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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 OF THE RAILWAY UNDERTAKING⁽¹⁾

- A.1 There are procedures put 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 the infrastructure manager, railway undertakings, the manufacturer, the maintenance supplier, the entity in charge of maintenance, the railway vehicle keeper, the service provider and the 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.

B. RISK CONTROL RELATED TO THE SUPPLY OF MAINTENANCE AND MATERIAL⁽²⁾

- B.1 There are procedures to derive maintenance requirements/standards/processes from safety data and from the assignment of rolling stock.
- B.2 There are procedures to adapt maintenance intervals according to the type and extent of service performed and/or data from rolling stock.
- B.3 There are procedures to ensure that the responsibility for maintenance is clearly defined, to identify the competencies required for maintenance posts and to allocate appropriate levels of responsibility.
- B.4 There are procedures to collect information on malfunctions and defects arising from day-to-day operation and to report them to those responsible for maintenance.
- B.5 There are procedures to identify and report risks arising from defects and construction non-conformities or malfunctions throughout the lifecycle to interested parties.
- B.6 There are procedures to verify and control the performance and results of maintenance to ensure that they comply with corporate standards.

C. RISK CONTROL RELATED TO THE USE OF CONTRACTORS AND CONTROL OF SUPPLIERS⁽³⁾

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- C.1 There are procedures to verify the competence of contractors (including subcontractors) and suppliers.
- C.2 There are procedures to verify and control the safety performance and results of all contracted services and products supplied either by the contractor or supplier to ensure that they comply with the requirements set out in the contract.
- C.3 Responsibilities and tasks relating to railway safety issues are clearly defined, known and allocated between the contracting partners and among all other interested parties.
- C.4 There are procedures to ensure traceability of safety-related documents and contracts.
- C.5 There are procedures to ensure that safety tasks, including the exchange of safety-related information, are performed by the contractors or the supplier according to relevant requirements set out in the contract.
- D. RISKS ARISING FROM THE ACTIVITIES OF OTHER PARTIES EXTERNAL TO THE RAILWAY SYSTEM⁽⁴⁾
 - D.1 There are procedures to identify potential risks from parties external to the railway system where appropriate and reasonable.
 - D.2 There are procedures to establish control measures to mitigate the risks identified under D1 insofar as the responsibilities of the applicant are concerned.
 - D.3 There are procedures to monitor the effectiveness of the measures identified under D2 and implement changes where appropriate.
- E. DOCUMENTATION OF THE SAFETY MANAGEMENT SYSTEM
 - E.1 There is a description of the activity that makes clear the type, extent and risk of operation.
 - E.2 There is a description of the structure of the safety management system, including the allocation of roles and responsibilities.
 - E.3 There is a description of safety management system procedures required by Article 9 and Annex III of Directive 2004/49/EC consistent with the type and extent of services operated.
 - E.4 Safety-critical processes and tasks relevant to the type of activity/service are listed and briefly described.
- F. DISTRIBUTION OF RESPONSIBILITIES⁽⁵⁾
 - F.1 There is a description of how coordination of safety management system activities across the organisation is ensured, based on proven knowledge and lead responsibility at management level.
 - F.2 There are procedures to ensure that staff with delegated responsibilities within the organisation have the authority, competence and appropriate resources to fulfil their duty.
 - F.3 Safety-related areas of responsibility, and the distribution of responsibilities to specific functions associated with them, together with their interfaces, are clearly defined.
 - F.4 There is a procedure to ensure that safety tasks are clearly defined and delegated to staff with appropriate competence.

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G. SECURING CONTROL BY THE MANAGEMENT ON DIFFERENT LEVELS⁽⁶⁾

G.1 There is a description of how responsibilities are allocated for each safety-related process throughout the organisation.

G.2 There is a procedure for regular monitoring of task performance assured by the line management chain that must intervene if the tasks are not being properly performed.

G.3 There are procedures to identify and manage the impact of other management activities on the safety management system.

G.4 There are procedures to hold those with a role in the management of safety accountable for their performance.

G.5 There are procedures to allocate resources to deliver the tasks under the safety management system.

H. INVOLVING STAFF AND THEIR REPRESENTATIVES ON ALL LEVELS⁽⁷⁾

H.1 There are procedures in place to ensure that staff and staff representatives are adequately represented and consulted in defining, proposing, reviewing and developing the safety aspects of operational procedures that may involve staff.

H.2 Staff involvement and consultation arrangements are documented.

I. ENSURING CONTINUOUS IMPROVEMENT⁽⁸⁾

There are procedures in place to ensure, where reasonably practicable, the continuous improvement of the safety management system; these shall include:

(a) procedures for periodic reviews of the safety management system, as found to be necessary;

(b) procedures for describing arrangements to monitor and analyse relevant safety data;

(c) procedures for describing how identified shortcomings are rectified;

(d) procedures for describing the implementation of new safety management rules based on development and lessons learnt;

(e) procedures for describing how internal audit findings are used to bring about improvement in the safety management system.

J. SAFETY POLICY APPROVED BY THE ORGANISATION'S CHIEF EXECUTIVE AND COMMUNICATED TO ALL STAFF⁽⁹⁾

A document describing the organisation's safety policy exists and is:

(a) communicated and made available to all staff, e.g. via the organisation's intranet;

(b) appropriate to the type and extent of service;

(c) approved by the organisation's chief executive.

K. QUALITATIVE AND QUANTATIVE TARGETS OF THE ORGANISATION FOR MAINTAINING AND ENHANCING SAFETY, AND PLANS AND PROCEDURES FOR REACHING THESE TARGETS⁽¹⁰⁾

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- K.1 There are procedures to determine relevant safety targets in line with the legal framework, and there is a document stating these targets.
- K.2 There are procedures to determine relevant safety targets consistent with the type and extent of the railway operations covered and the relevant risks.
- K.3 There are procedures to regularly assess overall safety performance in relation to the organisation's corporate safety targets and to those established on member state level.
- K.4 There are procedures in place to regularly monitor and review operational arrangements by:
- (a) collecting relevant safety data to derive trends in safety performance and assess compliance with targets;
 - (b) interpreting relevant data and implementing necessary changes.
- K.5 There are procedures in place by the railway undertaking to develop plans and procedures for reaching its targets.
- L. PROCEDURES TO MEET EXISTING, NEW AND ALTERED TECHNICAL AND OPERATIONAL STANDARDS OR OTHER PRESCRIPTIVE CONDITIONS⁽¹¹⁾
- L.1 For safety related requirements relevant to the type and extent of operations, there are procedures for:
- (a) identifying these requirements and updating relevant procedures to reflect changes made to them (change control management);
 - (b) implementing them;
 - (c) monitoring compliance with them;
 - (d) taking actions when non-compliance is identified.
- L.2 There are procedures in place to ensure that the right staff, procedures, specific documents, equipment and rolling stock are used for the purpose intended.
- L.3 The safety management system has procedures in place to ensure that maintenance is carried out according to the relevant requirements.
- M. PROCEDURES AND METHODS FOR CARRYING OUT RISK EVALUATION AND IMPLEMENTING RISK CONTROL MEASURES WHENEVER A CHANGE OF THE OPERATING CONDITIONS OR NEW MATERIAL IMPOSES NEW RISKS ON THE INFRASTRUCTURE OR ON OPERATION⁽¹²⁾
- M.1 There are management procedures for changes in equipment, procedures, organisation, staffing or interfaces.
- M.2 There are risk assessment procedures to manage changes and to apply the common safety method on risk evaluation and assessment as set out in Commission Regulation (EC) No 352/2009⁽¹³⁾ when required.
- M.3 The railway undertaking has procedures in place to feed the results of risk assessment into other processes within the organisation and make them visible to relevant staff.

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- N. PROVISION OF STAFF TRAINING PROGRAMMES AND SYSTEMS TO ENSURE THAT THE STAFF COMPETENCE IS MAINTAINED AND TASKS CARRIED OUT ACCORDINGLY⁽¹⁴⁾
- N.1 There is a competence management system that includes at least:
- (a) identification of the knowledge and skills required for safety related tasks;
 - (b) selection principles (basic educational level, mental aptitude and physical fitness required);
 - (c) initial training and certification of acquired competence and skills;
 - (d) ongoing training and periodical update of existing knowledge and skills;
 - (e) periodic checks of competence where appropriate;
 - (f) special measures in case of accidents/incidents or long absence from work, as required/ where appropriate;
 - (g) specific safety management system training for staff directly involved in ensuring that the safety management system works.
- N.2 There are procedures within the competence management system providing for:
- (a) the identification of posts that perform safety tasks;
 - (b) the identification of posts that entail responsibilities for taking operational decisions within the safety management system;
 - (c) staff to have the necessary knowledge, skills and aptitude (medical and psychological) appropriate to their tasks and periodically undergo retraining;
 - (d) allocating staff with the competence appropriate to relevant tasks;
 - (e) monitoring how tasks are performed and implementing corrective actions where required.
- O. ARRANGEMENTS FOR THE PROVISION OF SUFFICIENT INFORMATION WITHIN THE ORGANISATION AND, WHERE APPROPRIATE, BETWEEN ORGANISATIONS OPERATING ON THE SAME INFRASTRUCTURE⁽¹⁵⁾
- O.1 There are procedures to ensure that:
- (a) staff have knowledge and understanding of the safety management system and information is easily accessible; and
 - (b) appropriate documentation on the safety management system is given to relevant safety personnel.
- O.2 There are procedures to ensure that:
- (a) key operational information is relevant and valid;
 - (b) staff are aware of its existence before it is applied;
 - (c) it is available to staff and where required copies are formally given to them.
- O.3 There are arrangements in place for the sharing of information between railway organisations.

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- P. PROCEDURES AND FORMATS FOR DOCUMENTING SAFETY INFORMATION, AND DESIGNATION OF A PROCEDURE FOR CONFIGURATION CONTROL OF VITAL SAFETY INFORMATION⁽¹⁶⁾
- P.1 There are procedures to ensure that all relevant safety information is accurate, complete, consistent, easy to understand, appropriately updated, and duly documented.
- P.2 There are procedures to:
- (a) format, generate, distribute and manage control of changes to all relevant safety documentation;
 - (b) receive, collect and store all relevant documentation/information on paper or by other registration systems.
- P.3 There is a procedure for configuration control of vital safety information.
- Q. PROCEDURES TO ENSURE THAT ACCIDENTS, INCIDENTS, NEAR MISSES AND OTHER DANGEROUS OCCURRENCES ARE REPORTED, INVESTIGATED AND ANALYSED AND THAT NECESSARY PREVENTIVE MEASURES ARE TAKEN⁽¹⁷⁾
- Q.1 There are procedures to ensure that accidents, incidents, near misses and other dangerous occurrences:
- (a) are reported, logged, investigated and analysed;
 - (b) are reported, as required by relevant legislation, to national bodies.
- Q.2 There are procedures to ensure that:
- (a) recommendations from the national safety authority, from the national investigating body, and from industry/internal investigations are evaluated and implemented if appropriate or mandated;
 - (b) relevant reports/information from other railway undertakings, infrastructure managers, entities in charge of maintenance and railway vehicle keepers are considered and taken into account.
- Q.3 There are procedures for relevant information relating to the investigation and causes of accidents, incidents, near misses and other dangerous occurrences to be used to learn and, where required, to adopt preventive measures.
- R. PROVISION OF PLANS FOR ACTION AND ALERTS AND INFORMATION IN CASE OF EMERGENCY, AGREED UPON WITH THE APPROPRIATE PUBLIC AUTHORITIES⁽¹⁸⁾
- R.1 A document identifies all types of emergency, including degraded operations, and there are procedures in place to identify new ones.
- R.2 There are procedures in place to ensure that, for each identified type of emergency:
- (a) the emergency services can be promptly contacted;
 - (b) the emergency services are provided with all relevant information both in advance, to prepare their emergency response, and at the time of an emergency.

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- R.3 The roles and responsibilities of all parties are identified and set out in a document.
- R.4 Plans for action, alerts and information exist and include:
- (a) procedures to alert all staff with responsibility for emergency management;
 - (b) arrangements to communicate these to all parties, including emergency instructions for passengers;
 - (c) arrangements for contacting competent staff immediately so they can take any decisions required.
- R.5 There is a document describing how resources and means have been allocated and how training requirements have been identified.
- R.6 There are procedures in place to re-establish normal operating conditions as soon as possible.
- R.7 There are procedures for testing emergency plans in cooperation with other parties to train staff, test procedures, identify weak points and verify how potential emergency situations are managed.
- R.8 There are procedures to ensure that competent staff in charge (particularly relating to dangerous goods services), with adequate language skills, can be contacted easily and without delay by the infrastructure manager.
- R.9 There is a procedure to contact the entity in charge of maintenance or the railway vehicle keeper in the event of an emergency.
- S. PROVISIONS FOR RECURRENT INTERNAL AUDITING OF THE SAFETY MANAGEMENT SYSTEM⁽¹⁹⁾
- S.1 There is an internal auditing system which is independent and impartial and which acts in a transparent way.
- S.2 There is a schedule of planned internal audits which can be revised depending on the results of previous audits and monitoring of performance.
- S.3 There are procedures in place to identify and select suitably competent auditors.
- S.4 Procedures are in place to:
- (a) analyse and evaluate the results of the audits;
 - (b) recommend follow-up measures;
 - (c) follow up the effectiveness of measures;
 - (d) document the execution of audits and the results of audits.
- S.5 There are procedures to ensure that senior levels of the management chain are aware of the results of audits and take overall responsibility for implementation of changes to the safety management system.
- S.6 There is a document showing how audits are planned in relation to routine monitoring arrangements to ensure compliance with internal procedures and standards.

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- (1) Article 9(2) of Directive 2004/49/EC.
- (2) Article 9(2) of Directive.2004/49/EC.
- (3) Article 9(2) of Directive 2004/49/EC.
- (4) Article 9(2) of Directive 2004/49/EC.
- (5) Annex III to Directive 2004/49/EC, point 1.
- (6) Annex III to Directive 2004/49/EC, point 1.
- (7) Annex III to Directive 2004/49/EC, point 1.
- (8) Annex III to Directive 2004/49/EC, point 1.
- (9) Annex III to Directive 2004/49/EC, point 2(a).
- (10) Annex III to Directive 2004/49/EC, point 2(b).
- (11) Annex III to Directive 2004/49/EC, point 2(c).
- (12) Annex III to Directive 2004/49/EC, point 2(d).
- (13) [OJ L 108, 29.4.2009, p. 4.](#)
- (14) Annex III to Directive 2004/49/EC, point 2(e).
- (15) Annex III to Directive 2004/49/EC, point 2(f).
- (16) Annex III to Directive 2004/49/EC, point 2(g).
- (17) Annex III to Directive 2004/49/EC, point 2(h).
- (18) Annex III to Directive 2004/49/EC, point 2(i).
- (19) Annex III to Directive 2004/49/EC, point 2(j).

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