ANNEX II

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ANNEX II

Safety management system requirements related to infrastructure managers

- 3. **PLANNING**
- 3.1. Actions to address risks
- 3.1.1. Risk assessment
- 3.1.1.1. The organisation shall:
- identify and analyse all operational, organisational and technical risks relevant to the (a) character and extent of operations carried out by the organisation. Such risks shall include those arising from human and organisational factors such as workload, job design, fatigue or suitability of procedures, and the activities of other interested parties (see 1. Context of the organisation);
- evaluate the risks referred to in point (a) by applying appropriate risk assessment (b) methods:
- develop and put in place safety measures, with identification of associated (c) responsibilities (see 2.3. Organisational roles, responsibilities, accountabilities and authorities):
- (d) develop a system to monitor the effectiveness of safety measures (see 6.1. Monitoring):
- recognise the need to collaborate with other interested parties (such as railway (e) undertakings, infrastructure managers, manufacturer, maintenance supplier, entity in charge of maintenance, railway vehicle keeper, service provider and procurement entity), where appropriate, on shared risks and the putting in place of adequate safety measures:
- (f) communicate risks to staff and involved external parties (see 4.4. Information and communication).
- When assessing risk, an organisation shall take into account the need to determine, 3.1.1.2. provide and sustain a safe working environment which conforms to applicable legislation, in particular Directive 89/391/EEC.
- 3.1.2. Planning for change
- The organisation shall identify potential safety risks and appropriate safety measures 3.1.2.1. (see 3.1.1. Risk assessment) before the implementation of a change (see 5.4. Management of change) in accordance with the risk management process set out in Regulation (EU) No 402/2013, including consideration of the safety risks from the change process itself.
- 3.2. Safety objectives and planning
- The organisation shall establish safety objectives for relevant functions at relevant 3.2.1. levels to maintain and, where reasonably practicable, improve its safety performance.
- 322 The safety objectives shall:
- be consistent with the safety policy and the organisation's strategic objectives (where (a) applicable);

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- (b) be linked to the priority risks that influence the safety performance of the organisation;
- (c) be measurable;
- (d) take into account applicable legal and other requirements;
- (e) be reviewed as regards their achievements and revised as appropriate;
- (f) be communicated.
- 3.2.3. The organisation shall have plan(s) to describe how it will achieve its safety objectives.
- 3.2.4. The organisation shall describe the strategy and plan(s) used to monitor the achievement of the safety objectives (see 6.1. Monitoring).

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