

**Guideline**

**8/4**

**CLAP**

**FORM N°61**

**Version : 6**

**Directive 97/23/EC**

**Keywords :**

Risk analysis

Pressure

Essential requirements

**Directive references:**

Annex I Preliminary  
observation - 97/23 EC

**Adopted by WPG:** 08/11/1999

**Adopted by CLAP:** 08/11/1999

**Subject:** ESR particular – Hazard analysis

**Question:**

What shall be the extent of the hazard analysis specified in the third preliminary observation of Annex I?

How shall it be documented?

**Answer:**

The hazard analysis shall enable the manufacturer to identify and to determine the potential modes of failure due to loading of pressure equipment which could occur when this equipment is installed and used in reasonably foreseeable operating conditions.

After the manufacturer has fixed the limits of the equipment, he must complete a hazard analysis which will enable him to identify the essential requirements which are applicable to the equipment.

The results of this analysis (applicable essential requirements in relation to the foreseeable operating conditions) shall be included in the technical documentation, but the inclusion of full details of the analysis in the documentation is not required by PED.

REMARQUE for the French version only In the third preliminary observation of annex I, in the French version, one shall read "phénomènes dangereux" instead of "risque" in accordance with the English version (hazard) and the german one.

Modifications compared to the previous adopted version: copy of guideline 8/4 (08/11/99) and editorial correction on 2004-09-16.