

Guideline

H-06

CLAP

FORM N°X168

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Directive References: Annex I § 7

Subject: Other ESR – An equivalent overall level of safety

Question:

The first paragraph Annex I section 7 explicitly provides for exceptions to the general rules specified subsequently. How should the achievement of “an equivalent overall level of safety” in such a case be demonstrated?

Answer:

The specific quantitative requirements given in section 7 of Annex I are related to particular failure modes. If different values are used, the corresponding failure modes and their combination shall be identified and the measures taken to maintain an equivalent level of safety shall be provided in the technical documentation, with appropriate justifications.

The achievement of “an equivalent overall level of safety” may be assumed if the measures taken provide adequate safety margins against all relevant failure modes in a consistent manner. Safety margins are adequate, and deviation from a particular value is justified:

- a) by a reduced risk in the respective failure mode, or
- b) by additional means to ensure no increase of the risk.

When using a harmonised standard for pressure equipment which has been published in the Official Journal of the European Communities, no further justification is needed for the quantitative values which have been used as regard Annex I section 7 (refer also to Guideline G-01 (CLAP X138)).

The requirement to demonstrate an equivalent overall level of safety applies to the product itself, and to the measures taken to meet the essential safety requirements. The use of a "recognised" code is not, in itself, sufficient to demonstrate an equivalent overall level of safety (see also Guideline I-05 (CLAP X184)).