

U.S. Fire Administration/Technical Report Series

Special Report: Fires Involving Medical Oxygen Equipment

USFA-TR-107/March 1999



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U.S. Fire Administration Fire Investigations Program

The U.S. Fire Administration develops reports on selected major fires throughout the country. The fires usually involve multiple deaths or a large loss of property. But the primary criterion for deciding to do a report is whether it will result in significant “lessons learned.” In some cases these lessons bring to light new knowledge about fire--the effect of building construction or contents, human behavior in fire, etc. In other cases, the lessons are not new but are serious enough to highlight once again, with yet another fire tragedy report. In some cases, special reports are developed to discuss events, drills, or new technologies which are of interest to the fire service.

The reports are sent to fire magazines and are distributed at National and Regional fire meetings. The International Association of Fire Chiefs assists the USFA in disseminating the findings throughout the fire service. On a continuing basis the reports are available on request from the USFA; announcements of their availability are published widely in fire journals and newsletters.

This body of work provides detailed information on the nature of the fire problem for policymakers who must decide on allocations of resources between fire and other pressing problems, and within the fire service to improve codes and code enforcement, training, public fire education, building technology, and other related areas.

The Fire Administration, which has no regulatory authority, sends an experienced fire investigator into a community after a major incident only after having conferred with the local fire authorities to insure that the assistance and presence of the USFA would be supportive and would in no way interfere with any review of the incident they are themselves conducting. The intent is not to arrive during the event or even immediately after, but rather after the dust settles, so that a complete and objective review of all the important aspects of the incident can be made. Local authorities review the USFA’s report while it is in draft. The USFA investigator or team is available to local authorities should they wish to request technical assistance for their own investigation.

This report and its recommendations were developed by USFA staff and by Varley-Campbell & Associates, Inc. Miami and Chicago, its staff and consultants, who are under contract to assist the Fire Administration in carrying out the Fire Reports Program.

The U.S. Fire Administration greatly appreciates the cooperation received from Chief Tim McGrath and Chief Fred Friedl, III of the Gurnee Fire Department; Chief Bill Martin of the Union Colony Fire/Rescue Authority; Captain Kent Berg of the Greenville County Emergency Medical Service; David Wuertz of the Austin Emergency Medical Services; Chief Gerald Hammernik of the Oak Creek Fire Department; John Gillenwater of the Truckee Meadows Fire Protection District; Chief Steve Roehl of the Springfield Department of Fire and Life Safety; and the Compressed Gas Association.

For additional copies of this report write to the U.S. Fire Administration, 16825 South Seton Avenue, Emmitsburg, Maryland 21727. The report is available on the Administration’s Web site at <http://www.usfa.dhs.gov/>

Special Report: Fire Involving Medical Oxygen Equipment

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Mission Statement

As an entity of the Department of Homeland Security, the mission of the USFA is to reduce life and economic losses due to fire and related emergencies, through leadership, advocacy, coordination, and support. We serve the Nation independently, in coordination with other Federal agencies, and in partnership with fire protection and emergency service communities. With a commitment to excellence, we provide public education, training, technology, and data initiatives.



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Special Report: Fire Involving Medical Oxygen Equipment March 1999

OVERVIEW

The United States Fire Administration has noted with growing concern the number of flash fire incidents linked to lightweight, portable oxygen equipment. The following report describes the general hazards associated with oxygen-enriched atmospheres, including aluminum in contact with high-pressure oxygen, a number of recent incidents, maintenance recommendations, and contributing factors are also included.

The United States Food and Drug Administration (USFDA) has received 16 reports of flash fire incidents from 1993 to 1999. Each incident involved portable oxygen cylinders and combination pressure and flow regulators. Collectively, those incidents caused severe burns to 11 health care workers, emergency medical service providers, firefighters, and patients.

The typical applications of the equipment involved were ambulance/emergency jump bags. The incidents involved patient transfers both within and to health care facilities, and in some cases, people receiving continuous oxygen therapy which they carried with them. The combination pressure and flow regulators involved in the 16 fire incidents were constructed of aluminum and the aluminum was exposed to pure oxygen in the regulator's high-pressure section. The regulators were attached to "D" or "E" sizes high-pressure oxygen cylinders. Where oxygen cylinder construction was identified, aluminum cylinders were involved more often than steel. However, the recommendations, precautions, and procedures in this report apply regardless of the regulator's or cylinder's construction material.

This report contains information on ten flash fire incidents that involved either fire service or emergency medical service personnel. No attempt was made to analyze experience from the other application. The incidents resulted in serious injuries to emergency personnel and property damage, including the loss of two ambulances and considerable destruction to a fire station. Patient treatment was affected in some incidents as the newly injured had to be attended to and additional equipment and service providers placed into service.

Allied Healthcare Products estimated that **between one-quarter million to one million combination pressure and flow regulators are currently in service** in the United States. It is not clear how many of these regulators are constructed of aluminum versus other metals such as brass. While all of the ten incidents addressed in this report involved aluminum-bodied regulators, fires involving contaminated brass-bodied regulators on larger "H" size medical oxygen cylinders have also occurred. The type of metal that the regulator is constructed of **does not eliminate the fire hazard** associated with pure oxygen, especially when it is under high pressure. However, brass is substantially less likely to ignite than aluminum under the same conditions because it does not react as energetically with high-pressure oxygen.

KEY ISSUES

Issues	Comments
Pressure Regulator Construction Material	Aluminum and many aluminum alloys are susceptible to ignition in standard test in pure oxygen at pressures as low as 25 psi . Brass and metals rich in copper are much more resistant to ignition even at oxygen pressures above 8,000 psi.
Change in Material Flammability	Enriched oxygen atmospheres will change a material's flammability and ease of ignition. Most materials, including those considered noncombustible in air, can be ignited and will burn vigorously in an oxygen rich environment.
Contamination	While oxygen is a nonflammable gas, it enhances the ignition and combustion of many materials. Oxygen can react with contaminants resulting in a flash fire.
Heat of Compression	As the oxygen cylinder is opened, the pressure in the regulator rapidly increases and the result is a dramatic temperature climb. The temperature may reach a level where the contaminants present can ignite.
Aluminum Construction	The ten flash fires in this report all involved aluminum bodied regulators. The USFDA and some oxygen distributors recommend brass or nickel plated brass regulators for oxygen service because the metals are less of a flash fire hazard.

HAZARDS OF OXYGEN-ENRICHED ATMOSPHERES

By definition, an oxygen-enriched atmosphere exists whenever the oxygen concentration exceeds 21 percent by volume or the partial pressure of oxygen exceeds 160 millimeters of mercury¹. While not all oxygen-enriched atmospheres represent an increased fire hazard, the administration of medical oxygen will usually produce an area of increased fire hazard. During the use of medical oxygen, the atmospheric pressure does not change; however, the oxygen displaces the air which contains mostly inert nitrogen, thereby raising the oxygen volume above 21 percent.

A less obvious means to raise the oxygen concentration above 21 percent by volume is to increase the pressure in the space beyond the atmospheric pressure of 14.7 psi. Examples of these spaces are hospital hyperbaric treatment chambers, diving and decompression chambers, and deep underground or pressurized tunneling work. As the space's pressure increases above 14.7 psi, the oxygen concentration will rise even if the space is pressurized by using normal air. A several psi increase can qualify the higher-pressure atmosphere as oxygen-enriched.

The use of 100 percent oxygen during medical emergencies is a routine practice and all personnel should be familiar with the prohibitions of open flame and smoking when oxygen is in use. The volume (size) of the oxygen-enriched atmosphere will increase starting from the point of use. The amount of oxygen flowing, the size of the room or space, and the degree of confinement will determine the extent of the hazard. The interior of cars, ambulances, bathrooms, private offices, and bedrooms are examples of small volume area where the oxygen concentration could rise above 21 percent. Emergency responders should always consider the space within three feet of the oxygen release point as being oxygen-enriched.

¹Calculated by starting with atmospheric pressure at sea level of 760 millimeters of mercury (mm Hg) and multiply this number by the usual oxygen concentration by volume of 21 percent. Other forms of measurement of atmospheric pressure are 14.7 psi or 760 torr at sea level.

As the percentage of oxygen increases above 21 percent the fire hazard of most materials change making them easier to ignite and subsequent fires more intense. Materials which are difficult to burn or are even noncombustible in air can burn readily and intensely in 100 percent (or less) oxygen. Most types of clothing, the oxygen administration tubing and mask, valve seats, and even the metal pressure regulator and flow meter can burn. For example, a cutting torch uses oxygen under pressure to melt and burn through many metals and it is possible to shut off the fuel (typically acetylene gas) and keep the cut progressing using only oxygen. **Fires involving high-pressure oxygen regulators and similar metal equipment are very rapid and violent events.** The metal involved may melt and splatter around the vicinity of the incident to burn and ignite other combustibles.

Even minor contaminants such as skin and hair oils, hand lotions, hair care products, many lubricants, and some soap residues will burn readily in 100 percent oxygen. Surfaces and parts that come into contact with oxygen should be free of these contaminants at all times. Every effort should be made to keep the oxygen equipment clean when handling the oxygen cylinders, pressure and flow regulators, and filling connectors. Opening the oxygen cylinder valve raises the pressure inside of the equipment and develops heat that is commonly called "heat of compression". The more rapid the pressure rise from quickly opening the cylinder valve, the more heat produced. Heat of compression has been sufficient to ignite contaminants or equipment components in the incidents described in this report.

Pure oxygen accelerates combustion resulting in higher flame temperatures than would be associated with fires burning in ambient air. Combustible material exposed to an oxygen-enriched atmosphere lowers the material's ignition temperature. The resulting fires are very intense with rapid combustion and the release of large amounts of energy. If the fire is in a confined space, the rapid temperature rise and increase in pressure often results in the fire penetrating the walls of the enclosure quite quickly. The fire will involve all the combustible materials (flashover) in the room sooner than would be normally expected. Strong, relatively tight enclosures, such as a small room or an oxygen chamber, may experience nearly explosive like failure depending on the amount of combustible material (fuel loaded) and volume and percentage of pure oxygen available.

SPECIAL HAZARDS

Where the demand for oxygen is large, liquid oxygen may be stored and used. Hospitals, laboratories, industry, demolition operations, and some home healthcare services use liquid oxygen. Most hazards associated with the use of liquid oxygen are independent of the storage volume. The storage volume can determine the size of the area which could be affected by the accidental release. The storage containers are heavily insulated pressure vessels (up to 300 psi) that have pressure relief valves for releasing excess pressure. During periods of low or no oxygen use, the container will likely discharge pure oxygen gas to reduce the pressure and temperature (auto-refrigerates). This action generates an oxygen-enriched atmosphere around an idle liquid oxygen container. Some home use containers have loose fitting covers which can spill liquid oxygen if tipped over. Contact with cryogenic liquids will cause skin burns. The liquid can also generate unusual failures to other objects because of the very cold temperatures.

Spillage or leakage of liquid oxygen will rapidly raise the oxygen concentration in the surrounding space. Liquid oxygen is approximately four times heavier than air and will spread along the floor or ground when spilled. Liquid oxygen will remain in liquid form for some time as it boils away into a gas and the oxygen-enriched atmosphere will build from the floor upwards. The fuel and the elimination of ignition sources near the spill should be the responders' initial concern.

A variety of fires occurring Nationally have identified several incidents where home oxygen therapy equipment contributed to fire intensity and spread. The oxygen cylinders emptied during the fires as should be expected from the heat exposure. The sudden supply of pure oxygen dramatically accelerated the fires and firefighters had to retreat from the area, bring additional hose streams to bear, and wait out the release. In one incident, the crew experienced a close call when a cylinder close to their position discharged near the end of the fire attack phase and the fire intensified unexpectedly.

INCIDENT DESCRIPTIONS

Between 1993 and 1999, ten flash fire incidents with medical oxygen cylinders and pressure regulators were reported by fire departments and emergency medical service agencies. The information which follows briefly describes each incident in order to provide the reader with an understanding of what occurred immediately before, during, and after. Detailed information about each incident was not always available. The descriptions, which follow, are included for risk reduction and educational purposes only and are not intended to suggest liability or responsibility.

Department of Fire & Life Safety Springfield, Oregon

On the morning of December 27, 1993, Medic Unit 839 from Station 3 was dispatched to a cardiac incident in a single-family dwelling. The three-member crew (captain, paramedic, and driver) treated the patient, had started her on oxygen, placed her on a stretcher, and were in the process of moving the stretcher out a sliding glass door. The "D" size steel oxygen cylinder was strapped in the horizontal position to a bracket at the foot of the elevated stretcher. The aluminum-bodied combination pressure and flow regulator was on the patient's right side, as she lay face-up on the stretcher.

While the stretcher was passing through the sliding door, the regulator struck the metal doorframe. The driver at the stretcher's foot reported hearing a hissing sound from the area of the regulator for 1 to 2 seconds before a very bright fireball engulfed nearly the entire door opening. The fireball ignited the driver's station uniform, vest, and hair. He suffered first, second, and third degree burns to about 40 percent of his body. His fingers, hands, and wrists were the most seriously injured body parts. He exited the porch area and rolled on the ground to extinguish the flames.

The paramedic at the head of the stretcher dislodged the oxygen cylinder and regulator from the foot of the stretcher. It fell onto the concrete floor of the porch. The captain and paramedic moved the patient's feet and pulled away the remaining burning and smoldering material from the stretcher. The patient did not receive additional injury from the flash fire. There was some delay in patient transport from the scene, however, the effect the delay had on her condition was not identified.

With the patient out of immediate danger from the fire, the captain went to the injured driver and found him to be conscious and breathing. The driver's hair and some of his clothes were still smoking. The paramedic located and used a portable dry chemical fire extinguisher on the still smoldering materials from the stretcher and then on the clothing of the injured driver. The driver's shirt and vest were removed and treatment of the burns began at this point. The captain requested an engine company, another medic unit, and a Deputy Chief be dispatched to the scene.

Damage to the residence consisted of several one to two square inch burns in the carpet near the door, a modest smoke stain on the side of the kitchen cabinets, and about a three feet in diameter soot and pattern of debris on the porch ceiling. The sliding door and a nearby porch wall also received smoke damage and debris spray.

The oxygen cylinder was attached to the regulator on December 24, 1993 and a new washer was placed between the cylinder valve and the regulator. The firefighter who made the change did not believe that more than one washer was present. The oxygen kit had been used and checked since the cylinder change, but the oxygen cylinder pressure was not checked during the December 27, 1993 morning checkout. Instead of transfilling their own "D" size cylinders, the department obtained full cylinders from a local gas supplier. Samples of oxygen from three cylinders of the same lot number were tested and no evident of causal contamination was identified.

The involved aluminum-bodied regulator was an LSP Model 270-020. Most of the regulator's interior was melted and the fire consumed many internal components. The high-pressure section was damaged more extensively than the low-pressure section. The fire jetted out of the regulator's body between the two high-flow accessory outlets. These outlets were not being used at the time, only the liter flow valve was in operation. The regulator's inlet filter screen was completely consumed in the fire. Independent laboratory analysis conducted that the flash fire started in the area of the filter screen.

Damage to the oxygen cylinder consisted of some heat damage to the threads on the valve stem. The damage indicated that the valve was about one-third of a turn from being fully open. The valve's position was not believed to be relevant to the incident's cause. The flash fire did not affect the steel cylinder body.

The firefighter's eyeglasses and station uniform are believed to have reduced the amount and severity of his injuries. His uniform pants and long sleeve shirt were both flame/fire retardant. His wrists were injured because the shirtsleeves were partially rolled up. The sleeveless vest was the insulated nylon type and their use was discontinued after the incident.

The cause of flash fire was determined to be from the impact of the regulator with the doorframe. Two possible ignition scenarios were identified. The impact may have released hydrocarbon-based contamination inside the regulator that ignited on impact with the inlet filter screen. Another potential ignition scenario was the frictional heating of a hydrocarbon-based contaminant caught between the regulator and the cylinder valve stem or caught in the washer between the valve and the regulator. The extension of fire to the aluminum-bodied regulator followed the first material ignited.

Union Colony Fire/Rescue Authority Greeley, Colorado

On July 13, 1995, three members of Engine 3 were beginning to treat a patient complaining of chest pains. While the lieutenant and one firefighter were assessing the patient and taking vital sign measurements, the engineer was preparing a "D" size aluminum oxygen cylinder equipped with an aluminum-bodied combination pressure and flow regulator contained in a nylon sling bag. The oxygen mask had been handed off from the engineer for placement on the patient. The mask's tubing end was attached to the regulator's outlet. The engineer was opening the oxygen cylinder's valve with his left hand when the regulator erupted in flames. Witnesses reported hearing a sound similar to a small explosion or pressure rupture simultaneously with the flames. The sound of pressurized gas escaping accompanied the flames.

The engineer managed to close the cylinder valve before he dropped the nylon bag with the cylinder on the floor. He immediately exited the single-family residence's by the front door. The patient was being treated in the home's front entrance foyer. The lieutenant kicked the still burning bag and oxygen cylinder out the front door while the patient and firefighter proceeded a short distance up the stairs toward the second floor. The lieutenant followed the engineer and oxygen cylinder out the

front door where he requested additional resources and began treatment of the engineer's injuries. His injuries consisted of third degree burns on the left hand and second degree burns to the left arm, right hand, and abdomen. The engineer was wearing rubber gloves at the time of ignition and the left glove was melted on his hand. Immediate treatment consisted of cooling the burns with sterile water. The paramedic ambulance crew which arrived during the water application phase provided further treatment. The seriously injured engineer was transported to the hospital and admitted.

The original patient did not receive additional injuries from the oxygen cylinder and regulator fire. The heat and molten metal being scattered by the flames damaged the home's entrance area. In addition, smoke had to be removed from the inside of the house. Burn damage consisted of several charred spots on the floor, heat and flame marks on the walls, and heavy smoke stains on the outside screen door. Metal fragments and pieces of burned rubber glove were scattered on the floor near the entrance. The metal fragments were later collected for evidence as part of the scene investigation.

The firefighter who was providing most of the treatment to the original patient at the time of the incident reported removing a blanket which was hanging above the entrance area. A small portion of the blanket had ignited so the firefighter removed it from the entrance and brought it to the kitchen. In the kitchen the firefighter soaked the blanket with water at the sink to extinguish the flames. When a second ambulance arrived, the original cardiac patient was transported to the hospital.

Engine 2, one of the additional resources requested, arrived at the scene while the sling bag containing the oxygen cylinder was still burning. The crew extinguished the residual fire in the bag, assisted with the smoke removal from the house, and helped finish the assessment and transport of the original patient.

Engine 2's lieutenant reported these observations about the portable oxygen unit. "The cylinder's valve was turned off; the liter flow valve on the regulator was set at zero (0); and the pressure gauge on the regulator indicated 1,100 psi." Engine 2's lieutenant then proceeded to empty the oxygen cylinder by opening the valve. After the oxygen cylinder was emptied, the regulator was removed and both items retained by the department. The oxygen cylinder had a hydrostatic pressure test date of April, 1990. Date of manufacture for the regulator could not be determined.

Initially, local investigators externally examined the oxygen cylinder, cylinder valve, and regulator. Two consultants with oxygen system experience performed an extensive examination using various methods including electron microscopy. Visually the aluminum oxygen cylinder had fire debris and soot on the exterior but it did not receive significant fire damage. The cylinder valve also had soot and fire debris on the surface. In addition, the valve experienced external heating in the area of the indexing pins and gasket seal for the regulator's attachment. There was no evidence of internal combustion in the cylinder valve.

The aluminum-bodied oxygen regulator received the most fire damage both externally and internally. There was ignition and sustained combustion of the aluminum body and much of the internal mechanisms. Externally, there was a large opening in the side of the regulator. Internal examination indicated that the fire developed upstream (toward the oxygen cylinder) of the regulator's main valve seat and progressed downstream with the flow of oxygen. The violence and force of the oxygen fed metal combustion expelled molten metal and flames from the regulator.

More damage would likely have resulted to the regulator and probably the house if it were not for the engineer closing the cylinder valve before letting loose of the sling pack. His actions stopped the aluminum fire and probably prevented further damage to the cylinder valve and the surround-

ing area. The closing of the cylinder valve agrees with the post-incident observations of Engine 2's lieutenant and was likely an instinctive rather than a deliberate reaction.

Although the oxygen contained in the involved cylinder was lost, the department was refilling the "D" size cylinders from a two bottle "H" size oxygen cascade located at their Station 1. A sample from this cascade was analyzed and the test results indicated that the oxygen met all Compressed Gas Association medical oxygen standards.

The damaged regulator and the oxygen cylinder valve were chemically analyzed for residual hydrocarbon contamination. In addition, ten bourdon tubes from new oxygen regulator pressure gauges were chemically analyzed. A trace (0.02 to 0.06 milligrams) amount of total hydrocarbon was detected in the damaged regulator parts. The sample bourdon tubes contained significantly more total hydrocarbons ranging from 2.3 to 20 milligrams per tube.

Based on the testing, it was concluded that the most likely cause of the incident was hydrocarbon contamination with the source being the regulator pressure gauge's bourdon tube. The heat of compression from the high-pressure oxygen filling the regulator was the likely ignition source. Analysis of the internal damage to the regulator also supports the conclusion.

As a result of this incident, the Union Colony Fire/Rescue Authority has made the following procedural and equipment changes:

- Ceased transfilling "D" sized oxygen cylinders. They currently purchase (exchange) filled cylinders from a gas supplier.
- Removed all aluminum-bodied regulators from service and replaced them with brass/nickel plated regulators.
- Introduced operating procedures for closing the cylinder valve and turning the regulator's liter flow valve to zero (0) flow when not in use.
- Reviewed and reinforced the Emergency Medical Technician – Basic (EMT-B) training on the installation and operation of oxygen regulators.
- All maintenance and annual testing of oxygen regulators is performed by a commercial regulator maintenance facility.

Austin Fire Department Austin Emergency Medical Services Austin, Texas

A police officer complained of hearing loss and a firefighter received burn injuries to hands and face when a flash fire involving an oxygen cylinder occurred about 1:00 p.m. on June 14, 1996. The incident involved a "D" size aluminum oxygen cylinder and an aluminum-bodied regulator which was being used during a cardiac arrest incident inside a house.

The incident occurred as firefighters started to administer oxygen to a cardiac arrest patient from a cylinder that was standing upright in their airway supply bag. As the oxygen cylinder's valve was opened, a very loud pop (almost like a discharge from a firearm) was heard and the unit caught fire. The operator's reflex was to shut off the cylinder valve and another emergency responder threw the bag out the front of the house. The flash fire resulted in a few spot fires in the house from the regulator's molten metal being scattered about.

The Austin Fire Department and Emergency Medical Services were not refilling the “D” size cylinders from a larger cascade system at the time. A commercial gas supplier provided cylinder refills, inspection, and maintenance. The oxygen cylinder had been changed about 5:00 a.m. on the day of the incident and was operated at least twice before the fire occurred. One operation was during the daily vehicle checkout and the second was during another emergency medical call.

Because of pending litigation, details on the ignition sequence and the amount of damage to the oxygen cylinder and the regulator were not available. As a result of this incident, the Austin Emergency Medical Services and Austin Fire Department have removed all aluminum-bodied regulators from use and changed to brass regulators.

Houston Fire Department Houston, Texas

On Saturday, June 15, 1996, Engine 6 and Medic 1 were dispatched to a trouble breathing call at about 12:43 p.m. The engine company consisting of an officer, engineer/operator (E/O), and two firefighters arrived at the scene before the ambulance. The company was the first responder to the medical emergency. They carried the engine’s medical kit and portable oxygen caddy to the patient’s second floor apartment. The oxygen caddy is a canvas covered wire frame assembly containing a “D” size aluminum oxygen cylinder with an aluminum-bodied regulator. While the officer gathered medical history information, one firefighter measured vital signs and the patient was started on oxygen through a mask at six liters per minute (LPM). Medic 1’s two-member crew arrived during this process with their cardiac monitoring equipment, drug box, and another portable oxygen caddy. During the paramedic’s patient assessment, the oxygen mask was removed and laid on the carpeted floor. The incident investigation suggests that the oxygen continued to flow from the mask at six lpm.

A decision was made that Medic 1 would transport the patient. One of Engine 6’s firefighters was sent to bring Medic 1’s stretcher and the E/O began to gather the engine’s medical kit and transfer the patient to the medic unit’s portable oxygen caddy. The E/O opened Medic 1’s oxygen caddy and observed that the pressure gauge on the aluminum-bodied regulator indicated zero pressure. He opened the valve on the aluminum cylinder. Immediately a bright flash and a very loud pop occurred and personnel reported a hissing sound afterwards.

The flash fire contacted the E/O and his clothing ignited. The fire quickly engulfed both portable oxygen caddies, the carpeting, and spread to the furniture in the patient’s living room. The engine company officer immediately began to clear the room but the fire’s position blocked some occupants from reaching the apartment’s door. The burned E/O, an Engine 6 firefighter, and a member of Medic 1’s crew escaped out the door. The patient, company officer, and paramedic escaped through a nearby patio door onto the balcony. An urgent radio request from Medic 1 for a structure fire box assignment was made about 1:00 p.m.

The E/O was burned on his hands, arms, stomach, face and one leg. The extent of injury included third degree burns on both hands and arms; he also had first, second, and some third degree burns on the other body areas. The E/O described the flash as “blinding” in that he could not see anything afterwards. He did not remember exactly how he escaped the apartment or how the flames on his body and clothing were extinguished. Finding himself at the bottom of the stairs in the apartment building’s courtyard, the E/O proceeded toward the engine on his own. There he found the unit in pump and a hoseline off and he was quickly assisted into Medic 1. His on-scene treatment consisted of pouring saline water on the burns and rapid transport to an emergency burn center.

The hoseline and the engine being placed into pump was the work of the firefighter who had been sent for Medic 1's stretcher. The hoseline was advanced to the company officer on the balcony who directed it on the fire. A ladder from the engine was also placed to remove those trapped on the balcony. An engine company member confirmed with dispatcher Medic 1's urgent box alarm request. The original patient and paramedic were evacuated from the balcony. Another ambulance was brought to the scene for the original patient as Medic 1 transported the seriously injured E/O.

The fire destroyed most of the living room and caused significant damage to the dining room and kitchen. The Houston Arson Bureau investigated and documented the fire scene. The Bureau collected the two damaged oxygen units, Medic 1's equipment, the E/O's shirt and pants, and a section of carpet that had the oxygen tubing and facemask melted into it. The E/O's clothing and the carpet section were to be submitted for analysis of hydrocarbon contamination because of the rapid fire development. No results of this analysis were mentioned in the Bureau's reports and it is not certain that the testing was completed. The oxygen saturation of the carpet by the flowing oxygen mask could explain the rapid burning of the material.

The damage to one of the oxygen regulators was described as a hole about the size of a quarter in the side near the overpressure vent holes. The interior damage will be discussed below. The Bureau's cause and origin investigation concluded that the fire was caused by a malfunction in the oxygen bottle but the ignition source was not determined.

A safety investigation into the cause of the incident began immediately and involved the department's safety administrator, the Assistant Fire Chief of Safety and Staffing, and the on-duty District Chief of Safety and Staffing learned of the Austin, Texas medical oxygen incident of the previous day by coincidence while he attended another fire. He contacted the Austin Fire Department that night to obtain further information about their incident. One concern about possible oxygen gas contamination as a cause of the two incidents was concluded to be unlikely as two different compressed gas companies supplied the two departments. However, it was discovered that both departments used the same type aluminum-bodied regulators and the damage on each regulator was similar. The cause of the flash fire was unclear although the possibility of contamination and heat of compression as the ignition source were discussed.

On Tuesday morning, July 16, 1996, the Houston Fire Department experienced another flash fire involving Medic 31's portable oxygen caddy. The unit included a "D" size aluminum cylinder with an aluminum-bodied regulator. The ambulance was under-going an annual inspection by the Houston Health and Human Service Department.

The inspector removed the portable oxygen caddy from the ambulance and laid it on the ground. Opening the cover to expose the regulator, he opened the cylinder valve with his left hand while he held the bottle with his right hand. He heard a noise that he thought was the regulator leaking but observed that the pressure gauge moved and the flow meter was in the off position. As these observations were being made, he felt a burning sensation and observed flames around his right hand. He immediately shut off the oxygen cylinder's valve. As he completed shutting off the cylinder, an extremely loud pop/explosion came from the unit. After the noise he observed that the pressure gauge was now at zero and the fire had stopped. The inspector estimated that all of this activity occurred in a period of about three seconds. The inspector was wearing blue colored plastic gloves at the time. He received a first degree burn on a finger in his right hand and was given first aid treatment at the scene.

Another witness described the fire as a light around the oxygen regulator similar to a flashlight in the area. He also indicated that the explosion sounded like a shot from a .30-06 rifle. After the fire was out, the portable oxygen caddy was carried about 30 feet from the ambulance where it remained until the investigation began.

The Assistant Chief of Safety and Staffing was notified of the incident and he proceeded to the scene to direct the investigation. Written statements of those involved were made and the oxygen unit secured. The damage to the aluminum-bodied regulator in the second incident was not as severe as the first. Externally, a plastic plug in one of demand valve attachment ports was partially melted and some soot was observed on the regulator body.

The oxygen cylinders and combination pressure and flow regulators from both incidents were submitted to an independent testing laboratory on July 16, 1996. The Houston Fire Department issued a bulletin dated July 16, 1996 immediately discontinuing the use of all portable "D" size oxygen cylinders until further notice. Ambulance on-board oxygen systems were to remain in-service and could be used for patient treatment. All "D" size oxygen cylinder regulators were collected within each district and new regulators were purchased. Portable oxygen administration resumed after the new pressure regulators were received and placed in service.

Both aluminum-bodied pressure regulators were identified as LSP Model 270-020. The regulator from the first incident was removed from the aluminum oxygen cylinder, which had also been damaged in the fire. Department records indicate that the regulator was placed in service on November 29, 1994. Besides the quarter size hole burned through the body, the identification tag was illegible, and the rubber in metal ring gasket between the regulator and cylinder valve body was burned. The X-rays of the regulator indicated that most of the internal components were either consumed or damaged. The regulator was not disassembled further.

The pressure regulator from the second incident was also examined externally and X-rays taken. The plastic plug on one of the demand valve parts was damaged and the X-rays suggested that the internal parts were essentially intact. The regulator was carefully taken apart and the internal components and contamination were collected. A number of analytical tests were conducted to identify the contamination and the condition of the parts.

The regulator's stainless steel inlet screen was covered with visible particles consisting of copper colored metallic chips, white powder, and green plastic flakes. Inlet screens from 10 to 12 other LSP model regulators from the Houston Fire Department were also collected and examined. Various amounts of similar debris were found on all the screens. Through analytical testing, the copper colored metallic chips were determined to be brass. The source was believed to be grindings from the oxygen cylinder valve. The white powder was identified as aluminum oxide and the source was thought to be corrosion product from the regulator body. The green plastic flakes were Teflon, which was used as a coating on the oxygen cylinder valve threads.

Besides the visible (to the unaided human eye) particles, the screens contained invisible traces of chemicals associated with nylon. The source of this debris was believed to be the oxygen cylinder valve seal. The laboratory indicated another, but less likely source, as a combustion product of the damaged plastic plug in the demand valve port.

The laboratory concluded that the two flash fires were caused by the ignition of non-metallic contamination in the regulator either by heat of compression or by metallic particle impact. Another ignition scenario involved the Teflon seal on the control piston between the high and low pressure

sections. Metallic contamination embedded in the seal could have been ignited by impact on the seat and the subsequent ignition of the seal and regulator parts.

The Houston Fire Department contracted the same testing laboratory to examine two of the replacement oxygen regulators after about ten months of service. The regulators were constructed of anodized aluminum, which improved the ignition resistance. The units had an inlet filter constructed of sintered bronze rather than stainless steel.

The analysis indicated that, based on literature, the anodized aluminum would be more ignition resistant than non-anodized aluminum. But the material is still not as ignition resistant as brass. The analysis discovered that the sintered bronze filters were not performing in accordance with manufacturer specifications because the holes were larger than acceptable tolerance and did not prevent contaminants from entering the regulator.

The interior of both oxygen regulators contained visible (under magnifications of 1:1 to 30:1) particle contamination. The particles were identified as brass and Teflon consistent with that in the flash fire investigation and produced by the oxygen cylinder valve. Also, particles of anodized aluminum from the regulator were found in both the high and low pressure sections.

After the examination, the regulator manufacturer replaced the out of specification sintered bronze filters. The specified filters would prevent the larger particles from entering inside the regulator. However, the sintered bronze filter would accumulate this material and cleaning would be required. Also, small particles could pass through the filter and potentially collect inside the regulator. The laboratory report also suggested modifications to the oxygen cylinder valve to reduce the generation of brass and Teflon particles.

Gurnee Fire Department Gurnee, Illinois

On March 23, 1997 a firefighter was in the process of performing the usual daily equipment checks at about 8:00 a.m. on one of the department's modular paramedic ambulances. The unit involved was a 1993 Extra Heavy Duty Golden Eagle by Excellence, Inc. on a 4700 LP Navistar chassis. The firefighter had taken the portable Nylon bag containing an "E" size aluminum oxygen cylinder and aluminum pressure regulator from its storage location. The bag was placed on the gurney near the head end. Partially removing the bottle and regulator from the bag, the firefighter opened the oxygen cylinder's valve. He noticed that the regulators pressure gauge did not move as expected when the cylinder was opened.

As he lifted the pressure regulator to investigate, he later reported seeing a bright flash followed by intense pain and the inside of the ambulance was ignited. Other firefighters in the station responded to the fire in the bay and an alarm was sounded for a structure fire in the station. While some personnel attended to the injured firefighter, others were attempting to reach turnout gear and move adjacent apparatus from the station and to get a hoseline on the fire. By the time the fire was extinguished, the ambulance module and chassis were a total loss along with most of the equipment on the unit. One nearby apparatus suffered heat damage to the finish and plastic components. Smoke damage included the entire apparatus area and most of the living quarters. One other firefighter was transported to the hospital for smoke inhalation.

The firefighter involved with the ignition was seriously injured. At the bright flash, he instinctively raised his left arm and hand to shield his face. It received third degree burns from the hand to the

biceps. In addition, he received second degree burns to his face, neck, right hand, chest, and front of his legs. Some metal particles, believed to be inhaled during the incident were discovered in his lungs during x-rays. It was noted that the eyeglasses that he wore probably prevented injury to his eyes.

The oxygen cylinder, aluminum combination pressure and flow regulator, and nylon bag were less than five years old and were purchased with the ambulance. There were no prior reports of the cylinder or the regulator leaking or performing erratically before the incident. The date and time the portable oxygen bag and equipment was last used was unknown. The injured firefighter was beginning the shift and this was his first contact of the day with the equipment.

The post incident investigation revealed that the fire began in the oxygen cylinder's control (post) valve in the vicinity of the valve seat. The fire spread to involve the non-metallic gasket between the regulator and the cylinder valve body. The fire also spread to damage the regulator, consuming the aluminum piston, and burning through the body near the high flow check valve. The conclusion on the point of origin was based upon disassembly of the equipment remains to expose the burn patterns. The nonmetallic cylinder valve seal was damaged where the seal meets the metal valve seat. It is believed that the damage observed in this area was the result of wear or a combination of wear and contamination.

During the investigation, the metal screen in the combination pressure and flow regulator was examined. Under the electron microscope, the debris on the screen was identified as Teflon, copper, brass, and polyphenylene oxide from the nonmetallic valve seal. The screen was located between the oxygen cylinder and the regulator's pressure gauge. The debris captured by the screen may explain why the pressure gauge did not give a reading when the cylinder's valve was opened.

The Gurnee Fire Department has instituted procedures for the use of oxygen units that includes the following. Before opening the cylinder valve, the flow regulator should be set to zero (0). The cylinder valve should be opened slowly to reduce the heating caused by the oxygen's compression in the regulator's passages. The procedure is to be followed during equipment checks out and at emergency incidents. The department also intends to replace the aluminum-constructed regulators with ones constructed of brass, to reduce (but not entirely eliminate) the potential for similar ignitions.

Broward County Fire/Rescue Broward County, Florida

A firefighter at Station 17 was performing the daily vehicle checkout on June 12, 1998. The engine was used for basic life support emergencies and carried a jump bag style oxygen cylinder and regulator in a side compartment. The firefighter opened the bag, raised the cylinder to a vertical position, opened the cylinder valve, and the unit burst into flames. His injuries consisted of first, second, and third degree burns from the waist up on about 36 percent of his body.

The engine was parked on the ramp outside the station and two firefighters were in the process of washing the opposite side. These company members and on-duty medical personnel afforded a quick response to the flash fire. As one firefighter responded to the burning firefighter, the other directed the hose, which was being used to wash the apparatus, first on the burning firefighter and then into the compartment and the burning oxygen bag. Although the fire was confined to the one compartment, it was heavily damaged and all of the contents destroyed.

The Florida State Fire Marshal's Office assisted in the investigation and submitted the damaged oxygen cylinder and regulator to an independent testing laboratory for analysis. The expert's preliminary report suggested that the ignition sequence involved metal particles which were ignited by the heat of compression from the oxygen filling the regulator. The investigation was continuing at the time of this report. On February 5, 1999, NIOSH issued Firefighter Fatality Investigation Report 98F-23 on the incident. (See Appendix A)

Greenville County Emergency Medical Service Greenville, South Carolina

The fire incident involved a two year old Type I ambulance that was on a Ford chassis. The ambulance attendant was completing a vehicle checkout at about 6:00 p.m. on August 27, 1998 as part of a shift change. The unit was parked outside the station and the attendant was standing outside the ambulance at the passenger side door to the module. The oxygen cylinder and regulator were contained in a padded nylon bag, which was resting on the floor of the entrance. When the oxygen cylinder valve was opened, the bag burst into flames.

The attendant received second and third degree burns over 15 percent to 20 percent of her body. The areas affected included her hands, arms, abdomen, and thighs. No respiratory burns were received as a result of the incident. She was transported to a regional burn center for treatment.

At the time of the incident, the attendant was in a station uniform consisting of a polyester and cotton blend, blue on blue shirt and blue polyester pants. The pants did melt during the fire and attached to her thighs. Investigators believe that the attendant's injuries would have been more serious if she had been inside the ambulance module at the time of ignition.

Within the first two minutes after ignition, the entire ambulance interior was fully involved. The on-board oxygen system did not contribute to the extent and rapid fire spread. It was intact following the fire and was turned off at the oxygen cylinder. The ambulance, chassis, and contents have been declared a total loss.

The oxygen bag contained an "E" size aluminum cylinder and aluminum-bodied regulator. The age of the cylinder and regulator has not yet been determined. The oxygen cylinder was nearly full at 1,800 psi and was last used on the morning of the incident. No problems were reported with the unit's operation at that time. Greenville County EMS used an exchange program with a gas supplier for their portable cylinders. The regulator model was included in the May 1997 recall notice (See Appendix C). However, Greenville had not received the notice before the incident and the filter retrofit kit had not been installed. After the incident, Greenville contacted about 33 surrounding fire departments and emergency medical service providers and found that none had received the recall notice.

About 75 percent of the regulator was destroyed in the fire. The aluminum oxygen cylinder was very severely damaged. After the fire, the cylinder had about a four inch long vertical opening (slit) starting in the top dome and extending down into the vertical body. The ambulance attendant reported that a very large, bright fireball was emitted from the nylon bag as the cylinder valve was opened. The presence of a protective guard on the regulator pressure gauge may have contributed to the extent of the damages. The guard interfered with the regulator's vent holes that operate to relieve internal pressure. The interference resulted in the pressure developed by the internal fire being unable to vent properly. The cause of the flash fire is still under investigation. The remains of the regulator and cylinder were sent to an independent expert who is familiar with oxygen systems.

As a result of the incident, Greenville County EMS inspected all of the oxygen regulators on its 18-ambulance fleet. The regulators were specifically checked for the retrofit kit recommended by the manufacturer. They also investigated alternate regulators that are constructed of materials other than aluminum, and reviewed the Compressed Gas Association Bulletins concerning oxygen systems.

Oak Creek Fire Department Oak Creek, Wisconsin

About 7:2 a.m. in the morning on January 29, 1999, firefighters were performing daily equipment checks in accordance with department standard operating guidelines (SOGs). A nylon constructed airway equipment bag was removed from the third due ambulance at this station and placed on the floor. The bag contained a "D" size aluminum oxygen cylinder with an aluminum-bodied combination pressure and flow regulator. The firefighter first checked to make sure the flow meter valve and the main line gauge were on zero; he then opened the valve and the unit burst into flame. The exact ignition cause is still under investigation.

The firefighter received first and second degree burns to the face, neck, and inner thighs and second and third degree burns to the hands and arms. The firefighter's station uniform helped reduce the amount of burn injury on the covered parts of his body. The station uniform consisted of a 100 percent cotton tee shirt and fire retardant trousers. The department requires responding members to wear Nomex coveralls/jump suit over street clothes when not in uniform. The fire retardant trousers were heavily damaged by the incident.

The department estimated that the oxygen regulator involved was purchased between 1989 and 1990 and the ambulance was also obtained in 1990. However, equipment was routinely traded among the department's three ambulances at this station making equipment purchase date to unit date inaccurate. The records available suggest that the airway bag and regulator was last used with a patient in October 1998, some three months prior. The oxygen cylinder involved may not have changed since the last use with a patient and would have been checked daily according to department SOGs. However, the aluminum cylinder may have been changed or filled because the SOGs also indicate that a cylinder should be changed or filled when below 1700 psi. The department transfilled the "D" sized aluminum cylinders from an in-house cascade system.

The fire spread to the nylon airway equipment bag and its contents. Firefighters extinguished the fire with a carbon dioxide extinguisher and noted that the fire's intensity was decreasing at the time. This observation suggests that most of the oxygen in the cylinder had discharged. Damage to the station and equipment consisted of a scorched concrete floor, and minor paint damage and soot coating to the ambulance and a nearby equipment trailer. The removal of the bag from inside the ambulance contributed to the minimal station and equipment damage.

The aluminum-bodied regulator was a model (LSP) L270-020 and subject to the May 20, 1997 recall notice. Unfortunately, the department was not aware of the recall and the regulator was not retrofitted with the sintered bronze inlet filter. The department noted that the oxygen regulators were not subject to an annual maintenance or cleaning program. Such a program was not included in the manufacturer's instructions. Any oxygen regulator that failed the daily checkout was removed for repair.

Since this incident, the department has replaced the all aluminum pressure regulators with units having an aluminum body with brass inserts. The brass inserts improve the regulator's resistance to internal ignition. The department is also purchasing new aluminum oxygen cylinders with pressure

gauges. The gauge will eliminate the need to open the cylinder and charge the regulator to check the cylinder's pressure. The department has ordered additional cylinders to eliminate the need for transfilling from their oxygen cascade. An outside gas supplier will provide oxygen in the final use cylinder for the department.

Truckee Meadows Fire Protection District Reno, Nevada

On Monday morning, January 25, 1999, Engine 7 had returned from a structure fire and the unit was parked outside the station for the crew to clean and check equipment. The intermediate level 2 EMT firefighter on the company went to the rear of the engine to perform the daily check on the EMS equipment bag. The orange, 24 inch by 18 inch by 8 inch, nylon bag was kept in the upper rear compartment over the tailboard area. Inside the bag was a jumbo "D" sized aluminum oxygen cylinder and aluminum-bodied combination pressure and flow regulator. The bag also contained drugs, IV bags and tubing, airways, oxygen masks and tubing, bandages, blood pressure kit, etc.

The firefighter partially removed the EMS bag from the chest high compartment such that the bag was about one-half in and one-half out. The bag was opened enough to reach the oxygen cylinder and regulator which were lying on their side. Orienting the cylinder to observe the regulator's pressure gauge, the valve was opened and the sound of high pressure oxygen escaping was heard. The oxygen unit burst into flames and the firefighter yanked his hands out of the EMS bag. As the firefighter hurried to cool himself with water, the bag fell out of the compartment to the ground. The fall caused the neck of the cylinder to break separating the valve and regulator from the body. The separation resulted in some rocketing/spinning of the burning bag from the rapid depressurization of the oxygen cylinder.

2 Intermediate Level – Below paramedic certification but the level does include the administration of a limited number of drugs, intubation, starting of IV's, and cardiac defibrilization.

The firefighter's injuries consisted of second degree burns to both hands up to his wrist, some first degree burn on the side of his face, a small area of second degree burn behind his ear, and some burned hair on his head. His station uniform and the procedure utilized for opening the oxygen cylinder were both credited with limiting the burns and injuries. The firefighter was trained to turn his face away from the cylinder and close his eyes when opening the valve. The Nomex uniform trousers, heavy cotton uniform jacket, and cotton tee shirt performed very well. Melted parts of the EMS bag were found on the firefighter's hands and uniform jacket after the incident.

The engine was moved forward and the burning bag was extinguished with water from a nearby garden hose. The engine damage consisted of some melted lights and adjacent equipment and some soot marks and scorching on the paint. About one-half of the EMS bag was consumed in the fire. Part of the aluminum regulator was destroyed leaving melted aluminum on the oxygen cylinder. Most of the regulator remains and it will be analyzed in an attempt to identify the ignition sequence.

The department was unable to identify the age of the oxygen pressure regulator. It was one of about 50 the department owns. The regulator involved was an (LSP) L270-020 model and was equipped with the sintered bronze inlet filter. The department retrofitted the filter themselves as part of the Allied Healthcare Product recalls on May 20, 1997. Other regulator maintenance consisted of keeping the units clean and the daily equipment check. Manufacture instructions did not describe specific annual maintenance, testing, and cleaning procedures.

The oxygen cylinder was replaced the evening before and, other than opening it to check the seal between the cylinder and regulator at the change out time, it had not been used. The department was not transfilling oxygen cylinders and exchanged empty for full cylinders with a supplier. Each full cylinder had a paper sticker that indicated the oxygen lot number and would identify when the cylinder was filled. The sticker was destroyed in the flash fire.

As a result of the incident, the department has replaced all of its oxygen regulators with units constructed of chrome plated brass. They are also investigating a more durable means of tracking oxygen lot information than the paper stickers.

Additional Incidents

The FDA has reports of additional flash fire incidents with oxygen regulators. In addition, there has been at least one incident with a contaminated brass-bodied oxygen pressure regulator on a large, “H” sizes, steel cylinder. The regulator was attached to a cylinder for use on a wheeled cart in a health care facility and where it was used for patient oxygen therapy. The pressure regulator’s T-handled adjusting screw had become difficult to move. A maintenance employee used a popular hydrocarbon based lubricant spray on the screw’s threads. The lubrication was done without the knowledge of the nursing or respiratory therapy staff who would have likely recognized the danger in applying a hydrocarbon lubricant.

The next time the valve on the oxygen cylinder was opened, the heat of compression ignited the residual hydrocarbon contamination inside the regulator. The burning of the residual contamination was sufficient to start the internal parts of the pressure regulator and the brass body on fire. The health care worker who opened the oxygen cylinder was injured by the molten metal and blowtorch like flames. Once the cylinder valve was closed stopping the oxygen flow, the fire ceased.

OXYGEN REGULATOR RECALL AND SAFETY NOTICE

On May 20, 1997 Allied Healthcare Products, Inc. issued a recall/safety notice that affected two models of aluminum-bodied regulators. The models involved were Life Support Products (LSP) Models L270-020 and L270-050. The notice also advised to inspect all oxygen regulators for visible contamination and general condition. Any dirty or damaged regulator should be removed from service for special cleaning or repair.

The Allied notice indicated that Model Nos. L270-020 and L270-050 may have been involved in six fire incidents over the previous three years. Their investigation reports indicate that hydrocarbon contamination has been the most likely cause of the oxygen regulator fire incidents. The contamination, according to the notice, was introduced into the regulator during maintenance or use.

To improve their oxygen regulators’ resistance to the contamination, Allied Healthcare is providing a sintered bronze inlet filter to replace the current filter in existing regulators. The recall notice indicates that the new filter will be helpful in preventing contamination which may result in a fire. **The notice also cautioned that all possible flash fire scenarios would not be eliminated.** Allied Healthcare’s customer service can be reached at (800) 216-4624 or by FAX at (888) 231-5273. (See Appendix C for copy of the notice.)

The recall/safety notice and the attached information sheet stress the importance of keeping oxygen equipment clean and avoiding contamination of all kinds. In pure oxygen almost anything (dust, dirt, metal particles, oils, lubricants, etc.) can act as a fuel. Hydrocarbon based materials are especially susceptible to ignition and fire.

On February 4, 1999, Allied published a wider recall notice in *USA Today*. The recall included all Life Support Products (LSP) oxygen regulators. The recall's stated purpose is to replace aluminum components in the high-pressure sections with brass components. The model numbers listed in the recall are LSP 106, LSP 270, LSP 280, LSP 370, and LSP 375.

The recall notice also stressed the need to immediately remove from service all LSP regulators that did not have the sintered bronze filter installed. Also to be removed from service were all regulators made by Robertshaw Controls Company, Inc., LSP's predecessor corporation.

Allied also announced that they will stop the manufacture of aluminum-bodied regulators. They will offer a trade-in program for the aluminum regulators on its new brass regulators in the future. The contact information for the Recall Coordinator is:

Telephone: 800-216-4624 (Monday to Friday 8:00 a.m. to 5:00 p.m. CST)

Fax: 888-231-5273

Mail: LSP Regulator Recall Coordinator
Allied Healthcare Products
1720 Sublette Blvd.
St. Louis, MO 63110

The United States Food and Drug Administration (USFDA) is the government rule making authority for medical devices including oxygen regulators. The USFDA issued a Public Health Advisory dated February 4, 1999 titled "Explosions and Fire in Aluminum Oxygen Regulators" (See Appendix A). The Advisory briefly describes the problem, offers two recommendations, and provides information about reporting deaths, serious illnesses, and injuries associated with the use of medical devices. An addendum lists safe practices for handling and operating oxygen equipment.

The USFDA and NIOSH both advised that the combination of aluminum oxygen cylinders and aluminum-bodied regulators pose an increased fire hazard. Both agencies have concluded that aluminum cylinders can be safely used with brass regulators. The Advisory does not discuss the safety of using steel cylinders with aluminum regulators. The flash fire experience suggests that the problem involves aluminum flakes being propelled from the cylinder into the aluminum regulator when the cylinder valve is opened rapidly.

The aluminum flakes ignite from the impact or heat of compression. The impact ignition occurs when the small metal flakes traveling at high velocities (often in excess of the speed of sound) collide with and come to rest on a surface. The energy produced from the collision raises the particle to ignition temperature. The flake may be consumed without further consequence or ignition of nearby materials may occur. With regulators constructed of aluminum, the burning flake can ignite another component or even the regulator's body. The supply of high-pressure oxygen would allow the aluminum combustion to continue until the oxygen flow stops. Brass, being a more ignition resistant material, should tolerate the aluminum flake fires and contain them inside the regulator.

The Advisory recommends that aluminum-bodied regulators used with high-pressure oxygen be replaced with regulators made of brass. Until the regulators are replaced, users are referred to the recommendations in the safe practice section of the Advisory. Similar recommendations are included in the Contributing Factors section of this report.

MAINTENANCE

The first source of oxygen regulator maintenance information is the manufacturer. Their recommendations should be followed as a minimum. Some users have decided that an annual inspection and cleaning by a qualified oxygen regulator service center is beneficial. One purpose of the annual cleaning is to remove contaminants that may have collected metal flakes, particles from the cylinder's valve seat, and other potentially combustible debris. Removing or reducing the amount of potential fuel inside the regulator limits the flash fire risk.

The annual inspection and cleaning should be done by an oxygen regulator service center because of the special cleaning materials needed and the likely need to partially disassemble the regulator.

CONTRIBUTING FACTORS

The fire incidents described in the report include one or more of the following contributing factors. The construction materials of the regulators, valves, seals, and oxygen cylinders are not listed because flash fires have occurred with all types of construction. The following factors are issues to avoid:

- **Internal hydrocarbon contamination of the regulator or regulator parts.** Only equipment and parts designed for oxygen service should be attached to oxygen gas cylinders. Repairs to regulators and oxygen equipment must be done in clean facilities using tools cleaned for oxygen service. Store spare cleaned regulators in sealed containers such as a plastic bag to keep them free of dust, etc.
- **Contamination of the surfaces and areas which mate the oxygen cylinder to the regulator with combustible materials.** Example contaminants consist of dirty hands, cleaning solutions, dust, tape residue, and possibly skin oils and lotions. Protect spare cylinder valves with clean covers, caps, plastic bags, or plugs.
- **The use of dirty tools and parts on oxygen regulators.** Inadequate cleaning to remove combustible materials such as oils, greases, soldering flux, and solvent residues has contributed to the flash fire hazard.
- **Equipment cleaning agents that have not been tested and found suitable for use with oxygen.** Some agents may leave behind residues that could be dangerous and other agents may have limited effectiveness and may not remove all contaminants.
- **Petroleum based lubricants.** Such products must not be used on parts that come into contact with oxygen, especially high-pressure areas. Lubrication must be limited to special materials and is usually avoided in equipment used with used with pure oxygen.
- **Internal contamination from metal particles and flakes from inside high-pressure cylinders and valves have accumulated on regulator filters.** Inspection and maintenance of oxygen cylinder interiors should help to identify rust and corrosion that can be a source of particles and flakes. Rough handling and completely emptying cylinders can accelerate the production of such metal particles.
- **The rapid opening of cylinder valves and the "on" position of flow regulators.** High-pressure cylinder valves need to be opened slowly to bring the regulator's internal parts to pressure slowly. Flow valves should be off or at the zero flow position. Doing so minimizes the heat of compression and allows the heat to dissipate before ignition temperature is reached.

Users of portable oxygen equipment should also review the following recommendations.

- NIOSH recommends that oxygen cylinders be stored upright to minimize the carry over of particles into the regulator. Placing the cylinder in the upright position is also recommended before opening the valve for the same reason.
- The selection and performance of non-metallic seals and gaskets has been identified as a fuel source for the flash fires. While not something the user can usually change, older cylinders, valves, and oxygen equipment may not employ the more ignition resistant materials.
- Point regulators away from the operator and patient when opening the cylinder valve. Do not look at the regulator's gauge until after the unit is pressurized.
- Before attaching the regulator to a fresh oxygen cylinder, open the valve slowly and briefly. This action is recommended to push out dust or other solid contaminants that may have collected or entered the cylinder valve's outlet.
- Removing the oxygen equipment from the ambulance or apparatus is recommended before conducting daily checkouts. Locate the oxygen cylinder and regulator in a clear area away from equipment and contamination. If a flash fire occurs, escape should be easier and exposure damage minimized.
- Specifications for new oxygen equipment should include requirements for using modern non-metallic seals and gaskets. Appendix A has references for evaluating these materials and they could be incorporated into equipment specifications.

LESSONS LEARNED

1. **The handling, storage, and use of oxygen equipment must minimize the possibility of contamination.**

The types and sources of contamination which can cause flash fires in the oxygen equipment are varied and include materials which are considered noncombustible in normal atmosphere. In the list of materials are such items as clothing, valve seals, oxygen administration sets, bedding, and many metals especially when in the form of flakes or powder. Other sources are most lubricants, hydrocarbons, skin and hair oils, some lotions, and some soap residues. Handling of oxygen cylinders and regulators must avoid the contamination of mating surfaces and the introduction of foreign materials into the cylinder or regulator.

2. **Oxygen equipment operating procedures and practices should minimize heat of compression buildup.**

Cylinder valves should be opened slowly to allow pressure inside passages and the regulator to gradually increase. In addition to minimizing the amount of heat developed, this practice allows for heat dissipation within the regulator before the ignition temperatures of materials are reached. The oxygen flow valve should be set at zero (0) or not flow position before the cylinder valve is opened. By avoiding oxygen flowing through the regulator, the solid contaminants present will not migrate as far while the pressure increases and less heat is produced. Minimizing heat of compression eliminates a common ignition mechanism in oxygen equipment flash fires.

3. Maintenance of cylinders, valves, and regulators should be done only by trained technicians using tools and facilities specially cleaned for oxygen service.

Equipment used with 100 percent oxygen, while usually rugged in appearance, is sensitive to conditions which might be overlooked by users not familiar with the fire hazards of oxygen. Knowledge of regulator operation and clean facilities and tools are needed to properly service, maintain, or test equipment. The manufacturer of the equipment is the first source of maintenance and testing information regarding frequency and what should be done. Because of the metal flakes and valve seal particles produced by typical operation of the oxygen cylinder valve, some users are cleaning or replacing the regulator's inlet filter annually, even if not specifically directed to do so by the manufacturer instructions.

4. Some agencies are replacing aluminum-bodied regulators with units constructed with brass or nickel-plated brass bodies.

The USFDA, NIOSH, some gas distributors, users, and independent experts **do not recommend the use of aluminum components in high-pressure oxygen equipment**. This recommendation is based on high-pressure oxygen reacting vigorously with the aluminum promoting the ignition of the regulator's body. Brass and nickel-plated brass do not react as energetically with oxygen as does aluminum. Regardless of the material the regulator is constructed of, the precautions described in the other lessons learned should still be followed. Contamination of pressurized brass-bodied regulators can also result in flash fires.

5. Users must recognize that oxygen cylinders have more than a single hazard which can cause serious injury.

Most equipment users recognize the hazard from the high-pressure gas inside the oxygen cylinder. The incidents of cylinder failure and valves being broken off resulting in the cylinder rocketing off are noted in many training programs. Oxygen-enriched atmospheres make ignition of combustible materials easier; cause a change in material combustibility; and increase the intensity of a fire when released. Liquid oxygen presents all of these hazards plus the hazards associated with cryogenic liquids.

6. Station uniforms and outer clothing made a difference on the amount of body burned and the severity of the burns received.

In several incidents the personnel involved with the flash fire were wearing flame or fire retardant station uniforms or a heavy cotton jacket. This clothing is credited with reducing the severity of burns and even preventing some burn injury. Personnel wearing simple cotton tee shirts seemed to have less serious burns than those wearing cotton/polyester blends or polyester clothing. Where medical exam gloves ignited, their presence usually increased the severity of burns on the hands. Because of the number of flash fires that occurred during equipment check-outs, personnel may consider wearing turnout gear, including clean structural gloves during this time. However, possible contamination of the oxygen equipment from this clothing should be analyzed.

7. Because of the danger from the remaining high-pressure oxygen, caution must be exercised while investigating and collecting samples of both the oxygen and damaged equipment.

Contamination has been a cause in many of the oxygen incidents in this report. Identification of the contaminant and its source is important for preventing future incidents. One possible contamination source is the oxygen gas inside the cylinder. Preferably a sample of the oxygen from the involved cylinder can be collected for analysis. The ability to take the sample could be limited as the cylinder may be damaged and its integrity suspect. To minimize the transportation hazard, investigators may want to discharge the oxygen before moving the cylinder. One alternative is to reduce most of the pressure but leave enough to sample the oxygen contents later. Another is to collect the sample while discharging the cylinder. Keeping the cylinder, control valve, and regulator clean during evidence collection and storage process is also an important step. Storage should be separate from other fire debris samples.

APPENDIX A

Additional Information

Readers can find more information about the hazards and precautions of using pure oxygen in the following:

Compressed Gas Association, Inc.
1725 Jefferson Davis Highway, Suite 1004
Arlington, Virginia 22202-4102
(703) 412-0900
Fax-on-demand (800) 827-5242

1998 Directory of Cleaning Agents for Oxygen Service

Standard C-6 Standards for Visual Inspection of Steel Compressed Gas Cylinders

Standard C-6.1 Standards for Visual Inspection of High-Pressure Aluminum Compressed Gas Cylinder

Standard E-4 Standard for Gas Pressure Regulators

Standard E-7 American National and CGA Standard for Medical Gas Regulators and Flowmeters

Standard G-4 Oxygen

Standard G-4.1 Cleaning Equipment for Oxygen Service

Standard G-4.3 Commodity Specification for Oxygen

Standard P-2 Characteristics and Safe Handling of Medical Gases

Standard P-2.5 Transfilling of High Pressure Gaseous Oxygen To Be Used For Respiration

Standard P-14 Accident Prevention in Oxygen-Rich and Oxygen-Deficient Atmospheres

American Society for Testing and Materials (ASTM)
100 Barr Harbor Drive
West Conshohocken, Pennsylvania 19428-2959

ASTMG 63-92 Standard Guide for Evaluating Nonmetallic Materials for Oxygen Service

ASTM G88-90 Standard Guide for Designing Systems for Oxygen Service

ASTM G94-92 Standard Guide for Evaluating Metals for Oxygen Service

“ASTM Committee G-4 Metals Flammability Test Program: Data and Discussion”: Stoltzfus, Joel M., Homa, John M., Williams, Ralph E., and Benz, Frank J.; *Flammability and Sensitivity of Materials in Oxygen-Enriched Atmospheres: Third Volume*; ASTM STP 986; D.W. Schroll, Editor; 1988, pages 28-53.

National Fire Protection Association
One Batterymarch Park
Quincy, Massachusetts 02269-9101
(617) 770-3000

NFPA 53 Guide on Fire Hazards in Oxygen-Enriched Atmosphere

NFPA 99, Standard for Health Care Facilities

Fire Protection Handbook, 17th Edition, Section 3, Chapters 6 and 15

Allied Healthcare Products, Inc.
1720 Sublette
St. Louis, Missouri 63110
(800) 231-5273

Urgent Device Recall, Important Safety Information, May 20, 1997

United States Food and Drug Administration (USFDA)
Center for Devices and Radiological Health (CDRH)
Issues Management Staff
Office of Surveillance and Biometrics, HFZ-510
1350 Piccard Drive
Rockville, Maryland 20850
Fax: (301) 594-2968
Web Page: <http://www.fda.gov/cdrh/oxyreg.html>

Explosions and Fires in Aluminum Oxygen Regulators

Centers for Disease Control and Prevention (CDC)
National Institute for Occupational Safety and Health (NIOSH)
1095 Willowdale Road
Morgantown, West Virginia 26505-2888
Web Page: <http://www.cdc.gov/niosh/fire/>

Firefighter Fatality Investigation Report 98F-23, Oxygen Regulator

Flash Severely Burns One Firefighter – Florida

APPENDIX B

Compressed Gas Association Bulletins

Compressed Gas Association Bulletins are reprinted with the Association's permission.

Appendix B (Continued)



COMPRESSED GAS ASSOCIATION, INC.

SB-12—1998

SAFETY BULLETIN

1725 JEFFERSON DAVIS HWY., SUITE 1004
ARLINGTON, VA 22202-4102
703-412-0900

USE OF REGULATOR PRESSURE GAUGES

General precautions

Oxygen and hydrocarbons (oil and grease are common hydrocarbons) under certain conditions can react violently, resulting in explosions, fire, and damage or injury to personnel and property. Never allow oil or grease to come in contact with any external or internal part of the threaded fitting or internal portion of the pressure element assembly of oxygen gauges. Even a minute amount of hydrocarbon can be hazardous in the presence of oxygen.

Regulator gauges should be installed or replaced only by qualified personnel who have been properly instructed.

Installation precautions

- DO** maintain the pressure element assembly and connection cleanliness level required for the intended application.
- DO** refer to the manufacturer's instruction manual for the correct pressure ranges to be used.
- DO** use the wrench flats provided on the gauge connection and the proper size wrench to secure the gauge to the regulator.
- DO** use only the thread sealant recommended by the regulator manufacturer for the specific application.
- DO NOT** install a low pressure gauge into the high pressure port on a regulator.
- DO NOT** use the gauge case for wrenching.
- DO NOT** interchange gauges from one gas application to another.
- DO NOT** exchange gauges from one regulator to another.
- DO NOT** conduct calibration verification using air from shop air lines, oil, or a contaminated pressure source.
- DO NOT** remove the restrictor installed in the gauge connection. The restrictor limits gas flow and aids in limiting temperature rise due to adiabatic compression.

Operation precautions

Gauges can fail during operation and the energy contained in the compressed gases can produce violent effects should the pressure element assembly rupture.

- DO** always apply cylinder pressure slowly. Heat due to adiabatic compression can cause ignition.
- DO** use safety glasses or provide eye protection.
- DO** stand with the cylinder between yourself and the regulator (cylinder valve outlet facing away) when opening the cylinder valve.
- DO** read CGA Safety Bulletin SB-8, *Use of Oxy-Fuel Gas Welding and Cutting Apparatus*.

CGA GRANTS PERMISSION TO REPRODUCE THE SAFETY BULLETIN

Appendix B (Continued)

PAGE 2 COMPRESSED GAS ASSOCIATION, INC. CGA SB-12—1998

DO NOT stand in front of or behind the pressure gauges when applying cylinder pressure to the regulator. This will reduce the possibility of injury from flying parts should the pressure element assembly rupture.

DO NOT operate regulators without eye protection.

Related documents*

ASME B40.1	<i>Gauges—Pressure Indicating Dial Type—Elastic Element</i> The American Society of Mechanical Engineers 345 East 47th Street New York, NY 10017	UL 404	<i>Gauges, Indicating Pressure, for Compressed Gas Service</i> Underwriters Laboratories, Inc. 333 Pfingsten Road Northbrook, IL 60062
CGA SB-8	<i>Use of Oxy-Fuel Gas Welding and Cutting Apparatus</i> Compressed Gas Association, Inc. 1725 Jefferson Davis Highway Arlington, VA 22202-4102	UL 252A	<i>Compressed Gas Regulator Accessories</i> Underwriters Laboratories, Inc. 333 Pfingsten Road Northbrook, IL 60062
CGA E-4	<i>Standard for Gas Pressure Regulators</i> Compressed Gas Association, Inc. 1725 Jefferson Davis Highway Arlington, VA 22202-4102	AWS C-4.2	<i>Operator's Manual for Oxy-Fuel Cutting</i> American Welding Society P.O. Box 351040 Miami, FL 33135
		ANSI/ASC Z49.1	<i>Safety in Welding and Cutting</i> American National Standards Institute 11 West 42 nd Street New York, NY 10036

* Related documents are the most current versions

PLEASE NOTE:

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This document should not be confused with federal, state, provincial or municipal specifications or regulations, insurance requirements or national safety codes. While the Association recommends reference to or use of this document by government agencies and others, this document is purely voluntary and not binding.

A catalog listing of all publications, audiovisual programs, safety and technical bulletins, and safety posters is available at no charge upon request from the Compressed Gas Association, Inc. Phone 703-412-0900, ext. 799. Fax 703-412-0128. E-mail cga@cganet.com

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1725 JEFFERSON DAVIS HIGHWAY, ARLINGTON, VA 22202-4102

PRINTED IN U.S.A.

CGA GRANTS PERMISSION TO REPRODUCE THE TECHNICAL BULLETIN

Appendix B (Continued)



COMPRESSED GAS ASSOCIATION, INC.

TB-12—1997

TECHNICAL BULLETIN

1725 JEFFERSON DAVIS HWY., SUITE 1004
ARLINGTON, VA 22202-4102
703-412-0900

DESIGN CONSIDERATIONS FOR NONMETALLIC MATERIALS IN HIGH-PRESSURE OXYGEN SUPPLY SYSTEMS

INTRODUCTION

Chloro- and fluoro-plastics, elastomers, and lubricants that generally offer a greater resistance to ignition have, on occasion, been consumed in accidental ignitions in high-pressure oxygen supply systems. Over the past several years, a few incidents have been reported in which these nonmetallic materials have reacted with high-pressure oxygen in the supply system.

Combustion products of these materials are generally toxic. They may have a harmful effect on the health of patients in oxygen inhaled therapy or support depending on the level of toxicity and the degree of dilution. A major fire could result if the initial combustion reaction does not remain confined within the supply system.

The ignition resistance of certain materials used in high-pressure oxygen supply systems may not be sufficient to prevent ignition because of system configuration, operating or maintenance procedures, use conditions, or a combination of the above.

High-pressure oxygen supply systems require specialized design, proper maintenance, and adherence to proven safe operating procedures. Important considerations include material specifications, velocity limitations, impingement, adiabatic compression, and cleaning for oxygen service.

PURPOSE AND SCOPE

The intent of this bulletin is to raise the level of awareness to the potential degradation or ignition of nonmetallic materials resulting from the heat of compression produced when oxygen at high pressure is rapidly introduced into a system.

This bulletin covers high-pressure (breathing) gas supply systems for pure oxygen and gas mixtures that contain more than 23.5% oxygen by volume supplied at pressures above 435 psig (3000 kPa).¹

It is beyond the scope of this bulletin to present detailed component or system design specifications, material selection, or cleaning recommendations.

¹ In this publication kPa shall indicate gauge pressure unless otherwise noted - i.e., (kPa, abs) for absolute pressure and kPa, differential) for differential pressure. All kPa values are rounded off per CGA P-11, *Metric Practice Guide for the Compressed Gas Industry*.

Appendix B (Continued)

PAGE 2 _____ COMPRESSED GAS ASSOCIATION, INC. _____ CGA TB-12-1997

RECOMMENDATIONS

1. It is imperative that the information contained in references, such as those listed below, be taken into account by qualified technical personnel when designing, fabricating, and assembling high-pressure oxygen systems. Many factors are involved when evaluating the overall suitability of materials and components for oxygen service. Consultation with the gas supplier or other qualified professionals can be helpful to understand the circumstances that cause oxygen to react with its surroundings.

2. Nonmetallic materials have successfully demonstrated a superior capability of maintaining leak-free systems and, as a result, enhancing safety. However, the use of plastics, elastomers, and lubricants should be avoided, where practicable, or else minimized in high-pressure systems.

3. Where it is not practicable to avoid the use of plastics, elastomers, or lubricants (in high-pressure breathing oxygen systems), the following is strongly recommended:

- Minimize surface area exposed to the gas and make sure the nonmetallic material is well encased by ignition-resisting metal (heat sink) to help dissipate heat generated by adiabatic compression or other phenomenon and to quench, contain, or otherwise avoid burning propagation. Avoid placement of nonmetallics in the direct path of the oxygen flow.
- Minimize heat of compression by design. Avoid rapid pressurization, dead ending obstructions, and constrictions.
- Review assemblies where rapid pressurization is possible in use. Where the behavior of the components under consideration is unproven or not well known, an appropriate adiabatic compression test can be used to evaluate their suitability for such a condition.
- Where an incident has been reported, take any action deemed necessary to prevent similar recurrence.
- Avoid the use of materials that can generate particulate by aging or abrasion. The system should be free of thin-walled components, sharp feathered edges, leaks, incompatible materials, and contamination.

OTHER INFORMATION SOURCES AND REFERENCES*

*The edition bearing the latest date of issuance shall be used.

American Society for Testing and Materials (ASTM), 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959.

ASTM Standard Guides and Practices:

- ASTM G 63-92, *Standard Guide for Evaluating Nonmetallic Materials for Oxygen Service*
- ASTM G 88-90, *Standard Guide for Designing Systems for Oxygen Service*
- ASTM G 93-96, *Standard Practice for Cleaning Methods and Cleanliness Levels for Material and Equipment Used in Oxygen-Enriched Environments*
- ASTM G 94-92, *Standard Guide for Evaluating Metals for Oxygen Service*

ASTM Test Methods:

- ASTM G 72-82, *Standard Test Method for Autogenous Ignition Temperature of Liquids and Solids in a High-Pressure Oxygen-Enriched Environment*

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Appendix B (Continued)

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- ASTM G 74-82, *Standard Test Method for Ignition Sensitivity of Materials to Gaseous Fluid Impact*
- ASTM G 86-89, *Standard Test Method for Determining Ignition Sensitivity of Materials to Mechanical Impact in Pressurized Oxygen Environments*

Compressed Gas Association, Inc. (CGA), 1725 Jefferson Davis Highway, Suite 1004, Arlington VA 22202-4102.

- CGA E-4, *Standard for Gas Pressure Regulators*
- CGA E-9, *Standard for Medium Pressure [3000 psig] Flexible P.T.F.E.-Lined Pigtails for Compressed Gas Service*
- CGA G-4, *Oxygen*
- CGA G-4.1, *Cleaning Equipment for Oxygen Service*
- CGA G-4.4, *Industrial Practices for Gaseous Oxygen Transmission and Distribution Piping Systems*
- CGA P-2, *Characteristics and Safe Handling of Medical Gases*
- CGA P-2.5, *Transfilling of High Pressure Gaseous Oxygen To Be Used for Respiration*

National Aeronautics and Space Administration (NASA), Scientific and Technical Information Branch, Washington, DC 20546, c/o National Technical Information Service, U.S. Department of Commerce, Springfield, VA 22161:

- NASA Reference Publication RP-1113, 1983, *Design Guide for High Pressure Oxygen Systems*
- NASA Special Publication SB-3090, *ASRDI Oxygen Technology Survey Volume IX: Oxygen Systems Engineering Review (1975)*
- NASA Handbook NHB 8060.1c, 1991, *Flammability, Odor, Offgassing, and Compatibility Requirements and Test Procedures for Materials in Environments that Support Combustion*
- NASA Test Plan, TP-WSTF-712, 1992, *Guide for Oxygen Component Qualification Tests*
- NASA Test Plan, TP-WSTF-713, *Guide for Oxygen Hazards Analyses on Components and Systems*

National Fire Protection Association (NFPA), One Batterymarch Park, Quincy, MA 02269.

- NFPA 99, *Standard for Health Care Facilities*
- NFPA 410, *Standard for Aircraft Maintenance*
- NFPA 51, *Standard for the Design and Installation of Oxygen-Fuel Gas Systems for Welding, Cutting, and Allied Processes*
- NFPA 53, *Guide on Fire Hazards in Oxygen-Enriched Atmospheres*

Canadian Standards Association (CSA), 178 Rexdale Boulevard, Etobicoke, Ontario, Canada M9W 1R3:

- CAN/CSA-Z305.1-92, *Nonflammable Medical Gas Piping Systems*
- CAN/CSA-Z305.3-M87, *Pressure Regulators, Gauges and Flowmetering Devices for Medical Gases*

Information may also be available from gas, material or equipment suppliers, and other technical associations or standards writing organizations.

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Appendix B (Continued)

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APPENDIX C

Recall Notice

The Response Line telephone numbers on the recall are incorrect.
The voice line is (800) 216-4626 and the FAX number is (888) 231-5273.

Appendix C (Continued)



1720 Sublette
St. Louis, MO 63110

Response Line
1-800-231-5273
Fax 1-888-216-4624

URGENT DEVICE RECALL IMPORTANT SAFETY INFORMATION 20 MAY 1997

To Whom It May Concern,

Allied Healthcare Products, Inc. oxygen regulators model L270-020 and L270-050 have been associated with fires in six incidents reported over three years. We consider this issue to be very important. Equally important is that the investigative reports to date indicate that the regulator fires reported were the result of contamination (grease, oil or a substance containing hydrocarbons) introduced into the regulators during maintenance or use. *Immediately inspect your regulators carefully for visible contamination and general condition (irrespective of manufacturer).* Any regulator not in good condition should be removed from service until it can be reconditioned or replaced.

We believe it is vital to inform you about this matter and provide you with information by which you can reduce the risk of a similar event occurring within your device. It is imperative that anyone using medical oxygen equipment, such as oxygen regulators be aware that the maintenance, handling and/or filling procedures are all variables that should be carefully controlled to prevent contamination. The "Did You Know..." pamphlet enclosed discusses this topic and gives some pointers on good "cleaned for oxygen" practices.

To improve the resistance of your regulators to the kinds of contamination reported, we are providing sintered bronze inlet filters. In light of the safety concern, it is imperative that you change these filters. This filter will replace the filter currently found within the inlet port of certain Life Support Products (LSP) regulators. Because of the smaller pore size of the filter, it will improve filtration for the types of contamination reported. While this filter will be helpful, it is by no means fool proof in preventing contamination. Proper adherence to all maintenance and use requirements remains essential.

Please fax the enclosed "Fax Response" to Allied at (888) 216-4624 to obtain your free filters. (You may also contact Allied Healthcare Customer Service at (800) 231-5273 if you have any specific questions regarding this process). A retrofit kit will be forwarded to you which will include the requested number of filters(s), new label(s), allen wrench, and an instruction sheet necessary to retrofit your existing LSP regulators. Please affix the "Warning Label" to the regulator next to the nameplate.

Appendix C (Continued)

As will be further identified for you in the instruction sheet sent with the kits, replacement of the existing filter is easily accomplished by removing the regulator "T" handle, inlet screw and the old inlet filter. The new filter is then inserted, followed by the replacement of the inlet screw and "T" handle. The process requires about 45 seconds.

Should you have any questions please contact the Allied Healthcare Products response center at (800)231-5273 Monday through Friday between 8:00 AM and 5:00 PM central time. If you wish to have an authorized service center perform the replacement procedure, we will provide you that contact information upon request.

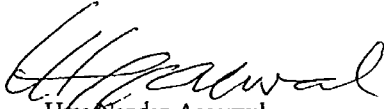
Again, we at Allied Healthcare would like to emphasize that proper care in the cleaning and maintenance of all oxygen administration equipment, including oxygen regulators, from whatever manufacturer, must be observed at all times.

This notification is being sent to all EMS agencies identified in the National Public Safety Information Bureau database. If you know of other agencies using these regulators, please forward this information to them for their immediate action.

FDA has been apprised of this action, and may contact you to verify that you have received this information and have taken appropriate action to minimize fire risk with your devices.

We regret any inconvenience that this issue may cause you. However, in the interest of safety we urge your cooperation. We remain committed to supporting you with the finest EMS products in the industry.

Sincerely,



Usha Nandan Aggarwal
President and CEO

cc: All Allied Healthcare Products Hospital, Home Care and EMS distributors.

Appendix C (Continued)

Fax Response Form

Thank you for your prompt attention to the retrofit program. In order to provide you with the materials you will need to perform the retrofits, we request that you provide us some information on this form, and then **Fax this form (Toll free) to (888) 216 - 4624**. It is important that you return this form even if you own no included LSP Products.

Please use the identification guide below to determine how many of these regulators you own, and put that number in the respective spaces at the bottom of the form, even if you don't own any. We will forward the number of retrofit kits requested as soon as we receive your information, along with the necessary tool and instructions on how to perform this simple retrofit.

If you have questions, please feel free to call our Retrofit Question Center at (800) 231-5273.

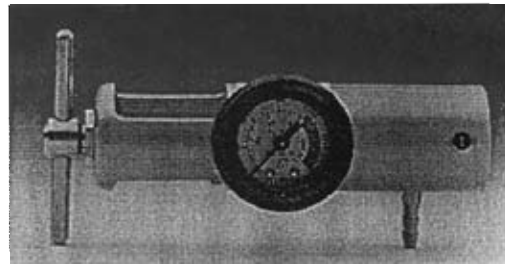
Thank You!

Identification Guide

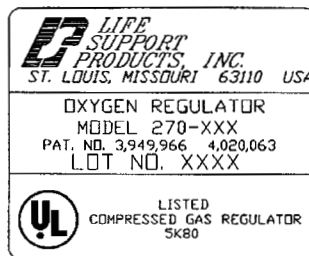
An L270-020 regulator looks like this:



An L270-050 regulator looks like this:



Both regulators have a label which looks like this:



Please Provide the following:

Agency Name _____
 Shipping Address _____
 City _____ State _____ Zip _____
 Contact Name _____
 Phone Number (____) - _____ Fax Number (____) _____

Please include the following counts:
 I have _____ L270-020 Style Regulators
 I have _____ L270-050 Style Regulators

Note: These are the only regulators involved in this program. No other regulators made by LSP or Allied are involved.

Upon receiving this form, we will immediately forward this number of retrofit kits.
PLEASE RETURN THIS FORM WHETHER YOU HAVE THESE REGULATORS OR NOT.
Thank You!

Appendix C (Continued)



1720 Sublette
St. Louis, MO 63119

Response Line
1-800-231-5273
Fax 1-888-216-4624

Answers to Some Questions You May Have

As with any issue, questions are always to be expected. In an effort to assist with some of the initial questions you might have, Life Support Products by Allied would like to offer the following answers.

Q. How serious is this?

A. There have been six incidents of varying severity reported to Allied over the last three years, two very recently. A search of the ECRI database showed 13 fire related incidents involving regulators from six manufacturers, including LSP, over the last seven years. We cannot say for certain how many regulators are in use, but it is not fewer than 250,000 and may be as high as one million. Although this would indicate the incidence of fires is very low, the consequences of a regulator fire can be serious. We believe this to be serious enough to warrant this voluntary recall and to ask your immediate cooperation.

Q. Why have the fires associated with LSP regulators occurred only within the past three years ?

A. We honestly don't know. However, since testing to date suggests outside contaminants are involved, the responsibility of EMS agencies to follow proper care and maintenance procedures could be an important factor. Recent discussions within the EMS community have suggested potential lapses in proper maintenance and care as more and more smaller agencies and municipalities begin to service their own regulation devices. If these agencies have not been properly trained in a maintenance program this trend could contribute toward the frequency of these incidences. EMS agencies also commonly do not have the kind of clean maintenance facility that would be ideal for maintenance of oxygen equipment, and they may be using the same tools to work on their vehicles.

Q. What are the mechanisms that come into play when a fire occurs?

A. For a fire to occur, you must have Fuel, Oxygen and Heat. This is commonly called the "Triangle of Fire". Oxygen related fires are unique because the high concentration of oxygen allows virtually anything (metal fragments, dust, dirt) to act as fuel.

Q. What are Hydrocarbons?

A. Hydrocarbons are oils and greases. (gasoline is a hydrocarbon, and so is the oil from your skin.) They are ideal fire starters, because they ignite almost spontaneously in oxygen.

Q. What should I do if I think my regulators may be contaminated?

A. When in doubt, please have your regulators inspected by a certified technician. LSP has several authorized service centers who are trained to assist. In either case, whether it is an LSP or other manufacturer's regulator, please follow the maintenance guidelines identified in your instruction manual. The consequences of not having a properly serviced or maintained regulator can be serious.

Q. How often should I have my regulator inspected?

A. LSP regulators should be tested periodically to ensure proper performance. The frequency of testing should be established according to usage, but it should be performed at least every two months.

Continued

Appendix C (Continued)

Q. How often should I have my regulator serviced?

A. LSP recommends that our regulators be sent to an authorized LSP service center every two years for overhaul and cleaning.

Q. What type of inlet filters do other regulator manufactures use?

A. Although we are not experts on other manufacturers filtration devices, of the units we have reviewed the vast majority use a sintered bronze filter or a stainless steel mesh filter.

Q. Are these fires a result of how LSP regulators are being manufactured?

A. Absolutely not. LSP regulators have been an industry standard for the EMS community for over 20 years. The same quality control checks and GMP guidelines that have provided these industry leading devices have never changed and in fact are continually monitored for continuous improvement.

Q. Why did LSP change their inlet filter from a stainless steel filter to a sintered bronze in the first place?

A. All testing information to date suggest these incidences were caused by outside contaminants. Although the stainless steel filter has performed well, the bronze filter adds a higher degree of filtration protection against the kind of contamination reported. We perceive this change as an enhancement over the current mesh filter. However, no filter is a guarantee against equipment that has not been checked or properly cleaned and serviced.

Q. I am using a different brand than LSP currently should I change their filters as well?

A. As with any life saving equipment, you should always follow the maintenance guidelines suggested by the manufacturer. Certainly ensuring your device has a new filter should be a top priority for your agency.

Q. Why is LSP the only ones having problems?

A. First, LSP is not the only manufacturer who has encountered this problem. According to a search of the ECRI database, 5 other companies have also experienced fire related incidences with their equipment. Secondly, with LSP having the dominant market share of regulators within the EMS community, the chances of an LSP device being involved is higher than any other. Being number one has its advantages and disadvantages.

Q. How long will it take my regulators to be repaired and what is the cost?

A. The actual retrofit change should take about 45 seconds to repair per unit. It involves simply an Allen wrench, screwdriver, washer, stem and filter. It can all be done without involving the internal components of the regulator. As for the cost, it's at no charge to you. Simply let us know how many units you will be retrofitting and the appropriate amount of kits will be sent immediately.

Q. Who is my nearest LSP authorized Service Center and how can I contact them?

A. LSP has several repair center conveniently located throughout the United States and overseas. Please call either our retrofit Question Center at (800) 231-5273 or our customer service department at (800) 444-3954 for the service center nearest you.

Q. Should I pull all of my LSP regulators out of service until I can change the filters?

A. No, we do not think that is necessary. Again, we believe the issue is associated with outside contaminants. Immediately inspect your regulators carefully for visible contamination and general condition (irrespective of manufacturer). Any regulator not in good condition should be removed from service until it can be reconditioned or replaced. It is imperative that you change the filters as quickly as possible, but if the regulator is clean and in good condition there is no need to stop using it.

Appendix C (Continued)

Did you know....

DOs and DON'Ts with Oxygen Handling Equipment

DO treat all your oxygen handling equipment with care. Store it in clean, dry locations.

DON'T use equipment which is visibly dirty, in poor repair, or damaged.

DO maintain all your oxygen handling equipment exactly as per the manufacturers instructions.

DON'T allow your oxygen handling equipment to get near any oil or grease. If it gets oil on it, condemn it until it can be properly cleaned.

DO use plugs, caps and plastic bags to protect "off duty" equipment from dust and dirt.

DON'T allow smoking around oxygen.

DO designate a special "clean area" for work with oxygen handling equipment.

DON'T work on oxygen handling equipment with ordinary tools.

DO designate special tools, clean them and store them for Use With Oxygen Equipment Only.

DON'T use parts which may have contacted oil or grease.

Did you know...

- Always wear gloves when working on oxygen hardware : It keeps the oil from your hands off the parts.

- If you need to clean parts:

Use Tri Sodium Phosphate in warm tap water, and scrub the parts carefully inside and out.

When clean, rinse the parts, discard the water and rinse again. Use deionized or distilled water for this.

Let the parts air dry. Don't try to wipe them off unless you have lint free towels (some lab wipes can work) Cover the parts when drying. They will take longer to dry, but you'll avoid getting dust on them.

Reassemble wearing gloves and using cleaned tools. If you store parts or complete product, store it in sealed plastic bags.

- The following standards are useful when handling parts for oxygen:

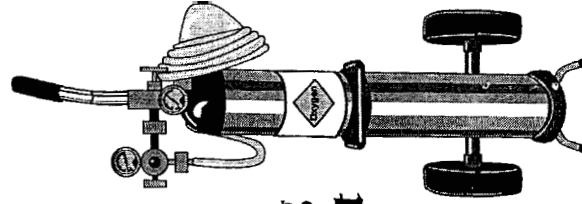
CGA 4.1 1985 "Cleaning Equipment for Oxygen Service"

CGA E-7 1992 "Standard for Medical Gas Regulators and Flowmeters"

CGA E-4 1994 "Standard for Gas Pressure Regulators"

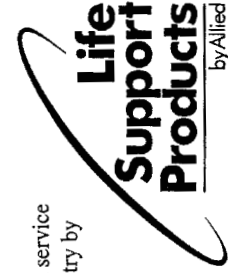
All three are available from the CGA at (703) 412 0900.

LSP O2 Pamphlet 5/97



Safety with Oxygen Handling Equipment

Provided as a service to the industry by



Appendix C (Continued)

Did you know...

- Oxygen in pure form - the kind we as medical professionals use every day - can be a dangerous substance.
- Pure O₂ will make a fire hot enough to burn metal.
- O₂ is stored at explosive pressures.
- Cryogenic oxygen is so cold it can cause instant frostbite - or worse.
- O₂ is regulated by the FDA as a drug and requires a prescription - "USP Oxygen - Dispense only on order of a Physician."

Oxygen also gives us the power to heal. Who would deny an EMS provider its life giving power in resuscitation, or the emphysema patient the freedom allowed them by their oxygen "walker"?

The difference between oxygen as a life saver and oxygen as a hazard to life comes from the equipment we choose to control and dispense it, and the care we take with that equipment.

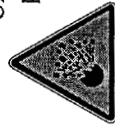
This pamphlet is not about the specifics of using or maintaining your equipment, but rather about the basic principles that apply to the safe use of all equipment used with Oxygen.

Problems and Consequences

Oxygen does not burn, but oxygen supports combustion. A fire which will burn in air will burn explosively in pure oxygen. A material which will not burn in air may burn very well in pure oxygen - for example the metal in the oxygen cylinder or the regulator.



Oxygen is stored at high pressures. A typical cylinder of gaseous oxygen will be pressurized to 2,200 psig.



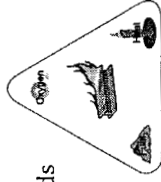
Released suddenly, as when a valve is broken off, there is enough power to drive a heavy cylinder through a concrete wall.



Sudden release of this very high pressure into an enclosed space (as when a cylinder valve is opened too rapidly) allows rapid compression. The result is heat which can raise the temperature inside of a regulator to thousands of degrees instantaneously, and make the outside so hot you can't touch it.

Principles

The Triangle of Fire
The Triangle reminds us that for a fire to occur, you must have Fuel, Oxygen, and Heat. Oxygen related fires are unique because the high concentration of oxygen allows virtually anything (metal fragments, dust, dirt) to act as fuel.



Heat of Compression
The Heat of Compression provides the necessary heat for fires to start - a cylinder valve opened too rapidly raises temperatures into the thousands of degrees.



Friction
Another source of heat, friction can be caused by the sudden motion of particles inside your equipment - as when a cylinder valve is first thrown open.

Hydrocarbons
Hydrocarbons are oils and greases. (gasoline is a hydrocarbon, and so is the oil from your skin.) They are the ideal fire starters, because they ignite almost spontaneously in oxygen.

