POSITION PAPER

Position Paper PP- 04 - 2011

Transfilling of Medical Gas Cylinders

TRANSFILLING OF MEDICAL GAS CYLINDERS

There have been incidents and unsafe practices pertaining to the transfilling of medical gas cylinders in healthcare facilities. These transfill procedures were usually carried out by unskilled and unqualified personnel. Such practices constitute a safety concern to the people carrying out the transfilling operations, and may cause damage to property and contamination of the product. The transfilling of gases, usually from a larger cylinder to a smaller cylinder, by unqualified persons has caused several accidents including a number of fatalities.

The safe filling of gas cylinders requires that the persons performing the operation have detailed and expert knowledge of gas properties, cylinder design, plant operation and relevant legislation. This is in addition to the use of the appropriate equipment and the inspection of the cylinder to be filled.

AIGA strongly recommends that only trained and qualified professionals be allowed to transfill medical gases, using cylinders and equipment specifically designed for the transfilling operation**.**

The intention of this position paper is not only to clarify AIGA's position, but also to elaborate on the reasons for this recommendation and the main hazards associated with the transfilling operation.

1. Definitions:

- *Medical gas* means any gas used in medical applications.
- *Medicinal gas* means any gas or mixture of gases classified as a medicinal product (EU Directives 2001/83/EEC).
- *Medicinal product* means
- Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
- Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.
- *Shall* : The use of the word 'shall' implies a very strong concern or instruction.
- *Should* : The use of the word 'should' indicates a recommendation.

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2. Risks of Transfilling Medical Gas Cylinders

There are many factors that may contribute to the failure of transfilling medical gases from one or more cylinders into other cylinders.

- The pressure of the cylinders being transfilled may be as high as 200 bars. Oxygen under pressure presents a hazard in the form of stored energy. A violent rupture of equipment can cause serious injuries or fatalities to people in the vicinity and significant property damage.

- The use of pressure equipment, gas cylinders and cylinder valves not compatible with the gases to be filled can cause ignition, rupture of equipment, or serious leakage of gases. These are all scenarios which can result in serious accidents.

- The cylinders and transfilling equipment used may be contaminated with hydrocarbons such as oil, grease or other combustible materials, including oil from the operator's hands or contaminated tools.

- Materials that burn in air will burn much more vigorously and at a higher temperature in oxygen-enriched atmospheres.

- The rapid release of high pressure oxygen and the presence of foreign particles can cause friction or impact resulting in temperatures that can be sufficient to ignite combustible materials.

- Liquefied gases such as nitrous oxide (N2O) and carbon dioxide (CO2), 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 equipment.

- A cylinder heats up as it is being filled from a high pressure source. The more rapidly the cylinder is filled, the higher the temperature rise in the cylinder resulting from the heat of compression of the gas. Excessive temperatures can result in the ignition of any combustible materials that are present.

- Toxic gases can be generated by the ignition or decomposition of some non-metallic materials in high pressure oxygen equipment, such as valves, gas pressure regulators, and flexible hoses.

3. Good Manufacturing Practice (GMP) Recommendations

The following is a partial list of guidelines from AIGA 023/05 'GMP Guidelines for Medicinal Gases' that are applicable to the production of medical gases. Persons engaged in transfilling of medical gases should understand and comply with these guidelines.

- Equipment (Clause 6.8)

  All equipment for manufacture, cylinder filling and analysis of medicinal gases shall be designed, qualified, calibrated and maintained to suit its intended purposes.

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- Maintenance and Cleaning (Clause 6.8.1)

  The design of manufacturing and cylinder filling equipment should permit easy and effective cleaning and evacuation to remove any internal contamination. Where the pipework or equipment requires specific cleaning, the system shall be designed so that any residual cleaning material can be easily removed prior to use. Detailed written procedures must be available to cover the appropriate methods of purging and cleaning all equipment.

- Material Selection (Clause 6.8.2)

  Manufacturing and cylinder filling equipment shall not present any hazard to the finished products. The parts of the equipment that come into contact with the product must not be reactive, additive or absorptive to such an extent that it will affect the quality of the product and thus present a hazard.
  This specifically includes halogenated materials that could produce toxic gases if they should ignite, such as under adiabatic compression conditions.

- Medicinal Cylinders (Clause 6.9.6)

  Cylinders in medicinal gas service shall be dedicated to that service and have the appropriate technical characteristics, according to international / national regulations.

4. Publications related to risks of transfilling medical gases

- AIGA 059/09 - Design consideration to mitigate the potential risks of toxicity when using non-metallic materials in high pressure oxygen breathing gas systems

- EIGA Position Paper PP-18 December 2007 – Transfilling of industrial gas cylinders.

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