WFSA Guideline for tendering for anaesthesia machines

As the supply of electricity and compressed gases to health care locations varies from country to country, and sometimes regionally, the specifications of anaesthesia machines and other medical equipment will also differ.

- In affluent countries, unlimited supplies of compressed gases, and uninterrupted electrical supply is usual.
- In many places around the world, the supply of gases and electricity is unreliable, fluctuates, or is absent.
- Sometimes, compressed gases may be available, but electricity is unreliable.

ISO standards for medical equipment are developed by international, multidisciplinary consultation, including input by end-users, in these cases, clinicians. The role of published ISO equipment standards is for use by manufacturers, as the minimum safety and performance requirements for equipment. In addition standards mandate that manufacturers consider all risks and usability aspects pertinent to their devices.

There are three ISO standards for anaesthesia machines or work-stations, so there is a suitable anaesthesia machine for each of these situations. These are:

- ISO 80601-2-13:2011 *Anaesthetic workstations*

  Electricity and compressed gas dependent, often electronic components

- ISO 8835-7:2011 *Anaesthetic systems for use in areas with limited logistical supplies of electricity and anaesthetic gases*

  Can operate without supply of electricity and compressed gas.

- ISO 5358:1992 *Anaesthetic machines for use with humans*

  Electricity is not required to operate, but dependent on supply of compressed gases

It is recognised that each environment has its unique problems of qualitative and quantitative supply of power and gases. When tendering for medical equipment, the purchasers must know what these problems are for their specific environment.

WFSA has been involved in the development of these, in particular ISO 8835-7:2011. WFSA endorses all three standards for anaesthesia machines and work-stations, and recommends that tender processes require compliance with the appropriate one of these standards.

A useful way of finding out about a standard is to visit the ISO website where a summary, usually the scope, of a standard is given. For example, anaesthesia workstations/machines are developed under the auspices of ISO/TC121/SC1, http://www.iso.org/iso/home/store/catalogue_tc/catalogue_tc_browse.htm?commid=51986

Although standards are written with users in mind they are not meant as a user practice document. It is not necessary for users to have a copy of these equipment standards.

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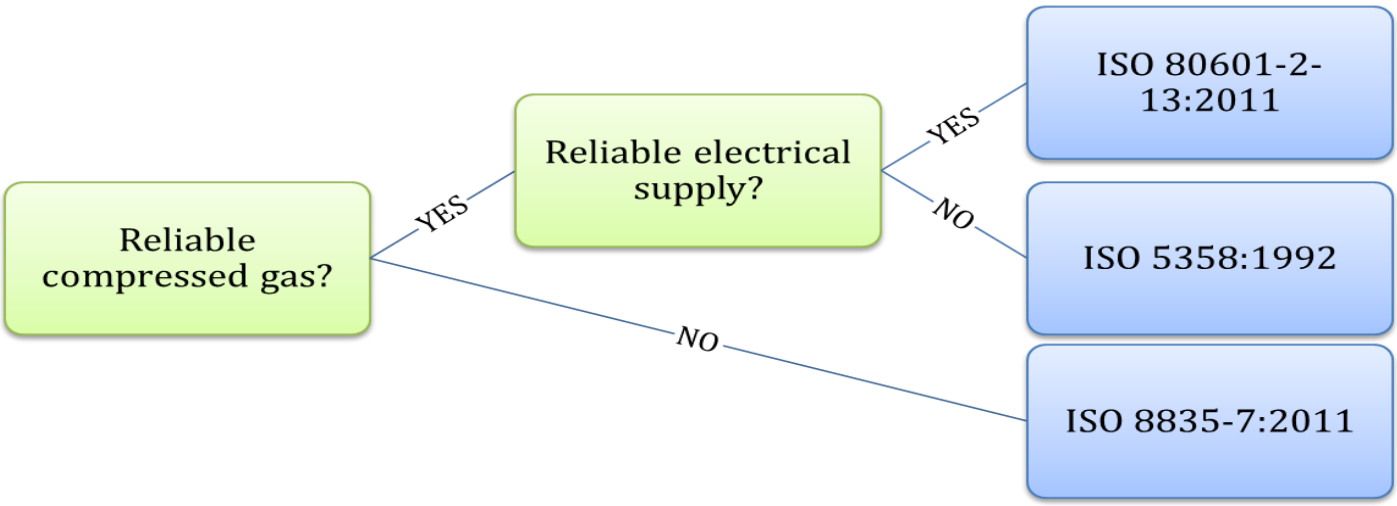
Fig 1: Tendering Flow Chart



	Anaesthesia machine/workstation ISO document number	Vaporizer ISO document number
Electricity & compressed gas	ISO 80601-2-13:2011	Included in ISO 80601-2-13:2011
Compressed gas	ISO 5358:1992	ISO 80601-2-13:2011 (Clause 201.104)
No electricity or compressed gas	ISO 8835-7:2011	ISO/DIS 18835

- ISO 80601-2-13:2011 *Anaesthetic workstations*
  Electricity and compressed gas dependent, often electronic components

- ISO 5358:1992 *Anaesthetic machines for use with humans*

  Electricity is not required to operate, but dependent on supply of compressed gases

- ISO 8835-7:2011 *Anaesthetic systems for use in areas with limited logistical supplies of electricity and anaesthetic gases*

  Can operate without supply of electricity and compressed gas

- ISO/DIS 18835 *Inhalational anaesthesia systems - Draw-over anaesthetic systems*

  Draw-over vaporiser for use with machines compliant with ISO 8835-7:2011

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