The new “Pressure Equipment Directive 2014/68/EU

Alignment to NLF and CLP – where are the relevant changes?

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**Overview**

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New Approach

A major success story

» Unique European concept – EU-Directives (law) plus harmonized standards ("practical tools")
» Central objective:
  Free circulation of goods on the common market while ensuring a high level of safety
» Excellent level of safety all across Europe
» Harmonized processes simplify business enormously
» Concept has been taken over by many economies outside EU:
  – Similar concept of technical regulations with harmonized standards exists now in Customs Union
    Russia – Belarus – Kazakhstan
  – Many elements from New Approach also in the Chinese system
  – South Africa implemented PED almost on a 1:1-basis

Why was PED-alignment carried out?

From New Approach to NLF

» After more than 20 years of EU-Directives:
  Certain – legal – elements had started diverging, a more unified approach was necessary
» Directives had undergone major developments during these 20 years (from SPVD in 1987 to
  Machinery Directive in 2006)
  ⇒ more consistent legal framework should be accomplished
» Decision 768/2008/EC established a (new) more consistent basis for
  – essential terms and definitions
  – tasks and duties of the different market players
  – conformity assessment procedures, notifications, content of modules etc.
» Together with EC-Regulation 765/2008 (accreditation, market surveillance) a new legal framework
  was created:
  ⇒ NLF – New Legislative Framework
Alignment to NLF: “Omnibus”-procedure

In total: 10 EU-Directives concerned by the alignment process

» A formal step in the first place

» Existing directive texts were to remain unchanged as far as possible; they were to be amended, however, by extensive NLF-text originating from 768/2008/EC

» No technical changes allowed, only formal/editorial alignment

⇒ quite an ambitious enterprise

» Among the directives to be aligned:


– Low Voltage Directive 2006/95/EC → 2014/35/EU


Alignment of PED – besides NLF there is also CLP...

PED-alignment more complex

» Temporal overlap:

in addition PED-alignment to new EU-Chemicals Regulation 1272/2008, better known as CLP-Regulation (“CLP” = Classification, Labeling and Packaging of Chemicals)

» NLF-CLP-alignment required an additional Impact Assessment for CLP, hence PED was treated separately from “Omnibus-process” (separate time frame)

⇒ Two different alignment steps for PED:

» Formal alignment to NLF without technical changes, NOT a full Revision

» More profound alignment to CLP with technical changes in the former Article 9 of the PED

– Changes restricted to hazard classification of fluids – no further technical revision

– Expertise from science and industry – good collaboration with EU-Commission
Timetable for directive alignment

Crucial dates for implementation

» 8 Omnibus-Directives (almost all of the original “candidates” except PED):
   – Mandatory coming into force on 20 April 2016

» Dates for PED slightly delayed:
   – Publication in OJEU on 27 June 2014
   – Mandatory from 19 July 2016 (formally without!!!) a transition period
   – One little exception: New paragraph on CLP already in force and mandatory since 01 June 2015

Why was the PED to be aligned with CLP?

Essential for fluid classification under PED

» PED classifies pressure equipment in hazard categories I to IV
» Criteria for this step:
   pressure, volume/nominal diameter, aggregate state of fluid, hazardousness of fluid
» For determining hazardousness of fluids the “old” PED made use of the characteristics of fluids
   listed in the European Chemicals Directive 67/548/EEC (DSD = Dangerous Substances
   Directive)
» DSD was completely replaced by CLP on 01 June 2015
» In order to avoid legal and formal gaps in the regulation: reference in PED fluid classification to
   CLP was necessary
» A “mere” change in reference was, however, not sufficient since CLP uses a different
   classification system – alignment of PED to this new CLP-System was necessary
Alignment of PED to CLP

What elements had to be changed?

» PED 97/23/EC groups in its Art. 9 fluids into dangerous fluids (group 1) and “other” (non-dangerous fluids (group 2) according to DSD

» Group 1:
  – explosive
  – extremely flammable, highly flammable, flammable (when $T_{\text{max}}$ is higher than flashpoint)
  – toxic and very toxic
  – oxidizing

» Group 2:
  – all other fluids

Important:
Fluid classification is only relevant for categorization in PED, no direct consequence for technical requirements of equipment (these come always from Annex I)!

Alignment of PED to CLP

Some basic information on CLP-Regulation

» Alignment of European chemicals legislation to GHS (Globally Harmonized System)

» Essential alterations (relevant for PED-aspects):
  – (Marginal) shift of flash point boundaries
  – Classification system for „extremely flammable“, „highly flammable“ etc. subdivided in a more complex manner
  – Toxicities: stronger focus on absorption by human body („toxic upon inhalation/ingestion/dermal contact“ under CLP vs. „toxic“ under DSD)
  – Replacement of R-phrases (DSD) by H-statements (CLP)

⇒ Only basis for fluid classification under PED is modified, NOT the basic concept (diagrams in PED remain unchanged)
Alignment of PED to CLP

How was transition from DSD to CLP carried out in PED-text?

» New Article 13 replaces former Art. 9
» Classification according to physical characteristics (explosive, flammable, oxidizing) remained almost identical
» More difficulties in assessing the “new” toxicities since new CLP-concept deviates from old DSD-approach
» The EU-Commission’s objective to keep the Status Quo as far as possible unchanged, still could be largely achieved
» Only for few items of pressure equipment – explicitly manufactured for very specific fluids – there might be changes in practice
» Potentially some effects on operating instructions (new pictograms, safety instructions)
» New Guideline B-41 links dangerous substances with H-statements

Alignment of PED to NLF – the new PED 2014/68/EU

One short summary in advance:

» Main objective was achieved: directives are now consistent among each other
» Very extensive alignment – PED-Text was enlarged by more than 50 %
» Changes primarily in the main text:
  Terms and definitions, duties of economic operators, notifications of notified bodies, but also changes in modules (Annex III)
» Technical requirements (Annex I) unchanged
» Still some modifications that can have impact beyond purely editorial alignment:
  – extensive editorial re-structuring of the main text
  – indiscriminate introduction of new terms that may lead to conflicting situations in connection with long-established processes
  – no transition period from “old” to “new” PED
The new PED 2014/68/EU – formal changes

Editorial re-structuring

» Art. 3(3)-vessels (do not have to fulfill requirements in Annex I of the PED due to their operating parameters, receive no CE for PED) will – from July 2016 – become “Art. 4(3)-vessels”

⇒ Many companies or institutions need to adapt their internal documentation to a significant extent

» Exclusions 1.3.1 to 1.3.21 become exclusions according to Art. 1(2)a to 1(2)u in the future

⇒ also in this case well-established terms (such as “exclusion 1.3.10”) are modified, possible effect on documentation

» All(!) guidelines to PED need to undergo a formal revision/re-assessment due to the numbering changes in the referenced articles and clauses

– New numbering scheme: the “old” Guideline 1/1 becomes A-01, GL 3/12 becomes C-12 etc.

– Only alignment of editorial references to PED-text and of some terms and definitions; no technical re-assessment of the guidelines

Some ambiguities with respect to responsibilities for language of operating instructions due to addition of wording from Decision 768/2008/EC

» Until now in Art. 4(3) (in the future: Art. 5(3)):

"Member States may require […] the information referred to in points 3.3 and 3.4 of Annex I to be provided in the official language(s) of the Union which may be determined by the Member State in which the equipment or assembly is made available on the market."

⇒ Guideline 9/21: “For pressure equipment specifically manufactured for a defined end user which is subject to contract between the supplier and user, they can also contractually agree who shall do the translation(s) […]”

» In the future there is an additional Art. 6(7):

"Manufacturers shall ensure that the pressure equipment or assemblies […] are accompanied by instructions and safety information in accordance with points 3.3 and 3.4 of Annex I, in a language which can be easily understood by consumers and other users, as determined by the Member State concerned. Such instructions and safety information shall be clear, understandable and intelligible."

⇒ Guideline 9/21 was confirmed! (new publication as I-21)
The new PED 2014/68/EU – formal changes

1:1-alignment of main text and Annex III (modules) to NLF

» Definitions and obligations for manufacturers, importers and distributors are now in main text (previously laid down in the – legally less binding – Commission’s “Blue Guide”)
» System includes now criminal penalties
» Extension of safeguard clauses (dangerous product or non-conformity)
» “Benannte Stellen” (former German translation of “notified bodies”) will become “Notifizierte Stellen”
» Modifications in denominations and description of modules(!)
  – A1 becomes A2, C1 becomes C2
  – B1 becomes “B (design type)”
  – B becomes “B (production type)”
  – Occasionally logical inconsistencies
⇒ Compare new module elements with “old” elements!!!

Important: Certificates and decisions issued by notified bodies remain valid!!!

The new PED 2014/68/EU – major(?) changes

Replacement of the term “Hazard” by the term “Risk”

» By far the most controversial change
» In many text passages the long-established term “hazard analysis” was replaced or amended by a requirement for a documented risk analysis and/or risk assessment (new in the modules)
» Modification goes – depending on the interpretation of the involved market players – far beyond a purely formal/editorial alignment
» Technical definition of the term “risk” (German Product Safety Law): Product of probability of the occurrence of an incident multiplied by extent of damage
» Paradigm change?
  – Estimation of damage extent? – normally for items of pressure equipment little or no information available with regard to exact installation conditions and environment
  – Probability for pressure-induced failure? – accepting such a “risk” is massive deviation from basic PED-concept (it is the MAIN objective of the PED to avoid such a pressure-induced failure)
⇒ Already today: different interpretations among the involved parties
The new PED 2014/68/EU – major(?) changes

“Risk” vs. “Hazard” – Proposal for a solution

» No „quantitative“ theoretical approach involving probabilities and estimates of damage, but rather prevention of pressure-induced failure by appropriate application of the PED:
» hazard- and risk analysis: covered by “old” hazard analysis under 97/23/EC
» risk assessment: assessment of the “identified hazards” under 97/23/EC taking into account the intended use as well as easily foreseeable misuse of the equipment, applying a 3-step concept:
» identification of the essential safety requirements in PED Annex I that are relevant for the manufacturing of the specific equipment ⇒ selection of materials, appropriate design methods and fabrication and testing procedures = constructive measures
» providing safety measures for those hazards/risks that can’t be addressed constructively
» covering remaining hazards that cannot otherwise be addressed in the operating instructions according to Annex I paragraph 3.4
⇒ Upon correct implementation of the requirements of the “old” PED no practical change in the manufacture of pressure equipment, apart from new requirement for a documented risk analysis

» New Guidelines H-04 und H-20 try to clarify the situation:
NO KEINE KONZEPTIONELLE ÄNDERUNG

Guideline H-20 (Draft, not yet confirmed by Commission)

Question:
Does the introduction of the term analysis and assessment of the risks in the new PED 2014/68/EU change the concept of “hazard analysis” that was originally laid out in the old PED 97/23/EC?

Answer:
No.

It was NOT the purpose of the newly introduced terms “risk analysis” and “risk assessment” to establish a completely new concept. The new terms do, however, describe more correctly the already existing concept that has been and still is underlying the conformity assessment and manufacturing process under the PED.

The hazard analysis under the “old” 97/23/EC already corresponded to the hazard AND risk analysis under the new 2014/68/EU. Consequently, a manufacturer who in the past correctly followed the concept of a “hazard analysis” as it was defined in 97/23/EC was – when combining it with the conformity assessment – carrying out a risk assessment as it is now formally required in 2014/68/EU.

Nevertheless, the new PED 2014/68/EU explicitly requires that the technical documentation includes a record of the analysis and assessment of the risk(s).
**Guideline H-04 (Draft, not yet confirmed by Commission)**

**Question:**
How shall the analysis of the hazards and risks [...] be carried out and documented?

**Answer:**
The analysis of the hazards and risks shall enable the manufacturer to identify and to determine the potential hazardous situations associated with the pressure equipment which could occur when his equipment is installed and used in reasonably foreseeable conditions.

The subsequent risk assessment does not require a quantitative approach with probabilistic analysis and/or assumptions of possible extents of damage. The goal of the risk assessment is rather the appropriate application of the essential safety requirements of the PED [...] in order to avoid failure of the pressure equipment. [...] After the manufacturer has decided the extent of the equipment and/or the assembly [...] and its intended use, he must identify the hazards and complete a risk assessment which will enable him to implement appropriate measures to address the essential safety requirements of Annex I [...].

The hazard and risk analysis process may be facilitated by using harmonized standards but they do not relieve the manufacturer of his obligation to carry out the analysis.

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**The new PED 2014/68/EU – major(?) changes**

**Manufacturing for own use**

» According to Art. 2(18):

A manufacturer is "[...] any natural or legal person who manufactures pressure equipment or an assembly or has such equipment or assembly designed or manufactured, and markets that pressure equipment or assembly under his name [...] or uses it for his own purposes"

» PED-requirements (including CE-marking etc.) are therefore mandatory also in case that pressure equipment made by a manufacturer is used on the manufacturer’s own premises

» But: What are the consequences for assemblies and installations?

– Under 97/23/EC: assembling of several items of pressure equipment under the user’s responsibility was considered “only” an installation (assembling process national in-service law), not an “assembly” in the sense of the PED

– Does this new definition of “assemblies for own use” create a new situation?

» EU-Commission: Such a significant change in established business processes was never intended and even not allowed in the alignment process; hence the new – modified – recital (7)

» Still currently different interpretations in different member states ⇒ clarification highly desirable (preferably via official statement by EU-Commission)
Pressure equipment for own use – Statement by EU-Commission

Statement from legal service of the EU-Commission:
“The question was raised on whether assemblies assembled on the site of the user under his entire responsibility and which are outside the scope of the current PED are covered by the new PED. The Commission services consider that the new PED has not changed the situation as regards this issue, and therefore the above mentioned assemblies remain outside the scope also of the new PED. […]
The Commission services reconfirm that the exclusion in recital 7 of the new PED of assemblies built on the site of a “user” under his entire responsibility remains fully applicable. The new PED did not modify the situation under current PED as regards the assemblies made on site under the responsibility of the user. This is in line with the purpose/intention of the alignment exercise, of the legislators and in coherence with the rest of the PED text and all discussions during the legislative process.”

Clear statement:
No change in the situation with respect to assembling of pressure equipment under the user’s responsibility.

The new PED 2014/68/EU – What happens on 19 July 2016?

No transitional period
» “New” PED becomes mandatory – according to the Directive text – on 19 July 2016 without transition phase
» For many manufacturers in practice hardly manageable (equipment on stock, very long manufacturing times of sometimes more than 2 years)
» Especially formal problems with Declaration of Conformity, not a technical problem
» Concerns ALL “Omnibus-Directives” – Discussions on – political – horizontal level
» Most practicable solution: Declaration of Conformity with reference to two Directives (old AND new one)
Declaration of Conformity before and after 19 July 2016

Proposal accepted in ATEX-Committee

“For products placed on the EU market as of 20 April 2016 (or, in the case of products manufactured for own use, put into service), the EU declaration of conformity must be in accordance with the new ATEX Directive 2014/34/EU. As the ATEX Directive requires the product to be accompanied by the declaration of conformity, it is difficult for manufacturers to ensure that the declaration is exchanged from one day to the next. In order to facilitate the transition to the new ATEX Directive 2014/34/EU, the EU declaration of conformity can already today (when conformity still has to be declared to the old Directive 94/9/EC) indicate the following:

‘The object of the declaration described above is in conformity with the relevant Union harmonisation legislation: Directive 94/9/EC (until April 19th, 2016) and Directive 2014/34/EU (from April 20th, 2016).’"

The new PED 2014/68/EU

Future prospects

» Ever-recurring question:  
  Will there be a full PED-revision in the near future? – certainly no activities before 2017

» IF a full revision was started: extensive wish list from various stakeholders
  – revision of content of Annex I (e.g. number values in paragraph 7.5, safety equipment in paragraphs 2.10 and 2.11)
  – integration of the approx. 240 guidelines
  – legal status of Art. 4(3)-equipment
  – heat exchangers (vessels or piping))
  – PED-assemblies
  – merging of SPVD and PED
  – role der harmonized standards
Thank you very much for your attention!