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QUALITY MANAGEMENT PRACTICES. IMPACT OF ISO 9001:2015 CERTIFICATION ON DIRECTIVE 2014/68/UE (PED)

Abstract: *This work aims to highlight the factors that characterize quality systems in the case of pressure equipment manufacturing. For the CE marking, according to the Pressure Equipment Directive (PED), the manufacturer may adopt conformity assessment modules based on the Quality System for production process, directly for the product, for its final inspection and testing or for full fabrication process, design included. At international level, the ISO 9001 standard is now consolidated and wide spread and was revised in 2015 with the introduction of new concepts. This article highlights the individual requirements of ISO 9001 which are directly and indirectly correlated with the Quality System factors required by PED. This allows to comply with the essential safety requirements of the directive following a Plan-Do-Check-Act approach and conforming to the formalization of the management systems provided by the High Level Structure.*

Keywords: *CE marking, Directive PED, HLS High Level Structure, ISO 9001:2015, pressure equipment, quality management system, risk based thinking*

1. Introduction

PED (Directive 2014/68/EU, 2014) provides the inclusion of the technical dossier prepared, in the application lodged by the manufacturer for quality modules, for one model of each type of pressure equipment or assembly intended to be manufactured. The technical file must contain at least the following parts or sections:

- design data and a general description of the equipment
- risk analysis
- a check-list to verify the compliance with the essential safety requirements (ESRs) of the directive
- applied code and standard
- results of design calculations
- tables and dimensional and construction drawings
- materials certificates and traceability procedures for components of the equipment which contribute to pressure resistance procedure for production and control
- permanent joining operating procedure and personnel records (welding book)
- quality control plan
- non-destructive test reports
- final inspection report (including proof test report and, for assemblies, a check of safety devices)

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- operating instructions
- declaration of conformity
- data plateand drawing

Risk hazard analysis and risk assessment is one of the key steps in the process and must be documented. The design of mechanical components depends, amongst other things, on the materials and manufacturing processes utilised. Risk analysis is a pragmatic way of managing the variability of such information and then the risk associated with design for manufacture decision-making (Cory, 2005; Edwards, 2005), in respect of the priority of hazard elimination or reduction. When measures to remove or reduce the hazard are not reasonably practicable, appropriate information shall be provided to users (information on residual hazards). The identification of the essential safety requirements (ESR), is the fundamental new element of the New Approach Directives, including the PED. If the manufacturer applies harmonized standards, the ESR are certainly satisfied (Faidy, 2005). The ESR must be met for all types of pressure equipment, e.g. vessels, piping, orheat exchangers, placed on the European market. The ESRs are listed in Annex I of PED and are generally of a qualitative nature, leaving the manufacturer the choice of the preferred solution to meet them. They are formalised as general principles to which the product must conform in order to ensure the minimum level of safety required to allow its free movement within the European market. The analysis and assessment of the fulfilment of the essential safety requirements is necessarily related to the hazard analysis as it allows to identify which ones apply to the pressure equipment to be produced.

2. Quality management system

The structure of the Quality Management System (QMS) is based on the following factors that are related to each other according to a Plan-Do-Check-Act (PDCA) logic:

- Scope
- Quality policy
- Organization chart
- Definition and management of operational processes
- Management of improvement processes
- Reference to operating procedures

The documentation plays a key role as it allows an objective and repetitive management of the processes. For the implementation of a QMS, it is necessary to initially define the purpose and the field of application in order to identify the areas of action of the various products manufactured by the company. Measurement, monitoring, analysis, and evaluation are critical for the assessment of the performance of the quality management system (QMS) (Abuhav, 2017). The processes developed internally and those managed in outsourcing must be pointed out. Therefore a management system must be documented to define and control the ways in which the activities are performed. It is possible to use various forms of documentation, for example flow charts, procedures, checklists, instructions, or forms, as long as they provide the information on the business functions involved, their degree of responsibility, and the operational logic flow for the control of activities. Documents can be in softcopy or paper format. The illustration of interaction between processes is certainly useful. This allows to visualize, through flow diagrams, the input and output factors and the temporal succession of the production cycle according to the level of organization adopted.

3. ISO 9001:2015

In 2015 the ISO (InternationalOrganization for Standardization) defined a new structure, common and mandatory for all Management System Standards (MSS) called High Level Structure (HLS), consisting of 10 points. The 2015 edition of ISO 9001 then has the HLS

structure (ISO 9001, 2015). Organisations implement requirements of the standard to demonstrate the ability to consistently provide products and services that meet customer and regulatory requirements. The main changes include context of organisation, risk based thinking, knowledge as resource, and leadership (Medić et al., 2016).

A summary of the contents of the individual paragraphs is reported below.

1. Scope

The ambit section defines when the standard applies and its aim. The quality management system should enable continuous improvement and ensure compliance with contractual requirements.

2. Normative references

This section is designed to make paragraph numbering consistent with other ISO standards.

3. Terms and definitions

Includes terms and definitions specific to the quality system.

4. Context of the organisation

This paragraph presents several new features compared to the previous editions of the standard. Consideration must be given to the various internal and external factors that may affect the organisation, like legal, technological, or local aspects. In addition, the needs of stakeholders should be considered. The different business processes must be identified by analysing and documenting input and output factors.

5. Leadership

Top management must demonstrate their leadership by defining policy and responsibilities focusing on customers. Senior management should promote compliance within the organization.

6. Planning

Management must use a risk-based approach. The standard requires the organization to address threats and opportunities, and to prevent or reduce unwanted effects.

7. Support

The organisation shall provide appropriate resources (competent personnel, infrastructure, work environments and equipment) to support and maintain the management system over time. The previous requirements on document control and record management have been replaced and incorporated by documented information. The organisation shall determine which documentation it deems necessary and the most appropriate criterion for its management.

8. Operation

With the introduction of HLS, this paragraph replaces the previous paragraph on operational control. The individual processes required for the realisation of the product (process planning and control, product and service requirements, design and development, control of external suppliers, provisions, product and service release) are analysed and managed (Wolniak, 2020).

9. Performance evaluation

The requirement examines the different factors that allow the evaluation and monitoring of performance. The paragraph also includes internal audits and management review.

10. Improvement

The standard requires the organisation to improve the adequacy and effectiveness of the management system. Through the management of non-conformities and corrective actions, organizations are required to analyze and eliminate the causes.

ISO 9001: 2015 quality management systems places an obligation on enterprisesto consider organizational knowledge as a resource (Wilson & Campbell, 2016).

4. Directive 2014/68/UE (PED)

In order to be placed on the European market, pressure equipment must meet the ESRs laid down in Annex 1 of PED and must bear the CE marking. In particular, the directive

applies to equipment with a maximum design pressure PS higher than 0.5 bar (Directive categories (I, II, III, IV). For each category, the manufacturer can choose the conformity assessment procedure (see Annex III) he considers most appropriate among those 2014/68/EU, 2014). PED classifiespressure equipment into 4 different and increasing risk provided. He may also choose to apply one of the procedures which apply to a higher category, if available.

Table 1. Modules for conformity assessment (PED, annex II)

Category	Modules
I	A
II	A2, D1, E1
III	B (design type) + D, B (design Type) + F, B (production type) + E, B (production type) + C2, H
IV	B (production type) + D, B (production type) + F, G, H1

Conformity assessment procedures include the implementation of a single module or the simultaneous application of two modules. Since for the CE marking products have to be subjected to conformity assessment for the design and production phases, the modules have to consider both of them according to the scheme shown in annex II. Modules are selected by the manufacturer on the basis of the equipment category. Implementing the "Global Approach" (European) Council Decision, manufacturers will be given the choice of various modules of conformity assessment. The modules a manufacturer can choose depend on the risk (category) of the equipment and the manufacturer's quality system (Zeman, 1998). When a product falls within the scope of a New Approach Directive, in order to affix the CE mark the manufacturer must comply with the ESRs, follow one of the required conformity assessment procedures, and draw up the technical documentation specified by the directive. Although not mandatory, a manufacturer can choose to satisfy the essential requirements through the application of European harmonised standards (Playle, 2010). The main harmonized series of standard in the field of pressure equipment is EN 13445 - Unfired Pressure Vessels, that provides rules for the design, the fabrication, and the inspection.

5. Module H1

The conformity assessment procedures, or "modules", provided by PED are under the responsibility of both the manufacturer and a Notified Body (NB). The "Quality Assurance Modules" D/D1 (quality assurance of the production process), E/E1 (quality assurance in product final inspection and testing), H/H1 (full quality assurance in design, manufacture, final product inspection and testing) are outlined in Annex III of PED, where the subjects to be addressed in the quality management system (QMS) are generally described. PED does not specifically requires the QMS to follow the ISO 9000 model, or to be certified by an accredited certification body. To reinforce the transparency of the modules and their effectiveness, at the request of the Commission, the ISO 9000 series of standards on quality assurance were harmonised at the European level and integrated into the modules. Thus, economic operators who use these tools in their voluntary quality management policies to reinforce their quality image on the market, can benefit from the use of the same tools in the regulated sectors (EC. 2016 and 2022). The alignment however is with the old standards of the ISO 9000 series (9001, 9002, 9003).

A key role is played by the design of the pressure equipment which must take all risks into account (e.g. corrosion, fatigue, creep). During the design phase with EN 13445 (Darlaston & Wintleb, 2007), it is necessary to verify that the safety factors are conservative and that the solutions adopted are such to mantain a high level of safety. The role of safety factors in pressure equipment is critical. Consider (Darlaston & Wintleb, 2007):

a) Safety factors for pressure equipment must not only provide confidence, but also demonstrate the level of confidence.
b) Safety factors should counter balance technological and human deficiencies.
c) Safety factors should be related to the hazard of the equipment.

Any repairs to the pressure equipment must not lead to a reduction in the overall safety factor defined during design.

In particular the module H1 is the conformity assessment procedure, based on full quality assurance plus design examination and special surveillance of the final assessment, where by the manufacturer verifies and declares, under his own responsibility, that the pressure equipment placed on the market meets the requirements of PED. The manufacturer shall apply a quality system approved by the NB for design, manufacture, and final product inspection and testing. The adequacy of the technical design of the pressure equipment shall be subject to examination by the NB.

The NB shall carry out periodic audits at the manufacturer to verify the application of the quality system with verifications both at a documentary and operational level. Recently, taking into account the Covid-19 pandemic, specific procedures have been developed to conduct audits remotely (Giacobbe & Bemporad, 2020; Balistreri et al., 2020). These procedures made it possible to verify the maintenance of the efficiency and the compliance of the quality system and therefore of the product certification, in spite of the restrictions imposed by the pandemic emergency.

6. Comparison between H1 module of PED and ISO 9001

When operating simultaneously with several management systems, their implementation should be carried out in an integrated form. This eliminates redundant processes and increases the overall efficiency of the system (Mancuso et al., 2014). According to the evolution of such management systems, it is increasingly desirable and feasible to integrate these systems into a single complex system (Labodová, 2004). The HLS implemented in the ISO management system standards starting from 2012 made this integration easy and effective.

The PED directive does not provide for the explicit formalisation of requirements but requires the implementation of factors characterising the control of the entire production process phases from design to final testing. These factors are not structured according to an HLS type scheme and do not have any reference numbering. NBs should also have a management system and if they operate under several Directives (e.g. PED and Directive 2010/35/EU or TPED) an integrated system should be implemented (Fortuni & Giacobbe, 2016). Table 2 reports the requirements as described in the PED for the module H1.

Table 2. Correlation between H1 quality system requirements and ISO 9001 paragraphs

Quality system requirements according to module H1 of the PED		**ISO 9001:15 requirements**	
		direct correlation	**indirect correlation**
ID	**description**		
A	*— the quality objectives and the organizational structure, responsibilities and powers of the management with regard to design and product quality*	5.1 Leadership and commitment 5.3 Organizational roles, responsibilities and authorities 6.2 Quality objectives and planning to achieve them	4.3 Determining the scope of the quality management system 4.4 Quality management system and its processes 5.2 Policy 7.2 Competence 7.3 Awareness 7.5 Documented information 7.5.1 General 7.5.2 Creating and updating 10.3 Continual improvement
B	*— the technical design specifications, including standards, that will be applied and, where relevant harmonised standards will not be applied in full, the means that will be used to ensure that the essential safety requirements of the Directive that apply to the pressure equipment will be met*	8.2 Requirements for product and services 8.3.1 General 8.3.3 Design and development inputs 8.3.5 Design and development outputs	6.1 Actions to address risks and opportunities 8.3.2 Design and development planning
C	*— the design control and design verification techniques, processes and systematic actions that will be used when designing the pressure equipment pertaining to the pressure equipment type covered, particularly with regard to materials in accordance with point 4 of Annex I*	8.3.4 Design and development controls 8.3.5 Design and development outputs	8.3.6 Design and development changes 8.5.6 Control of changes
D	*— the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used, particularly the procedures for the permanent joining of parts as approved in accordance with point 3.1.2 of Annex I*	8.4 Control of externally provided processes, products and services. 8.5.1 Control of production and service provision 8.5.2 Identification and traceability 8.5.4 Preservation	8.1 Operational planning and control 8.7 Control of nonconforming outputs
E	*— the examinations and tests that will be carried out before and during manufacture, and the frequency with which they will be carried out*	7.1.5 Monitoring and measuring resources 8.6 Release of products and services 9.1 Monitoring, measurement, analysis and evaluation	

F	*— the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly those of the personnel undertaking the permanent joining of parts and the non-destructive tests in accordance with points 3.1.2 and 3.1.3 of Annex I, etc.*	7.5.3 Control of documented information	7.5 Documented information 7.5.2 Creating and updating
G	*— the means of monitoring the achievement of the required design and pressure equipment quality and the effective operation of the quality system*	9.1.3 Analysis and evaluation 9.2 Internal audit 9.3 Management review 10.2 Nonconformity and corrective action	6.1 Actions to address risks and opportunities

The essential differences between a quality system certified to ISO 9001:2015 and the requirements of the Directive's quality modules were outlined by the Conformity Assessment Bodies Forum PED/SPV (CABF) in one of its Recommendation (CABF, 2019), highliting that some elements of ISO 9001:2015 are not required for the PED, particularly:

a. Section 4 (Context of the Organisation)
b. Section 10.3 (Continual Improvement)
c. A Process-based approach.

CABF also pointed out that some elements of Annex III of the PED (Conformity assessment pocedures) are not specifically included in ISO 9001, specifically:

a. The requirement in Annex III, Modules D1 and E1 para 5.2, and Modules D, H and H1 para 3.2 for written policies,
b. procedures and instructions for all elements relevant to the production of CE-marked product.
c. The requirement in Annex III Modules D1 and E1 para 5.5, and Modules D, H and H1 para 3.5 to obtain NB approval of any proposed changes to the quality system.

Further specificities are;

– According to Annex III Modules D1 and E1 para 5.3, and Modules D, H and H1 para 3.3, where a manufacturer is certified to ISO 9001 the NB shall presume conformity.
– The auditing team shall have at least one member experienced as assessor in the pressure equipment technology concerned, and knowledge of the applicable requirements of the Directive.As already mentioned ISO 9001:2015 is harmonised with the New Legal Framework, 768/2008/EU, which identifies the requirements for the Modules listed above but it is not a mandatory requirement for approval to the quality modules.

The Blue Guide (EC, 2016) Annex 5 gave advice on the relationship between ISO 9001:2008 and the quality system modules, but did not refer to ISO 9001:2015. Recently a new edition of the Blue Guide (EC, 2022) was published but the new Annex 5 concerns now Frequently Asked Questions on CE marking. In the present work the correlation with ISO 9001 has been differentiated on 2 levels. With the direct correlation the requirements that have an explicit link are highlighted, making it easy to comment and analyze the subject more in detail. In order to implement the factors of the Quality System according to PED it is however necessary to consider also the ISO 9001 requirements that have an impact in the production of Pressure Equipment. These are shown in the column

"indirect correlation" of table 2. For manufacturers who already adopt a certified ISO 9001 system it will be necessary to customize the quality manual both for direct and indirect correlations.

Special processes are fundamental for both PED and ISO 9001. Special processes supervision consists of activities leading to obtain a finished product that meets certain quality conditions (Ulewicz & Novy, 2019).

Non-destructive testing during production can be carried out using classic techniques (e.g. liquid penetrant test, ultrasonic test, radiography) or innovative techniques (e.g. digital tomography) that allow detailed analyses even in 3D (Bonaccorsi et al., 2012).

The new edition of ISO 9001 considers the risk analysis factor to be decisive for process control and improvement. The PED is also based on risk assessment, even if the risk concerned is not just the same, and consequently on the definition of preventive measures (to be implemented in the design phase) and mitigation actions. It is possible to define a risk index from the hazard analysis by considering the incidence of the likelihood and the level of impact of each identified hazard. The lowest risk index is obtained in cases of simultaneous low level of damage resulting from a hazard and a low frequency of occurrence of that hazard.

6.1. Focus on clause 8 Operational planning and control

The H1 module of conformity based on full quality assurance plus design examination, is the most complex and complete among the quality modules and is suitable for equipment classified in the highest risk category (IV). The module H1 structure is valid to ensure compliance with PED for all the categories into which pressure equipment can be classified (I, II, III and IV).

The requirements of clause 8 of ISO 9001:2015 are essential for managing the ESR sin Annex 1 of the PED. The clause 8 requirements deal with planning for product and include determining and reviewing the product requirements, design and development, and external supplying followed by the manufacturer of a product. The final requirements of clause 8 deal with quality control and product or service non conformities.

Table 3 allows to examine in detail how, through the implementation of the individual requirements of clause 8 individual ESRs of PED can be satisfied.

Table 3. Correlation between Essential Safety Requirements (ESR) and ISO 9001 clause 8

Clause	ISO 9001: 2015	Point	Annex 1 of PED Essential Safety Requirements (ESR)
8.1	Operational Planning and Control	2.3	Provisions to ensure safe handling and operation
		3.1	Manufacturing procedures
8.2	Requirements for Products and Services	1.1	Pressure equipment shall be designed, manufactured and checked
8.3	Design and Development of Products and Services	1.3	The pressure equipment shall be designed to prevent risks
		2.1	The pressure equipment shall be properly designed and incorporate appropriate safety coefficients
		2.2	Design for adequate strength
		2.2.1	Factors to be taken into account in design
		2.2.2	Methods of design for adequate strength (calculation method, experimental design method)
		2.2.3	Calculation method
		2.2.4	Experimental design method
		2.4	Means of examination necessary to ensure safety
		2.5	Means of draining and venting

		2.6	Adequate allowance or protection against corrosion or other chemical attack
		2.7	Severe conditions of erosion or abrasion (wear)
		2.8	Criteria for assembly design (suitability and reliability of components and their proper integration and assembly)
		2.9	Provisions for filling and discharge
		2.10	Protection against exceeding the allowable limits of pressure equipment
		2.11	Safety accessories
		2.12	External fire
8.4	Control of Externally Provided Products and Services	4	Materials used for the manufacture of pressure equipment
		4.1	General requirements for materials (appropriate properties, chemical resistance, unaffectionby ageing, suitability for intended processing procedures, avoidance of undesirable effects)
8.5	Production and Service Provision	3.1.1	Preparation of the component parts
		3.1.3	Non-destructive tests
		3.1.4	Heat treatment
		3.1.5	Traceability
		3.3	Marking and labelling
		4.2	Manufacturer obligations for material (definition of values and characteristics, compliance with the directive specifications)
		4.3	Manufacturers obligations to certify conformity of the materials for the main pressure bearing parts of equipment in categories II, III and IV
8.6	Release of Products and Services	3.1.3	Non-destructive tests
		3.2	Final assessment
8.7	Control of Nonconforming Outputs	3.1.3	Non-destructive tests
		3.2	Final assessment

7. PED requirements for quality modules in the light of the Deming Cycle

An innovative and alternative interpretation of PED requirements for quality modules allows to draw a parallel with the plan-do-check-act (PDCA) concept first discussed by Walter A. Shewhart in his 1939 book, Statistical Method From the Viewpoint of Quality Control and then named as a cycle and promoted as a primary means of achieving Control Process Improvemente by W. Edwards Deming (Johnson, 2016).

PDCA cycle implementation promotes a quality culture aimed at the continuos improvement of processes and the optimal management of resources

The opportunities for improvement take shape after the sequential application of the four steps of the cycle.

The cyclicity allows to achieve over time conditions of managerial and productive excellence.

Tables 4, 5, 6 and 7 present the correlation among the seven requirements reported in the first column of table 2 (identified by the letters from A to G), of the Quality System that the manufacturer shall adopt according to the PED quality modules and the production and management phases related to the pressure equipment manufacturing. Particularly, such phases as design, material supply, permanent joining, final inspection relate to the “product” scope, while such management activities as supplier

qualification, product nonconformity assessment, internal audit, management review relate to the "system" scope. The phases where the NB is involved are transversal and reported in italic.

Plan

The manufacturing process of a pressure equipment begins with planning step, obviously preparatory for the next step of doing the activities. Planning also provides system management activities (table 4).

Do

At the end of the planning step, the manufacturer proceeds with the fabrication of the equipment/assembly including the following activities (table 5).

Table 4. "Plan" step activities for pressure equiment manufacturing under PED (module H1)

Scope	Production or System phase	QS requirements in PED
System	Definition of the organisational structure and job description	A
Product	Analisys of the technical design specifications provided by the customer / Identification and layout of the product to be manufactured	A
System	Preparation and approval of written Quality System documents (Manual, Procedures, Operative Instruction, Forms)	A
System	Definition of the quality objectives	A
Product	Identification of the binding legislation*	B
Product	Definition and verification of the needed resources (e.g. materials, staff, facilities)	A
Product	Definition and description of the typical equipment/assembly parameters, category included	B
Product	Choice of the conformity assessment procedure (in this case module H1)	B
Product	Design activity beginning (hazard and risk analysis)	B
Product	Definition of the technical solutions that must be adopted to fulfil PED Essentially Safety Requirements	B
Choiche of the NB		
Product	Design and fabrication activity scheduling	A
Commission of the NB		

* Most times the applicable reference standards are not a free choice of the manufacturer but are identified by the customer

Table 5. "Do" step activities for pressure equiment manufacturing under PED (module H1)

Scope	Production or System phase	QS requirements in PED
Product	Final design (drawing and diagrams, calculation for the required loads, examination and test identification, material assessment, operating instructions, definition of the required procedures for the permanent joining of pressure equipment/assmebly parts)**	B C
Assessment of the design conformity by the NB		
System/ Product	Application for the approval of or checking of the previous approved procedures and qualifications of the personnel for the permanent joining of pressure parts**, ***	C D
System/ Product	Application for the approval of or checking of the previous approved qualification of the personnel undertaking the non-destructive test (NDT)**	C D E
System/ Product	Material supply	C

System/ Product	Execution of the work (cutting, beveling, bending, roll bending, welding, coating, etc.)	D
System/ Product	Execution of the in process and final controls	E
System	Machinery maintenance (e.g. roll bending and welding machine)	F
System/ Product	Management of the measurement instrumentation	F
System/ Product	Management of the nonconforming products	F
System	Management of QS records	F
System/ Product	Storage of the technical documentation****	F

** same of these services could be externally provided (e.g. design calculation, NDT, heat treatment, sheet metal forming), in these cases the criteria for evaluation, selection, monitoring of the performance and re-evaluation of the external providers must be well determined, applied and documented (Giacobbe et al., 2020);
*** the NB that qualifies or previously qualified the permanent joining procedures and/or personnel can not be the same that assesses the conformity of the module;
**** the manufacturer shall submit technical documentation for one model of each type of pressure equipment intended to be manufactured. The documentation must provide a description or concept of an item or assembly that identifies the repeatable outputs that account for all variations and relevant properties that constitute the range of items proposed (CABF, 2017).

Check

During the normal course of the planning and fabrication phases, verification activities shall be provided to ensure that what is achieved is consistent with the planning. These activities are defined periodically to check the performances of the QS through the following tasks (table 6).

Table 6. "Check" step activities for pressure equiment manufacturing under PED (module H1)

Scope	Production or System phase	QS requirements in PED
System	Internal auditing	G
System/ Product	Rewiev of eventual modifications	C
System/ Product	Review of product nonconformities	G
System	Review of the suitability of the resources	G
System/ Product	Considerations about eventual updates of legislative and/or regulatory requirements concerning the design and/or the fabrication and their communication to the NB*****	B C D
System	Management review	G

***** The manufacturer shall keep the NB informed of any intended change to the QS. The NB shall evaluate any proposed changes and decide whether the modified QS will continue to satisfy the requirements or whether a re-assessment is necessary. It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision (Directive 2014/68/EU or PED).

Act

The fourth and last step of the cycle, do, includes the necessary initiatives to resolve three steps. The corrective and or preventive actions shall be formalised to eminate the causes of actual or potential nonconformity and procedures and processed shall be modified in order to pursue continuous improvement. The following actions shall particularly be defined (table 7).

Table 7. "Act" step activities for pressure equiment manufacturing under PED (module H1)

Scope	Production or System phase	QS requirements in PED
System	Analysis and treatment of the system nonconformity	G
System	Management of the corrective and preventive actions	G
System/ Product	Continual improvement actions	G
Receiving of the certificate by the NB		
System/ Product	Issuing of the Declaration of Conformity*****	F

***** after receiving the certificate by the NB (according to the Annex IV of PED the Declaration shall report the certificate and the NB numbers)

Next PDCA cycles

The actions undertaken by the manufacturer improve the system and give raise to the next cycle with the "Plan" step.

8. Conclusion

ISO 9001:2015 is currently in line with modern business management and quality management concepts and it will be a useful tool for companies (Fonseca & Domingues, 2017).

For the conformity assessment of pressure equipment, manufacturers who want to place their product on the European market may use, at their choice, a module that provides for the adoption of a Quality System (e.g. module H1). The implementation is not bound to ISO 9001 but this standard offers a good opportunity for reference. In case the manufacturer decides to take this opportunity, it is necessary to arrange the design, production and control processes according to the requirements of the PED. In the present work a comparison scheme between H1 module of PED and ISO 9001 has been illustrated and correlation factors have been identified. For pressure equipment manufacturers it is certainly useful to integrate an ISO 9001 certified Quality System with PED requirements. This integration makes it easy to implement the conformity assessment requirements according to the quality modules (e.g. module H1). Both systems are based on risk assessment and on the great opportunities that arise from "risk based thinking".

The implementation of a quality system certainly has positive effects on the organization and control of the manufacturer's production processes by providing guarantees on product conformity (Del Castillo-Peces et al, 2018).

The fulfilment of PED requirements form Module H1 finally results in line with the actions required in the scope of a Deming (PDCA) cycle, still in the perspective of continual improvement.

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