Application of the FMEA method for the assessment of technical safety levels

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Abstract. The responsibility for ensuring technical safety rests in part with technical equipment designers. Their job is to choose solutions that will remain effective throughout the usable life of relevant equipment. The solutions they select must ensure the required level of safety while complying with mandatory laws and regulations. Rather than specifying what the right solutions are, laws only indicate the required level of safety, which needs to be checked using specific risk assessment methods that are appropriate for the solutions in place. The use of the FMEA (Failure Mode and Effects Analysis) to identify irregularities helped define advisable improvements that will enable organizations to achieve the required safety level. These can be viewed as design guidelines for ensuring the proper operation of a device in the workplace free of hazards to the labor force. The paper analyzed the impact of the construction measures applied to reduce the use risk. The applied solutions were evaluated and the level of tolerated risk was recognized as a determinant of ensuring the possibility of safe work performance.

1. Introduction
A prerequisite for ensuring the safe operation of technical equipment is to adopt solutions that reduce threats resulting from inadequate design. Such solutions should eliminate or mitigate hazards and ensure that technical equipment is used as intended [1].

It is essential to account for specific aspects of risks and irregularities. These include aspects associated with the human operators of systems that include a technical element. Such aspects are most commonly applied to the ergonomic requirements adopted to optimize the strains to which human operators are subjected. The risk and irregularities are not limited solely to technical operational considerations [2 - 4]. Due to the complexity of such irregularities and the need to examine them in detail, organizations are compelled to employ tools that will help them identify any relevant irregularities as well as any solutions that will reduce their occurrence and mitigate their impacts on individuals in risk areas.

The aim of this paper is to assess the applicability of the FMEA (Failure Mode and Effects Analysis) for detecting irregularities, identify relevant improvements and assess their effectiveness against the safety level that organizations manage to achieve. Once proper solutions have been defined and adopted, they will help perform work without endangering individuals in risk areas.

2. Guidelines for the use of the FMEA
The FMEA helps analyze the adequacy of design solutions [5]. Such solutions are assessed against the adopted use of technical equipment and the nature of the tasks performed by workers.
In the design of technical equipment, the FMEA helps identify the strengths and weaknesses of existing solutions and ensure optimal design. The irregularities that may potentially be subject to analysis are associated with:

- The functions of technical equipment,
- The reliability of equipment during operation,
- The ease of operation and maintenance,
- The ease of repairs and overhauls,
- The production technologies for which the technical equipment is employed.

The FMEA may be used to design a wide range of technical equipment with a view to eliminating risks. The findings of FMEA analysis can be referred to actual operating parameters [5, 6]. This poses a significant challenge for the designers seeking to keep technical equipment users safe. The above applies in particular to circumstances in which no standards have been defined to guide the design process. Compliance with requirements should then be viewed as key to ensuring operational safety. Such compliance can be defined as the achievement of the required technical design standard [2]. Once such a standard is achieved, risk assessment is the only appropriate approach to maintaining threats below the acceptable level of impact [6]. This course of action is recommended in particular for any equipment that is new or largely modified, any equipment that incorporates new materials or production technologies, any equipment to be used in new ways, any equipment for which no design defects affecting its operation are acceptable, any equipment intended for operation in particularly harsh conditions and any equipment whose production is particularly costly.

To effectively apply the FMEA, it is essential to define all critical points, identify relevant issues and analyze each of them separately. This can be a major challenge for organizations faced with multiple issues [7], as such issues will have to be aggregated to a single global value that reflects all existing irregularities [8].

Another vital factor limiting the use of the FMEA is its complexity. FMEA users need to be well trained to conduct reliable analyses [2]. One way to offset inadequate training is to employ a multidisciplinary team with each individual team member responsible for a specific aspect of risk identification and assessment. An equally valid issue that has been raised by some authors, is the need to recognize the psychological factors that influence risk perceptions [8]. This is particularly important for risks that directly affect human operators [9].

3. Level of technical safety

3.1. Technical safety assessment guidelines

Organizations need to conform to design requirements in order to ensure proper operating conditions that help mitigate operational risks [10, 11].

To eliminate irregularities permanently, one needs to identify their causes and apply solutions that are adequate for their nature all the while ensuring compliance with mandatory legal requirements. The solutions an organization employs should help meet all relevant safety standards. Additional verification criteria include normative requirements laid down in harmonized standards, which are seen as optional design requirements. Their use helps select the most appropriate solutions that ensure the achievement of acceptable risk levels. Such solutions are designed on the basis of analyses of the effects of deploying technical measures on safety levels defined as risk mitigation. The FMEA helps analyze issues and identify their causes and effects. The extent of the effects is described by reference to risk severity. Such severity is a compound ratio composed of [12, 13]:

- The frequency of exposures to circumstances that trigger the occurrence of risks,
- The likelihood of the occurrence of hazardous events,
- The technical and human capacity to avoid damage caused by risks,
- The ability to identify the risks that cause damage,
- The extent of all possible damage affecting humans and/or technical elements.
According to FMEA guidelines, hazard assessment scores fall within the range of 1 to 10, as shown in Table 1.

Table 1. Scale used in assessing the effects of hazards

| O – Occurrence       | S – Severity | D – Detection                                                                 |
|----------------------|--------------|-------------------------------------------------------------------------------|
| 1 Unlikely (risk practically non-existent) | 1 None (risk having negligible effect on operation of technical equipment) | 1 Almost certain (current identification methods suggest that the defect in question is a certain threat) |
| 2 Very low           | 2 Highly negligible | 2 Very high                                                                   |
| 3 Low                | 3 Negligible  | 3 High                                                                        |
| 4 Average            | 4 Very low   | 4 Moderately high                                                              |
| 5                    | 5 Low        | 5 Moderate                                                                    |
| 6                    | 6 Average    | 6 Low                                                                         |
| 7 High               | 7 High       | 7 Very low                                                                    |
| 8                    | 8 Very high  | 8 Remote                                                                      |
| 9 Very high (critical risk, risk occurs very often) | 9 Dangerous with warning | 9 Very remote                                                                   |
| 10                   | 10 Dangerous without warning | 10 Nearly impossible (no threat symptoms)                                    |

In assessing the danger of the occurrence of an irregularity, one should follow this three-step procedure:

- Examine the technical item to consider the options of assessing technical safety levels for specific solutions,
- Conduct an analysis to identify issues in the process that may potentially generate defects; the identification of defects can rely on the CAUSE ---> DEFECT ---> EFFECT relationship and specific effects,
- Take and oversee preventive measures to either eliminate or mitigate the effects of irregularities.

The measures to be taken to that end, grouped into assessment stages, are summarized in Table 2.

Table 2. Measures taken in the course of assessment, as advised by FMEA guidelines

| Stage of assessment | Measures taken in the course of given assessment |
|---------------------|-------------------------------------------------|
| State 1: Preparation Identification of issue and its causes | - Appoint team to analyze issue and authorize improvement measures, |
|                     | - Identify area to be covered by FMEA, |
|                     | - Define the limits of the system in reference to which issue will be analyzed, |
|                     | - Select elements, functions and measures to be analyzed, |
|                     | - Identify specific issue, its causes and effects. |
| Stage 2: Analysis proper Calculation of indicators for identified threats | - Identify potential defects (irregularities) for selected elements and functions of equipment as well as their causes and effects, |
|                     | - Link such defects, effects and causes (irregularities) with values representing defect severity, i.e. the severity of the impact of the defects on the performance of workers and technical equipment (S), the likelihood of occurrence of such causes and defects (O) and the chances of detecting the causes (D), |
|                     | - Calculate the risk priority number (RPN = S · O · D). |
| Stage 3: Adoption of and oversight over preventive measures | - Assess risk priority number against the adopted acceptable risk level, |
|                     | - Identify adequate improvement measures, |
|                     | - Analyze the effects of measures on lowering the RPN, i.e. indicate the impact of the measures taken on the technical safety level, |
|                     | - Examine possible application of solutions that meet design guidelines (harmonized standards), |
|                     | - Oversee the implementation of measures selected for use. |
The above course of action will enable an organization to identify protective measures that are adequate up to the level of residual risk at which further risk mitigation makes no financial sense. Furthermore, adherence to ISO 12100 [10] guidelines will result in compliance with relevant laws, including Directive 2006/42/EC [6].

3.2. Sample application of the FMEA to assess the conformity of technical solutions with requirements

By basing the assessment on the FMEA, it is possible to identify relevant requirements and adequate solutions that will ensure the safe operation of technical equipment. The design procedure should follow the following steps [9, 12, 14]:

- Identify threats associated with the potential use of equipment given specific design solutions,
- Identify viable improvements that ensure the safe operation of technical equipment,
- Apply solutions that mitigate the impacts of risk factors on users,
- Apply solutions that comply with legal requirements and normative standards.

The measures, including impact assessments, are checked against the outcomes of the assessments of risk and the effectiveness of the applied measures. The risk aspect should be viewed in reference to the required safety level.

Given below is an example of the use of the FMEA to analyze operating risks arising in the course of the application of specified design solutions.

SITUATION UNDER ANALYSIS:
The piece of equipment in question is a tank, whose operation requires proper access to an inspection hatch. Due to the placement of the hatch, the worker needs to climb onto a platform from which he/she will be able to reach it.

The analysis focuses on a design that would allow the worker to safely mount the platform and access the hatch. The solution is illustrated in Figure 1.

![Figure 1. Constructional solution subjected to FMEA analysis.](image)

It meets the technical safety guidelines, as ascertained through Steps 1 and 2 of the improvement check. As the environment in which the worker operates is highly humid, the traction of feet against the platform surface is considerably reduced making the platform harder to navigate.

CHECK ORIGINAL STATE:
- Describe state: structure fails to protect worker from falling. The design of the platform used for access has been judged inadequate. The worker is unable to securely grip the railing to retain balance while entering the platform. This leads to the conclusion that:
  - The steps taken to ensure access were a stop-gap measure that fails to comply with Directive 2006/42/EC,
  - The technical solution in place does not ensure the required level of technical safety.
- Assess identified state:
S = 9  
O = 9  
D = 8  
RPN = 648

- Adopted solutions do not ensure safety,
- Adopted solutions are incompliant with relevant laws
- Threat is practically unavoidable
- Measures taken are very unlikely to detect threat
Unacceptable risk

CHECK IMPROVEMENTS (Step 1):
- Describe state:
  - Ad hoc but effective solutions were applied to enable worker to mount platform, grip railing and be protected from falling,
  - By virtue of their design, the solutions in place cannot be seen as fully safe, e.g. the step area is too small to effectively prevent slipping,
  - Occurrence of a hazard only under specific conditions will facilitate its detection
- Assess identified state:
  S = 6  
  O = 6  
  D = 6  
  RPN = 216
  - Risk causes clear discomfort and compromises safety
  - Risk very likely to occur
  - Risk symptoms are detectable
  Moderate risk

CHECK EXECUTION OF IMPROVEMENTS (Step 2):
- Describe current state:
  - Effective solutions were applied that allow workers to safely climb onto platform and securely grip railing as a safeguard against falling,
  - The design makes for an entirely safe solution – for instance, the step is made so as to prevent slipping,
  - The use of effective operating solutions will help to further improve the detection of potentially occurring hazards.
- Assess identified state:
  S = 3  
  O = 3  
  D = 5  
  RPN = 45
  - Risk is of little significance
  - Risk symptoms manifested in certain circumstances
  - Oversight measures and checks are likely to help detect risk
  Acceptable risk

The procedure has helped define the effects of measures on the technical safety level in the context of applicable risks. The resulting changes in risk levels are shown in Figure 2. The solutions that make worker protections more robust improve operating worker safety. For further improvements, it is advised to consider solutions compliant with the harmonized standards. Although such solutions do not increase safety, they make it easier to ensure compliance with mandatory legal requirements.

| Unacceptable risk | Average risk | Acceptable risk |
|-------------------|--------------|----------------|
| Significant risk  | Moderate risk| Acceptable risk|
| 1000              | 600          | 150            |
| ORIGINAL STATUS   | IMPROVEMENT  | IMPROVEMENT    |
|                   | (Step 1)     | (Step 2)       |

**Figure 2.** Impact of design solutions on safety level described in terms of risk level.
4. Conclusion
FMEA-guideline-based analyses help identify irregularities in existing equipment design as well as the causes of events with their specific consequences. By applying the FMEA method in the assessment process and adopting proper solutions, organizations stand to improve the operating performance of their equipment. Such an approach is helpful in identifying the causes of events that may result in damage to technical equipment and in worker injuries and death. All of these consequences may potentially result from failures to meet the design requirements laid down in Directive 2006/42/EC and in the harmonized standards.

The adopted improvements enable organizations to reduce losses associated with any technical solutions that fail to ensure the safe operation of technological processes.

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