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HEADLINE: Officials Warn of Hazards of Aluminum Oxygen Regulators

The FDA and the National Institute for Occupational Safety and Health (NIOSH) have issued a public health advisory to highlight the hazards of oxygen regulators made of aluminum, amid mounting concerns about explosions and fires in these devices.

Over the past 5 years, the FDA has received 16 reports of aluminum regulators used with oxygen cylinders burning or exploding. These incidents caused severe burns to 11 healthcare workers and patients. Many of the incidents occurred during emergency medical use or during routine equipment checkout. The organizations say that they believe the aluminum in these regulators was a major factor in the ignition and severity of the fires, although there are probably 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.

Last week, Allied announced that it is recalling all oxygen regulators sold under the Life Support Products brand to replace aluminum components in the units' high-pressure chambers with brass components. In a statement, the company said its actions were prompted by reports of fires and explosions, "the exact causes of which remain unknown." The models subject to the recall consist of the LSP 106, LSP 270, LSP 280, LSP 370 and LSP 735 series regulators. Users of the LSP oxygen regulators, which include fire departments and emergency medical services units, will be able to have the parts replaced at pre-existing authorized service centers nationwide. Allied said that the recall is being undertaken in cooperation with FDA to minimize the potential for fires and explosions, an inherent risk with any high-pressure oxygen delivery system

Allied said in a statement, "Due to industry-wide fires and Allied's understanding that the FDA is recommending the elimination of all aluminum in oxygen regulators, Allied has voluntarily initiated the recall to replace all aluminum high-pressure parts with brass parts. This is strictly an interim measure that will enable the regulators to be used during the period required to manufacture the new brass regulators."

Because aluminum is lighter in weight than steel, it is also used in oxygen cylinders, the FDA and NIOSH explained. The two organizations believe that aluminum cylinders can be used safely with brass regulators, but that combining both oxygen regulators and cylinders made from aluminum poses an increased fire hazard. Contaminating the oxygen supply with particulate matter can also increase the

risk of fire. Most oxygen regulators are made of brass or aluminum. However, 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 thought to be safer than aluminum oxygen regulators for use with high pressure compressed oxygen. The 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).

The FDA says it 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, the two organizations advise that the following precautions be taken to avoid explosions and fires from oxygen regulators containing aluminum:

If you are currently 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 aren't available, it is recommended that you follow precautions to minimize the risk of fires until brass replacement regulators become available.

General guidelines for handling and operating oxygen equipment can be accessed via the FDA web site, http://www.fda.gov/cdrh/oxyreg.html.

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