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The New PED Directive – Confirmations and changes with specific reference to products Trading and their Safety Appreciation

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1) FOREWORD

The Official Journal of European Union dated June 27, 2014 publicise the Directive 2014/68/EU of May 15 2014, known as New PED which, in respect of previous 97/23/EC, has been reorganized and revised to take into account the New Legislative Framework (NLF) and specifically the provisions of:

- Regulation (EC) n° 765/2008 which lays down rules on the accreditation of Conformity Assessment Bodies and also provides a framework for the market surveillance of products and for the controls on products from third countries also laying down general principles of CE marking;
- Decision n° 768/2008/EC which lays down rules for a common framework for the marketing of products into the common market providing harmonized definitions regarding Economic Operators, Standards, Specifications, Conformity evaluation and rules and conditions for CE marking.

The review process of the previous Directive has been performed having in mind the following main objectives:

- To improve and strengthen the competitiveness of the Enterprises who implement the obligations of the Directive in respect of those who gamble them;
- To improve the functioning of the internal market assuring equal treatment to all actors in particular Importers and Distributors;
- Not to introduce other commercial burdens to those economic operators who already respect the laws.

All new Product Directives have neither modified the field of application nor the Essential Safety Requirements (ESR).

2) THE NEW DIRECTIVE AND SOME CONSIDERATIONS

The structure of the new PED, common to the other directives which have been reissued, is as follows:

- Chapter 1: General Provisions articles from 1 to 5
- Chapter 2: Obligations of Economic Operators articles from 6 to 11
- Chapter 3: Conformity and Classification of Pressure Equipment and Assemblies articles from 12 to 19
- Chapter 4: Notification of conformity Assessment Bodies articles from 20 to 38
- Chapter 5: Union Market Surveillance, Control of Pressure Equipment and Assemblies entering the Union market and Union Safeguard Procedure articles from 39 to 43
- Chapter 6: Committee Procedure and Delegated Acts articles from 44 to 46
- Chapter 7: Transitional and final Provisions articles from 47 to 51

To be noted in the new text articles are numbered progressively for all chapters.

Annexes: **Reorganized for conformity to the new text**

- Annex I: Unchanged;
- Annex II: Unchanged;
- Annex III: Some formal changes (see Annex VI – correlation Table);
- Annex IV: EU Declaration of Conformity;
- Annex V : Repealed Directive with list of successive amendments thereto;
- Annex VI: Correlation Table.

Some principles to be kept in mind

1) Valves are pressure accessories considered as piping and classified on the basis of the nominal size (Annex II tables 6 to 9) and therefore with maximum category III;
2) Pressure Safety Valves are Safety Accessories to which the Directive assigns a risk category IV. To be noted that the valve itself (as pressure bearing equipment) rests in category III but its certification must follow a conformity module applicable to a category IV item that is: B_d+ D; H1; B_p+ F and G;
3) Mass production are, as a rule, certified using module H although other modules can be applied (B_d+ D; B_d + F; B_p+ E; B_p + C2);
4) Annex III of the new Directive does not include new regulations nor changes to conformity modules implementation but allows more clean definition of obligations of the Manufacturer and duties of No.Bo. to avoid arbitrary interpretations.

To day exist over 25 standards applicable to valves harmonized to PED.

The sensibility of Manufacturers to the need of compliance to the Standards and compliance to PED has grown and to-day the presence on the market of items of formal compliance but technical non compliance is much lower than some time ago.

Some examples of conformity problems as well as of different positions amid different Notified Bodies are reported .

Product Conformity

Major problems:

1. Products certified with documents not issued by the manufacturer;
2. Rolled bar certified as forging;
3. Centrifuged products certified as casting or forging;
4. Products already used in field (scrap material) requalified and recertified as new;
5. Material certified originally for structural use, re-certified for pressure purpose;
6. Heat treatment carried out only on test specimens and not on the base material.

Product Conformity

Minor Problems:

1. Materials certificates EN 10204 type 3.1 and 3.2 issued by stockist are authorized by standard only if he carries out “property-changing” operations;

2. Ref. EN 10204, traceability problems, starting from the identification of base material and test specimens, to arrive at the loss of product correlation with the mandatory technical file (valve serial number);

Notify Bodies Behaviour

- **Case A -** Charpy Impact Tests for SA-105.
  - NoBo(1) – Mandatory test for all ferritic steels independent of the operating temperature.
  - NoBo(2) – Test not required till -29°C.

    Supported by:
    - ASME 31.3 Process Piping – Table A-1 Note 6.
    - EN 1503-2 Valves - Materials for bodies, bonnets and covers - Steels other than those specified in European Standards – Par 3.

Notify Bodies Behaviour

- **Case B –** Tensile test at high temperature for ASME / ASTM materials.
  - NoBo(1) – Test not required;
  - NoBo(2) – Always required;
  - NoBo(3) – Test required only if the values are not listed on reference Codes (i.e. ASME B31.1, ASME B31.3, ASME II part D).

Notify Bodies Behaviour

- **Case C –** Design Appraisal for **safety elements** certified as per Module G, H1, B+D, B+F.
  - NoBo(1) – Mandatory to include the SAR (Safety Analysis Report), in the design package, to support the functionality of the component (valve, actuator, etc…) through time;
  - NoBo(2) – Any requirement.

As a consequence products exhibit Cost Differences as well as Quality Differences which might endanger Safety and Environment.

3) ENCOUNTERED PROBLEMS IN PED APPLICATION TO VALVE MANUFACTURERS

Application of conformity assessment procedures, based on quality assurance, usually represent a problem because some Manufacturers continue to make confusion amid ISO 9001 and PED Directive.

For design Fabrication and testing essential are the standards and not the methodologies to monitor the System but, in the meantime, the system is essential to guarantee the quality of the product.

Above concept is still not fully clear to some Manufacturers which do not understand the necessity of adequate technical knowledge and justification especially when treating Design, Risk analysis and RES Check List.

Certification of products according module H and H1 is for No.Bo. the most difficult job because certification is initially issued on «Manufacturers Declared Intentions» which, during surveillance, can be only verified on a statistical basis.

4) Additional considerations on PSV's certification and SIL evaluation

PSV's are Cat. III items certified, according to Directive, in Cat. IV because are safety accessories. The certification process includes, as a consequence, specific design, type tests, calibration and, specifically, conformance to requirements of point 2.1 of PED Annex I. Besides redundancy principle is to-day common practice to apply to these items the SIL concept. PSV's alone have a SIL maximum of 2.

Safety Integrity Level (SIL)	Probability of a dangerous failure on demand of the safety function (PFD)
4	≥ 10–5 to < 10–4
3	≥ 10–4 to < 10–3
2	≥ 10–3 to < 10–2
1	≥ 10–2 to < 10–1

Definitions:

SIL = Safety Integrity Level (see IEC 61508-4 para. 3.5.8)

PFD = Probability of dangerous failure on demand (see IEC 61508-4 para. 3.6.17)

Documentation of SIL level of the PSV alone or of integrated safety systems must be provided in a Safety Analysis Report (SAR).

SAR / SIL (IEC 61508)
Quality of calculation data

IEC 61508-2010 allows to calculate the reliability by two ways:

1. Route 1H (failure rates from commercial data base);
2. Route 2H (failure rates from field data collected according ISO 14224).

Whichever the calculation is performed reference data are affected by poor reliability.

Data for a tailored data base as per ISO 14224:

Manufacturer Input Data (reliable):

- Valve model;
- Dimension;
- Pressure;
- Fluids;
- Operating conditions;
- Endurance Tests.

User Input Data (unreliable)

- Valve Operating Start Date;
- Valve Cycles/Year;
- Life Failures Data.

SAR / SIL (IEC 61508)
Quality of calculation data

Calculation methodologies can be applied as follows:

1) Organize a Manufacturer's **tailored** failure data base, collecting data from shop endurance tests and service's field data, updating the document on annual base and recorded over the last 10 years;

2) Utilise a generic commercial failure data base with generic and superseded data with option to choice favourable data.

Comments:

Option 1 : Good reliability level, high cost and periodic re-evaluation of the SAR (5 / 10 Years).

Option 2 : Poor reliability level, low cost, no SAR re-evaluation in the time.

5) Possible Improvement also with reference to the US approach

Suggestions:

1. PED Directive

   Should be more restrictive (i.e. issuance of specific guidelines);

   Collect the European Standards in books as per type of application (e.g. Power Piping, Process Piping, etc…).

2. Sub-Supplier

   Manufacturers should qualify the sub-suppliers, not only considering the costs, but in function of the quality of product and/or service (i.e. API standard foresee qualification specifications API 6A, 6D and for the future years foresee the qualification of sub-suppliers and of their products as per API 20A, 20B, 20C, 20E).

5) Possible Improvement also with reference to the US approach

Suggestions cont.:

3. Notified Body

   The new NLF requirements to NoBo are in favor of more quality even for NoBo subsidiaries in other countries.

   But is still necessary to increase the inspection quality level:

   - Inspectors skill have to be focused on a consolidated experience and knowledge in the sector of the specific product (valve, welds and materials);
   - Increase the inspection time.

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N.B.

Valves comply with the standards API and / or ASME can be certified only by the manufacturer.