Compliance Matters

Medical Gas Mix-ups Still Haunt Our Industry

By Bob Yeoman, B&R Compliance

In Compliance Matters, Bob Yeoman, President and CEO of B&R Compliance Associates LLC, examines the broad range of compliance management issues affecting companies in the industrial and medical gas industry. Here you'll find insight and information on FDA issues, for which B&R Compliance is well-known, as well as other regulatory management issues affecting readers of *CryoGas International*, including those relating to safety, the environment, transportation, and security.

Beginning in the early1990s, the medical gas industry endured a series of medical mix-ups — including incidents that involved patient fatalities. While medical gas mix-ups have probably been around as long as medical gases themselves, this decade long rash of mix-up events provoked a profound series of changes in the industry. These changes have been highly effective in reducing the number of incidents. However, a recent incident in a dentist office points out that opportunities for medical gas mix-ups still exist. This article examines some of the most common causes of medical gas mix-ups, and steps firms can take to prevent them.

Historically, the majority of medical gas mix-ups have come from connecting the wrong gas to a supply system. The prevention of these types of medical gas mix-ups relies on a system of layered protections designed to ensure the correct product is supplied to patients. For these systems to be reliably effective, both the product manufacturers and the end-users must use them. Medical gas mix-ups have traditionally occurred when one of the parties in the medical gas supply chain circumvented some, or all, of the protections that are in place to prevent these issues.

Preventing medical gas mix-ups starts with a product label. This label is applied to the container by the drug manufacturer. Each container is required to have a product label that denotes the type of gas and (for mixtures) the constituents of the container contents. In the gases industry the label is, and has always been, the primary means of determining gas container contents. Therefore, reading the label is the first and primary layer of protection.

A secondary means of preventing product mix-ups is a standardized system of product-specific outlet connections developed by our industry. By design, these outlet connections on containers of respirable medical gases are different in style than those holding inert gases. The industry foresaw the potential for medical gas mix-ups in its infancy and, through the Compressed Gas Association (CGA), established a system of non-interchangeable connections for different types and classes of gases. These connections are specifically designed to prevent end-users from connecting the wrong gas to their system.

A tertiary third layer of protection, at least for high-pressure cylinders, is the container color. Following an industry/Food and Drug Administration (FDA) meeting it was agreed that the medical gas industry would adhere to the CGA C-9 color code scheme for medical gas cylinders. While this agreement is not an official FDA regulation yet, some states, such as Ohio and Pennsylvania, have already made this a state requirement. In our opinion the agreement between the agency and the medical gas industry to use C-9 is a binding requirement on all firms who fill medical gases in the US today. Compliance with C-9 would also include any customer-owned cylinders filled by a medical gas firm. This means that every medical gas cylinder that your firm fills, whether customer-owned or not, must comply with the CGA C-9 color code requirements.

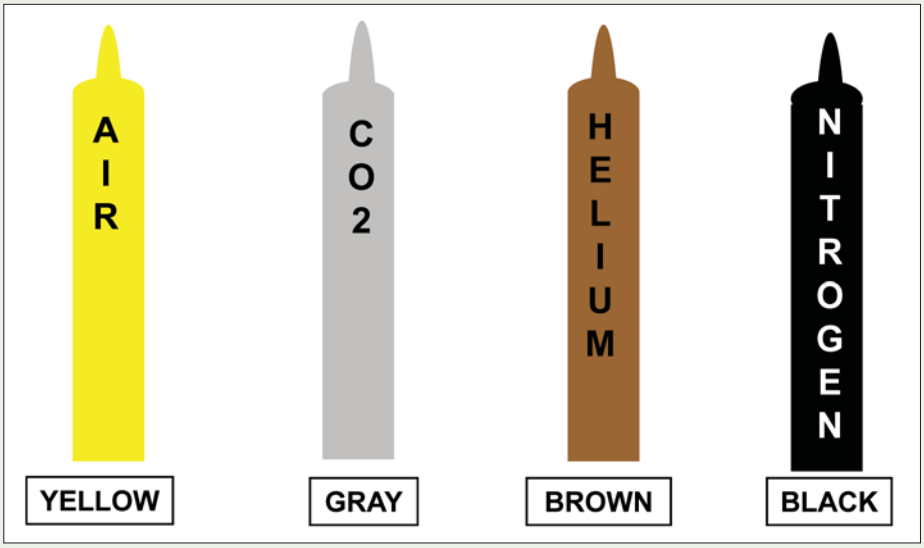
A fourth layer of protection was added for portable liquid cryogenic cylinders in early 2001. The driving force behind this initiative was a number of incidents involving both healthcare facilities and manufacturers/distributors circumventing the product-specific outlet connection system and mistakenly connecting an inert gas to a respirable gas system. Virtually every one of these incidents resulted in patient fatalities. In response to these incidents, the industry adopted the CGA standard SB-26 as a mandatory requirement for medical gas manufacturers. This standard requires that outlet fittings on portable liquid cryogenic cylinders either be permanently brazed in, or be retained with a specialized locking device that cannot be removed by the end-user without destroying the connection. All firms should be following this requirement, which has proven to be a highly effective method in eliminating mix-ups involving cryogenic liquid cylinders. Since adopting this standard there have been no reported incidents of medical gas mix-ups involving portable liquid cryogenic cylinders in the US.

While the industry has made great strides in establishing systems to ensure that the right medical gas gets connected to the proper hose/system connector, this has not completely eliminated the potential for medical gas mix-ups. A recent incident in Kansas, where the oxygen and nitrous oxide systems in a dentist's office were transposed, resulted in a serious and possibly permanent injury to a high school student and points out that the need for diligence and caution still exists.

Early reports on this March 2009 incident appear to indicate that the installer of the Kansas system may have somehow cross connected the oxygen and nitrous oxide systems. This was a new system, and the individual injured was one of the facility's first patients. It also appears that a third party medical gas piping system verifier may not have been hired to assess the system prior to use.

In our opinion, there are a number of safeguards that all firms involved in installing and maintaining medical gas piping and gas delivery systems should be following today.

MEDICAL CYLINDER COLOR CODING



B&R Compliance uses this slide to illustrate how color coding cylinders can improve safety. It is important to note, however, that color coding is an added visual safety reminder and is not meant to replace reading the cylinder label to confirm its contents. Reading the cylinder label is primary to safe-handling cylinder practices. Illustration courtesy of B&R Compliance Associates, LLC.

First, only individuals certified to the American Society of Safety Engineers (ASSE) 6010 standard should be hired to install medical gas piping systems or to perform repairs. (Please note: B&R Compliance has no knowledge that the installers of the Kansas system were not certified to the ASSE standard.) The ASSE 6000 series of standards is a nationally recognized, American National Standards Insitute (ANSI) accredited, professional qualification standard for medical gas system personnel. By hiring ASSE certified installers medical gas firms can be assured those individuals have met a minimum level of training and qualification for medical gas work.

The second precaution we strongly recommend is that a third party medical gas system verifier, one who is certified to the ASSE 6030 standard, be engaged to assess any system that will deliver respirable medical gas. This is especially true where multiple gases are installed at the same facility, and the potential for cross connection/mix-up of the gases exists. While hiring a third party verifier is the accepted practice at most healthcare facilities today, there is no national requirement, and therefore it is not always done in some areas of the country, particularly at facilities such as surgical centers and dentist offices. Even if state or local regulations do not specifically mandate a third-party verification of medical gas systems, we strongly recommend you use a verifier. It is cheap insurance against a potential medical gas mix-up. In our opinion, using a third party verifier for all respirable gas systems is something the industry should consider adopting as a requirement in CGA standards.

Clearly the "commodity mentality" associated with medical gases works against preventing mix-ups. Having medical gases handled by the maintenance department in healthcare facilities — instead of the pharmacy — is one likely factor in past mix-up incidents. However, drug mix-ups have occurred with traditional pharmaceuticals as well. The systems and training programs developed and adopted by the medical gas industry over the past decade have proven very effective at reducing/eliminating human error in mix-up incidents. The prevention of medical gas mix-ups is something our industry will always work toward. One incident is one too many. As manufacturers/distributors of these gases, we must always be on guard. As the Kansas incident clearly illustrates, medical gas mix-ups can pop up when and where you might least expect them.

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