

Commission Regulation (EU) No 1158/2010 of 9 December 2010 on a common safety method for assessing conformity with the requirements for obtaining railway safety certificates (Text with EEA relevance) (repealed)

Article 1	Subject-matter
Article 2	Definitions
Article 3	Procedures for assessing applications
Article 4	Supervision
Article 5	Entry into force
	Signature

ANNEX I

Procedure for assessing conformity with requirements for obtaining safety certificates to be issued in accordance with Article 10(2)(a) and (b) of Directive 2004/49/EC

1. The procedures that a national safety authority puts in place...
 - (a) Setting up and reviewing the assessment process
 - (b) Quality of the assessment process
 - (c) Scope of the assessment
 - (d) Timing of the assessment
 - (e) Decision making during the assessment
2. The national safety authority shall assess whether the application for...
3. In particular, the national safety authority shall assess whether the...
4. When granting a safety certificate, compliance of the applicant's safety...
5. When identifying a point of query or possible non-compliance, the...
6. If a railway undertaking applies for both Part A and...
7. The general framework procedures in place for assessing applications for...
8. A national safety authority's assessment of an application for a...
9. These assessment criteria are based on showing that the results...
10. National safety authorities shall cooperate to address issues of non-compliance...

ANNEX II

Criteria for assessing conformity with the requirements for obtaining safety certificates to be issued in accordance with Article 10(2)(a)

of Directive 2004/49/EC related to the railway undertaking's safety management system as described in Article 9 and Annex III of that Directive

- A. RISK CONTROL MEASURES FOR ALL RISKS ASSOCIATED WITH THE ACTIVITY...
 - A.1 There are procedures put in place to identify risks associated...
 - A.2 There are procedures in place to develop and put in...
 - A.3 There are procedures in place to monitor the effectiveness of...
 - A.4 There are procedures in place to recognise the need to...
 - A.5 There are procedures for agreed documentation and communication with the...
 - A.6 There are procedures to monitor the effectiveness of these arrangements...

- B. RISK CONTROL RELATED TO THE SUPPLY OF MAINTENANCE AND MATERIAL...
 - B.1 There are procedures to derive maintenance requirements/standards/processes from safety data...
 - B.2 There are procedures to adapt maintenance intervals according to the...
 - B.3 There are procedures to ensure that the responsibility for maintenance...
 - B.4 There are procedures to collect information on malfunctions and defects...
 - B.5 There are procedures to identify and report risks arising from...
 - B.6 There are procedures to verify and control the performance and...

- C. RISK CONTROL RELATED TO THE USE OF CONTRACTORS AND CONTROL...
 - C.1 There are procedures to verify the competence of contractors (including...
 - C.2 There are procedures to verify and control the safety performance...
 - C.3 Responsibilities and tasks relating to railway safety issues are clearly...
 - C.4 There are procedures to ensure traceability of safety-related documents and...
 - C.5 There are procedures to ensure that safety tasks, including the...

- D. RISKS ARISING FROM THE ACTIVITIES OF OTHER PARTIES EXTERNAL TO...
 - D.1 There are procedures to identify potential risks from parties external...
 - D.2 There are procedures to establish control measures to mitigate the...
 - D.3 There are procedures to monitor the effectiveness of the measures...

- E. DOCUMENTATION OF THE SAFETY MANAGEMENT SYSTEM
 - E.1 There is a description of the activity that makes clear...
 - E.2 There is a description of the structure of the safety...
 - E.3 There is a description of safety management system procedures required...
 - E.4 Safety-critical processes and tasks relevant to the type of activity/service...

- F. DISTRIBUTION OF RESPONSIBILITIES
 - F.1 There is a description of how coordination of safety management...
 - F.2 There are procedures to ensure that staff with delegated responsibilities...
 - F.3 Safety-related areas of responsibility, and the distribution of responsibilities to...
 - F.4 There is a procedure to ensure that safety tasks are...

- G. SECURING CONTROL BY THE MANAGEMENT ON DIFFERENT LEVELS
 - G.1 There is a description of how responsibilities are allocated for...
 - G.2 There is a procedure for regular monitoring of task performance...
 - G.3 There are procedures to identify and manage the impact of...
 - G.4 There are procedures to hold those with a role in...

- G.5 There are procedures to allocate resources to deliver the tasks...
- H. INVOLVING STAFF AND THEIR REPRESENTATIVES ON ALL LEVELS
 - H.1 There are procedures in place to ensure that staff and...
 - H.2 Staff involvement and consultation arrangements are documented.
- I. ENSURING CONTINUOUS IMPROVEMENT
- J. SAFETY POLICY APPROVED BY THE ORGANISATION'S CHIEF EXECUTIVE AND COMMUNICATED...
- K. QUALITATIVE AND QUANTATIVE TARGETS OF THE ORGANISATION FOR MAINTAINING AND...
 - K.1 There are procedures to determine relevant safety targets in line...
 - K.2 There are procedures to determine relevant safety targets consistent with...
 - K.3 There are procedures to regularly assess overall safety performance in...
 - K.4 There are procedures in place to regularly monitor and review...
 - K.5 There are procedures in place by the railway undertaking to...
- L. PROCEDURES TO MEET EXISTING, NEW AND ALTERED TECHNICAL AND OPERATIONAL...
 - L.1 For safety related requirements relevant to the type and extent...
 - L.2 There are procedures in place to ensure that the right...
 - L.3 The safety management system has procedures in place to ensure...
- M. PROCEDURES AND METHODS FOR CARRYING OUT RISK EVALUATION AND IMPLEMENTING...
 - M.1 There are management procedures for changes in equipment, procedures, organisation,...
 - M.2 There are risk assessment procedures to manage changes and to...
 - M.3 The railway undertaking has procedures in place to feed the...
- N. PROVISION OF STAFF TRAINING PROGRAMMES AND SYSTEMS TO ENSURE THAT...
 - N.1 There is a competence management system that includes at least:...
 - N.2 There are procedures within the competence management system providing for:...
- O. ARRANGEMENTS FOR THE PROVISION OF SUFFICIENT INFORMATION WITHIN THE ORGANISATION...
 - O.1 There are procedures to ensure that:
 - O.2 There are procedures to ensure that:
 - O.3 There are arrangements in place for the sharing of information...
- P. PROCEDURES AND FORMATS FOR DOCUMENTING SAFETY INFORMATION, AND DESIGNATION OF...
 - P.1 There are procedures to ensure that all relevant safety information...
 - P.2 There are procedures to:
 - P.3 There is a procedure for configuration control of vital safety...
- Q. PROCEDURES TO ENSURE THAT ACCIDENTS, INCIDENTS, NEAR MISSES AND OTHER...
 - Q.1 There are procedures to ensure that accidents, incidents, near misses...

- Q.2 There are procedures to ensure that:
- Q.3 There are procedures for relevant information relating to the investigation...
- R. PROVISION OF PLANS FOR ACTION AND ALERTS AND INFORMATION IN...
 - R.1 A document identifies all types of emergency, including degraded operations,...
 - R.2 There are procedures in place to ensure that, for each...
 - R.3 The roles and responsibilities of all parties are identified and...
 - R.4 Plans for action, alerts and information exist and include:
 - R.5 There is a document describing how resources and means have...
 - R.6 There are procedures in place to re-establish normal operating conditions...
 - R.7 There are procedures for testing emergency plans in cooperation with...
 - R.8 There are procedures to ensure that competent staff in charge...
 - R.9 There is a procedure to contact the entity in charge...
- S. PROVISIONS FOR RECURRENT INTERNAL AUDITING OF THE SAFETY MANAGEMENT SYSTEM...
 - S.1 There is an internal auditing system which is independent and...
 - S.2 There is a schedule of planned internal audits which can...
 - S.3 There are procedures in place to identify and select suitably...
 - S.4 Procedures are in place to:
 - S.5 There are procedures to ensure that senior levels of the...
 - S.6 There is a document showing how audits are planned in...

ANNEX III

Criteria for assessing conformity with the requirements for obtaining safety certificates to be issued in accordance with Article 10(2)(b) of the Directive 2004/49/EC

GENERAL

- A. COMPLIANCE WITH NETWORK-SPECIFIC RULES
 - A.1 There are documents containing results to show that the specific...
 - A.2 Network interfaces with other parties involved in railway operation on...
 - A.3 There are documents showing how the railway undertaking will interact...
 - A.4 There are documents showing how the railway undertaking will deal...
 - A.5 There are documents identifying any specific accident/incident investigation rules and...
- B. COMPLIANCE WITH NETWORK-SPECIFIC REQUIREMENTS FOR STAFF COMPETENCE
 - B.1 The documentation demonstrates that the applicant's safety management system contains...
 - B.2 The documentation demonstrates that there are arrangements put in place...
 - B.3 The documentation demonstrates the applicant's ability to produce documents to...
- C. COMPLIANCE WITH NETWORK-SPECIFIC REQUIREMENTS FOR MANAGEMENT OF ROLLING STOCK
 - C.1 In the documentation, the types of rolling stock to be...
 - C.2 The documentation outlines how the railway undertaking complies with any...

- C.3 In the documentation, any additional maintenance requirements for the network...
- C.4 In the documentation, any additional requirements to manage rolling stock...

ANNEX IV

Principles for supervision after the award of a Part A or Part B certificate

1. The approach of national safety authorities to supervision of railway...
2. National safety authorities shall apply the principle of proportionality between...
3. National safety authorities shall apply the principle of consistency of...
4. National safety authority supervision activity shall be targeted primarily at...
5. National safety authorities shall decide on priorities to use their...
6. National safety authorities shall apply the principle of transparency to...
7. National safety authorities shall be accountable for their decisions in...
8. National safety authorities shall develop cooperation arrangements between each other...

Status: This is the original version (as it was originally adopted).

- (1) [OJ L 164, 30.4.2004, p. 44.](#)
- (2) [OJ L 315, 3.12.2007, p. 51.](#)
- (3) http://ec.europa.eu/transport/rail/interoperability/doc/signed_mou_on_ecm.pdf