

Commission Regulation (EU) No 1078/2012 of 16 November 2012 on a common safety method for monitoring to be applied by railway undertakings, infrastructure managers after receiving a safety certificate or safety authorisation and by entities in charge of maintenance (Text with EEA relevance)

## ANNEX

### THE MONITORING PROCESS

#### 1. **General**

- 1.1. The inputs to the monitoring process shall be all the processes and procedures contained in the management system, including technical, operational and organisational risk control measures.
- 1.2. The activities referred in Article 3(2) of the monitoring process are described in Sections 2 to 6.
- 1.3. This monitoring process is repetitive and iterative, as shown in the diagram below in the Appendix.

#### 2. **Definition of a strategy, priorities and plan(s) for monitoring**

- 2.1. Based on their management system, each railway undertaking, infrastructure manager and entity in charge of maintenance shall be responsible for defining its strategy, priorities and plan(s) for monitoring.
- 2.2. The decision on what to prioritise shall take into account information from areas that give rise to the greatest risks and, if not monitored effectively, could lead to adverse consequences for safety. An order of priority for monitoring activities shall be set, and the time, effort and resources required shall be indicated. Prioritisation shall also take into account results from previous applications of the monitoring process.
- 2.3. The monitoring process shall identify as early as possible instances of non-compliance in the application of the management system that might result in accidents, incidents, near-misses or other dangerous occurrences. It shall lead to the implementation of measures to remedy such instances of non-compliance.
- 2.4. The monitoring strategy and plan(s) shall define either quantitative or qualitative indicators or a mixture of both that can:
  - (a) give early warnings of any deviation from the expected outcome, or assurance that the expected outcome is achieved as planned;
  - (b) give information about unwanted outcomes;
  - (c) support decision making.

#### 3. **Collection and analysis of information**

- 3.1. The collection and analysis of information shall be carried out according to the strategy, priorities and plan(s) defined for the monitoring.
- 3.2. For each defined indicator referred to in point 2.4, the following shall be carried out:
  - (a) a collection of necessary information;
  - (b) an evaluation as to whether the processes, procedures, technical, operational and organisational risk control measures are correctly implemented;
  - (c) a check on whether the processes, procedures, technical, operational and organisational risk control measures are effective and whether they achieve the expected outcomes;

- (d) an evaluation of whether the management system as a whole is correctly applied and whether it achieves the expected outcomes;
- (e) an analysis and evaluation of instances of identified non-compliance with points (b), (c) and (d), as well as identification of their causes.

#### 4. **Drawing up of an action plan**

4.1. For identified instances of non-compliance that are considered unacceptable, an action plan shall be drawn up. This shall:

- (a) lead to the enforcement of correctly implemented processes, procedures, technical, operational and organisational risk control measures as specified; or
- (b) improve existing processes, procedures, technical, operational and organisational risk control measures; or
- (c) identify and implement additional risk control measures.

4.2. The action plan shall in particular include the following information:

- (a) objectives and results expected;
- (b) corrective, preventive or both types of measures required;
- (c) person responsible for implementing actions;
- (d) dates by which actions are to be implemented;
- (e) person responsible for evaluating the effectiveness of the action plan measures in accordance with Section 6;
- (f) a review of the impact of the action plan on the monitoring strategy, priorities and plan(s).

4.3. For managing safety at interfaces the railway undertaking, infrastructure manager or entity in charge of maintenance shall decide, in agreement with the other actors involved, who shall be in charge of implementing the required action plan or parts of it.

#### 5. **Implementation of the action plan**

5.1. The action plan defined in Section 4 shall be implemented so as to correct identified instances of non-compliance.

#### 6. **Evaluation of the effectiveness of the action plan measures**

6.1. Correct implementation, appropriateness and effectiveness of measures identified in the action plan shall be checked using the same monitoring process as described in this Annex.

6.2. Evaluation of the action plan's effectiveness shall in particular include the following actions:

- (a) verification of whether the action plan is correctly implemented and completed according to schedule;
- (b) verification of whether the expected outcome is achieved;

- (c) verification of whether in the meantime the initial conditions have changed and the risk control measures defined in the action plan are still appropriate for the given circumstances;
  - (d) verification of whether other risk control measures are necessary.
7. **Evidence from the application of the monitoring process**
- 7.1. The monitoring process shall be documented to prove it has been applied correctly. This documentation shall be made available primarily for internal assessment purposes. Upon request:
- (a) railway undertakings and infrastructure managers shall make this documentation available to the national safety authority;
  - (b) entities in charge of maintenance shall make this documentation available to the certification body. If interfaces are managed through contracts, the entities in charge of maintenance shall make this documentation available to the respective railway undertakings and infrastructure managers.
- 7.2. The documentation produced under point 7.1 shall include in particular:
- (a) a description of the organisation and staff appointed to carry out the monitoring process;
  - (b) the results of the different activities of the monitoring process listed in Article 3(2) and in particular the decisions made;
  - (c) in the case of instances of identified non-compliance that are considered unacceptable, a list of all necessary measures to be implemented to achieve the required outcome.

## Appendix

### Framework for the monitoring process

