

PROPOSAL FOR USP STANDARDS BASED ON MEDICAL GAS MIX-UPS

DESCRIPTION OF THE PROBLEM:

The proper handling of medical gases has been called into question over the past several years. Numerous incidents resulting in patient harm and even death have been documented since 1996. In most cases, the deaths and injuries occurred to patients who were thought to be receiving medical grade oxygen, but were receiving a different gas (e.g., nitrogen, argon) that had been mistakenly connected to the oxygen supply system. The FDA alert and supplemental information is provided below.

FDA, JCAHO, and USP have received these reports of medical gas mix-ups as follows:

FDA REPORTS AND RECOMMENDATIONS:

The Food and Drug Administration (FDA) received reports during the past 4 years from hospitals and nursing homes involving 7 deaths and 15 injuries to patients who were thought to be receiving medical grade oxygen, but were receiving a different gas that had been mistakenly connected to the oxygen supply system. A copy of the FDA Public Health Advisory is attached.

There were several striking similarities among the FDA reports:

The person connecting the medical gas tank to the oxygen system lacked proper training. When connecting the tank, the untrained employee failed to examine the labels carefully and as a result, selected the wrong cryogenic vessel. The employee was unable to connect the incorrect cryogenic vessel to the oxygen system because of the distinctive valve fittings, so the employee removed the fitting from the incorrect cryogenic vessel and replaced it with an oxygen fitting from an empty oxygen tank. The employee failed to realize that the incompatibility is a built-in safeguard, i.e., that connectors for the oxygen vessels are specially fitted so they are only compatible with oxygen delivery systems.

The Agency recommended that facilities implement the following:

1. If the facility receives medical gas deliveries, it should store medical grade products separately from industrial grade products. The storage area for medical grade products should be well defined with one area for receiving full cryogenic vessels and another area for storing empty vessels.
2. All personnel who will be handling medical gases should be trained to recognize the various medical gas labels. Personnel should be trained to examine all labels carefully.
3. If the supplier uses 360-degree wrap-around labels to designate *medical oxygen*, personnel should be specifically trained to make sure each vessel they connect to the oxygen system bears such a label.
4. All personnel in their facility who are responsible for changing or installing cryogenic vessels must be trained to connect medical gas vessels properly. Personnel should understand how vessels are connected to the oxygen supply system and be alerted to the serious consequences of changing connections.

5. The facility should emphasize repeatedly that the fittings on the vessels should ***not be changed*** under any circumstances. If a cryogenic vessel fitting does not seem to connect to the oxygen supply system fitting, the supplier should be contacted immediately. The vessel should be returned to the supplier to determine the fitting or connection problem.
6. Once a cryogenic vessel is connected to the oxygen supply system, but ***prior*** to introducing the product into the system, a knowledgeable person should ensure that the correct vessel has been connected properly.

JCAHO REPORTS AND RECOMMENDATIONS:

The Joint Commission received two reports of medical gas mix-ups in 2000 that resulted in the death of four patients and injury to five patients. JCAHO issued a *Sentinel Event Alert* (copy attached) to help spread the word to health care organizations about steps that can be taken to prevent deaths and injuries from compressed gases, which include industrial and medical grade gases. JCAHO recommends that organizations address the recommendations with respect to personnel training, equipment and gas storage as listed in the FDA Guidelines.

USP REPORT:

The USP Medication Errors Reporting (MER) Program received a report from a community hospital concerning medical gas tanks that were mislabeled. According to the report, the hospital received four yellow air tanks with air tank fittings (valves) from its supplier that were mislabeled as nitrogen. A respiratory therapist was alerted to the error by the distinctive air valve on the tank. This error did not result in patient harm. At the request of the FDA, USP posted a *Practitioner Reporting News* article (see attached) to alert practitioners about the deaths reported to FDA that included the guidelines issued by FDA.

SUGGESTED ACTIONS:

On June 13, 2001 USP staff met to review possible USP actions to explore with the FDA for standards to reduce the errors associated with medical gas mix-ups. Numerous areas were identified for consideration. A meeting was held on August 28, 2001, with FDA and USP staff.

POSSIBLE USP ACTIONS THAT WERE DISCUSSED INCLUDED:

1. Mandating and documenting in the monographs a color-code system for medical gas containers and connections (see also #2). The system should consider harmonizing the differences in the United States and Canadian recommendations (see attached)
2. Requiring color-coded hookups (perhaps through plastic tabs or rings) on the hospital or nursing home walls where the system connections are made (possibly work with JCAHO/American Society of Healthcare Engineers to achieve this)
3. Through the USP Labeling and Nomenclature committee, explore the possibility of changing the USP labels to read “Medical Oxygen USP,” “Medical Air USP,” “Medical ...USP” Changes should parallel our proposals (e.g., 360 degree tape).

(This would require revising the container and labeling sections of the General Notices.)

4. Requiring a poster or placard posted at the connection site (perhaps in English and Spanish) alerting personnel to the dangers of medical gas mix-ups.
5. Revising the Packaging and Storage sections of the monographs with a view to precluding mix-ups.
6. Revising the existing gas monographs to make the specifications more in line with modern industry practices (the monographs are currently under review).
7. Add information on color coding to an existing general chapter or create a new general chapter.
8. Add to general chapter <661> (Containers) information such as “cryogenic vessels for medical gases should have the following characteristics . . . “ which would include labeling requirements that would apply to all medical gases.

POSSIBLE FDA ACTIONS INCLUDED:

1. FDA regulations (201 series) and guidelines to look for evidence of requirements or recommendations saying that a drug intended for another use, should be so labeled (e.g., “intended for research use only”).
2. CGMP guidance could be developed specifically for gases.
3. Continued work with JCAHO on developing a standard.
4. Continue to develop and distribute education materials. Ask affected organizations to hand out new flier at conferences. This effort has been well received by organization.

In the following table, The Compressed Gas Association, Inc., identifies the color markings for compressed gas containers intended for medical use:

Gas Intended for Medical Use Color	United States	Canada Colour
Oxygen	Green	White ¹
Carbon Dioxide	Gray	Gray
Nitrous Oxide	Blue	Blue
Cyclopropane	Orange	Orange
Helium	Brown	Brown
Nitrogen	Black	Black
Air	Yellow ¹	Black and White
Gas Mixtures (other than Mixtures of oxygen and Nitrogen)	Color marking of mixtures shall be a combination of colors corresponding to each component gas in accordance with 4.3	
Gas Mixtures of Oxygen and Nitrogen:		
19.5% to 28.5% Oxygen	Yellow ¹	Black and White
All other Oxygen Concentrations	Black and Green	Pink

¹ Historically, white has been used in the United States, and yellow used in Canada, to identify vacuum systems. Therefore, it is recommended that white not be used in the United States, and yellow not be used in Canada, as a marking to identify containers for use with any medical gas.