

# Hyperbaric Chambers

*Key compliance elements for hospital installations*

Over the last decade, there has been a large increase in the installation and use of hyperbaric chambers as new therapeutic applications have been developed and approved. Today, patients in almost every part of the U.S. have access to hyperbaric treatment, and new hyperbaric units are being installed all the time. Often we find hospital administrators, as well as hyperbaric system installers themselves, do not have a clear understanding of the regulatory requirements for these installations. This article will examine the key compliance elements of hyperbaric medical gas system installations at hospitals.

In addition to FDA regulatory requirements, there are two consensus standards that cover hyperbaric installations: CGA

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publication M-1 and NFPA 99. Hyperbaric medical gas installations at hospitals are considered Level 1 systems, which means they are considered essential to sustain a patient's life, and if a system should fail there is the immediate risk of serious injury or death to a patient.

FDA regulations apply to hyperbaric medical gas systems because these systems store and dispense a pharmaceutical. A quick outline of FDA requirements for healthcare facility medical gas systems includes personnel training and certification, the use of standard operating procedures for installations, system qualification and validation, maintenance, and system documentation and recordkeeping.

Level 1 medical gas systems are the type of systems installed at hospitals across America to supply oxygen inside the facility. Requirements for these systems include adequate primary storage capacity, a minimum 24-hour reserve sup-

ply, automatic reserve activation, a supply manifold with a dual regulation system, adequate vaporization capacity and an alarm system that alerts the health care facility. Level 1 systems also must be installed by trained and certified personnel, in full accordance with FDA cGMP requirements. If a standalone hyperbaric system is installed at a Level 1 facility, it must meet all these requirements.

A common pitfall is to add a hyperbaric unit, or units, to an existing system without considering whether the primary and reserve tanks need to be upgraded. Hyperbaric units can draw a lot of medical gas over a relatively short time. A heavy hyperbaric treatment day at a facility with an undersized or marginally sized primary storage tank has the potential to draw the healthcare facility's medical oxygen supply down to a dangerously low level, or even put them onto their reserve system. Once this happens, the facility must either receive an emergency oxygen delivery or begin to curtail activities like surgical procedures.

GAWDA member firms that install Level 1 hyperbaric systems which do not comply with the requirements of NFPA 99 and CGA M-1 not only are potentially violating the law, they also may be generating a serious business liability to their companies. In today's litigious society, if an incident were to occur involving a non-compliant hyperbaric medical oxygen system, the system installer/gas supplier would likely be drawn into the center stage of any potential ensuing litigation, in addition to any FDA or regulatory authority action that may ensue.

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