

# STATE OF CONNECTICUT

## DEPARTMENT OF PUBLIC HEALTH




Renée D. Coleman-Mitchell, MPH  
Commissioner

Ned Lamont  
Governor  
Susan Bysiewicz  
Lt. Governor

HEALTHCARE QUALITY AND SAFETY BRANCH

### BLAST FAX 2019-11

**TO:** Hospitals, Nursing Homes, RHNS, ASCs, Outpatient Clinics, Family Planning Clinics, Inpatient Hospice

**FROM:** Donna Ortelle, R.N., M.S.N.   
Section Chief  
Facility Licensing and Investigations Section

**DATE:** July 23, 2019

**SUBJECT:** LSP Oxygen Regulator Recall

---

It has come to our attention that there are some facilities and ambulance services that are still using LSP aluminum oxygen regulators that were recalled in 1999 due to risk for fires and explosions.

The National Institute for Occupational Safety and Health (NIOSH) has determined that aluminum body regulators used in high-pressure oxygen systems are at risk for fires and explosions. The NIOSH report recommends immediately replacing all aluminum regulators used in high-pressure oxygen systems with brass regulators. Flash fires can result from friction and heat generated by particle impact during the release of high-pressure oxygen flowing through the aluminum regulator. The fires can start in aluminum oxygen regulators at pressures as low as 25 pounds per square inch (psi), while brass regulators will not ignite at pressures below 10,000 psi.

Please see the attached article and contact the Allied Healthcare Products (contact information is in the attachment) with any specific questions.



Phone: (860) 509-7400 • Fax: (860) 509-7543  
Telecommunications Relay Service 7-1-1  
410 Capitol Avenue, P.O. Box 340308  
Hartford, Connecticut 06134-0308  
[www.ct.gov/dph](http://www.ct.gov/dph)

*Affirmative Action/Equal Opportunity Employer*



# LSP Oxygen Regulator Recall

The National Institute for Occupational Safety and Health (NIOSH) has determined that aluminum body regulators used in high-pressure oxygen systems are at risk for fires and explosions. The NIOSH report recommends immediately replacing all aluminum regulators used in high-pressure oxygen systems with brass regulators. Flash fires can result from friction and heat generated by particle impact during the release of high-pressure oxygen flowing through the aluminum regulator. The fires can start in aluminum oxygen regulators at pressures as low as 25 pounds per square inch (psi), while brass regulators will not ignite at pressures below 10,000 psi.

At the IAFF's request, NIOSH initiated an investigation in July 1998 to review the oxygen regulator fire that resulted in severe burns to a member of IAFF Local 3333 Broward County, FL. The NIOSH investigation also included technical experts from the FDA, the National Aeronautic and Space Administration (NASA), as well as additional outside experts. There have also been oxygen regulator fires in numerous IAFF locals: Austin, TX Local 975; Houston, TX Local 341; Greeley, CO IAFF Local 888.; Springfield, OR IAFF Local 1395; Gurnee, IL IAFF Local 3598; and most recently in Oak Creek, WI Local 1848; and Truckee Meadows, NV Local 2487. The FDA is aware of at least 16 explosions in the past five years. Every aluminum regulator used on high-pressure oxygen cylinders has the potential to ignite a flash fire.

## Prompting the Investigation

In 1996, IAFF Local 341 informed the IAFF of an oxygen regulator that flashed in Houston, Texas. The IAFF assisted the local and the fire department in reporting this incident to the Food and Drug Administration, which has jurisdiction over this product as a medical device. Soon after, the IAFF was informed of a similar incident in Greeley, Colo. The IAFF met with the IAFF local affiliate to determine if this was an isolated incident or a problem inherent with a specific manufacturer's resuscitator.

Soon after the IAFF heard of a similar incident in Austin, Texas, the IAFF again contacted the FDA and requested an investigation. Again, the IAFF was told that an investigation had to be initiated by the device's owner. The IAFF asked if similar incidents had occurred, and was informed that they do not provide this information. In April 1997, the IAFF requested copies of all reports, MedWatch complaints, FDA directives, inspections, and any other information related to Life Safety Products' (LSP) or any other manufacturer's oxygen regulators utilized on emergency resuscitation oxygen tanks from January 1, 1995. This request was made through the Freedom of Information Act.

The IAFF finally received the information from FDA, but all the information was on microfiche--the only way they claimed they could provide this information. The IAFF had to have all the film then printed. A review of the information revealed that most, if not all of the 1,000s of pages failed to any useful information. The information was essentially page after page of computer printout of complaints about resuscitators. The files did not contain investigative reports or recall notices. The printouts also involved all oxygen resuscitator companies, not just LSP.

In May 1997, Allied Healthcare Products issued a "recall" of oxygen regulator model L270-020 and L270-050. The "recall" was really a notice to retrofit existing aluminum regulators with a sintered brass mesh screen to filter out contaminants.

### Getting the Word Out

Upon learning of Broward County, Fla., fire, the IAFF published a notice of the manufacturer's "recall" in the IAFF Leader, which is sent to all IAFF local affiliate presidents. Additionally, the recall notice and the FDA investigation form were placed on the IAFF web site. Likewise, an article on the issue was in the International Firefighter, which is distributed to all IAFF members. In fact, the LSP "recall" was not a product recall, but an alert for users to keep oxygen cylinders and regulators clean and an offer for a replacement inlet filter to improve the resistance of the regulator to contamination. Neither Allied Healthcare Products or the FDA directed the products to be removed from service nor were any regulators "recalled."

Specific to the LSP regulators and their "recall," the IAFF asked that NIOSH provide technical assistance to the IAFF by investigating this incident. The IAFF does not believe that the FDA has conducted a proper evaluation of the failures of this device in the field in any of the locations reported to the IAFF (Austin, Broward County, Greeley, Houston, Oak Park, or Truckee Meadows). It is obvious to the IAFF that FDA's alliance is with the medical device companies and not the user of the product. Unlike NIOSH, the FDA relies solely on the manufacturer's investigation and the resulting recommendations or "recalls."

On February 4, 1999, Allied Healthcare Products issued a new "recall" to replace its LSP aluminum oxygen regulators with brass regulators. This is a voluntary action by the manufacturer and not mandated by FDA. Furthermore, the "recall" only affects LSP regulators, approximately 60 percent of the high-pressure oxygen regulator market. The FDA has done nothing to ensure that the remaining manufacturer's regulators will be recalled.

**In light of the NIOSH report, the IAFF immediately sent a letter to the Food and Drug Administration (FDA) demanding a full recall of all aluminum body regulators used in high-pressure oxygen cylinders. Furthermore, the IAFF demanded that the FDA require each manufacturer to contact each regulator owner, document the contact, and provide the retrofit brass regulators at no cost to the owners.**

IAFF members should immediately check the high-pressure oxygen regulators owned by their fire department. **All aluminum regulators must be replaced with brass regulators.** Until the aluminum regulators are replaced, the NIOSH and FDA report has made interim recommendations.

Allied Healthcare Products, manufacturer of LSP regulators, has agreed to replace the aluminum regulators with brass regulators. If a different company manufactures the aluminum regulators, fire departments should contact that company or the distributor from whom they bought the regulator. Fire departments should demand that the aluminum regulators be replaced with brass. Fire Departments can contact the Allied Healthcare Products recall coordinator at:

LSP Regulator Recall Center  
Allied Healthcare Products, Inc.  
1720 Sublette Blvd.  
St. Louis, MO 63110  
(800) 231-5273  
(Monday through Friday 8 a.m.-5 p.m. CST)  
(888) 216-4624 (fax)

For more information please contact the IAFF's Department of Occupational Health and Safety.

### What You Can Do

#### Oxygen Regulator Storage, Maintenance and Handling

- Prohibit smoking around oxygen.
- Store oxygen cylinders in an upright position.
- Store oxygen in clean, dry locations away from direct sunlight.
- Prevent post valves, regulators, gauges, and fittings from contacting 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.
- Minimize particulate migration from the cylinder by installing a standoff tube (bayonet) at the inlet of the post valve.

### Oxygen Regulator Use

- Replace aluminum regulators with oxygen regulators constructed of materials having oxygen compatibility at least equivalent to brass.
- Make sure that staff using oxygen equipment are adequately trained in its operation and in oxygen safety, and have knowledge of manufacturer's 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.