

Material requirements for PED/97/23/EC

Material Requirements for the European Community's (EC) Pressure Equipment Directive (97/23/EC)

The working group on pressure for the EC's Pressure Equipment Directive issued a revised guideline (Guideline 7/2*) clarifying the requirements regarding materials used to fabricate main pressure bearing parts of equipment that is to be CE-marked and placed on the market in the European Community.

Per Guideline 7/2*, "Materials used for main pressure bearing parts of pressure equipment intended for CE-marking must be produced (manufactured) by an organization that either:

1. Has been certified by a qualified Notified Body to meet the requirements of the PED (97/23/EC). "Qualified" means that the Notified Body's scope of accreditation must include certification of material manufacturers. The material manufacturer should be able to provide proof of the certification with the Notified Body clearly identified.
or

2. Has a Quality Management System that has been registered/certified by a legal entity in the EC. The material manufacturer should be able to provide a copy of their current ISO certificate, naming the registrar. The address of the registrar can be used to confirm that the registrar is a "legal entity" (i.e., the address of the registrar must be in one of the countries of the European Union).

This material requirement is effective immediately and failure to comply with it may result in disqualifying pressure equipment manufactured from non-conforming materials (e.g., materials that can not be supported with objective evidence that the Guideline 7/2 has been met) from consideration for PED certification and a CE-mark.

Under the revised Guideline, the ISO 9001 registrar that approved the material manufacturer's quality system has to be legally resident in the European Community.

It is **NO LONGER** the location of the "Accreditation Body", or whether it is on the "IAF" website, that determines PED acceptability. It is the "location" of the Registrar, which must now be a "legal entity" (headquarters with physical office) in the EC.

* Guideline 7/2 from the European Pressure Equipment Directive 97/23

A "competent body" for certification of the quality systems of material manufacturers can be any third party body established as a legal entity within the Community which has recognized competence in the assessment of quality (assurance) systems for the manufacture of materials and in the technology of the materials concerned. Competence can be demonstrated, for example, by accreditation.

Note 1: A body not established as a legal entity within the Community, even if it has a recognition agreement through the International Accreditation Forum, does not comply with the requirements of Annex I section 4.3.

Note 2: A notified body may perform this task only if it has a recognized competence in the field of quality assurance, materials and related process technology. For this certification, the possible use of the notification number for PED is irrelevant.

Note 3: The certificate of quality system shall make reference to the legal entity established in the Community and its address