section, if FRA approval is required for a product, the railroad shall not operate the product in revenue service until after the Associate Administrator for Safety has approved the petition for approval for that product pursuant to § 236.913.

(3) If after product implementation FRA elects, for cause, to treat the informational filing for the product as a petition for approval, the product may remain in use if otherwise consistent with the applicable law and regulations. FRA may impose special conditions for use of the product during the period of review for cause.

(b) *How does the PSP relate to operation of the product?* Each railroad shall comply with all provisions in the PSP for each product it uses and shall operate within the scope of initial operational assumptions and predefined changes identified by the PSP. Railroads may at any time submit an amended PSP according to the procedures outlined in § 236.913.

(c) *What precautions must be taken prior to interference with the normal functioning of a product?* The normal functioning of any safety-critical product must not be interfered with in testing or otherwise without first taking measures to provide for safe movement of trains, locomotives, roadway workers and on-track equipment that depend on normal functioning of such product.

(d) *What actions must be taken immediately upon failure of a safety-critical*

component? When any safety-critical product component fails to perform its intended function, the cause must be determined and the faulty component adjusted, repaired, or replaced without undue delay. Until repair of such essential components are completed, a railroad shall take appropriate action as specified in the PSP. See also §§ 236.907(d), 236.917(b).

§ 236.917 Retention of records.

(a) *What life-cycle and maintenance records must be maintained?* (1) The railroad shall maintain at a designated office on the railroad:

(i) For the life-cycle of the product, adequate documentation to demonstrate that the PSP meets the safety requirements of the railroad's RSPP and applicable standards in this subpart, including the risk assessment; and

(ii) An Operations and Maintenance Manual, pursuant to § 236.919; and

(iii) Training records pursuant to § 236.923(b).

(2) Results of inspections and tests specified in the PSP must be recorded as prescribed in § 236.110.

(3) Contractors of the railroad shall maintain at a designated office training records pursuant to § 236.923(b).

(b) *What actions must the railroad take in the event of occurrence of a safety-relevant hazard?* After the product is placed in service, the railroad shall maintain a database of all safety-relevant hazards as set forth in the PSP and those that had not been previously identified in the PSP. If the frequency of the safety-relevant hazards exceeds the threshold set forth in the PSP (see § 236.907(a)(6)), then the railroad shall:

(1) Report the inconsistency in writing (by mail, facsimile, e-mail, or hand delivery to the Director, Office of Safety Assurance and Compliance, FRA, 1120 Vermont Ave., NW., Mail Stop 25, Washington, DC 20590, within 15 days of discovery. Documents that are hand delivered must not be enclosed in an envelope;

(2) Take prompt countermeasures to reduce the frequency of the safety-relevant hazard(s) below the threshold set forth in the PSP; and

(3) Provide a final report to the FRA Director, Office of Safety Assurance