

POSITIONSPAPIER



CE- Marking of Gas Supply systems and its Components

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1 Introduction

For supplying customers with industrial gases, industrial installations (gas supply systems) are made available, which can consist of various components. Exemplary, these can be storage vessels for cryogenic liquefied gases, vaporizers, pipelines, pumps and various pressure equipment such as regulators, valves, etc.

For pressure retaining components, the Pressure Equipment Directive can be of importance, just as the Machinery Directive for pumps (incomplete machines) and for others, for example, the Directive for electromagnetic compatibility. Since different requirements are also defined in various directives, it is to be clarified how the marking process is to be dealt with as in the case of a gas supply system in which these components are used.

The objective of this position paper is to clarify the need for CE marking of such gas supply systems.

2 Scope

This position paper applies to gas supply systems for technical gases and their system components. It does not apply to supply devices to medical gases and components intended to supply medical gases.

3 Definition of Terms

Pressure equipment in accordance with Directive 2014/68/EU (PED) Article 2 (1)

A component exposed to a maximum pressure (PS) of more than 0.5 bar gauge pressure (e.g., pressure regulator, valve, or pipeline)

Vessels in accordance with Directive 2014/68/EU (PED), Article 2 (2)

A vessel means a housing designed and built to contain fluids under pressure including its direct attachments up to the coupling point connecting it to other equipment; a vessel may be composed of more than one chamber.

Assembly in accordance with Directive 2014/68/EU (PED) Article 2 (6)

An assembly is a functional unit that consists of several pressure devices and is placed on the market by the manufacturer as such a coherent functional unit (e.g., storage vessel for cryogenic liquefied gases and its piping and accessories).

Incomplete machines in accordance with Directive 2006/42/EC (Machinery Directive)

This includes pumps in process plants, for example.

"An incomplete machine is an assembly that is almost a complete machine, but which cannot perform a specific function by itself. A drive system is an incomplete machine. An incomplete machine is intended to be incorporated into other machines or other incomplete machinery or equipment or to be joined with them to form a machine together with them within the meaning of this directive."

(http://www.maschinenrichtlinie.de/fileadmin/veroeffentlichungen/Unvollstaendige_Maschinen_Maschinenrichtlinie_2006-42-EG.pdf)

Work equipment in accordance with the Ordinance on Industrial Safety and Health (BetrSichV)

Section 2 (1) and (2)

(National Implementation of the European Work Equipment Directive 2009/104/EC)

Work equipment refers to tools, equipment, machinery or equipment used for work as well as installations subject to monitoring. The use of work equipment includes, inter alia, the installation and mounting of the system. The scale of use is defined in the Ordinance on Industrial Safety and Health (BetrSichV) as follows: Mounting and installing, operating, stopping or shutting down, or adjusting, using, operating, repairing, cleaning, checking, modifying, testing, disassembling, transporting and monitoring.

Installations subject to monitoring in accordance with the Ordinance on Industrial Safety and Health (BetrSichV) Section 2 (13)

Installations subject to monitoring are systems according to Section 2 number 30 of the Product Safety Act, insofar as they are listed in Appendix 2 to the Ordinance on Industrial Safety and Health (BetrSichV). The risk of explosions (section 3) and pressure equipment (section 4) are treated in particular in sections 3 and 4.

Pressure systems in accordance with the Ordinance on Industrial Safety and Health (BetrSichV) Appendix 2, Section 4 (2.1)

Pressure systems are or include pressure equipment, vessels and assemblies. A gas supply system usually consists of one or more of these components and is therefore usually also an installation subject to monitoring.

4 Position of IGV

Any product placed on the market by a manufacturer and at the same time subject to EU directives such as the Machine or Pressure Equipment Directive shall be provided with a CE mark. With that, the manufacturer documents compliance with applicable provisions for his product.

4.1 Process plants from the point of view of Directive 2014/68/EU (Pressure Equipment Directive)

Gas supply systems for technical gases are assembled on the site of the end-user for its order and for its application (installed and mounted). Due to the uniqueness of the application cases with regard to local circumstances, consumption points, consumption profiles, etc., no system is generally identical to another one. Therefore, prefabrication and placing on the market as an assembly in accordance with Directive 2014/68/EU (Pressure Equipment Directive) does not make sense. Therefore, these gas supply systems shall not bear an overall CE mark.

This view is also supported in **Recital (7) of Directive 2014/68/EU** (quote: “**However, this Directive should not apply to the assembly of pressure equipment on the site and under the responsibility of a user who is not the manufacturer, as in the case of industrial installations**”).

The intention of recital 7 is, to exclude the installation on the site of the end-user, since the free movement of goods within the internal market is not affected.

Industrial gas companies assembling gas supply systems on the site and under the responsibility of the end-user are **not** manufacturers as defined in Art.2.18 of Directive 2014/68/EU.

The individual components, from which the system consists, must very well bear a CE mark to signal the conformity with applicable provisions (e.g., vessels according to the Pressure Equipment Directive, pumps according to the Machinery Directive, electrical components according to Low-Voltage Directive and electromagnetic compatibility, etc.).

Exceptions to this are products subject to Article 4 (3) of Directive 2014/68/EU (Pressure Equipment Directive). These shall be designed and fabricated according to "good engineering practice" and shall not bear a CE marking. For example, these include pipelines for gases up to DN 25 and for inert gases up to DN 32. However, pressure regulators and valves may also fall under Article 4 (3).

The responsibility for the correct combination of components and consequently for the functionality and safety of the system lies with the planner or erector of the plant.

As a rule, the gas supply systems for technical gases are industrial installations in accordance with the Ordinance on Industrial Safety and Health (BetrSichV). Therefore, the requirements described there such as risk assessments, tests before commissioning and recurrent tests must be taken into account.

Pressure vessels represent a special situation, which were placed on the market before May 27, 2002. These were designed and manufactured, for example, in accordance with the pressure vessel regulation applicable at that time and they can be further operated and do not require CE marking if they do not experience any significant change in their operating mode. This is also supported by Directive 2014/68/EU on the L189/170 (59) page (quote: “Directive 97/23/EC provides for a transitional system that states pressure equipment and assemblies can to be put into operation, which comply with the national rules applicable at the time of application of Directive 97/23/EC. For reasons of legal certainty, it is necessary to include this transitional regulation in the present Directive.”) The non-marking also applies if they have been repaired and reworked without changing their original purpose, provided that the later user has been informed (Product Safety Act [ProdSG] Section 1 (3), No.2).

4.2 Process plants from the point of view of Directive 2006/42/EU (Machinery Directive)

The evaluation of process engineering systems with regard to the Directive 2006/42/EC (Machinery Directive) are described in:

VCI Guide to the application of the Machinery Directive in process engineering systems

The decisive reasons are formulated in Section 4 of the VCI Guideline:

Demarcation of machines – totality of machinery – process engineering systems

“In the Machinery Directive, a machine is considered the totality of machines that are arranged and controlled so that they function as an integral whole to achieve the same end.

According to the BMAS (German Federal Ministry of Labour and Social Affairs) interpretation paper of May 5, 2011, a ‘totality of machines’ within the meaning of the Machinery Directive only exists if there is a production and safety engineering relationship. **For systems in the chemical and pharmaceutical industry, the production engineering context is often seen, but not the safety relationship. Consequently, even according to the opinion of the BMAS, such installations are not as a whole subject to the requirements of the Machinery Directive in the sense of the totality of machines.** However, a subdivision into several individual system components in the sense of a totality of machines is assessed as possible.

Machines in process engineering systems usually meet a specific intended use and are separated from one another by pressure devices (pressure vessels and pipelines). Pressure equipment as an essential component of process engineering systems is excluded from the Machinery Directive except if it is not part of a machine.

Consequently, the term machine in process engineering systems only relates to the machines used therein. The machines concerned are to be considered as self-contained units designed and constructed for a specific use resulting from the boundary conditions of the process engineering process.

The CE marking and the EC declaration of conformity according to the Machinery Directive refer to the machine concerned, but not to the entire process engineering system. The requirements of the Machinery Directive are to be met for the intended use of the machines”

4.3 Process plants from the point of view of Directive 2009/104/EU (Work Equipment Directive) and its implementation in Germany: the Ordinance on Industrial Safety and Health – BetrSichV

Pressure equipment and pressure systems refer to work equipment as defined in Article 2 a) of Directive 2009/104/EC: “Work equipment are all machines, instruments, tools or systems used at work.”

The link of European product directives with the European Work Equipment Directive is described in the Blue Guide to the Implementation of Product Requirements of the EU 2016, Section 3.6 [6]:

- In contrast to economic operators, end users are not defined in the harmonization legislation in the European Union and are not subject to obligations.
- Many of the products covered by EU harmonization legislation are used at work and are therefore subject to the legislation on safety at work.

According to the directive on the minimum safety and health requirements for the use of work equipment by workers at work (2009/104/EC), an employer has to take the necessary steps to ensure that work equipment provided to workers (e.g., machinery and equipment) is suitable for the respective work, so that the safety and health of workers is ensured when they use it."

The European Work Equipment Directive [7] and its implementation in Germany, the Ordinance on Industrial Safety and Health (BetrSichV), oblige each employer (plant operator) to carry out a risk assessment for all pressure equipment and pressure systems of his company and to document such in writing. On this basis, an employer is to take measures to protect workers against the risks of health hazards occurring during their work.

Industrial gas companies are constructing complete and functioning gas supply systems for the supply of their customers with industrial gases.

The responsibility for the correct combination of components and thereby for the functionality and safety of the installation has the planer respectively the raiser of the installation

The transition of responsibility is that moment, at which the responsibility for the safe condition of the sourced work equipment passes from the raiser of the installation to the customer acting as the employer (see BekBS 1113 [10]).

The inspection prior to putting into service according §15 BetrSichV being carried out generally after the transition of responsibility under the responsibility of the employer (plant operator).

The employer (plant operator) is to review the effectiveness of the protective measures before using the work equipment for the first time. The risk assessment must be checked regularly. In this context, the state of the art is to be taken into account, including in the selection of work equipment [8].

At the installation of pressure equipment for a pressure system on the site and under the responsibility of an employer, the Directive 2014/68/EU (Pressure Equipment Directive) and the application of the relevant harmonized standards [9] or AD2000-Merkblätter are considered as state of the art concerning the requirements to the construction of equipment.

The employer can then assume that the essential safety requirements are met.

The conformity of the pressure system with the essential safety requirements of the Ordinance on Industrial Safety and Health (BetrSichV) and Appendix I to Directive 2014/68/EU (Pressure Equipment Directive) is determined in the context of the inspection prior putting into service in accordance with §15 BetrSichV, see TRBS 1201 part 2, para 6.4:

"Assembling a pressure system from pressure equipment under the responsibility of the employer

(1) When assembling a pressure system from pressure equipment, or when incorporating additional pressure equipment or assemblies into existing pressure systems or an industrial installation on the premises and under the responsibility of the employer, the necessary inspections shall likewise be carried out by an approved inspection body/person authorised to inspect.

(2) Directive 2014/68/EU (Pressure Equipment Directive) or Directive 2014/29/EU (simple pressure vessels) shall, as the current state of the art, hereby apply to the technical product requirements regarding the individual pressure equipment. When applying the relevant harmonised standards, the employer may assume that the essential safety requirements have been met.

(3) The alignment of the pressure system to the essential safety requirements of the *BetrSichV* and

of Appendix 1 of Directive 2014/68/EU (Pressure Equipment Directive) shall be determined in the course of an inspection, in accordance with Section 15 *BetrSichV*.

In this case, for example, the following inspections shall be necessary:

- Assessment of components, e.g. connecting pipes, necessary for assembling pressure systems for own purposes. These shall be conform to the essential safety requirements of Appendix 1 of Directive 2014/68/EU but shall not require CE marking or a declaration of conformity,
- Assessment of the assembly of pressure equipment to a pressure system (including pumps, compressors, connecting pipes) within the meaning of Appendix I Sections 2.3, 2.8 and 2.9 of Directive 2014/68/EU (Pressure Equipment Directive),
- Assessment of protection against any exceedance of the operating limits in accordance with Appendix I Sections 2.10, 2.11 and 3.2.3 of Directive 2014/68/EU (Pressure Equipment Directive)
(4) The approved inspection body/person authorised to inspect has, in particular, the following tasks (provided they have not yet been carried out within the framework of manufacture):
 - Assessment of technical documentation regarding design (concept, manufacturing, production process);
 - Assessment of used materials, in the event that they do not correspond to current harmonised standard specifications or a European Approval for Materials for pressure system materials;
 - Assessment of certificates of material inspections conducted/issued by the material manufacturer or the person authorised for acceptance by the employer;
 - Assessment of adequate competence of qualified personnel to run permanent connections;
 - Assessment of adequate competence of qualified personnel to run non-destructive tests;
 - Assessment of the pressure system, comprised of
 - Testing the concordance with the pre-examined design,
 - A strength test, particularly of the connection lines and connection points of connected pressure equipment, ordinarily as a hydrostatic pressure test. The strength test may be substituted with other measures, provided the employer presents an inspection concept, approved by an approved inspection body, which enables technical safety-related findings of an equivalent value. If applicable: testing of equipment parts with safety function.

(5) The approved inspection body/person authorised to inspect is to document the above-mentioned test steps as part of the inspection prior to putting into service.

(6) As it involves the assembly of pressure systems – for instance in industrial installations – on the premises and under the responsibility of an employer, a global assessment of conformity as an assembly in accordance with Article 14, para. 6 of Directive 2014/68/EU shall not be required”.

5 Summary

Industrial gas companies are constructing gas supply systems to supply their customers with industrial gases.

Because the assembly of pressure equipment, for example in industrial installations, is on the site and under the responsibility of an employer, a global assessment of conformity as an assembly in accordance with Article 14 (6) of Directive 2014/68/EU is not required.

The gas supply systems often consist not only of pressure equipment such as storage vessels,

vaporizers , valves and piping, but also include other components such as pumps, sensors and other electrical components.

If required in the relevant directives, each of the individual components shall bear a CE mark to document compliance with applicable provisions.

There is no European directive for process plants (industrial installations).

Therefore, the entire system shall not bear a global CE mark, because the necessary legal basis is lacking in the European directives.

The conformity of the pressure system with the essential safety requirements of the Ordinance on Industrial Safety and Health (BetrSichV) and Appendix I to Directive 2014/68/EU (Pressure Equipment Directive), in accordance with §15 BetrSichV (Ordinance on Industrial Safety and Health), is determined in the context of the inspection before putting into service under the responsibility of the employer.

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