

**Guideline**

**H-04**

**CLAP**

**FORM N°X229**

**Version : 1**

**Directive 2014/68/EU**

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**Directive References:** Annex I

Annex III

**Subject:** Others ESR – Risk assessment

**Question:**

The third preliminary observation of Annex I of the PED requires that the manufacturer shall "...analyse the hazards and risks in order to identify those which apply to his equipment on account of pressure". In addition, the modules of Annex III require that "The technical documentation.....shall include an adequate analysis and assessment of the risk(s)".

How shall this be carried out and documented?

**Answer:**

As a first stage the manufacturer shall determine and record the characteristics, extent, surrounding and circumstances of the intended use of the pressure equipment or the assembly. Next, it is necessary to identify hazards and/or hazardous situations that could occur during the life cycle of the pressure equipment or the assembly in reasonably foreseeable conditions.

The manufacturer shall analyse each hazard and/or hazardous situation and evaluate the significance of the risk for each identified applicable hazard and/or hazardous situation and follow the mitigation measures as listed in Annex I section 1.2.

The goal of the risk assessment is the appropriate application of the relevant essential safety requirements (Annex I) of the PED and the implementation of associated measures. The manufacturer shall record the risk assessment that has been carried out.

The methods of the risk assessment, a list of the essential safety requirements applied to the equipment and the corresponding protective measures shall be included in the technical documentation.

See also Blue Guide 2016: Section 4.3 "Technical documentation" and ISO/IEC-Guide 51.

Note 1: The risk assessment may be carried out by the manufacturer himself, by his authorised representative or by another person acting on their behalf.

If the risk assessment is carried out on behalf of the manufacturer or by another person, the manufacturer remains responsible for the risk assessment and the implementation of the necessary protective measures during the design and manufacture of product.

Note 2: The hazard and risk analysis process may be facilitated by using harmonised standards but they do not relieve the manufacturer of his obligation to carry out the analysis. See also Blue Guide 2016: Section 4.1.2.2 "Role of harmonised standards".

Note 3: The risk assessment can include, but does not require, a quantitative approach with probabilistic analysis and/or assumptions of possible extents of damage. It is up to the manufacturer to decide about the most appropriate method taking into account the pressure equipment technology used and current practice.