

Commission Regulation (EC) No 352/2009 of 24 April 2009 on the adoption of a common safety method on risk evaluation and assessment as referred to in Article 6(3)(a) of Directive 2004/49/EC of the European Parliament and of the Council (Text with EEA relevance) (repealed)

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ANNEX I

1. GENERAL PRINCIPLES APPLICABLE TO THE RISK MANAGEMENT PROCESS
 - 1.1. General principles and obligations
 - 1.1.1. The risk management process covered by this Regulation shall start...
 - 1.1.2. This iterative risk management process:
 - 1.1.3. The proposer in charge of the risk management process required...
 - 1.1.4. The actors who already have in place methods or tools...
 - 1.1.5. Without prejudice to civil liability in accordance with the legal...
 - 1.1.6. The first step of the risk management process shall be...
 - 1.1.7. Evaluation of the correct application of the risk management process...
 - 1.2. Interfaces management
 - 1.2.1. For each interface relevant to the system under assessment and...
 - 1.2.2. When, in order to fulfil a safety requirement, an actor...
 - 1.2.3. For the system under assessment, any actor who discovers that...
 - 1.2.4. The actor implementing the safety measure shall then inform all...
 - 1.2.5. When agreement cannot be found between two or more actors...
 - 1.2.6. When a requirement in a notified national rule can not...
 - 1.2.7. Independently from the definition of the system under assessment, the...
2. DESCRIPTION OF THE RISK ASSESSMENT PROCESS
 - 2.1. General description
 - 2.1.1. The risk assessment process is the overall iterative process that...
 - 2.1.2. The system definition should address at least the following issues:...
 - 2.1.3. A hazard identification shall be carried out on the defined...
 - 2.1.4. The risk acceptability of the system under assessment shall be...
 - 2.1.5. The proposer shall demonstrate in the risk evaluation that the...

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- 2.1.6. The application of these risk acceptance principles shall identify possible...
 - 2.1.7. The iterative risk assessment process can be considered as completed...
 - 2.2. Hazard identification
 - 2.2.1. The proposer shall systematically identify, using wide-ranging expertise from a...
 - 2.2.2. To focus the risk assessment efforts upon the most important...
 - 2.2.3. As a criterion, risks resulting from hazards may be classified...
 - 2.2.4. During the hazard identification, safety measures may be identified. They...
 - 2.2.5. The hazard identification only needs to be carried out at...
 - 2.2.6. Whenever a code of practices or a reference system is...
 - 2.3. Use of codes of practice and risk evaluation
 - 2.3.1. The proposer, with the support of other involved actors and...
 - 2.3.2. The codes of practice shall satisfy at least the following...
 - 2.3.3. Where compliance with TSIs is required by Directive 2008/57/EC and...
 - 2.3.4. National rules notified in accordance with Article 8 of Directive...
 - 2.3.5. If one or more hazards are controlled by codes of...
 - 2.3.6. Where an alternative approach is not fully compliant with a...
 - 2.3.7. If the risk for a particular hazard cannot be made...
 - 2.3.8. When all hazards are controlled by codes of practice, the...
 - 2.4. Use of reference system and risk evaluation
 - 2.4.1. The proposer, with the support of other involved actors, shall...
 - 2.4.2. A reference system shall satisfy at least the following requirements:...
 - 2.4.3. If a reference system fulfils the requirements listed in point...
 - 2.4.4. If the system under assessment deviates from the reference system,...
 - 2.4.5. If the same safety level as the reference system cannot...
 - 2.5. Explicit risk estimation and evaluation
 - 2.5.1. When the hazards are not covered by one of the...
 - 2.5.2. The acceptability of the estimated risks shall be evaluated using...
 - 2.5.3. When the risk associated with one or a combination of...
 - 2.5.4. Where hazards arise from failures of technical systems not covered...
 - 2.5.5. Without prejudice to the procedure specified in Article 8 of...
 - 2.5.6. If a technical system is developed by applying the 10-9...
 - 2.5.7. The explicit risk estimation and evaluation shall satisfy at least...
 - 3. DEMONSTRATION OF COMPLIANCE WITH SAFETY REQUIREMENTS
 - 3.1. Prior to the safety acceptance of the change, fulfilment of...
 - 3.2. This demonstration shall be carried out by each of the...
 - 3.3. The approach chosen for demonstrating compliance with the safety requirements...
 - 3.4. Any inadequacy of safety measures expected to fulfil the safety...
 - 4. HAZARD MANAGEMENT
 - 4.1. Hazard management process
 - 4.1.1. Hazard record(s) shall be created or updated (where they already...
 - 4.1.2. The hazard record shall include all hazards, together with all...
 - 4.2. Exchange of information
 - 5. EVIDENCE FROM THE APPLICATION OF THE RISK MANAGEMENT PROCESS
 - 5.1. The risk management process used to assess the safety levels...

- 5.2. The document produced by the proposer under point 5.1. shall...

Appendix

Risk management process and independent assessment

ANNEX II

CRITERIA WHICH MUST BE FULFILLED BY THE ASSESSMENT BODIES

1. The assessment body may not become involved either directly or...
2. The assessment body must carry out the assessment with the...
3. The assessment body must possess the means required to perform...
4. The staff responsible for the assessments must possess:
5. The independence of the staff responsible for the independent assessments...
6. Where the assessment body is external to the proposer's organisation...
7. Where the assessment body is external to the proposer's organisation...

Status: This is the original version (as it was originally adopted).

- (1) OJ L 164, 30.4.2004, p. 44; corrected by OJ L 220, 21.6.2004, p. 16.
- (2) OJ L 237, 24.8.1991, p. 25.
- (3) OJ L 191, 18.7.2008, p. 1.