Commission Regulation (EU) No 1169/2010 of 10 December 2010 on a common safety method for assessing conformity with the requirements for obtaining a railway safety authorisation (Text with EEA relevance)

COMMISSION REGULATION (EU) No 1169/2010

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2004/49/EC of the European Parliament and of the Council of 29 April 2004 on safety on the Community's railways and amending Council Directive 95/18/EC on the licensing of railway undertakings and Directive 2001/14/EC on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure and safety certification (Railway Safety Directive)[(1)], and in particular Article 6(1) thereof,

Having regard to Recommendation ERA/REC/SAF/09-2009 from the European Railway Agency, delivered to the Commission on 18 September 2009, on a common safety method (CSM) for conformity assessment,

Whereas:

(1) The purpose of the common safety method (CSM) to be established is to provide a framework for national safety authorities to harmonise their decision-making criteria across the Union, in accordance with Article 17(4) of Directive 2004/49/EC. It should enable national safety authorities to assess conformity with requirements in a uniform manner.

(2) The CSM should include all the harmonised requirements and assessment methods to enable national safety authorities to issue an infrastructure manager with a safety authorisation covering the adequacy of the safety management system in general and any network-specific authorisation. Furthermore, it is likely that the infrastructure manager will apply for the network-specific part of the authorisation at the same time as it applies for a general authorisation based on its safety management system.

(3) National safety authorities assess the ability of an infrastructure manager to comply with all the requirements required to operate in general and on the specific network for which it is seeking an authorisation by assessing its safety management system at global level.

(4) Each national safety authority needs to put in place arrangements to examine whether the results outlined in the application for a safety authorisation are being delivered in operation after the award of the authorisation and whether all the necessary requirements are complied with on a continuous basis, as required by Article 16(2)(f)

Changes to legislation: *Commission Regulation (EU) No 1169/2010 is up to date with all changes known to be in force on or before 25 December 2020. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

and Article 17(2) of Directive 2004/49/EC. This therefore requires the development of a post-award supervision regime based on key fundamental principles in order to ensure a harmonised approach by national safety authorities in each Member State.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Committee referred to in Article 27(1) of Directive 2004/49/EC,

HAS ADOPTED THIS REGULATION:

Article 1

Subject-matter

This Regulation establishes a common safety method (CSM) for assessing conformity with requirements for obtaining safety authorisation as referred to in Article 6(3)(b) of Directive 2004/49/EC.

The CSM includes:

(a) a procedure and criteria for assessing applications by infrastructure managers for safety authorisations as referred to in Article 11(1)(a) and (b) of Directive 2004/49/EC, as set out in Annex I and II to this Regulation;

(b) principles for supervising compliance with the requirements of Directive 2004/49/EC after the national safety authority has granted the authorisation, as set out in Annex III to this Regulation.

Article 2

Definition

For the purposes of this Regulation, the following definition shall apply:

‘supervision’ means the arrangements put in place by the national safety authority to oversee safety performance after it has granted a safety authorisation.

Article 3

Procedures for assessing applications

1 When examining applications for safety authorisations submitted after the entry into force of this Regulation, national safety authorities shall apply the procedure set out in Annex I to this Regulation for assessing their conformity with requirements in Directive 2004/49/EC. The national safety authorities shall also use the assessment criteria set out in Annex II to this Regulation.

2 During assessment, national safety authorities may accept commitments by applicants that they will manage risks through the use of contracts with third parties. The contracts shall also specify the exchange of information needed to ensure the safe operation of vehicles, especially in areas relating to managing maintenance.

3 Products or services provided by contractors or suppliers to infrastructure managers shall be presumed to conform to safety requirements if the contractors, suppliers, or products are

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certified in accordance with relevant certification schemes established under Union legislation, for the provision of such products and services.

Article 4

Supervision

After granting a safety authorisation, national safety authorities shall supervise infrastructure managers' continued application of their safety management system and shall apply the principles for supervision set out in Annex III.

Article 5

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 10 December 2010.

For the Commission

The President

José Manuel BARROSO

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ANNEX I

Procedure for assessing conformity with requirements for obtaining safety authorisations to be issued in accordance with Article 11(1)(a) and (b) of Directive 2004/49/EC

1. The procedures that a national safety authority puts in place to receive and assess applications and to award safety authorisation shall be built upon the following framework principles.

(a) Setting up and reviewing the assessment process

National safety authorities shall develop structured and auditable processes to be undertaken by suitably competent persons. They shall scrutinise applications against the assessment criteria for safety management systems set out in Annex II. They shall record and give reasons for all decisions. The national safety authority's overall assessment process shall be periodically internally reviewed and continuously improved to secure its continued effectiveness and efficiency.

(b) Quality of the assessment process

National safety authorities shall monitor the quality of their own performance at key stages in the processing of applications for safety authorisations.

(c) Scope of the assessment

The assessment shall be at management-system level and process-driven. Where scrutiny reveals shortcomings, the national safety authority may exercise discretion and, depending on the nature and seriousness of the non-conformity, shall outline the points which need to be enhanced. Ultimately, the national safety authority shall exercise its power to reject an application.

The assessment shall be:

— appropriate to the risks, character and extent of operations of the applicant;

— based on judgments of the infrastructure manager's overall ability to operate safely as described in its safety management system.

(d) Timing of the assessment

National safety authorities shall complete the assessment within the time required by Article 12 of Directive 2004/49/EC whilst ensuring that the evidence provided by the applicant is sufficiently examined. The national safety authority shall inform infrastructure managers of issues of major concern as early as practically possible during the assessment phase.

(e) Decision making during the assessment

A decision to accept or reject an application for a safety authorisation shall be based on the evidence provided by the applicant and on whether compliance with the relevant requirements has been shown or not.

2. The national safety authority shall assess whether the attached summary of the safety management system manual allows an initial judgment on the quality and appropriateness of the safety management system and shall decide in which areas further information is necessary. The national safety authority may, as part of this request for more information, seek as much detailed information as it deems reasonably necessary to help its assessment of the application.

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3. When granting a safety authorisation, compliance of the applicant's safety management system with the assessment criteria shall be documented in relation to each assessment criterion.

4. When identifying a point of query or possible non-compliance, the national safety authority shall be specific and help the applicant to understand the level of detail expected in the response. To do this it shall:

(a) refer accurately to the relevant criteria and ensure that the applicant has understood clearly the identified areas of non-compliance;

(b) identify the relevant part of related regulations, rules, and standards;

(c) state why the assessment criterion is not met;

(d) agree on further commitments, information and any supporting evidence to be provided, as required by the level of detail of the criterion, and specify both the action required by the applicant to rectify the deficiency and the timeframe for compliance;

(e) specify areas which could be subject to further scrutiny through supervision after the award of the authorisation.

ANNEX II

Criteria for assessing conformity with the requirements for obtaining safety authorisations to be issued in accordance with Article 11(1)(a) and (b) of Directive 2004/49/EC

A.RISK CONTROL MEASURES FOR ALL RISKS ASSOCIATED WITH THE ACTIVITY OF THE INFRASTRUCTURE MANAGER[(2)]

A.1. There are procedures in place to identify risks associated with railway operations, including those directly arising from work activities, job design or workload and the activities of other organisations/persons.

A.2. There are procedures in place to develop and put in place risk control measures.

A.3. There are procedures in place to monitor the effectiveness of risk control arrangements and to implement changes when required.

A.4. There are procedures in place to recognise the need to work together with other entities (such as railway undertakings, manufacturer, maintenance supplier, entity in charge of maintenance, railway vehicle keeper, service provider and procurement entity), where appropriate, on issues where they have shared interfaces that are likely to affect the putting in place of adequate risk control measures in accordance with Article 4(3) of Directive 2004/49/EC.

A.5. There are procedures for agreed documentation and communication with the relevant entities, including the identification of roles and responsibilities of each participating organisation and the specifications for information exchanges.

A.6. There are procedures to monitor the effectiveness of these arrangements and to implement changes when required.