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PUBLIC HEALTH ALERT

Filling of Oxygen Cylinders and Aluminum Regulators in High-Pressure Oxygen Systems June 1999

Filling of Oxygen Cylinders

In November 1996, the New Jersey Department of Health and Senior Services (NJDHSS) and the New Jersey Department of Community Affairs (DCA) sent out a Public Health Alert on Self-Contained Breathing Apparatus Cylinder Failure to all fire departments in the state.

The NJDHSS's Public Employees Occupational Safety and Health (PEOSH) Program is now **extending** this alert to oxygen cylinders since they can be made of the same materials, subject to the same high pressure as SCBA cylinders, and re-filled in a similar manner.

In addition, on July 26, 1994, the Federal Department of Transportation issued a safety advisory notice on High Pressure Aluminum Seamless and Aluminum Composite Hoop-Wrapped Cylinders.

Since July 1996, there have been two catastrophic failures of self-contained breathing apparatus (SCBA) cylinders in New Jersey. The first occurred in Morris County, and resulted in severe injuries to a firefighter. The second occurred in Somerset County, and also resulted in injuries to a firefighter. These injuries occurred while the SCBA cylinders were being filled.

It is important to note that in both of these incidents, the SCBA cylinders were being filled from cascade systems that were not equipped with pressure regulators or fragmentation shields.

At a minimum, the person filling the oxygen cylinders must receive training, and the cascade system must be equipped with facilities to ensure the safety of the cascade station operator and nearby personnel.



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Training must include:

- the procedure for inspecting the oxygen cylinder for damage prior to re-filling,
- information to ensure that the cylinder has the proper hydrostatic test date,
- information to ensure that composite cylinders older than 15 years are not re-filled and are removed from service,
- the procedure for safely operating the cascade system, and
- information on the consequences of cylinder failure.

The cascade system must be equipped with:

- an adjustable pressure regulator,
- a regulated pressure gauge,
- an inlet pressure gauge,
- a fill control valve,
- isolation valves (for cascade filling),
- fill hose with bleed valves, and
- a fragmentation shield that would contain the cylinder in the event of failure.

If a cylinder is found empty and it is not known how it was emptied DO NOT REFILL the cylinder until it is determined that the cylinder can be safely refilled. It is possible that the cylinder has a flaw that caused the cylinder to leak.

In addition, the attached DOT Safety Advisory should be followed. The precautionary measures outlined in this Safety Advisory should be implemented. These precautionary measures include:

- determine if the first aid squad has any cylinders made of aluminum alloy 6351-T6. For aid in determining whether a cylinder is made of aluminum alloy 6351-T6, contact the cylinder manufacturer or distributor,
- do not overfill a cylinder to greater than marked service pressure,
- do not fill or use a cylinder that is beyond its required retest date, and
- inspect the interior of any cylinder made of aluminum alloy 6351-T6 for cracks in the neck and shoulder area. Any evidence of a crack or crack-like defect may require further evaluation.

This alert should be posted by the cascade filling area and a copy of this alert provided to personnel responsible for filling oxygen cylinders.

Aluminum Regulators in High-Pressure Oxygen Systems

In February 1999 the Food Drug Administration (FDA) and the National Institute for Occupational Safety and Health issued a joint Public Health Advisory entitled Explosions and Fires in Aluminum Oxygen Regulators.

Over the past 5 years, FDA has received 16 reports of aluminum regulators used with oxygen cylinders burning or exploding. Most of the reports received by the FDA were for Model L270 series of aluminum regulators manufactured by Life Support Products Inc. and Allied Healthcare

Products Inc. (Earlier models were known as 270 regulators.)

FDA is pursuing plans to work with manufactures 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 explosion 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 the FDA and NIOSH Public Health Alert to minimize the risk of fires until brass replacement regulators become available.

If you have any questions concerning this alert, please call the PEOSH Program at (609) 984-1863.

Attachments: RSPA Safety Alert: SCBA Cylinders
FDA and NIOSH Public Health Advisory: Explosions and Fires in Aluminum Oxygen Regulators

Other documents which are available from the PEOSH Program include: Bloodborne Pathogen Standard, Model Exposure Control Program for Bloodborne Pathogens, Tuberculosis Requirements, Model Tuberculosis Infection-Control Program, Respiratory Protection Standard, and Respiratory Protection Standard for *M. tuberculosis*.

For information on how to obtain these documents or for other information, contact the PEOSH Program at (609) 984-1863 or visit us at www.state.nj.us/health/eoh/peoshweb.

[Federal Register: July 26, 1994]

DEPARTMENT OF TRANSPORTATION
Research and Special Programs Administration
[Notice No. 94-7]

Safety Advisory; High Pressure Aluminum Seamless and Aluminum Composite
Hoop-Wrapped Cylinders

AGENCY: Research and Special Programs Administration (RSPA), DOT.

ACTION: Safety advisory notice.

SUMMARY: RSPA is aware of ruptures involving two DOT-3AL cylinders made of aluminum alloy 6351-T6. Cylinder ruptures pose a risk of death, serious personal injury, and property damage. The purpose of this notice is to advise owners of certain cylinders made of aluminum alloy 6351-T6 to follow the precautionary measures outlined in this notice. RSPA also seeks information on ruptures involving other cylinders made of aluminum alloy 6351-T6.

FOR FURTHER INFORMATION CONTACT: Charles H. Hochman or Gopala K. Vinjamuri, telephone (202) 366-4545, Office of Hazardous Materials Technology, Research and Special Programs Administration, U.S. Department of Transportation, 400 Seventh Street SW, Washington, DC 20590-0001. Office hours are: 8:30 a.m. to 5 p.m., Monday through Friday, except holidays.

SUPPLEMENTARY INFORMATION: RSPA has been notified of the rupture of two DOT-3AL aluminum cylinders made of aluminum alloy 6351-T6. The first cylinder rupture occurred in Deer Park, Texas. This cylinder was manufactured in 1977 and was part of a self-contained breathing apparatus (SCBA) unit. It ruptured while being filled to its marked service pressure of 2216 pounds per square inch gauge (psig). The second cylinder rupture occurred in North Miami, Florida. This cylinder was manufactured in 1982 and was part of a self-contained underwater breathing apparatus (SCUBA) unit. It ruptured while being filled to its marked service pressure of 3000 psig. The person filling the SCUBA cylinder sustained serious injury. In both ruptures, a piece of the cylinder neck separated from the cylinder.

RSPA estimates that approximately seven million cylinders have been manufactured using aluminum alloy 6351-T6. RSPA presently does not know which cylinders among this population have the potential for similar failure. Cylinders made of aluminum alloy 6351-T6 are known to be susceptible to sustained load cracking (SLC) in the neck and shoulder area of the cylinder. Extensive research, testing and analysis have been performed on cylinders made of aluminum alloy 6351-T6 to determine any correlation between SLC and

the probability of rupture. Findings indicated that cylinders with a marked service pressure below 4000 psig failing due to SLC would leak and not rupture. Present data are inconclusive as to why the two cylinders noted here ruptured instead of leaked. RSPA is continuing to investigate the incidents.

Aluminum cylinders are widely used in industrial, medical, SCUBA and SCBA services. Aluminum alloy 6351-T6 has been used in the manufacture of the following DOT high pressure cylinders:

1. Cylinders (seamless aluminum) marked "DOT 3AL", including those marked with "DOT 3AL" above or near one of the following exemption or special permit numbers:

6498

7042

8107

8364

8422

2. Composite cylinders (aluminum-lined with hoop-wrapped, fiber-reinforced plastic) marked with one of the following exemption numbers:

7235

8023

8115

To RSPA's knowledge, no cylinders have been manufactured under the exemption or special permit numbers listed above, except DOT-E 7235, since 1984. Any cylinder marked with one of these exemption or special permit numbers most likely is made of aluminum alloy 6351-T6. (DOT-E 7235 cylinders are discussed more fully below.) If in doubt, contact the cylinder manufacturer or distributor to identify the material of construction.

The primary domestic manufacturers of DOT-3AL cylinders currently in service are Luxfer USA; Walter Kidde Co.; Cliff Impact Division of Parker Hannifin Corporation; and Catalina Cylinders, a division of Aluminum Precision Products Inc. Luxfer USA is the only manufacturer of DOT-E 7235 cylinders. Between 1987 and 1989, Luxfer USA discontinued using alloy 6351-T6 and changed to alloy 6061-T6 for DOT-3AL cylinders and DOT-E 7235 cylinder liners. Cylinders manufactured from alloy 6061-T6 are not believed to be susceptible to SLC; therefore, they are not subject to this advisory notice. According to Luxfer USA data, the following types of cylinders stamped as manufactured by Luxfer USA before the dates indicated below likely are made from alloy 6351-T6.

DOT	Service and type cylinder	Part no.	Date mfd.
CO²			
Spec. 3AL.....	1.2 and 1.5 lb.....	C1.2, C1.5	1-89
Do.....	2.18 lb.....	C2-18	11-88
Do.....	10 lb.....	C10	8-88
Do.....	5 lb.....	C5	6-88
Do.....	15 lb.....	C15	11-87
Do.....	20 and 35 lb.....	C20, C35	4-88
Do.....	50 lb.....	C50	2-88
SCBA			
Do.....	7, 8 and 13 cu. ft.....	L7, L8, L13	9-87
Do.....	13.3 cu. ft.....	L13-30	5-88
Do.....	15 cu. ft.....	L15	1-89
Do.....	26 cu. ft.....	L26	2-88
Do.....	45 cu. ft.....	L45	11-87
SCUBA			
Do.....	30 and 63 cu. ft.....	S30, S63	5-88
Do.....	40 cu. ft.....	S40	6-88
Do.....	50 and 92 cu. ft.....	S50, S92	4-88
Do.....	72 and 100 cu. ft.....	S72, S100	8-87
Do.....	80 cu. ft.....	S80	1-88
Do.....	80.8 cu. ft.....	S80.8	5-87
Medical O1			
Do.....	C.....	M9	1-88
Do.....	D and E.....	MD, ME	12-87
Industrial			
Do.....	22 and 150 cu. ft.....	N22, N150	5-88
Do.....	33 cu. ft.....	N33	11-88
Do.....	60 and 122 cu. ft.....	N60, N122	12-87
Do.....	88 cu. ft.....	N88	12-88
Do.....	Service Pressures 2016 and 3000 psig.....		8-89
E-7235.....	Service Pressure 4500 psig.....		See below.

All Walter Kidde DOT-3AL cylinders, of which production ceased in January 1990, are made of alloy 6351-T6. Cliff Impact DOT-3AL cylinders were made from alloy 6351-T6 before July 1990, at which time Cliff Impact changed to alloy 6061-T6. Catalina Cylinders did not produce any DOT-3AL cylinders from alloy 6351-T6; therefore, cylinders manufactured by Catalina are not subject to this notice.

Until determined otherwise, any DOT-3AL or DOT-E 7235 cylinder should be assumed to be made of alloy 6351-T6, if it was:

1. Manufactured by Luxfer USA before the applicable date listed in the chart above;
2. Manufactured by Cliff-Impact before July 1990;
3. Manufactured by any other company in the United States, excluding Catalina, before February 1990; or
4. Manufactured outside the United States.

For aid in determining whether a cylinder is constructed with alloy 6351-T6, contact the cylinder manufacturer or distributor. RSPA will provide further information as it becomes available.

Any person who owns, uses, fills or retests an affected cylinder should take the following precautions:

1. Do not fill the cylinder to greater than the marked service pressure, except during a hydrostatic test.
2. Do not fill a cylinder that is beyond its required retest date.
3. Do not use a SCUBA or SCBA cylinder that is beyond its required retest date.
4. Whenever you remove the cylinder valve, visually inspect the interior of the cylinder neck and shoulder area for cracks.

Any evidence of a crack or crack-like defect may require further evaluation. Contact the cylinder retester, distributor or manufacturer for the procedure to be used in performing the visual inspection and for rejection criteria. For guidance on inspecting Luxfer USA cylinders, contact Luxfer USA Limited, Customer Service Department, PO Box 5300, Riverside CA 92517, telephone (909) 684-5110.

RSPA wishes to reiterate two previous advisories it has issued regarding DOT-E 7235 cylinders. On August 15, 1985, RSPA published an exemption-related notice [Notice 85-4, 50 FR 32944] to alert users that any cylinder marked DOT-E 7235, with a service pressure of 4500 psig and not equipped with a neckring was required to be removed from service by October 1, 1985. On March 24, 1993, RSPA published a safety advisory notice [Notice 93-8, 58 FR 15895] after being notified of the rupture of a cylinder authorized under DOT-E 7235 that had not been fitted with a neckring. Cylinders properly fitted with the required neckring are not susceptible to rupture. That notice stated in part:

Persons finding cylinders without the required neckring should immediately take the following precautions.

1. If a cylinder has been filled, its entire contents should be vented in order to relieve internal pressure.
2. The vented cylinders should be segregated from all other cylinders by being placed in a secured area and marked conspicuously with a tag bearing the notation "Do Not Use" or similar warning.
3. Under no circumstances should any of the cylinders in question be sold or otherwise transferred, filled, refilled or used for any purpose.

Once the above procedures have been taken, persons finding cylinders without neckrings should contact the company, or distributor from whom they were purchased, for their disposition.

Any person who is aware of the rupture of any DOT-3AL cylinder or any other cylinder manufactured from aluminum alloy 6351-T6, whether the incident was domestic or foreign, is requested to contact RSPA as soon as possible.

Issued in Washington, DC on July 20, 1994.

Alan I. Roberts, Associate Administrator for Hazardous Materials Safety.

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FOR IMMEDIATE RELEASE

February 1999

FDA AND NIOSH PUBLIC HEALTH ADVISORY: EXPLOSIONS AND FIRES IN ALUMINUM OXYGEN REGULATORS

(You are encouraged to copy and distribute this Advisory)

Manufacturer's press release

To: Fire Departments	Rescue Squads
Safety Directors	State EMS Systems
Biomedical Engineers	Hospital Administrators
Nursing Homes	Home Health Care
Emergency Transportation	Agencies
Services	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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D. Bruce Burlington, M.D.
Director, Center for Devices
and
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Nancy Stout, Ed. D.
Director, Division of Safety
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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

Last Updated: February 19, 1999

Mr. [redacted] has consented to the

- [illegible]

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1. The Commission has received information from the public that the Commission's current procedures for handling complaints are not adequate to ensure the timely and effective resolution of complaints. The Commission is currently reviewing the procedures and will report to the public on the results of the review.

- [illegible]