



# POSITION PAPER

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## Transfilling of Industrial, Medical and Food Grade Gas Cylinders

**The safe filling of gas cylinders requires that the persons performing the operation have detailed and expert knowledge of, in particular; gas properties, cylinder design, plant operation and relevant legislation. This is in addition to use of the appropriate equipment and inspection of the cylinder to be filled. Experience has shown that transfilling of gases, usually from a larger cylinder to a smaller cylinder, by unqualified persons have caused serious incidents including a number of fatalities.**

**EIGA's position is that only competent and trained professionals transfill industrial, medical and food grade gases using cylinders and equipment specifically designed for the cylinder transfilling operation.**

**Transfilling of medical gases is only allowed if a specific manufacturing licence has been issued by the competent health authority.**

The intention of this Position Paper is to clarify EIGA's position on cylinder transfilling and to explain the reasons for this and the main hazards with an uncontrolled transfilling operation.

### 1. Legal situation

In all EU Member States there is comprehensive safety and health legislation to protect workers, consumers and the public. Major parts of the legislation are based on directives and regulations issued by the European Union. Some of the most important directives that could be relevant to transfill activities, are detailed in the following sections:

- *ADR, the European Agreement concerning the International Carriage of Dangerous Goods by Road* covers national and international road transport in EU. The ADR states that the filling of gas receptacles shall only be carried out by specially equipped centres with qualified staff using appropriate procedures. These include;
  - conformity to regulations of receptacles and accessories;
  - their compatibility with the carried gas;
  - the absence of damage which might affect safety;
  - compliance with appropriate fill specifications (pressure or level); and
  - compliance with markings and identification regulations.
- The risks to safety and health shall be assessed and controlled for all work;
  - Directive 89/391 EEC *on the introduction of measures to encourage improvements in the safety and health of workers at work,*
  - Directive 89/654 EEC *concerning the minimum safety and health requirements for the workplace,*

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- Directive 2009/104/EC of the European Parliament and of the Council of 16 September 2009 concerning the minimum safety and health requirements for the use of work equipment by workers at work (second individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) The risks from handling of chemical substances shall be assessed and properly controlled;
- Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work,
- The risks when handling cylinders shall be assessed and controlled;
  - Directive 90/269 EEC on the minimum health and safety requirements for the manual handling of loads where there is a risk particularly of back injury to workers.
- The risks caused by the potential for an explosive atmosphere when handling flammable gases and liquids shall be assessed and controlled;
  - Directive 1999/92/EC on minimum requirements for improving the safety and health protection of workers potentially at risk from explosive atmospheres.
- Personal protective equipment shall be offered and used as required;
  - Directive 89/656 EEC on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace.
- Emergency procedures shall be established.
- The pressure system shall be designed, installed, constructed and maintained as required for safe use;
  - Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (PED).
- Provide appropriate means for the disposal of waste gases;
  - Directive 2010/75/EU on industrial emissions (integrated pollution prevention and control).
- Cylinders which have been filled shall be labelled to comply with transport of dangerous goods regulations and regulations for chemical substances. The label shall include essential safety and health information and bear the name of the organisation that has filled the cylinder. Safety data sheets describing the properties and risks with the delivered gas shall be made available.
  - Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.
- Gases delivered to private persons shall have comprehensive information;
  - Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety.
- The gas cylinders shall be designed, manufactured and maintained as required by the directives, European or international standards and any national requirements.
- The gas cylinders shall be approved as required by;
  - Directive 2010/35/EC on Transportable Pressure Equipment (TPED); and

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- any other national approval.
- If transfilling of medical gases is carried out the following legislation shall be considered:
  - Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use;
  - Directive 2003/94/EC - with guidelines for Good Manufacturing Practice in respect of medicinal products for human use;
  - Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices; and
  - Good Manufacturing Practice Annex 6 - Manufacture of medicinal gases.
- Production and filling of medical gases shall be authorised by the appropriate medical authority. EIGA does not support transfilling of medical gases by hospitals, private providers and users such as fire-departments, and ambulance providers because of safety and patients' health issues.
- EIGA does not support transfilling of medical and breathing gases when:
  - medical gas operations is not carried out in compliance with the GMP / GDP or with the authorization of the national competent authority;
  - breathing gas operations, even if not regulated like medical gas operations, does not follow best practices comparable to the GMP / GDP standard;
  - there is no guarantee of maintaining an effective state of control and traceability of the operations in the supply chain, hence it makes it impossible to recall the product in case of product quality issues;
  - there is no guarantee that the product quality meets the European Pharmacopoeia monograph specification;
  - the suitability of the package (cylinder and valve) for the intended use is not assured: contaminations or not validated operations could lead to a safety risk for the final user;
  - the information for the final user are poor, not reviewed and approved;
  - personnel is not duly trained about the risks related to the operations with the gases; and
  - medicinal gases should be certified by a Qualified Person who is registered by the National Competent Authority before being used.

## 2. Risks when transfilling gases

The risks when transfilling gases include and are not limited to:

- The pressure in a gas cylinder could be as high as 360 bar and the entire pressure package including the gas cylinders and cylinder valves, as well as any transfilling equipment shall be designed and maintained for the maximum working pressure. If not, a violent rupture of equipment can occur, causing serious injuries or fatalities to people in the vicinity.
- Incorrect handling of flammable or oxidizing gases can cause an ignition within the pressure system, in turn causing a sudden pressure increase and consequently, a catastrophic rupture. Released flammable gases can ignite causing fire or vapour cloud explosion.

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- The use of pressure equipment, gas cylinders and cylinder valves not compatible with the gases to be filled can cause ignition in the system, rupture of equipment, serious leakage of gases, and other scenarios that can cause serious accidents.
- Released gases can, depending on the properties of the gas, cause poisoning, asphyxiation, explosions or oxygen enrichment. Enrichment of oxidizing gases in itself not be dangerous, but the risk and intensity of any consequent fire will increase considerably – many non-flammable materials (even metals) will burn fiercely in an oxygen enriched atmosphere.
- Liquefied gases such as liquefied petroleum gas (LPG), nitrous oxide (N<sub>2</sub>O), ammonia (NH<sub>3</sub>), carbon dioxide (CO<sub>2</sub>), if trapped between closed valves or if the maximum filling ratio of a cylinder is exceeded, will generate a considerable pressure increase, which can rupture many equipment items.
- Any waste gas shall be vented safely - see EIGA Doc 30 *Disposal of Gases*. Cylinders not being inspected or retested may be altered/compromised and consequently fail when filled.

### 3. Checks before transfilling gases

The checks before transfilling gases include and are not limited to:

- The gas cylinders shall be inspected before each filling to ensure that they are safe to continue to use for the intended gas, the fill pressure and do not contain any residuals.
- The cylinder valve has to be free of damage and the functionality has to be checked.
- The gas compatibility of all cylinder package components and the filling equipment (hose, gauges etc.) has to be guaranteed.
- Check the next inspection date of the cylinder: Never fill gas into a cylinder after the next retest date.
- Clear and unambiguous interpretation of the stamp marks on the cylinder shoulder.

### 4. Conclusion

EIGA's position is that transfilling of industrial, breathing and medical gases from cylinders into another shall not be carried out by non-professional persons or enterprises because this cannot be carried out safely and according to the applicable legislation

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