

World Standards for Medical Gas Systems

A Comparison



- ◆ What is a Medical Gas?
 - A medical gas a medicinal product (pharmaceutical) used for treating or preventing disease and for life support of human beings.
 - The use of medical gases should be subject to prescription by a clinician.
 - The physical and chemical composition of a medical gas, the maximum levels of its contaminants and the way in which it is administered and packaged are governed by the European Pharmacopoeia and the Medicines Act.
- ◆ Medical air is regulated as a drug under the European Pharmacopoeia
- ◆ **Medical air is the only drug manufactured in a hospital; by a medical air plant**



- ◆ The Four Tenets of Medical Gas System Safety:
 - **Continuity** – the gas supplies must always be available
 - **Adequacy** – the correct flow and pressure must always be delivered
 - **Identity** – the correct gas should always be administered
 - **Quality** – gases must be safe and pure

- ◆ There are two main standards in use internationally that provide best practice guidance for medical gas systems and products – NFPA 99 (US) and HTM 02-01 (UK)

- ◆ How does each standard maximise the safety of users and patients?

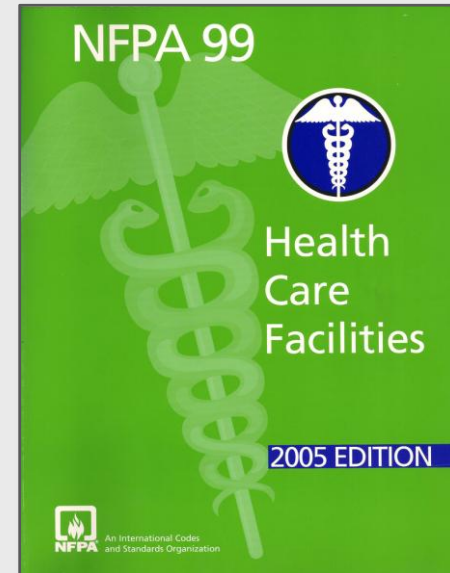
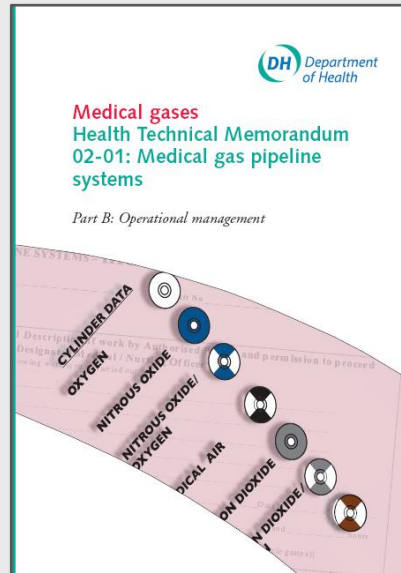
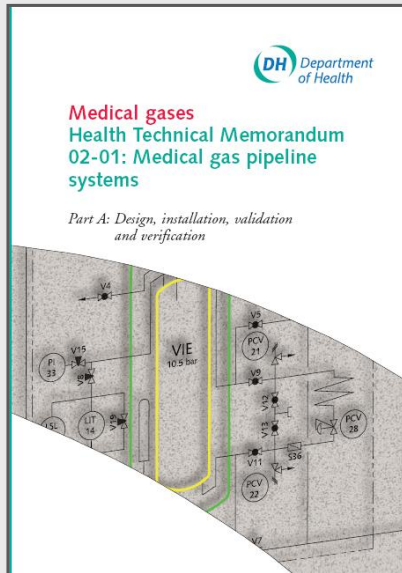


Penlon Medical Gas Standards Comparison



HTM 02-01 Parts A and B

NFPA 99



Overview and Principles	NFPA 99	HTM 02-01
Date of First Publication	1984	1972
Years of Embedded Experience	21	34
Number of Pages Dedicated to Medical Gases	136	330
Published by a Government Agency	x	✓
Equipment Fault Tolerance Levels	1	2
Management Structure Defined - CP, AP, AE roles	x	✓
Products Regulated – CE Mark to the MDD	x	✓
Quality Control Pharmacist Verification of Gas Purity	x	✓
European Pharmacopoeia Quality Compliance	x	✓
Risk Management to ISO 14971	x	✓

Design Elements	NFPA 99	HTM 02-01
Terminal Unit and Gas Flow Schedules	x	✓
Auto Ignition Testing of High Pressure Regulators	x	✓
Halogenated Polymers Banned in HP O ₂ Service	x	✓
Bacteria Filters for Protection of Medical Vacuum	x	✓
Refrigerant Dryers Disallowed	x	✓
Medical Air Dew Point (ppm v/v)	1833	67
Minimum Pressure Vessel Sizes	x	✓
Liquid Sealed Pumps/Compressors Disallowed	x	✓
AGS and Medical Vacuum Supplies Separate	x	✓
Duplex Emergency Backup Manifolds	x	✓

Operational Management Elements	NFPA 99	HTM 02-01
Operational Policy	x	✓
Maintenance Contract Guidance	x	✓
Equipment Maintenance Procedures Defined	x	✓
Verification Procedures and Forms	x	✓
Permit to Work System	x	✓
Management Processes – CP, AP, AE, DNO roles	x	✓
Minimum Training Requirements Defined	x	✓

Medical Air Safety Limits

Component	NFPA 99	HTM 02-01*
Oxygen	19.5-23.5 %	20.4-21.4 %
Oil	Not specified	0.1 mg/m3
Water	1833 ppm	67 ppm
Carbon Monoxide (CO)	10 ppm	5 ppm
Carbon Dioxide (CO2)	500 ppm	500 ppm
Nitrogen Dioxide (NO2)	Not specified	2 ppm
Nitric Oxide (NO)	Not specified	2 ppm
Sulphur Dioxide (SO2)	Not specified	1 ppm

*HTM 02-01 Reflects European Law. Must be verified by an independent QC pharmacist.

The Four Tenets	NFPA 99	HTM 02-01
Continuity	★★	★★★
Adequacy	★★	★★★
Identity	★★★	★★★
Quality	★	★★★
Other Key Measures		
Sustainability	★	★★★
Useability	★★	★★★
Overall Value	★★	★★★

- ◆ In the US, the FDA do not consider medical gas equipment to be medical devices
 - The FDA does not regulate the products or the companies making them
- ◆ In Europe, most authorities consider medical gas products to be medical devices
 - Medical gas products therefore are regulated under the medical device directive 93/42/EEC
 - Medical device companies in Europe must have a stringent ISO 13485 quality management systems that are regularly audited
- ◆ US medical gas pipeline equipment making NFPA 99 equipment are not required to have any formal quality management system
- ◆ **Would you take the risk?**

- ◆ Medical Air Dew Point (water concentration)
 - NFPA allows a water concentration of 1833 ppm whereas HTM 02-01 and European Law states the maximum water concentration should be 67 ppm
 - European Law limits are **27 times lower** than NFPA 99!
- ◆ Why?
 - A very low dew point inhibits bacteria survival and growth, reducing infection
 - At low ambient temperatures, liquid water could form if the air is too humid
 - Anaesthesia machines and ventilators are damaged by liquid water
 - At freezing temperatures ice can form, blocking the pipeline
 - Higher humidity promotes oxidation of the inside of piped distribution system (copper oxide), which will inevitably contaminate the supply
- ◆ **Would you take the risk?**

- ◆ Periodic maintenance of compressors and vacuum pumps is required to protect your investment and maximise service life
- ◆ Single fault tolerance should be assured during maintenance
 - NFPA 99 requires only a single level of fault tolerance on supply systems
 - During maintenance of a supply there is an unacceptable risk of supply failure
 - HTM 02-01 as well as European and International Standards require a single level of fault tolerance to be maintained during maintenance
- ◆ What would happen if a compressor or vacuum pumps fails during maintenance of another?
 - NFPA – **the supply would fail – patients are at risk**
 - HTM 02-01 – the supply is maintained - patients are unaffected

- ◆ High pressure oxygen cylinders require pressure regulators to reduce the pressure before distribution to a pipeline
- ◆ A significant risk of explosion exists unless the pressure regulator is designed to tolerate high temperature during adiabatic compression
- ◆ HTM 02-01 and other International Standards mandate auto-ignition testing is performed to prove the pressure regulator design
- ◆ NFPA 99 does not mandate such a test is performed
- ◆ **Would you take the risk?**

- ◆ Exhaled anaesthetic gas mixtures are captured and removed from breathing circuits to prevent ill health of clinical staff subjected to long-term exposure
- ◆ HTM 02-01 and International Standards mandate a dedicated pipeline system and plant for this purpose
- ◆ NFPA 99 allows the use of the medical vacuum system for this purpose
 - The mixture of high oxygen concentration with anaesthetic agents in contact with high temperature oil in vacuum pumps is believed to have led to many fires in hospital plant rooms
- ◆ **Would you take the risk?**

- ◆ Medical vacuum systems are used to collect and extract many highly infectious materials in hospitals
- ◆ The vacuum system transfers the potentially infected air out of the hospital
- ◆ HTM 02-01 and other International Standards mandate the fitting of bacteria filters to protect the plant and exhausts contamination with harmful bacteria
- ◆ NFPA 99 does not specify the fitting of bacteria filters and so provides no protection
- ◆ **Would you take the risk?**

- ◆ The two major standards for medical gas pipeline systems contain many differences
- ◆ HTM 02-01 was developed with a view to maximise patient safety and product reliability
- ◆ The differences between the standards are subtle, the consequences may not be
- ◆ **Would you take the risk?**