Directive 2014/90/EU (MED) - guidelines for the risk analysis

Requirements of Directive 2014/90/EU

Directive 2014/90/EU, in Annex II, Part I „Module B, EC Type Examination", paragraph 3, requires that the technical documentation submitted for approval includes an adequate analysis and assessment of risk.

MarED Recommendations

According to MarED Draft Recommendation GEN-046:

- The Manufacturer is responsible for risk analysis and assessment.
- If the Manufacturer assesses that the applicable standards cover all reasonably expected risks, he may simply declare it in the technical documentation.
- If the Manufacturer assesses that the applicable standards do not cover all reasonably expected risks, he shall identify and analyse the risks and describe measures to be taken to eliminate hazards or reduce associated risk.
- The Notified Body verifies the Manufacturer's proceedings in this scope.

Basic definitions:

- **Hazard** – any source of potential damage.
- **Risk** – The combination of the probability and severity of an adverse event (body injury or deterioration of health state).
- **Risk analysis** – combination of specified restrictions related to machinery, identification of hazards and risk estimation.
- **Risk estimation** – determination of probable severity of adverse effect and probability of its occurrence.
- **Risk evaluation** – determination on the basis of risk analysis if the risk should be reduced.
- **Risk assessment** – complete process including risk analysis and risk evaluation.
- **Safe „machinery"** – the machinery fitted for its function and adapted for transport, installation, adjustment, maintenance, dismantling and scrapping, without causing injuries or deterioration of health state, under conditions conforming with its purpose, defined in technical and operation documentation.

Proceedings

In some cases applicable standards, referred to in MED Directive, specify such requirements, whose fulfilling eliminates risk occurrence.

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If not, in such case, adequate analysis and assessment of additional risks shall be performed to define requirements in scope of health care and safety during the product service and operation.

With this purpose:

- hazards posed by the product for all kinds of work and all its phases shall be identified,
- evaluation of risk related to the hazards shall be performed and decision on risk reduction shall be made.

Standards associated with risk assessment

In use are basic standards related to safety of machinery and complementary standards related to particular aspects of safety (such as electrical equipment of machinery), protection equipment (e.g. emergency stop switch) and to particular kinds of products.

Basic standards are:

- PN-EN ISO 14121-1 Safety of machinery - Risk assessment – Part 1: Principles.

  Principles of setting restrictions related to machinery, hazards identification, risk estimation and assessment are presented. Documentation related requirements are given.
- PN-EN ISO 12100 Safety of machinery - General principles for design – Risk assessment and risk reduction.

The above standards refer to the below hazards:

- mechanical hazards,
- electrical hazards,
- thermal hazards,
- noise hazards,
- hazards due to mechanical vibrations,
- hazards due to radiation,
- hazards due to effect of materials and substances,
- hazards due to non-observance of ergonomic principles in machinery design,
- combination of hazards.

Risk assessment and its reduction at the stage of product design

With the purpose to execute the risk assessment and its reduction strategy, the designer shall take the following activities in the below sequence:

1. define the restrictions concerning the product, including its use according to purpose and each foreseeable incorrect use,
2. identify hazards and associated situations,
3. estimate the risk for each identified hazard as a multiplied probability of its occurrence and magnitude of effects,
4. apply risk evaluation and make a decision on the necessity of its reduction,

5. eliminate the hazard or reduce an associated risk, using protective measures,
6. it is essential that the designer checks if applying new protective measures did not cause occurrence of new hazards.

Aspects to be considered during risk estimation:

- exposed persons,
- kind, frequency and duration of exposure,
- relation between exposure and effects,
- human factors,
- reliability of safety functions,
- possibility to prevent the action or disregard safety measures,
- possibility to maintain the safety measures in proper condition,
- information on the use.

Documentation of risk assessment and risk reduction

The documentation shall include:

- ✓ information on the product,
- ✓ any adopted essential assumptions,
- ✓ identified hazards,
- ✓ risk estimation, its evaluation, protective measures applied for each identified hazard,
- ✓ it is recommended to mention, where applicable, the standards or other technical requirements used to select protective measures.

The risk assessment may be conveniently presented in the form of tables.