

Medical Gas Mix-ups: FDA Advisory

The US Food and Drug Administration (FDA) issued an advisory bulletin April 6, 2001 on the subject of medical gas mix-ups in healthcare facilities. The bulletin noted a striking similarity linking reports of injuries and deaths in hospitals and nursing homes from medical gas mix-ups over the past four years.

Untrained personnel substituted toxic gases like industrial-grade nitrogen, argon and carbon dioxide for medical oxygen when replacing empty pressurized oxygen cylinders for the facilities' wall-vent oxygen systems.

In each incident, according to the FDA, the person did not understand that the connectors on industrial gas cylinders are deliberately made different than those on medical oxygen cylinders to avoid mix-ups. The untrained person substituted the oxygen regulator from an empty medical oxygen tank for the industrial-type regulator on the industrial gas cylinder, then connected the industrial gas to the facility's oxygen supply.

The FDA's Recommendations

Medical gas products should be stored separately from industrial-grade gases. In the space for medical products there should be a separate area defined for full tanks and one for

empties.

All personnel who handle medical gases should be trained to recognize medical gas labels and to examine them carefully.

If the supplier uses 360-degree wrap-around labels for medical oxygen, personnel should be trained to make sure each cylinder they connect to the oxygen system has such a label.

All personnel who re-connect gas cylinders should be trained to do it properly and should be alerted to the serious consequences of doing it improperly. All personnel should be taught that the fittings on gas cylinders should never be changed. If a fitting does not seem to work properly, the supplier should be contacted and, if necessary, the cylinder should be returned to the supplier to obtain a proper fitting rather than being changed in-house at the facility.

After a cylinder has been connected, and before gas is introduced into the facility's wall-vent system, a knowledgeable person should double-check to see that the right gas cylinder has been used and connected properly.

Go to <http://www.fda.gov/cder/guidance/index.htm> for more information.

FEDERAL REGISTER, April 6, 2001
Page 18257

Urine Leak From Foley System: Injury Lawsuit From Family Member's Fall On Wet Floor In ICU.

The Court of Appeal of Louisiana awarded a family member \$7,710 from the hospital. She fell because the floor was slippery from urine which leaked from a Foley system in the ICU.

The family member, the patient's fourteen year-old granddaughter, had been treated in the hospital's own E.R. at no charge to her, but still had \$710 in medical bills at her own doctor's office. Her pain and suffering for a low back strain was valued at \$7,000.

The court discounted the patient's nurse's testimony that the Foley system is a closed system. That is, the tube from the patient's catheter leads to a metering container that permits the nurse to monitor urine output over time, and that connects directly to a urine collection bag.

Whenever a Foley catheter is in use, it is foreseeable that liquid may leak onto the floor and cause a visitor to slip and fall.

From the ICU nurse's station the nurse could only see one side of the patient's bed.

However, the Foley drainage tubes, urine metering container and collection bag were on the other side, the side of the bed the nurse could not see.

COURT OF APPEAL OF LOUISIANA, 2000.

Twenty minutes after the fall was reported the nurse did find a small amount of urine on the floor. She admitted it in her statement to a hospital loss control investigator and also in her court testimony.

The family member's mother reported the urine on the floor to the nurse when she reported the fall.

The law makes it difficult for any owner of business premises to defend a slip-and-fall case filed by a business patron when there is a foreign substance on the floor of the business.

The same general rule applies to hospitals. Patients and visiting family members are considered to be the hospital's business patrons. ***Mosley v. Methodist Health System Foundation, Inc., 776 So. 2d 21 (La. App., 2000).***