

Commission Delegated Regulation (EU) 2018/762 of 8 March 2018 establishing common safety methods on safety management system requirements pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulations (EU) No 1158/2010 and (EU) No 1169/2010 (Text with EEA relevance)

Article 1	Subject matter and scope
Article 2	Definition
Article 3	Safety management system requirements related to railway undertakings
Article 4	Safety management system requirements related to infrastructure managers
Article 5	Repeal
Article 6	Entry into force and application
	Signature

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ANNEX I

Safety management system requirements related to railway undertakings

1. CONTEXT OF THE ORGANISATION
  - 1.1. The organisation shall:
2. LEADERSHIP
  - 2.1. Leadership and commitment
    - 2.1.1. Top management shall demonstrate leadership and commitment to the development,...
  - 2.2. Safety policy
    - 2.2.1. A document describing the organisation's safety policy is established by...
    - 2.2.2. The safety policy shall:
  - 2.3. Organisational roles, responsibilities, accountabilities and authorities
    - 2.3.1. The responsibilities, accountabilities and authorities of staff having a role...
    - 2.3.2. The organisation shall ensure that staff with delegated responsibilities for...
    - 2.3.3. Delegation of responsibility for safety-related tasks shall be documented and...
    - 2.3.4. The organisation shall describe the allocation of roles referred to...
  - 2.4. Consultation of staff and other parties
    - 2.4.1. Staff, their representatives and external interested parties, as appropriate and...
    - 2.4.2. The organisation shall facilitate the consultation of staff by providing...
3. PLANNING
  - 3.1. Actions to address risks
    - 3.1.1. Risk assessment

- 3.1.1.1. The organisation shall:
      - 3.1.1.2. When assessing risk, an organisation shall take into account the...
    - 3.1.2. Planning for change
      - 3.1.2.1. The organisation shall identify potential safety risks and appropriate safety...
  - 3.2. Safety objectives and planning
    - 3.2.1. The organisation shall establish safety objectives for relevant functions at...
    - 3.2.2. The safety objectives shall:
    - 3.2.3. The organisation shall have plan(s) to describe how it will...
    - 3.2.4. The organisation shall describe the strategy and plan(s) used to...
- 4. SUPPORT
  - 4.1. Resources
    - 4.1.1. The organisation shall provide the resources, including competent staff and...
  - 4.2. Competence
    - 4.2.1. The organisation's competence management system shall ensure that staff having...
    - 4.2.2. The organisation shall provide a training programme, as referred to...
    - 4.2.3. Back to work arrangements shall be in place for staff...
  - 4.3. Awareness
    - 4.3.1. Top management shall ensure that they and their staff having...
  - 4.4. Information and communication
    - 4.4.1. The organisation shall define adequate communication channels to ensure that...
    - 4.4.2. To ensure that safety-related information reaches those making judgements and...
    - 4.4.3. The organisation shall ensure that safety-related information is:
  - 4.5. Documented information
    - 4.5.1. Safety management system documentation
      - 4.5.1.1. There is a description of the safety management system including:...
      - 4.5.1.2. The organisation shall ensure that an annual safety report is...
    - 4.5.2. Creating and updating
      - 4.5.2.1. The organisation shall ensure that when creating and updating documented...
    - 4.5.3. Control of documented information
      - 4.5.3.1. The organisation shall control documented information related to the safety...
  - 4.6. Integration of human and organisational factors
    - 4.6.1. The organisation shall demonstrate a systematic approach to integrating human...
- 5. OPERATION
  - 5.1. Operational planning and control
    - 5.1.1. When planning, developing, implementing and reviewing its operational processes, the...
    - 5.1.2. The organisation shall ensure that its operational arrangements conform to...
    - 5.1.3. To control risks where relevant for the safety of operational...
    - 5.1.4. To control the allocation of responsibilities where relevant for the...

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- 5.1.5. To control information and communication where relevant for the safety...
- 5.1.6. To control competence where relevant for the safety of operational...
- 5.2. Asset management
  - 5.2.1. The organisation shall manage the safety risks associated with physical...
  - 5.2.2. The organisation shall:
  - 5.2.3. The organisation shall ensure that its asset management arrangements, where...
  - 5.2.4. To control risks where relevant for the supply of maintenance...
  - 5.2.5. To control information and communication where relevant for the safe...
- 5.3. Contractors, partners and suppliers
  - 5.3.1. The organisation shall identify and control safety risks arising from...
  - 5.3.2. To control the safety risks referred to in paragraph 5.3.1,...
  - 5.3.3. In accordance with the process set out in Article 3...
- 5.4. Management of change
  - 5.4.1. The organisation shall implement and control changes to the safety...
- 5.5. Emergency management
  - 5.5.1. The organisation shall identify the emergency situations and associated timely...
  - 5.5.2. The organisation shall ensure that, for each identified type of...
  - 5.5.3. The organisation shall identify and document the roles and responsibilities...
  - 5.5.4. The organisation shall have plans for action, alerts and information...
  - 5.5.5. The organisation shall describe how resources and means for emergency...
  - 5.5.6. The emergency arrangements are regularly tested in cooperation with other...
  - 5.5.7. The organisation shall ensure that competent staff in charge, with...
  - 5.5.8. The organisation shall have a procedure to contact the entity...
- 6. PERFORMANCE EVALUATION
  - 6.1. Monitoring
    - 6.1.1. The organisation shall perform monitoring in accordance with Regulation (EU)...
    - 6.1.2. The organisation shall regularly monitor at all levels within the...
  - 6.2. Internal auditing
    - 6.2.1. The organisation shall conduct internal audits in an independent, impartial...
  - 6.3. Management review
    - 6.3.1. Top management shall regularly review the continuing adequacy and effectiveness...
    - 6.3.2. Based on the outputs of its management review, the top...
- 7. IMPROVEMENT
  - 7.1. Learning from accidents and incidents
    - 7.1.1. Accidents and incidents related to the organisation's railway operations shall...
    - 7.1.2. The organisation shall ensure that:
    - 7.1.3. The organisation shall use information relating to the investigation to...
  - 7.2. Continual improvement

- 7.2.1. The organisation shall continually improve the adequacy and effectiveness of...
- 7.2.2. The organisation shall provide means to motivating staff and other...
- 7.2.3. The organisation shall provide a strategy to continually improve its...

## ANNEX II

### Safety management system requirements related to infrastructure managers

1. **CONTEXT OF THE ORGANISATION**
  - 1.1. The organisation shall:
  - 1.2. For the purpose of this Annex the following definitions are...
2. **LEADERSHIP**
  - 2.1. Leadership and commitment
    - 2.1.1. Top management shall demonstrate leadership and commitment to the development,...
  - 2.2. Safety policy
    - 2.2.1. A document describing the organisation's safety policy is established by...
    - 2.2.2. The safety policy shall:
  - 2.3. Organisational roles, responsibilities, accountabilities and authorities
    - 2.3.1. The responsibilities, accountabilities and authorities of staff having a role...
    - 2.3.2. The organisation shall ensure that staff with delegated responsibilities for...
    - 2.3.3. Delegation of responsibility for safety-related tasks shall be documented and...
    - 2.3.4. The organisation shall describe the allocation of roles referred to...
  - 2.4. Consultation of staff and other parties
    - 2.4.1. Staff, their representatives and external interested parties, as appropriate and...
    - 2.4.2. The organisation shall facilitate the consultation of staff by providing...
3. **PLANNING**
  - 3.1. Actions to address risks
    - 3.1.1. Risk assessment
      - 3.1.1.1. The organisation shall:
      - 3.1.1.2. When assessing risk, an organisation shall take into account the...
    - 3.1.2. Planning for change
      - 3.1.2.1. The organisation shall identify potential safety risks and appropriate safety...
  - 3.2. Safety objectives and planning
    - 3.2.1. The organisation shall establish safety objectives for relevant functions at...
    - 3.2.2. The safety objectives shall:
    - 3.2.3. The organisation shall have plan(s) to describe how it will...
    - 3.2.4. The organisation shall describe the strategy and plan(s) used to...
4. **SUPPORT**
  - 4.1. Resources

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- 4.1.1. The organisation shall provide the resources, including competent staff and...
  - 4.2. Competence
    - 4.2.1. The organisation's competence management system shall ensure that staff having...
    - 4.2.2. The organisation shall provide a training programme, as referred to...
    - 4.2.3. Back to work arrangements shall be in place for staff...
  - 4.3. Awareness
    - 4.3.1. Top management shall ensure that they and their staff having...
  - 4.4. Information and communication
    - 4.4.1. The organisation shall define adequate communication channels to ensure that...
    - 4.4.2. To ensure that safety-related information reaches those making judgements and...
    - 4.4.3. The organisation shall ensure that safety-related information is:
  - 4.5. Documented information
    - 4.5.1. Safety management system documentation
      - 4.5.1.1. There is a description of the safety management system including:...
      - 4.5.1.2. The organisation shall ensure that an annual safety report is...
    - 4.5.2. Creating and updating
      - 4.5.2.1. The organisation shall ensure that when creating and updating documented...
    - 4.5.3. Control of documented information
      - 4.5.3.1. The organisation shall control documented information related to the safety...
  - 4.6. Integration of human and organisational factors
    - 4.6.1. The organisation shall demonstrate a systematic approach to integrating human...
- 5. OPERATION
  - 5.1. Operational planning and control
    - 5.1.1. When planning, developing, implementing and reviewing its operational processes, the...
    - 5.1.2. The organisation shall ensure that its operational arrangements conform to...
    - 5.1.3. To control risks where relevant for the safety of operational...
    - 5.1.4. To control the allocation of responsibilities where relevant for the...
    - 5.1.5. To control information and communication where relevant for the safety...
    - 5.1.6. To control competence where relevant for the safety of operational...
  - 5.2. Asset management
    - 5.2.1. The organisation shall manage the safety risks associated with physical...
    - 5.2.2. The organisation shall:
    - 5.2.3. The organisation shall ensure that its asset management arrangements, where...
    - 5.2.4. To control risks where relevant for the supply of maintenance...
    - 5.2.5. To control information and communication where relevant for the safe...
  - 5.3. Contractors, partners and suppliers
    - 5.3.1. The organisation shall identify and control safety risks arising from...
    - 5.3.2. To control the safety risks referred to in paragraph 5.3.1,...

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- 5.3.3. In accordance with the process set out in Article 3...
- 5.4. Management of change
  - 5.4.1. The organisation shall implement and control changes to the safety...
- 5.5. Emergency management
  - 5.5.1. The organisation shall identify the emergency situations and associated timely...
  - 5.5.2. The organisation shall ensure that, for each identified type of...
  - 5.5.3. The organisation shall identify and document the roles and responsibilities...
  - 5.5.4. The organisation shall have plans for action, alerts and information...
  - 5.5.5. The organisation shall describe how resources and means for emergency...
  - 5.5.6. The emergency arrangements are regularly tested in cooperation with other...
  - 5.5.7. The organisation shall coordinate emergency plans with all railway undertakings...
  - 5.5.8. The organisation shall have arrangements to halt operations and railway...
  - 5.5.9. For cross-border infrastructure, the cooperation between the relevant infrastructure managers...
- 6. PERFORMANCE EVALUATION
  - 6.1. Monitoring
    - 6.1.1. The organisation shall perform monitoring in accordance with Regulation (EU)...
    - 6.1.2. The organisation shall regularly monitor at all levels within the...
  - 6.2. Internal auditing
    - 6.2.1. The organisation shall conduct internal audits in an independent, impartial...
  - 6.3. Management review
    - 6.3.1. Top management shall regularly review the continuing adequacy and effectiveness...
    - 6.3.2. Based on the outputs of its management review, the top...
- 7. IMPROVEMENT
  - 7.1. Learning from accidents and incidents
    - 7.1.1. Accidents and incidents related to the organisation's railway operations shall...
    - 7.1.2. The organisation shall ensure that:
    - 7.1.3. The organisation shall use information relating to the investigation to...
  - 7.2. Continual improvement
    - 7.2.1. The organisation shall continually improve the adequacy and effectiveness of...
    - 7.2.2. The organisation shall provide means to motivating staff and other...
    - 7.2.3. The organisation shall provide a strategy to continually improve its...

- (1) [OJ L 138, 26.5.2016, p. 102.](#)
- (2) Commission Implementing Decision of 1 September 2016 on a mandate to the European Union Agency for Railways for the revision of the common safety methods for conformity assessment and the common safety method for supervision and repealing Implementing Decision C(2014) 1649 final (C(2016) 5504 final).
- (3) 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 ([OJ L 326, 10.12.2010, p. 11.](#))
- (4) 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 ([OJ L 327, 11.12.2010, p. 13.](#))
- (5) Commission Regulation (EU) No 1077/2012 of 16 November 2012 on a common safety method for supervision by national safety authorities after issuing a safety certificate or safety authorisation ([OJ L 320, 17.11.2012, p. 3.](#))
- (6) ISO/IEC Directives, Part 1, consolidated supplement 2016, Annex SL Appendix 2.
- (7) Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work ([OJ L 183, 29.6.1989, p. 1.](#))
- (8) Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods ([OJ L 260, 30.9.2008, p. 13.](#))
- (9) 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) ([OJ L 164, 30.4.2004, p. 44.](#))

**Changes to legislation:**

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