DESIGN CONSIDERATIONS AND GUIDANCE FOR THE SAFE USE OF MEDICAL GAS VIPR

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1. Introduction

EIGA member companies have been successfully using valves with an integrated pressure regulator (VIPR) for many years in medical gases applications. The VIPR represents a major improvement compared to the former practice when separate customer owned and maintained pressure regulators were used.

There have been a small number of incidents involving medical gas cylinders, (primarily oxygen) using VIPRs. These incidents are well known within the gases industry as well as to the medical gas regulatory authorities. EIGA has prepared this document as an industry response to help minimise future incidents.

2. Scope and Purpose

This document covers medical gas cylinders fitted with VIPRs, designed in accordance with EN ISO 10524-3, *Pressure regulators for use with medical gases -- Part 3*, [1].

The purpose of this document is to:

- review the known incidents involving medical gas cylinders fitted with VIPRs designed and filled up to 300 bar; and
- prepare recommendations for those responsible for specifying, manufacturing, cylinder filling and maintaining such devices as well as for end-users and authorities.

3. Definitions

VIPR: Valve with Integrated Pressure Regulator, i.e. a combination of a pressure regulator and cylinder valve intended to be permanently fitted to a medical gas cylinder, EN ISO 10524-3 [1])

4. Summary of incident reports

EIGA member companies have reported a small number of incidents with VIPRs from a number of different valve manufacturers.

These incidents occurred between 2003 and 2011 with VIPRs manufactured between 2002 and 2010.

The majority of the incidents reported occurred within Europe, although for the purpose of this review all known incidents were considered.

The incidents occurred at both customer premises and gas company filling facilities in approximately equal number.

The review of the investigations showed that the consequences of a VIPR incident could be broken down into the following types:

- mechanical damage without ignition;
- internal ignition causing limited damage within the VIPR; and
- internal ignition leading to severe damage to the VIPR and / or the cylinder package.

Where the causes of the incidents were identified they were found to include:

- improper design;
- use of inappropriate materials;

- improper manufacture, and
- improper operation.

The corrective actions taken following specific incident reviews included:

- withdrawal of the VIPR from service via a product recall;
- redesign of the VIPR,
- improvement of the VIPR manufacturing process and procedures;
- improvement of the cylinder filling procedures and personnel training, and
- improvements to the customer user instructions.

5. Design considerations

The VIPR shall be designed and approved in accordance with the requirements of the Transportable Pressure Equipment Directive [2] (RID/ADR/ADN) and the Medical Devices Directive, (MDD,) [3].

5.1 Materials

Selection of materials is critical to the development of a safe VIPR. All components in the VIPR shall be reviewed for gas compatibility. In addition the operating conditions (pressure, flowrate and temperature) and whether the component is in the wetted area, in normal or single fault condition, shall form part of the material selection process.

VIPRs and their associated filling connectors (see 5.6) shall be tested to validate the material selection. This validation shall be in the form of an ignition test of the VIPR and its associated filling connector using adiabatic compression conducted in accordance with the procedure as described in EN ISO 10524-3. [1]

An accelerated life cycle endurance test and environmental testing on the VIPR shall also be undertaken as part of the validation of the design as required in EN ISO 10524-3 [1].

Non-Metallic components are the most susceptible to ignition and therefore their use in the gas wetted areas of the VIPR shall be minimised. Typical examples of uses of non-metallic components include, but are not restricted to valve seats, O-rings, diaphragms and lubricants.

The material selection of non-metallic components shall consider not only the compatibility with oxygen but also the consequence of any ignition. There are limitations in medical applications on the use of polymers that may give off a toxic gas during combustion (e.g. halogenated polymers), reference ISO 15001,*Anaesthetic and respiratory equipment -- Compatibility with oxygen* [4] and EIGA Doc 73, *Design Considerations to Mitigate the Potential Risks of Toxicity when using Non-Metallic Materials in High Pressure Oxygen Breathing Gas Systems* [5].

Non-metallic components can be affected over time and operation due to creep and ageing. These factors shall be considered when specifying the components. The implementation of a quality control process during manufacturing and assembly is essential to ensure components used are of the correct composition and specification.

Metallic components are more resistant to combustion than non-metallic components; however correct material choice is no less important as in a pure oxygen environment many metals will burn with a large release of energy and can propagate a fire. Aluminium alloys and stainless steels are examples of metals that can burn at a very low oxygen pressure. Their use shall be limited, and an alternative material chosen, which is more resistant to combustion and subsequent propagation (higher exemption pressure) e.g. brass and Monel®. Where it is not possible to use an alternative, the material shall be assessed and its compatibility with oxygen demonstrated via a suitable test ,e.g.

using ASTM G175 *Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators Used for Medical and Emergency Applications* [6].

5.2 Filters

A filter represents a high risk of ignition in an oxygen VIPR as it creates an impingement zone for any free flowing particles. The use of filters shall therefore be limited, and the materials of construction, filter mesh size, shape and location in the VIPR considered carefully to reduce the risks.

Where possible filters shall be limited to a position immediately upstream of the regulator inlet where they protect the regulator seat from particle damage and subsequent failure to operate as designed.

The material of the filter is critical, typically a nickel, Monel® or sintered bronze is selected and stainless steel or aluminium bronze shall be avoided. If a filter is dismountable the VIPR should be adiabatically tested with and without the filter.

Filters should be located such that they are not subjected to bi-directional flow because of the risk of particles collecting on the filter and then being pushed as a concentrated mass of material to an impingement site when the gas flow reverses.

The VIPR design should be such that it is not possible to trap particles between filters.

Use of a short anti-dust tube as an alternative to a filter in the VIPR to cylinder connection presents a reduced impingement and contamination trap whilst still offering protection from particles entering the VIPR from the cylinder.

NOTE: When using an anti-dust tube, the protection of the regulator seat by a filter remains necessary

5.3 VIPR to cylinder connection

VIPRs shall be installed using the defined torque in accordance with ISO 13341*, Gas cylinders -- Fitting of valves to gas cylinders* [7] . The lower end of the recommended torque range shall be used to minimise the potential to damage the mechanisms within the VIPR.

Incidents have been documented with cylinder valves and VIPRs having a parallel thread on the valve to cylinder connection. Therefore it is not recommended to use a guard mounted on the valve when a parallel thread is selected as it can:

- Facilitate the accidental unscrewing of the VIPR from the cylinder.
- Increase the risk of an ignition at the VIPR to cylinder neck interface, if the package is dropped. The consequence of this can be very severe when applied to aluminium alloy cylinders.
- Lead to breaking of the connection thread in the VIPR due to overstressing, if the package is dropped (also applicable to tapered thread).

When valve guards are fitted they shall be designed and tested in accordance with ISO 11117, *Gas cylinders -- Valve protection caps and valve guards -- Design, construction and tests,* [8].

Formal procedures and training are recommended to ensure the above plus the correct thread matching, choice of O-ring seal size and materials. Reference shall be made to ISO 15245, *Gas cylinders -- Parallel threads for connection of valves to gas cylinders* [9].

5.4 Pressure gauges

The high pressure gauge on a VIPR is used as a contents indicator and should not be considered as a calibrated measuring device.

The gauge should be designed to resist excessive moisture ingress (e.g. IP54 of IEC 60529, *Degrees of protection provided by enclosures (IP Code*) [10]) and environmental conditions that it could be subjected to under operating conditions.

Where a mechanical gauge is utilised it shall have an inlet restrictor to protect the tube from a sudden rush of pressure and to minimise the rate of gas release if the gauge is damaged. The gauge, irrespective of type, should be protected from external impact damage.

The pressure gauge may be active or passive. An active gauge is preferred as this is subjected to constant pressure, rather than being subjected to a large pressure surge whenever the shut-off valve in the VIPR is opened. With an active gauge, extra care shall be taken in the design and inspection to prevent leaks as this can lead to the depletion of the cylinder contents.

In the event of a leak within the gauge, its casing should be designed such that the pressure is safely relieved to prevent a hazardous overpressure that could lead to a rupture.

Consideration shall be given to the placement of the inlet flow restrictor on the pressure gauge port. The restrictor in the body of the VIPR offers additional protection in the event of an ignition by reducing the flowrate.

5.5 Shut off function

There are two options for this functionality;

- shut off valve, and
- on/off valve.

5.5.1 Shut off valve

The shut off valve isolates the low pressure (downstream of regulator) from the high pressure (cylinder) side of the VIPR. This may be a separate valve or be part of the flow control valve.

The shut off valve shall be designed for maximum cylinder developed pressure and to operate under a high differential pressure. It normally has an O-ring outer spindle seal with the inner spindle either of the rotating or non-rotating type.

The material of the valve seat is important to ensure a gas tight seal and is often a non-metallic insert in a metallic holder. The guidelines in 5.1 shall be considered.

The gland on the valve stem is a potential source of a leak of oxygen, which may be outwards under a high pressure or inwards when the cylinder is being vacuumed prior to filling. The number and type of O-rings in this area is an important design consideration.

The shut off valve shall have controlled opening characteristics to limit the opportunity for ignition through adiabatic compression (i.e. not fast open such as a ball valve). The required force to operate the valve shall be defined to ensure ease of operation for the end user.

5.5.2 On/Off Valve

The on/off valve isolates the cylinder content on the low pressure side from the user outlet(s). This is typically a valve positioned after the pressure regulator and associated relief devices

The on/off valve shall be designed for set pressure of the relief valve (typically 10 bar). The material of the valve seat is important to ensure a gas tight seal and is often a non-metallic insert in a metallic holder. The guidelines in 5.1 shall be considered.

The design of the regulator has to be considered when using an on/off valve, as it will be permanently loaded with cylinder pressure which may lead to creep and activation of the relief valve.

5.6 Filling port

The VIPR shall have a dedicated filling port. The filling port shall include an integral non return valve that is opened when connected to the filling system by a filling adaptor. This non return valve prevents the release of gas from the cylinder in customer service.

Filling ports are described as:

- Active
- Semi Active
- Passive

An active port does not have any form of isolation valve, and the non return valve is therefore always exposed to the cylinder pressure. This type of fill port is not recommended because there is no positive isolation and should only be used if all hazards are understood.

A semi active port has an isolation valve which is opened during use, exposing the non return valve to cylinder pressure.

A passive port has an isolation valve that is designed only for the filling process. This valve would be closed at all other times.

The material of construction of the non-return valve O-rings and spring shall be designed to ensure an appropriate level of oxygen compatibility. The filling adaptor and valve combination shall also be subjected to an adiabatic compression test as stipulated in 5.1.

It is recommended that the filling adaptor used to fill the package is designed by the VIPR manufacturer to ensure all material dimensions are accurate. A poorly fitting filling adaptor is a high risk and multiple incidents have been linked to wrong fitting or excessively worn filling adaptors.

Any design changes to the VIPR or the fill connector shall result in the re-qualification and testing of the combination.

Though the filling port is designed mainly for one directional flow, the effects of a backflow from the cylinder need to be understood. There have been incidents where O-rings on the fill connector have become dislodged during reverse flow leading to an ignition. It is normally possible to depressurize the cylinder via the fill port prior to filling or testing using a tool to open the non return valve. Therefore the requirements generated by this reverse flow need to be considered in the design and material selection of the fill system and VIPR, and this design should be confirmed by an appropriate test.

The fill port connection is not used by the customer so can be freely chosen from an accepted valve outlet standard or be a proprietary design assuming there are no mandatory national regulations. ISO 5145 *Cylinder valve outlets for gases and gas mixtures. Selection and dimensioning* [11] has an extensive range of specific outlets dedicated for medical use.

The filling port can be susceptible to the ingress of airborne particle if left unprotected in transport, storage or customer service. The use of a cap or shrink wrap to protect the port is recommended. If a gas tight seal is formed the release of pressure in the event of a fill port non return valve leak shall be considered.

5.7 Residual Pressure Valve (RPV)

An RPV shall be built in to the design of the VIPR to ensure a positive residual pressure is maintained in the cylinder. The RPV may have a dual function and be designed to prevent back flow from the customer. Maintaining a positive pressure and protecting from back flow prevents ingress of moisture and particles into the cylinder thereby reducing the risk of cylinder corrosion and out of specification

product. The RPV should comply with the requirements of ISO 15996, *Gas cylinders -- Residual pressure valves -- General requirements and type testing*, [12].

5.8 Pressure regulator

The pressure regulator is designed to reduce the cylinder pressure (typically 200-300 bar) down to the user pressure (approximately 4 bar) which varies with national medical practices.

The design of the regulator may be either a piston or diaphragm type, with a single or multiple stages. The effect on the outlet pressure of decreasing inlet pressure (regulating characteristic) needs to be understood during the design of the VIPR to be certain that the outlet pressure remains within the required design tolerances.

The design of the regulator seat shall be such that if, the regulator seat burns, there is no direct gas path from the high pressure side to the low pressure side through the seat cavity.

The low pressure side of the regulator shall be protected by a pressure relief device. This device shall activate if the low pressure side is subjected to high pressure. The primary relief device is set to relief the pressure to prevent a pressure higher than 10 bar in the low pressure side. The relief device maybe either a relief valve or a combination of a relief valve and a bursting disc. If a bursting disc is used it shall be set at a higher pressure than the relief device such that it acts as a secondary protection.

When the operation of the relief device is due to an ignition of internal parts of the pressure regulator, the relief device itself may ignite or expel a flame that could impinge on to the cylinder guard. Consideration shall be given to the location and size of the vent holes and the materials of the guard.

Alternative to pressure relief devices may be considered, though at the moment they are not widely used in the medical application. This would include a downstream design suitable for maximum pressure or a high pressure automatic closure valve in case of failure of the regulator.

The outlet(s) of any relief device need to be designed to minimise the risk of water ingress which, for example, if frozen may cause a blockage.

Care needs to be taken to mitigate any risk of a lubricant from the low pressure side finding its way back into the high pressure side, where its compatibility with the gas stream at the elevated pressures may be greatly reduced.

Where possible the low pressure side shall be designed to withstand the high pressure conditions.

5.9 Flowmeter

Two types of device are used to select the flowrate. Type 1: a “flow selector," device allowing the selection of one flowrate among a number of preset flowrates, via a series of fixed positions and type 2, a "fully adjustable" device where the flow is continuously controlled by adjusting the pressure upstream a fixed orifice.

Type 1 is the most commonly used and should by preferred for usability reason. The flowrates are fixed by a rotating flow disc. The material of the disc, O-rings and its lubrication are important as any sticking or chemical reaction may affect the ability of the device to deliver the required flowrate.

The selection of specific flows should be via a series of fixed positions rather than a fully adjustable dial, reference EN ISO 10524-3 [1]

5.10 Pressure outlet connection

The pressure outlet connection is usually a quick connector, designed in accordance with the acceptable medical regulations in the country of operation. The type of connection is gas specific and is generally the same as that used on the medical gas pipeline system.

The pressure outlet connection normally incorporates a non-return valve which is opened by inserting the appropriate connector.

5.11 Flow outlet connection

The flow outlet connection should be designed as a male connection to accept a push-on hose at atmospheric pressures. This type of design is often referred to as a fir tree, see EN13544-2 *Respiratory therapy equipment. Tubing and connectors*, [13]

5.12 Tamper evident seal and outlet covers

Protection of the outlet connection ports needs to be considered, as with the fill port (5.6), as the other ports may also be susceptible to particulate ingress. There have also been documented incidents in the Industrial Gases industry of insects being found in these ports.

In addition to being used as protection, connection port caps and seals can be used to indicate the condition of the cylinder (commonly known as tamper evidence seals). This is seen most commonly immediately after filling when the addition of a cap/seal to the customer outlet designates a full cylinder.

Finally caps may also be used to deter incorrect customer operation of the valve. Fill ports (which are only used by the gas supplier) are often sealed with a cap displaying a label or pictogram warning the customer not to connect anything to the port.

5.13 Operating device and flow selector / flow indication

The ergonomics of the handwheel / selector shall be designed taking into consideration the maximum force that an end user can apply to enable them to open the VIPR.

5.14 Valve Protection

Where a VIPR is fitted with a guard, it shall comply with the requirements of ISO 11117, *Gas cylinders -- Valve protection caps and valve guards -- Design, construction and tests* [8]. The guard may be made of a plastic or metal material and should be designed to assist with the correct handling of the cylinder package. The effects of environmental factors shall be considered, e.g. UV resistance for plastic and corrosion resistance for metal guards. Flame resistance (V1 acc. to IEC 60950 *Information Technology Equipment - Safety* [14]) should also be considered.

The maximum gross weight for which the guard is designed should be indelibly marked on the guard. (ISO 11117 [8])

For the design of the guard, consideration should be given to the mode of use of the cylinder package, especially when small cylinders are directly attached to hospital beds or are placed adjacent to the patient.

If a guard is not fitted, care should be taken to ensure the cylinder valve is designed to withstand this use and/or protected to prevent damage and potentially hazardous pressure or product release.

6. Operational and Safety considerations

6.1 Filling activities

6.1.1 Safety recommendations

It is recommended that a site specific hazard review is completed to identify all potential hazards to the operators. The location of the filling area and the surrounding hazards may differ greatly depending on the site and give rise to requirements for protective barriers.

There are a number of generic recommendations that should be implemented for the protection of the operator via Personal Protective Equipment, see EIGA Doc 136, *Selection of Personal Protective Equipment,* [15]

6.1.2 Filling equipment design

The design and location of the filling equipment is as important as the design of the cylinder package and similar considerations need to be given to material selection and cleanliness.

Medical cylinders would usually be segregated from non-medical cylinders and in many cases the filling racks are dedicated to medical. The equipment used in medical filling racks may differ from non-medical practice due to the requirement to use polymers that are approved for medical use such as EPDM, (Ethylene Propylene Diene Monomer) instead of Viton® even though they may have a lower auto-ignition temperature in oxygen, see EIGA Doc 73, [5].

The necessity for filters to be installed on filling equipment should be considered. If used, they shall be carefully designed with compatible materials and able to be easily maintained. The flow through the filter must be unidirectional (never bidirectional). Any gas released from the cylinders must not pass through a filter before being vented to the atmosphere.

6.1.3 Inspection prior to filling

In addition to the generic pre-fill inspection requirements, (e.g. EN1920, *Transportable Gas Cylinders – Cylinders for compressed gases, (excluding acetylene) – Inspection at time of filling*, [16]) a specific visual pre-fill inspection shall be performed and include:

- expiration date for the VIPR;
- inspection of the filling port for contamination;
- absence of contamination from the patient or user (e.g. blood, body fluid, alcohol based hand cleaner gel, etc.), see EIGA TB 03*, Handling and cleaning externally soiled medicinal gas containers,* [17];
- condition of the pressure gauge, and
- conditions of customer flow and pressure outlets.

It is important to carry out a residual pressure test prior to filling to indicate that there has been no internal contamination of the cylinder.

The residual pressure check can be performed by:

- checking content gauge;
- if no content indicated, open shut off valve, select flow and check for gas flowing; or
- if no flow, gently push (prod) non-return valve in filling port with an appropriate tool.

If no residual pressure is detected, send cylinder package for maintenance

6.1.4 Evacuation and/or purging

It is recommended by Good Manufacturing Practice Annex 6, Manufacture of Medicinal Gases [18] that cylinders that have been returned for refilling should be prepared with care in order to minimise the risks of contamination, in line with the procedures defined in the Marketing Authorisation. These procedures which should include evacuation and/or purging operations should be validated. It is

acceptable to vent the cylinder individually via the customer outlet (s) or to vent them via the filling port when connected to the filling manifold.

Where the cylinder is vented via the filling manifold this may only be done when the filling port has been designed for bi-directional flow.

6.1.5 Filling

The process of filling can introduce risks; fill connectors as well as VIPRs shall be subjected to an adiabatic compression test.

Prior to connecting the filling adaptor ensure that the main shut off function is closed and the valve vented through the low pressure outlet (e.g. flow selector). This will release the residual pressure in VIPR, avoiding damaging the VIPR and/or fill connector.

The filling process may include a vacuum and/or purge step(s) depending on the local filling procedure.

6.1.6 Filling inspection

The general process for checking for leaks during filling shall be conducted during the initial stages of the filling process as with any other oxygen cylinder. This ensures that there are no loose connections, damaged fill connectors or VIPR components.

If leaks are discovered the filling process should be stopped and the filling system depressurised before correction of the leak is attempted. The risks to filling personnel shall be considered whilst completing this inspection.

6.1.7 Post Filling Inspection

The cylinders shall be checked to ensure that they have been successfully filled; this is after the cylinder is disconnected from the filling system. This is usually either via touching the cylinder shell, which, if filled, should have an elevated temperature or by checking the VIPR contents indicator. Where cylinders are filled individually the process control system may render such checks unnecessary.

After filling a leak check shall be completed, checking for leaks on the VIPR, its ports and the cylinder to VIPR connection. If a leak detection fluid is used, it shall be approved for the application (EIGA Doc 78, *Leak detection fluids - Gas Cylinder Packages* [19]). Where used it shall be ensured that this does not ingress in to the VIPR ports.

There is a specific medical requirement to check that the VIPR is functioning correctly. The procedure for this shall be documented. This may need to be agreed with the relevant Authorities. For example the operator could select a flow and confirm there is gas being released from the cylinder.

6.2 Maintenance

If the VIPR needs to be removed from the cylinder this shall be in accordance with ISO 25760 *Gas cylinders. Operational procedures for the safe removal of valves from gas cylinders* [20], and all safety considerations addressed with specific tooling to avoid damage to the VIPR.

Only trained maintenance staff shall be used for repairs and refurbishments to VIPRs in accordance with written procedures approved by the manufacturer. This would require the original manufacturer to be engaged to obtain approval for the location and personnel approved for the work.

When maintaining the VIPR only spare parts approved by the original manufacturers (OEM) shall be used. This is a requirement of the medical device design file, which forms part of the CE approval. If alternative spares are sourced they shall be the subject of a technical review and approval prior to use by the VIPR manufacturer.

The VIPR manufacturer shall advise the type and frequency of the maintenance and/or inspection of the device and subsequent testing as required in the user instructions.

7. Recommendations to the end user

Care shall be taken when operating a medical oxygen package incorporating a VIPR. The end user shall be familiar with the operating instructions and the functionality of the VIPR. The location of the cylinder, whilst in use shall be considered, and sources of ignition and storage of consumable materials minimised. The operating instructions shall require the user to contact the gas supplier if there is any doubt about the correct operation and storage of the VIPR package.

When the cylinder is not in use, ensure the main shut off function is in the closed position. If there is a separate flow selector, this should be reduced to the lowest flow possible to avoid incidents on start up with high initial flow after the shut off function is opened.

The general conditions for cylinder storage require careful consideration; it is advised to keep medical cylinders inside a purpose designed cylinder storage area, clean, with adequate ventilation, and protection from the elements and extreme temperatures. These precautions are particularly important for a VIPR due to the additional components and functionality.

8. References

[1] EN ISO 10524-3; Pressure regulators for use with medical gases -- Part 3

[2] Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment

[3] Directive 93/42/EU of the European parliament and of the Council for Medical Devices

[4] ISO 15001; Anaesthetic and respiratory equipment -- Compatibility with oxygen

[5] EIGA Doc 73; Design Considerations to Mitigate the Potential Risks of Toxicity when using Non-Metallic Materials in High Pressure Oxygen Breathing Gas Systems

[6] ASTM G175; Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators Used for Medical and Emergency Applications

[7] ISO 13341; Gas cylinders -- Fitting of valves to gas cylinders

[8] ISO 11117; Gas cylinders -- Valve protection caps and valve guards -- Design, construction and tests

[9] ISO 15245 Gas cylinders -- Parallel threads for connection of valves to gas cylinders

[10] IEC 60529 Degrees of protection provided by enclosures (IP Code)

[11] ISO 5145 Cylinder valve outlets for gases and gas mixtures. Selection and dimensioning

[12] EN ISO 15996; Gas cylinders. Residual pressure valves; General requirements and type testing

[13] EN13544-2; Respiratory therapy equipment. Tubing and connectors,

[14] IEC 60950; Information Technology Equipment - Safety

[15] EIGA Doc 136; Selection of Personal Protective Equipment,

[16] EN1920; Transportable Gas Cylinders – Cylinders for compressed gases, (excluding acetylene) – Inspection at time of filling,

[17] EIGA TB/03; Handling and cleaning externally soiled medicinal gas containers

[18] Good Manufacturing Practice GMP Annex 6, Manufacture of Medicinal Gases

[19] EIGA Doc 78; Leak detection fluids - Gas Cylinder Packages

[20] ISO 25760; Gas cylinders. Operational procedures for the safe removal of valves from gas cylinders