

Bilaga remissvar autonoma fordon, utdrag ur EN 50126 (The specification and demonstration of dependability, reliability, availability, maintainability and safety, RAMS)

4.6 Risk

4.6.1 Risk concept:

The concept of risk is the combination of two elements:

- the probability of occurrence of an event or combination of events leading to a hazard, or the frequency of such occurrences;
- the consequence of the hazard.

4.6.2 Risk analysis:

4.6.2.1 Risk analysis shall be performed at various phases of the system life cycle by the authority responsible for that phase and shall be documented. The documentation shall contain, as a minimum:

- a) analysis methodology;
- b) assumptions, limitations and justification of the methodology;
- c) hazard identification results;
- d) risk estimation results and their confidence levels;
- e) results of trade-off studies;
- f) data, their sources and confidence levels;
- g) references.

Table 2 provides, in qualitative terms, typical categories of probability or frequency of occurrence of a hazardous event and a description of each category for a railway system. The categories, their numbers, and their numerical scaling to be applied shall be defined by the Railway Authority, appropriate to the application under consideration.

Table 2: Frequency of Occurrence of Hazardous Events

Category	Description
Frequent	Likely to occur frequently. The hazard will be continually experienced
Probable	Will occur several times. The hazard can be expected to occur often
Occasional	Likely to occur several times. The hazard can be expected to occur several times
Remote	Likely to occur sometime in the system life cycle. The hazard can reasonably be expected to occur
Improbable	Unlikely to occur but possible. It can be assumed that the hazard may exceptionally occur.
Incredible	Extremely unlikely to occur. It can be assumed that the hazard may not occur.

4.6.2.3 Consequence analysis shall be used to estimate the likely impact.

Table 3 describes typical hazard severity levels and the consequences associated with each severity level for all railway systems. The number of severity levels and the consequences for each severity level to be applied shall be defined by the Railway Authority, appropriate for the application under consideration.

Table 3: Hazard Severity Level

Severity Level	Consequence to Persons or Environment	Consequence to Service
Catastrophic	Fatalities and/or multiple severe injuries and/or major damage to the environment.	
Critical	Single fatality and/or severe injury and/or significant damage to the environment.	Loss of a major system
Marginal	Minor injury and/or significant threat to the environment	Severe system(s) damage
Insignificant	Possible minor injury	Minor system damage

4.6.3 Risk evaluation and acceptance

4.6.3.1 This subclause deals with the formation of a "frequency - consequence" matrix for evaluation of the results of risk analysis, risk categorisation, actions for risk reduction or elimination of intolerable risks, and for risk acceptance.

4.6.3.2 Risk evaluation shall be performed by combining the frequency of occurrence of a hazardous event with the severity of its consequence to establish the level of risk generated by the hazardous event. A "frequency - consequence" matrix is shown in table 4.

Table 4: Frequency - Consequence Matrix

Frequency of occurrence of a hazardous event	Risk Levels			
Frequent				
Probable				
Occasional				
Remote				
Improbable				
Incredible				
	Insignificant	Marginal	Critical	Catastrophic
	Severity Levels of Hazard Consequence			

4.6.3.3 Risk acceptance should be based on a generally accepted principle. A number of principles are available that may be utilised. Some examples are as follows: (Also see annex D for more information on these principles):

- As Low As Reasonably Practicable (ALARP principle as practised in UK);
- Globalement Au Moins Aussi Bon (GAMAB principle as practised in France). The complete formulation of this principle is "All new guided transport systems must offer a level of risk globally at least as good as the one offered by any equivalent existing system";
- Minimum Endogenous Mortality (MEM principle as practised in Germany).

Table 5 defines qualitative categories of risk and the actions to be applied against each category. The Railway Authority shall be responsible for defining principle to be adopted and the tolerability level of a risk and the levels that fall into the different risk categories.

Table 5: Qualitative Risk Categories

Risk Category	Actions to be applied against each category
Intolerable	Shall be eliminated
Undesirable	Shall only be accepted when risk reduction is impracticable and with the agreement of the Railway Authority or the Safety Regulatory Authority, as appropriate
Tolerable	Acceptable with adequate control and with the agreement of the Railway Authority
Negligible	Acceptable with/without the agreement of the Railway Authority

Table 6 shows an example of risk evaluation and risk reduction/controls for risk acceptance.

Table 6: Typical Example of Risk Evaluation and Acceptance

* Frequency of occurrence of a hazardous event	Risk Levels			
	Frequent	Undesirable	Intolerable	Intolerable
Probable	Tolerable	Undesirable	Intolerable	Intolerable
Occasional	Tolerable	Undesirable	Undesirable	Intolerable
Remote	Negligible	Tolerable	Undesirable	Undesirable
Improbable	Negligible	Negligible	Tolerable	Tolerable
Incredible	Negligible	Negligible	Negligible	Negligible
	Insignificant	Marginal	Critical	Catastrophic
	Severity Levels of Hazard Consequence			

* Scaling for the frequency of occurrence of hazardous events will depend on the application under consideration (4.6.2.2)

Risk Evaluation

Intolerable

Undesirable

Tolerable

Negligible

Risk reduction/control

Shall be eliminated

Shall only be accepted when risk reduction is impracticable and with the agreement of the Railway Authority.

Acceptable with adequate control and the agreement of the Railway Authority

Acceptable without any agreement