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Directive 97/23/EC

Keywords :	Quality assurance		
	EC design examination		
	EC type examination		
Directive references:	Annex III Module D - 97/23 EC	Annex III Module H - 97/23 EC	
	Annex III Module E - 97/23 EC		

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Subject: Conformity assessment – Scope of products

Question: What information shall be included in the quality system approval notification document issued by the notified body concerning the scope of products?

Answer:

The document for all quality system modules shall contain sufficient information to clearly define the scope of products covered by the approval and where applicable, any limitations or restrictions.

The following list of examples is not exhaustive:
- Product description (e.g. pressure vessels, shell boilers, shut-off valves, safety valves, piping, assembly)
- Product design code(s) applied (e.g. EN 13445, EN 12952, EN 12953, EN ISO 4126, EN 13480)
- Materials (e.g. ferritic steels, austenitic steels, non-ferrous, metals, plastics)
- Limitation/restrictions, if applicable (e.g. dimensions, weight, performance)

In the case of modules D and E the initial quality system approval notification document shall include a listing of the relevant EC-type examination or EC- design examination certificates.

In the case of module H1, it is not required that the results of the EC design examinations are listed in the initial quality system approval document. For module H1, in addition to the requirements of module H, the notified body must examine the application and, where the design meets the provisions of the Directive which apply to it, issue an EC design examination certificate to the applicant. The certificate must contain the conclusions of the examination, the conditions for its validity, the necessary data for identification of the approved design, and if relevant, a description of the functioning of the pressure equipment or accessories. So the initial stage of H1 is an approval of the management system.

In all cases the procedure must require the assessment of whether new or modified products will necessitate changes to the quality system, and that these are submitted to the notified body. The Notified Body shall inform the manufacturer if a reassessment of the quality system is required or if the new or modified products are within the scope of the existing system. In cases where no changes are required, a new quality system approval document does not need to be issued.

Any re-issue of the document shall update the list of approval certificates.

Modification compared to previous adopted version: copy of guideline 4/12 (07/12/2007).