



# Workshop on the Pressure Equipment Directive (PORT 8485)

**Riga, Latvia  
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For the benefit of business and people



## SUMMARY

- 1** Conformity Assessment Bodies
- 2** Hazard categories
- 3** Conformity Assessment Modules



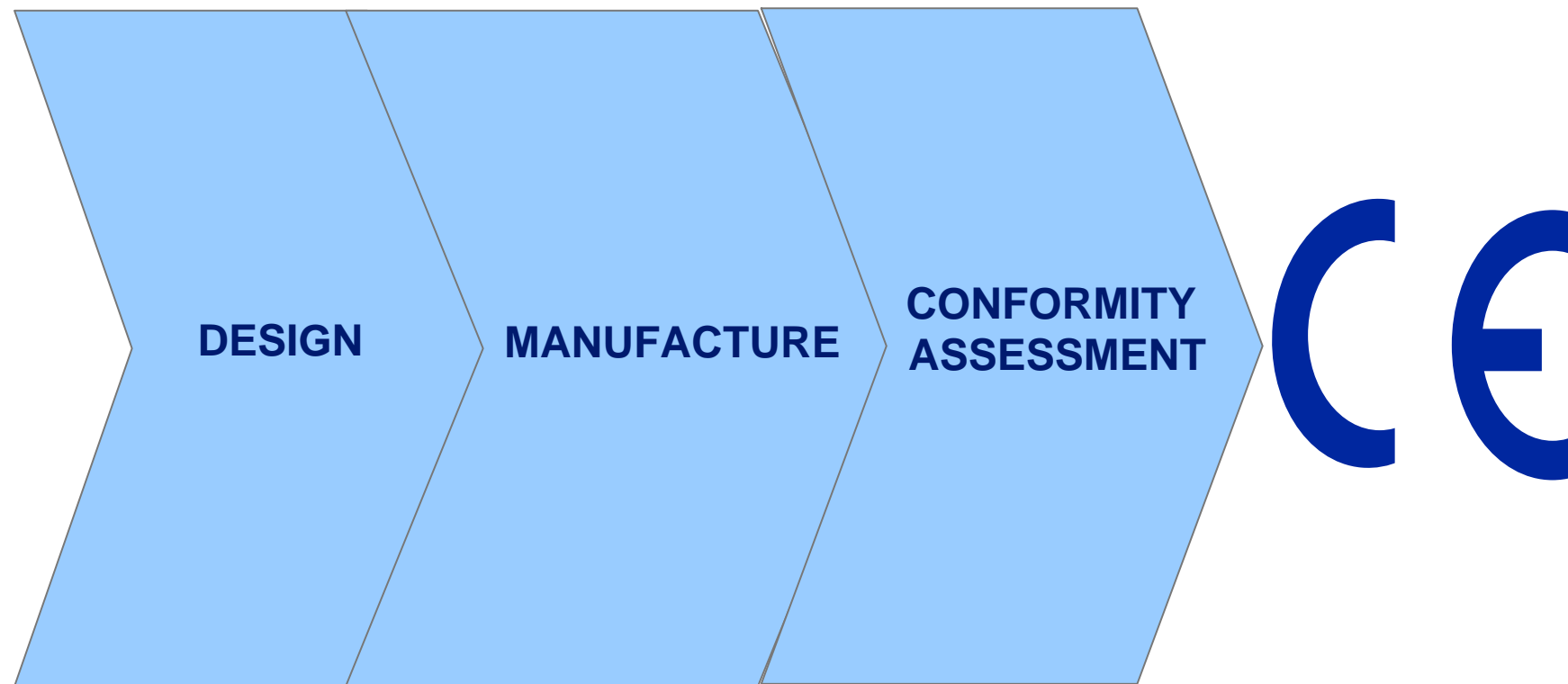


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# Conformity Assessment Bodies



## Requirements for Pressure equipment



► **Type of bodies involved with Conformity Assessment:**

- **Notified Bodies**
- **Recognised Third Party Organisations**
- **User Inspectorates**



**To assist manufacturer in bringing products to the market in conformity with the directive(s)**

**Under the jurisdiction of and appointed by a Member State of EU**

**May operate any where in world**

**Generally, existing European Inspection Bodies, e.g. TÜV., Lloyds, Bureau Veritas, DNV, etc**

**Required to apply requirements consistently (Co-ordination of NoBos)**

## ► Requirements of CAB (Annex IV)

- Independence, impartiality, integrity and competence
- Personnel and facilities
  - Sound technical training
  - Satisfactory knowledge and experience
  - Ability to prepare reports, certificates, etc
- Professional liability insurance
- Confidentiality



► **Requirements of a CAB (Blue Guide)**

- Shall participate in co-ordination activities .
- They shall take part directly or be represented in European standardisation.
- Coherent application of conformity assessment procedures require close cooperation between Notified Bodies, Commission and Member States
- Commission facilitates Forum for Notified Body - Groups for all Directives





Notified Bodies: appointed by a Member State of EU  
for any or all Conformity Assessment Modules

Approval of Technical Documentation  
Inspection of pressure equipment  
A1, B1, B, C1, F, G

Approval of Quality systems  
D, D1, E, E1, H, H1



Recognised Third Party Organisations are appointed by a Member State of EU

For approval of:

Joining Procedures/Operators

NDT Operators



Appointed by a Member State of EU

**Second Party Inspection Body**  
usually part of a Group, e.g. Petroleum Company, etc.

**Perform activities indicated for Notified Body in  
Modules A1, C1 F and G only**

**May only work on equipment destined for the user**

**Equipment must not have CE Marking**  
**No freedom of movement**



## Basis for appointment

**Requirements specified in Annex IV**

**Accreditation according to EN 45000 series supports this assessment but is not mandatory**

**Assessment generally performed by National Accreditation Body, result advised to member State**

**Member State appoints body and “Notifies” the Commission**



- ▶ **May have part of work performed by others**
- ▶ **Sub-contractor must be technically competent, meet criteria for independence, etc**
- ▶ **Member State must ensure effective monitoring of subcontractor by Notified Body**
- ▶ **Must carry out substantial and coherent parts of the assessment**
- ▶ **Based on a contract**
- ▶ **The Notified Body remains responsible for all work performed by sub-contractor**
- ▶ **Certificates are issued by the Notified Body**



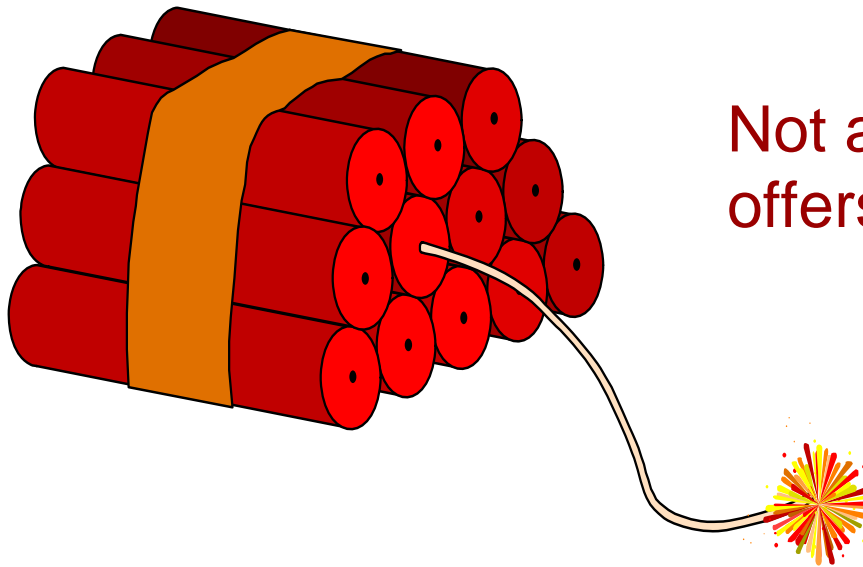


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# Categorisation of Pressure Equipment

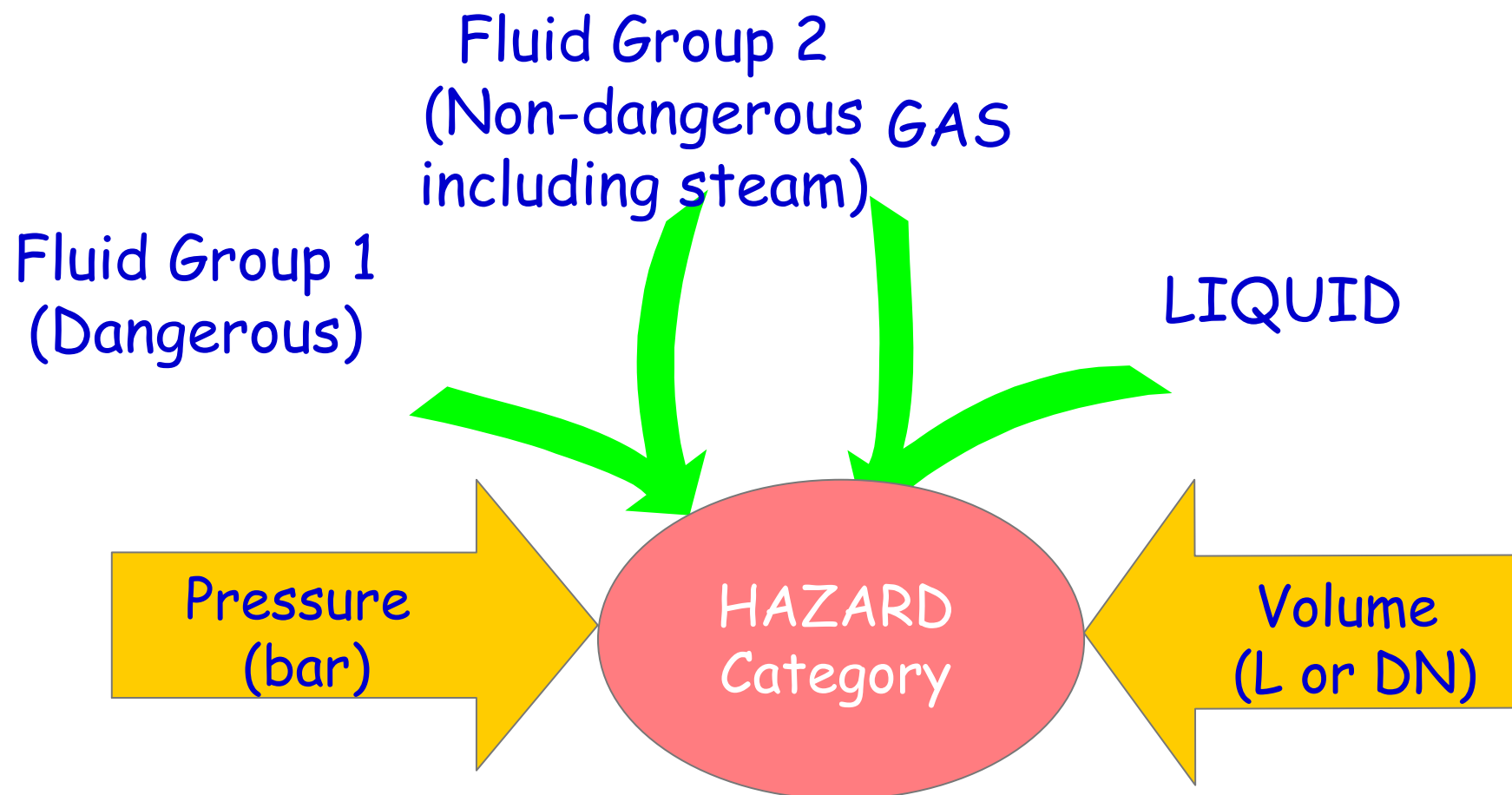


## Determining category of pressure equipment



Not all pressure equipment offers the same level of risk

**PED offers different requirements for different levels of risk**





## DIRECTIVE "67/548/EEC"

- |                       |             |
|-----------------------|-------------|
| - Explosive           | <i>E</i>    |
| - Oxidizing           | <i>O</i>    |
| - Extremely flammable | <i>F +</i>  |
| - Highly flammable    | <i>F</i>    |
| - Flammable           | <i>R 10</i> |
| - Very toxic          | <i>T +</i>  |
| - Toxic               | <i>T</i>    |

GROUP 1

*P.E.D*

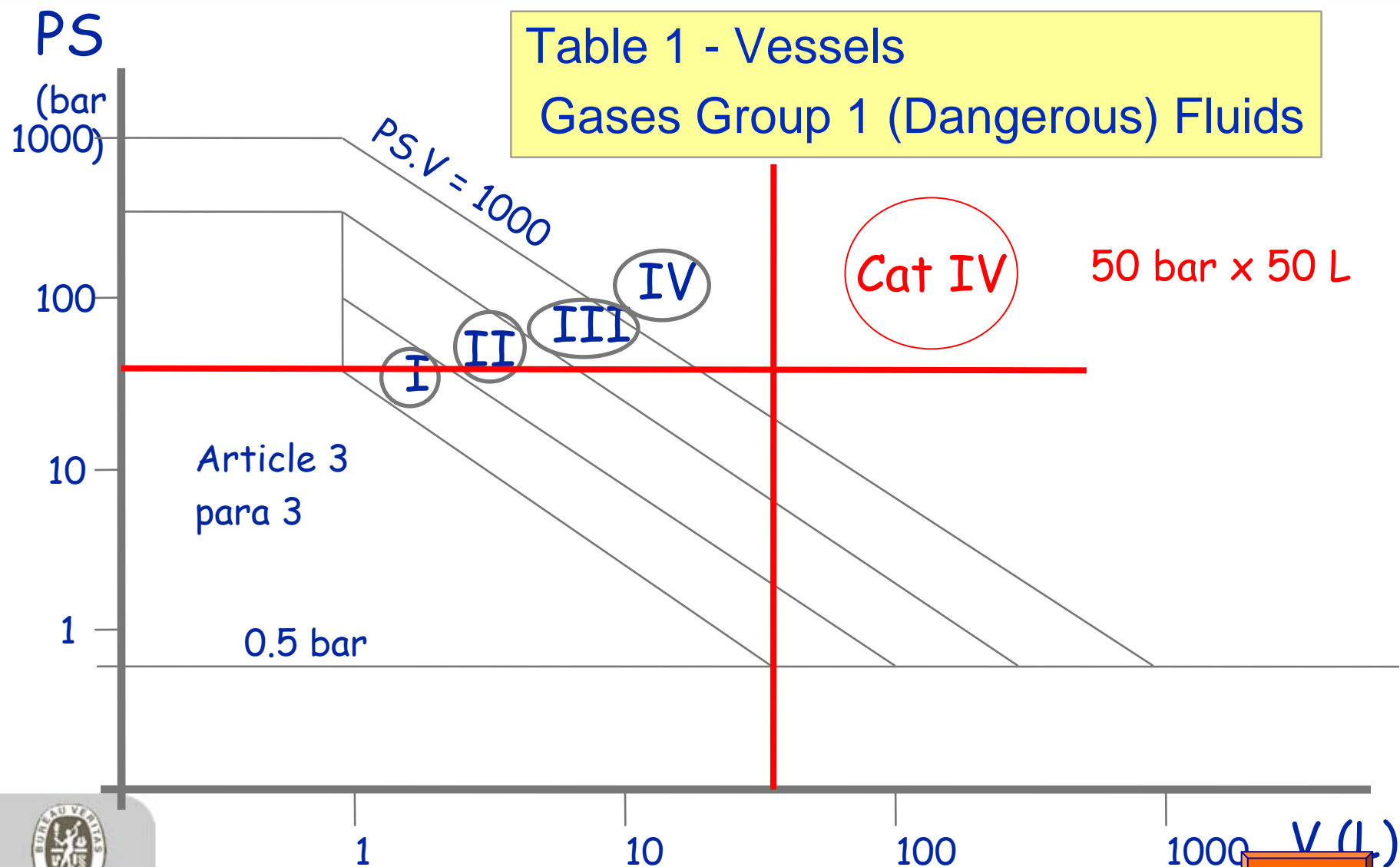
- |                             |                                  |
|-----------------------------|----------------------------------|
| - Harmful                   | <i>Xn</i>                        |
| - Corrosive                 | <i>C</i>                         |
| - Irritant                  | <i>Xi</i>                        |
| - Sensitizing               | <i>R 42 and/or R 43</i>          |
| - Carcinogenic              | <i>Carc. Cat.</i>                |
| - Mutagenic                 | <i>Mut. Cat.</i>                 |
| - Toxic for reproduction    | <i>Repr. Cat.</i>                |
| - Dangerous for environment | <i>N and/or R 52, R 53, R 59</i> |

GROUP 2

*P.E.D*

Table 1 - Vessels

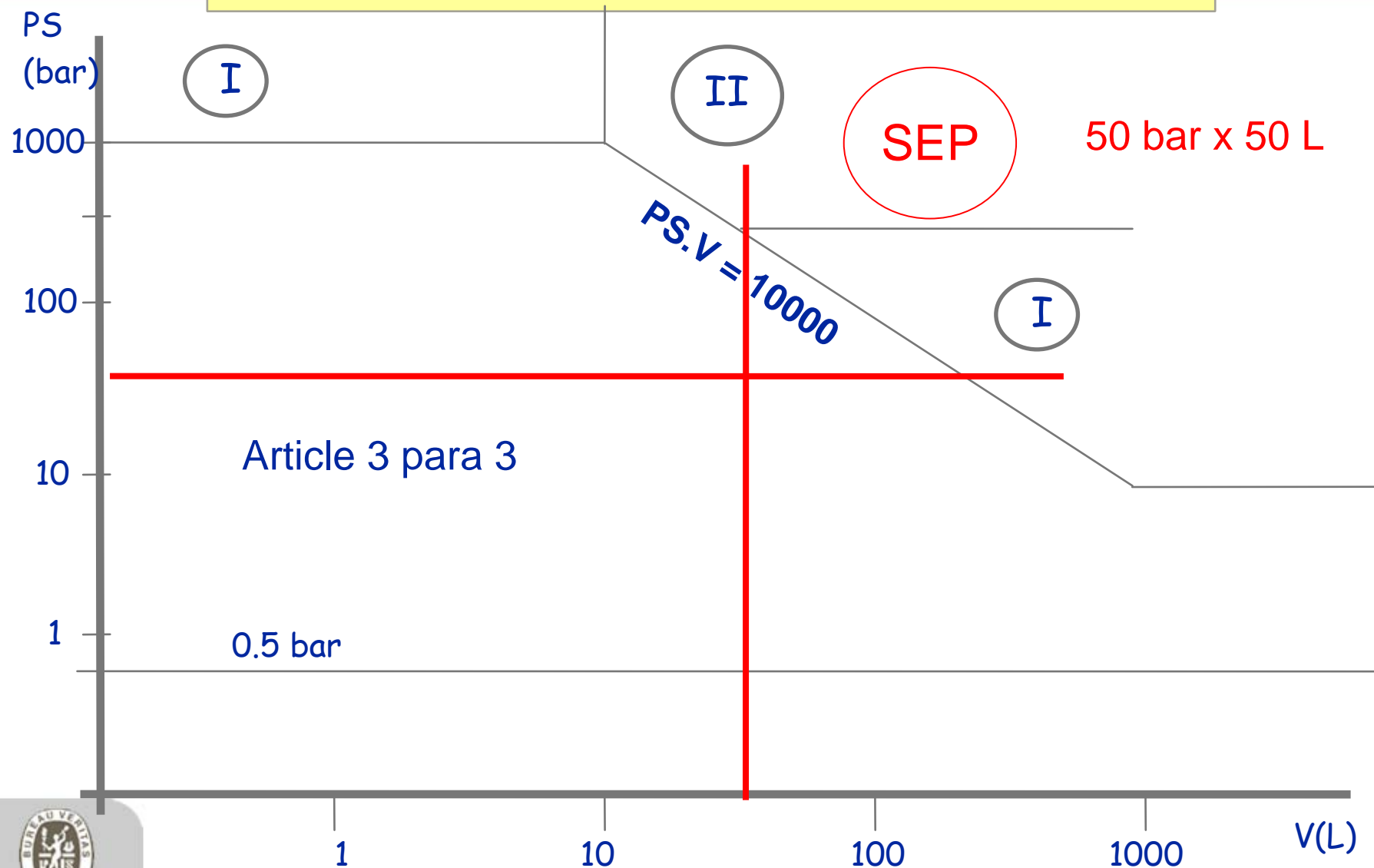
Gases Group 1 (Dangerous) Fluids



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## Categorization

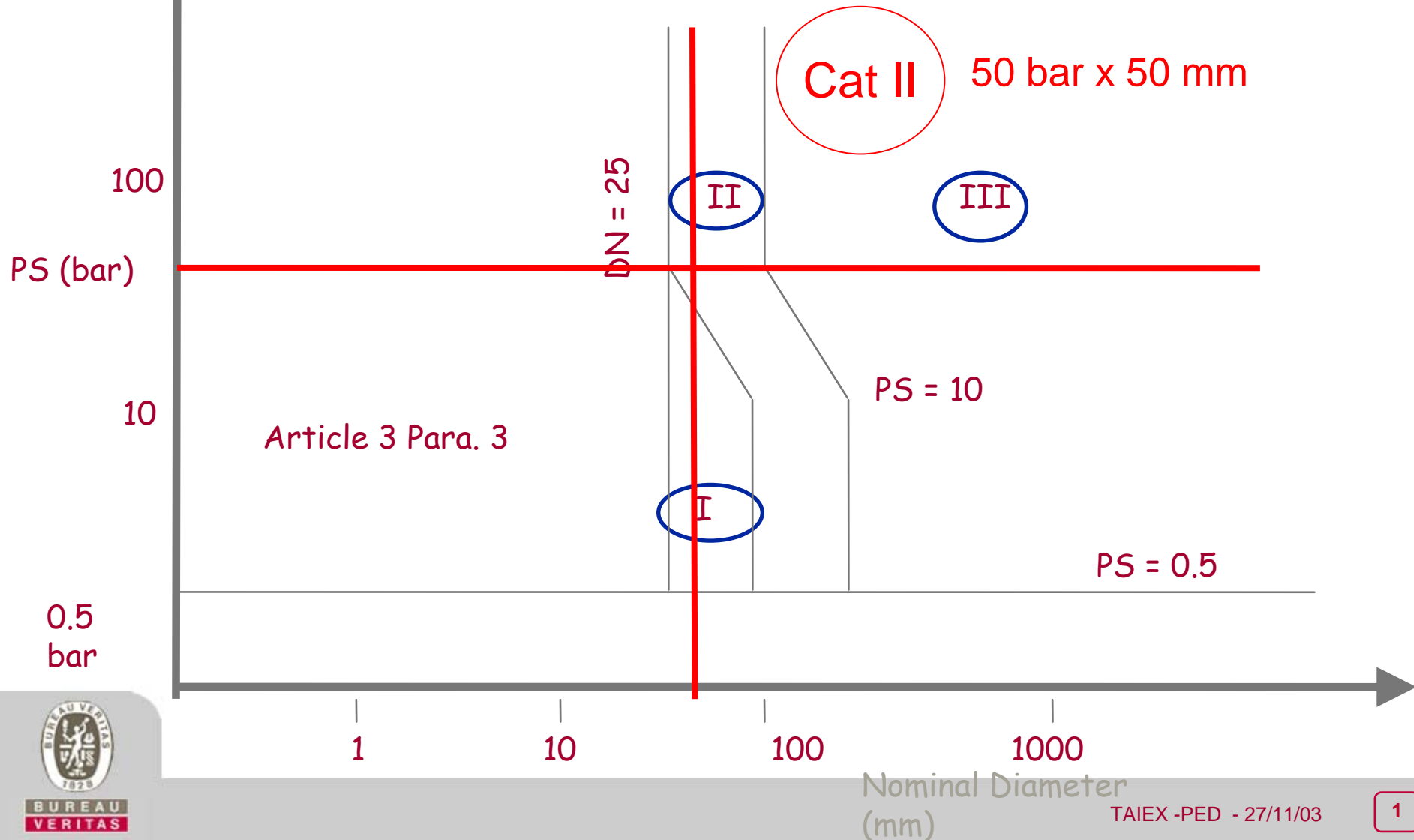
Table 4 - Vessels Liquids Group 2 (non-dangerous)

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## Categorization

Table 6 - Piping - Gases - Group 1 (dangerous) fluids

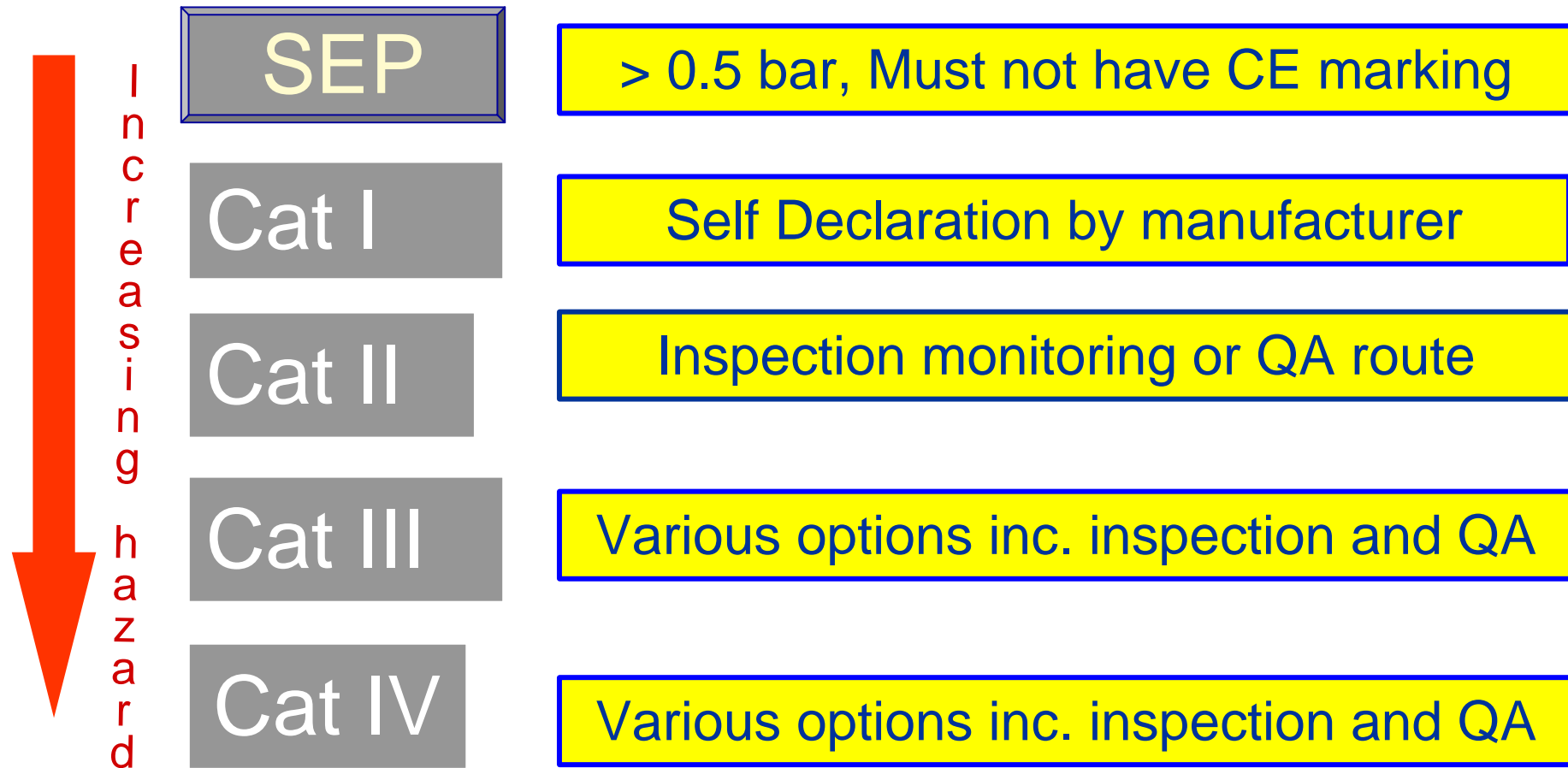




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## > Conformity Assessment Modules





**Cat I**

**Module A = Prepare technical documentation and self declare conformity**

**Cat II**

**Module A1 = As Module A but Notified Body monitors final test**

**Module D1 = Production QA (ISO 9002) + Prepare technical documentation**

**Module E1 = Product QA (ISO 9003) + prepare technical documentation**



**Cat III**

**Module B1 + D, B1 + F,  
B + E, B + C1, H**

**Module B1 = Design Examination (Design approval)**

**Module B = EC Type Examination (DA + product exam)**

**Module D = Production QA**

**Module E = Product QA**

**Module C1 = Conformity to type (random final inspection)**

**Module F = Product verification (final inspection)**

**Module H = Full QA (ISO 9001)**

**B, B1, and H all require preparation of Technical Documentation**





**Cat IV**

**Modules: B + D,  
B + F, G & H1**

**Module B = EC Type Examination**

**Module D - Production QA**

**Module F = Product verification**

**Module G = EC Unit verification (Design Approval  
and**

**in-process Inspection)**

**Module H1 = Full QA, with design examination and  
special surveillance**

**Module G & H1 require preparation of Technical Documentation**



## Advantages

Reduction in participation by NoBo

## Details

Module E - Product Quality Assurance  
Module D - Production Quality Assurance  
Module H - Full Quality Assurance

Similar to ISO 9003, 9002, 9001 (1994)  
BUT NOT THE SAME

Quality System must be assessed by Notified Body,  
then subject to Surveillance and Unexpected Visits



Cat	Conventional Inspection		Quality Assurance	
	Single prod	Series prod	Single prod	Series prod
I	A	A*		
II	A1	A1	D1 or E1	D1 or E1
III	B1+F	B+C1	B1+D or H	B+E or H
IV	G	B+F	H1	B+D

\* final test for series production may be on statistical basis



**Manufacturer chooses from options**

**May choose higher module**

**QA module is always a choice**

**Safety Accessories in Hazard Category IV**

**Assemblies subject to Global Conformity assessment**



Assemblies shall be subject to global conformity assessment (Art 10 (2)).

Assess each item of pressure equipment not CE marked

Assessment of *integration*

- Safe handling and operation
- Components are suitable

Assessment of protection of assemblies

conformity module determined by category of each item

determined by the highest category of equipment concerned other than that applicable to any safety device

- Properly integrated
- Provisions for filling and discharge

Safety accessories monitoring devices





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You made it to the end



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