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Explosions and Fires in Aluminum Oxygen Regulators

FDA And NIOSH Public Health Advisory: Explosions and Fires in Aluminum Oxygen Regulators (You are encouraged to copy and distribute this Advisory)

February 1999

To: Fire Departments
Safety Directors
Biomedical Engineers
Nursing Homes
Emergency Transportation Services

Rescue Squads
State EMS Systems
Hospital Administrators
Home Health Care Agencies
Risk Managers

This notice is to advise you of hazards with oxygen regulators made of aluminum and to provide recommendations regarding these devices.

THE PROBLEM

Over the past 5 years, FDA has received 16 reports of aluminum regulators used with oxygen cylinders burning or exploding. These incidents caused severe burns to 11 health care workers and patients. Many of the incidents occurred during emergency medical use or during routine equipment checkout. FDA and The National Institute for Occupational Safety and Health (NIOSH) believe that the aluminum in these regulators was a major factor in both the ignition and severity of the fires, although there are likely other contributing factors. Most of the reports received by FDA were for the Model L270 series of aluminum regulators manufactured by Life Support Products Inc. and Allied Healthcare Products Inc. (Earlier models were known as "270" regulators.)

Allied Healthcare Products currently has 60% of the market share of oxygen regulators for emergency use. The manufacturer has plans to cease the distribution of all regulators containing aluminum and solely manufacture brass regulators. In an effort to avoid potential product shortages, Allied is instituting an interim measure wherein they will replace internal high-pressure aluminum components with brass components in all models manufactured.

Because aluminum is lighter in weight than steel, it is also used in oxygen cylinders. FDA and NIOSH believe that aluminum cylinders can be used safely with brass regulators, but that the combination of both oxygen regulators and cylinders made from aluminum poses an increased fire

hazard. Contamination of the oxygen supply with particulate matter can also increase the risk of fire.

BACKGROUND

Most oxygen regulators are made of brass or aluminum. Aluminum and its alloys are more likely to ignite than brass. In standard tests, aluminum can burn vigorously at pressures as low as 25 pounds per square inch (psi), while brass does not burn at pressures below 10,000 psi. Although there are rare instances of fires in brass oxygen regulators, they have a long history of safe use and are believed to be safer than aluminum oxygen regulators for use with high pressure compressed oxygen. FDA has no reports of fire or explosion with aluminum oxygen regulators used in low pressure systems (e.g., piped distribution to wall mounted supply taps at <50 psi).

RECOMMENDATIONS

FDA is pursuing plans to work with manufacturers to improve the safety of oxygen regulators and restrict the use of aluminum exposed to high-pressure oxygen in regulators. In the meantime, FDA and NIOSH advise that the following precautions be taken to avoid explosions and fires from oxygen regulators containing aluminum:

- If you are presently using high pressure oxygen regulators which contain any aluminum exposed to high-pressure oxygen, replace them with regulators made of brass. Consult the manufacturer if you don't know what material is used in your regulators.
- If non-aluminum oxygen regulators are not available, it is recommended that you follow the precautions as described in the addendum to this advisory to minimize the risk of fires until brass replacement regulators become available.

REPORTING ADVERSE EVENTS TO FDA

The Safe Medical Devices Act of 1990 requires hospitals and other user facilities to report deaths, serious illnesses, and injuries associated with the use of medical devices. Questions about mandatory reporting can be answered by the Division of Surveillance Systems, Reporting Systems Branch by phone on (301) 594-2735 or FAX, (301) 827-0038 or write to FDA, CDRH, MDR User Reporting, P.O. Box 3002, Rockville, MD 20847-3002. Written reports will go into FDA's MDR data base. Submit voluntary reports directly to the FDA's voluntary reporting program, MedWatch; by telephone at (800) FDA-1088, by FAX at (800) FDA-0178, or by mail to: MedWatch, Food and Drug Administration (HFA-2), 5600 Fishers Lane, Rockville, MD 20857-9787.

GETTING MORE INFORMATION

Send questions about this Public Health Advisory to the Issues Management Staff, Office of Surveillance and Biometrics, HFZ-510, 1350 Piccard Drive, Rockville, Maryland, 20850, FAX (301) 594-2968, or e-mail ssm@cdrh.fda.gov or aag@cdrh.fda.gov. You may photocopy or print this notice from the CDRH homepage at www.fda.gov/cdrh/safety.html.

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Sincerely yours,

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Safe Practices for Handling and Operating Oxygen Equipment

Oxygen used in the medical profession can be very hazardous. Although oxygen does not burn, it does support combustion. A material which will not burn in air may burn in high pressure pure oxygen - such as the metal in oxygen regulators or cylinders. Comprehensive guidelines and training on safe practices for handling oxygen are available from several sources listed at the end of this section. Some general guidelines for minimizing the chance of fire are provided below:

Storage, Maintenance and Handling:

- Do not allow smoking around oxygen.
- Store oxygen in clean, dry locations away from direct sunlight.
- Do not allow post valves, regulators, gauges, and fittings to come into contact with oils, greases, organic lubricants, rubber or any other combustible substance.
- Make sure that any cleaning, repair or transfilling of oxygen equipment is performed by qualified, properly trained staff.
- Do not work on oxygen equipment with ordinary tools. Designate special tools, clean them and store them for Use With Oxygen Equipment Only.
- Ensure that any components added to the regulator, e.g., gauge guards, are installed so that they do not block the regulator vent holes.
- Use plugs, caps and plastic bags to protect "off duty" equipment from dust and dirt.
- Particulate migration from the cylinder can be minimized by the installation of a standoff tube (bayonette) at the inlet of the post valve.

Use:

- Make sure that staff using oxygen equipment are adequately trained in its operation and in oxygen safety and have knowledge of manufacturers instructions for using the equipment.
- Visually inspect the post valve gasket and regulator inlet prior to installation. If they are not visually clean they should not be used.
- Momentarily open and close ("Crack") the post valve to blow out debris prior to installing a

regulator.

- Ensure that the regulator is set with the flow knob in the off position before attaching it to the cylinder.
- Position the equipment so that valve is pointed away from the user and any other persons.
- Open the cylinder valve slowly and completely to minimize the heat produced and achieve the desired flow conditions within the equipment.
- Do not look at the regulator pressure gauge until the cylinder valve is fully opened.

Additional information, guidance and training regarding oxygen and fire safety can be obtained from a number of sources, including the following organizations:

- Compressed Gas Association, 1725 Jefferson Davis Highway, Suite 1004, Arlington, VA 22202-4102 (www.cganet.com)
- National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269-9101 (www.nfpa.org)
- American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959 (www.astm.org)
- Centers for Disease Control and Prevention National Institute for Occupational Safety and Health, Division of Safety Research. **Oxygen Regulator Flash Severely Burns One Fire Fighter - Florida**, Report Number 98-F23. This report is available on the NIOSH homepage at: (www.cdc.gov/niosh/firehome.html).

Updated February 4, 1999

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